Summary: Selected Health & Human Services Legislation 113th Congress

Updated October 2013

Joy Johnson Wilson, Health & Human Services Policy Director
Rachel Morgan, Health & Human Services Committee Director
Tamra Spielvogel, Health & Human Services Committee, Senior Fellow

TABLE OF CONTENTS

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
HEALTH REFORM RELATED			
No Subsidies Without Verification Act (H.R. 2775) ***Sponsor: Representative Black (R-PA)***	**Description** ▪ Prohibits the distribution of premium tax credits and cost reduction subsidies under the Affordable Care Act (ACA) before a program is in place to verify household income and other coverage qualifications is operational. **State Issues** ▪ May alter state processes for enrollment in the health insurance marketplaces. **Summary** ▪ Prohibits the distribution of premium tax credits and cost reduction subsidies under the ACA before a program is in place to verify household income and other coverage qualifications is operational.	▪ Adopted in the House by recorded vote, 235 yeas–191 nays. [H. Rpt. 113-206 filed] (09-12-2013).	**NCSL Policy** ▪ NCSL has no policy.
Helping Sick Americans Now Act (H.R. 1549) ***Sponsor: Representative Pitts (R-PA)***	**Description** ▪ Amends the Public Health Act to direct the Department of Health and Human Services (HHS) to transfer unobligated amounts of from the Prevention and Public Health Fund (PPHF) for fiscal years (FY) 2013 through 2016 to help carry out a program that provides temporary health insurance for qualified individuals with pre-existing health conditions. **State Issues** ▪ Terminates the Prevention and Public Health Fund after 2016 and authorizes $5 billion for an optional state-based high risk pool program for calendar year 2014. **Summary** ▪ Redirects funding to the Pre-existing Condition	▪ Reported favorably to the House by the House Committee on Energy and Commerce [H. Rept. 113-45] (04/19/2013).	**NCSL Policy** ▪ NCSL has no policy.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	Insurance Program (PCIP) from the PPHF for FY 2013 through 2016. ▪ Eliminates the requirement that enrollees go without insurance coverage for the six-months prior to enrolling in the program as a condition of eligibility. ▪ Directs approximately $4 billion to the PCIP, and provides $840 million in deficit reduction.		
Fairness for American Families Act (H.R. 2668) ***Sponsor: Representative Young (R-IN)***	**Description** ▪ Amends the Internal Revenue Code, as amended by the PPACA, to delay until 2015 the requirement that individuals maintain minimal essential health care coverage. **State Issues** ▪ Affects states as employers. **Summary** ▪ Amends the Internal Revenue Code, as amended by the PPACA, to delay until 2015 the requirement that individuals maintain minimal essential health care coverage.	▪ Adopted in the House, 251 yeas– 174 nays (07/17/2013).	**NCSL Policy** ▪ NCSL has no policy.
Authority for Mandate Delay Act (H.R. 2667) ***Sponsor: Representative***	**Description** ▪ Delays by one year the implementation of the employer mandate requiring employers of 50 or more employees to provide essential minimum coverage. **State Issues** ▪ Affects states as employers. **Summary** ▪ Amends the ACA to delay until 2015 enforcement of requirements that large	▪ Adopted in the House, 264 yeas– 161 nays (07/17/2013).	**NCSL Policy** ▪ NCSL has no policy.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	employers offer their full-time employees the opportunity to enroll in minimum essential coverage. ▪ Delays the effective date of related reporting requirements for employers and for providers of minimum essential coverage.		
HEALTH WORKFORCE			
Veteran Emergency Medical Technician Support Act of 2013 (H.R. 235)	**[See details in "Veterans" section]**		
Children's Hospital GME Support Reauthorization Act of 2013 (H.R.297) ***Sponsors: Representative Pitts (R-PA)***	**Description** ▪ Amends the Public Health Service Act to extend and reauthorize appropriations for payments associated with operating approved graduate medical residency training programs. **State Issues** ▪ Reauthorizes funding for medical residency training programs. **Summary** ▪ Amends the Public Health Service Act to extend and reauthorize appropriations for payments associated with operating approved graduate medical residency training programs through fiscal year 2017.	▪ Adopted in the House under suspension of the rules by roll call vote, 352 yeas– 3 nays (02-04-2013).	**NCSL Policy** **Medicaid Administrative Actions and Medicaid Fiscal Assistance** ▪ NCSL urges Congress to enact legislation to ensure the maintain Medicaid reimbursement for Graduate Medical Education to provide continued support for our primary care physician workforce.
MEDICARE			

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
The Medicare Patient Access and Quality Improvement Act of 2013 (H.R. 2810) ***Sponsor: Representative Burgess (R-TX)***	**Description** ▪ Repeals the sustainable growth rate[1] (SGR) system for payment to participating physicians in the Medicare program, and replaces it with a system based on quality performance. **Summary** ▪ Repeals the current Medicare SGR mechanism for payment that places a global cap on Medicare spending on provider services. ▪ Provides an annual statutory update of 0.5 percent per year for fiscal year (FY) 2014 through 2018, keeping in place current incentive programs. ▪ Beginning in FY 2019, providers will receive an annual update of 0.5 percent. ▪ Physicians practicing in fee-for-service will receive an additional update adjustment based on quality performance under a new *Update Incentive Program* (UIP). ▪ Provider performance will be assessed among peer cohorts of like providers providing like services. ▪ High performing providers will have an opportunity to earn a one percent bonus payment based on previous performance, while low performing providers will see a one percent reduction in payments. ▪ Providers failing to report any quality data will receive the current two percent reductions in	▪ Ordered to be favorably reported to the full House by the House Committee on Energy and Commerce. (7/31/2013).	**NCSL Policy** ▪ NCSL has no policy.

[1] Medicare payments for physicians' services are based on a fee schedule, which reflects the relative level of time and effort required for each service and the relative complexity of each. These relative amounts per service are translated into dollars through a conversion factor, which is updated each calendar year based on the ***sustainable growth rate (SGR)*** mechanism specified in law. The SGR system compares the accumulated amount of actual physician-related spending to a specified target level. If actual cumulative spending exceeds the target cumulative spending level, then one or more future physician payment updates per service will be reduced so that future actual expenditures will be lower and ultimately reach the target amount allowed under the law.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS

	payments under the *Physicians Quality Reporting Program*[2] (PQRS), and an additional three percent reduction under UIP.
	Alternative Payment Models (APMs)
	▪ Establishes an additional avenue for the development, testing, and approval of APMs beginning in FY 2015.
	Supporting Care Coordination and Medical Homes
	▪ Establishes new payment codes for complex chronic care management for providers treating individuals with complex chronic conditions.
	▪ Ensures that Medicare payment is available for care coordination services performed by physicians who:
	  ▪ Are certified as a Level III Medical Home by the National Committee on Quality Assurance (NCQA);
	  ▪ Are recognized as a patient-centered specialty practice by NCQA; and
	  ▪ Have received equivalent certification, or meet other comparable qualifications.
	▪ Expands access to Medicare data for certain certified entities.
	Improving Payment Accuracy
	▪ Directs the Medicare program to identify improperly valued services under the fee schedule that would result in a net reduction of one percent of the projected amount of expenditures for a year during FY 2016 through FY 2018.		

MENTAL HEALTH			
Mental Health Awareness and Improvement Act of 2013 (S. 689)	**Description** ▪ Reauthorizes and improves programs administered by the Departments of Education	▪ Reported to the Senate with an amendment in the nature of a substitute	**NCSL Policy** ▪ Public Health - Health Promotion and Disease Prevention

[2] PQRS is a reporting program that uses a combination of incentive payments and payment adjustments to promote reporting of quality information by eligible professionals (EPs).

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
Sponsors: Senator Harkin (D-IA)	and Health and Human Services (HHS) related to awareness, prevention, and early identification off mental health conditions. **State Issues** ▪ Reauthorizes grant funding for a number of existing programs in the states. ▪ Offers grants to states. **Summary (Health Provisions)** ▪ Reauthorizes and improves programs administered by the Departments of Education and Health and Human Services (HHS) related to awareness, prevention, and early identification off mental health conditions. ***Garret Lee Smith Memorial Act Reauthorization*** ▪ Codifies the Suicide Prevention Technical Assistance Center to provide information and training for suicide prevention, surveillance, and intervention strategies for all ages. Authorizes approximately $5 million annually for these purposes. ▪ Reauthorizes the Youth Suicide Early Intervention and Prevention Strategies grants to states and tribes. Authorizes approximately $30 million annually for these purposes. ▪ Reauthorizes the Mental Health and Substance Use Disorder Services on Campuses grant program and updates the use of funds to allow for the education of students, families, faculty, and staff to increase awareness and training to respond effectively to students with mental health and substance use disorders, to provide outreach to administrator voluntary screenings and assessments to students, and enhance	and without a written report by the Senate Health, Education, Labor and Pensions Committee (04/11/2013).	▪ **Chronic Disease Management** - NCSL urges Congress to continue to support initiatives that promote the management of chronic conditions including mental health disorders. ▪ Substance Abuse Prevention and Treatment Block Grant and the Community Mental Health Services Block Grant ▪ NCSL supports the Substance Abuse Prevention and Treatment Block Grant and the Community Mental Health Services Block grant that provide critical assistance to state governments to help address alcohol, substance abuse, and behavior health issues using a broad range of strategies and services.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	networks with health care providers who treat mental health and substance use disorders. Authorizes approximately $5 million annually for these purposes. ▪ Incorporates consideration of the needs of veterans enrolled as students on campus. ***Mental Health Awareness Training*** ▪ Reauthorizes grants to states, political subdivisions of states, Indian tribes, tribal organizations, and nonprofit private entities to train teachers, appropriate school personnel, emergency services personnel, and others, as appropriate: ▪ to recognize the signs and symptoms of mental illness, ▪ to become familiar with resources in the community for individuals with mental illness, and ▪ for the purpose of the safe de-escalation of crisis situations involving individuals with mental illness. ▪ Authorizes approximately $20 million annually for these purposes. This program has not received an appropriation since its expiration in 2003. ***Children's Recovery from Trauma*** ▪ Reauthorizes the National Child Traumatic Stress Initiative (NCTSI), which supports a national network of child trauma centers, including university, hospital, and community-based centers and affiliate members. ▪ Authorizes approximately $46 million annually for these purposes. ***Governmental Accountability Report (GAO)***		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	▪ Directs GAO to report on the federal requirements impacting access to mental health and substance use disorder treatment related to integration with primary care, administrative and regulatory issues, quality measurement and accountability, and data sharing. ▪ Improving Education and Awareness of Treatment for Opioid Use Disorders ▪ Directs the Substance Abuse and Mental Health Services Administration (SAMHSA) to advance through its current programs, the education and awareness of providers, patients, and other stakeholders regarding Food and Drug Administration approved products to treat Opioid use disorders. ***Examining Mental Health Care for Children*** ▪ Requires a GAO report on the utilization of mental health services for children, including information about how children access care and referrals; the tools and assessments available for children; and the usage of psychotropic medications. ***Evidence-Based Practices for Older Adults*** ▪ Encourages HHS to disseminate information and provide technical assistance on evidence-based practices for mental health and substance use disorders in older adults. ***National Violent Death Reporting System*** ▪ Encourages the Director of the Centers for Disease Control and Prevention to improve, particularly through the inclusion of other states, the existing National Violent Death Reporting System. ▪ The reporting system was created in 2002 and		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	currently collects surveillance data from 18 states. ***GAO Study on Virginia Tech Recommendations*** ▪ Recommendations were outlined in a report to President Bush in 2007 by HHS, the Department of Education, and the U.S. Attorney General after the Virginia Tech tragedy. This provision requires a GAO study on the status of implementation of the recommendations, as well as identification of any barriers to implementation and identification of additional actions the federal government can take to support states and local communities to ensure the federal government and laws are not obstacles at the community level. ▪ The report will only address those recommendations that require participation by the HHS. ▪ Amends the Elementary and Secondary Education Act of 1965 (ESEA) to support school-based mental health programs and other activities ▪ Encourages states to provide technical assistance to Local Educational Agencies and school personnel on the implementation of school-based mental health programs and other approaches designed to improve learning environments in schools. ▪ Promotes the formation of school-based mental health partnerships designed to help schools link students with the clinical mental health services they need.		
NUTRITION ISSUES			

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
Nutrition Reform and Work Opportunity Act of 2013 (H.R. 3102) Sponsor: Representative Lucas (R-OK)	**Description** ▪ Reauthorizes for three more years the Supplemental Nutrition Assistance Program (SNAP) and makes significant programmatic changes that would reduce spending by $39 billion over the 2014-2023 periods. **State Issues** ▪ Makes several changes to the SNAP program including the limitation of categorical program eligibility to those households receiving cash assistance, and reduces direct spending by $39 billion over the 2014–2023 periods. **Summary** ▪ Reauthorizes for three more years the SNAP Program. ▪ Reduces the number of waivers available for certain childless adults who would otherwise be subject to work requirements or time limits. ▪ Restricts categorical eligibility for SNAP based on receipt of benefits in other programs for low-income people. ▪ Reinstating the asset and income test in the supplemental nutrition assistance program (SNAP) law by limiting categorical program eligibility to only those households receiving cash assistance from other low-income programs; ▪ Requires a household to receive a low-income heating and energy assistance program (LIHEAP) payment of $20 or more annually in order to receive the SNAP utility allowance deduction that increases SNAP benefits. ▪ Prevents the USDA and states from advertising or promoting SNAP.	▪ Adopted in the House by recorded vote, 217 yeas–210 nays (09-19-2013).	**NCSL Policy** **Nutrition Assistance: SNAP** ▪ NCSL supports continued federal financing of the SNAP program at levels sufficient to provide assistance to all that are eligible. Especially in times of economic hardship, this program, along with other nutrition assistance programs, offers a vital safety net for low-income Americans.
PHARMACEUTICAL ISSUES			
Drug Quality and Security	**Description**	▪ Adopted in the House by	**NCSL Policy**

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
Act (H.R. 3204) Sponsor: Representative Upton (R-MI)	▪ Amends the Food, Drug, and Cosmetic Act clarify the laws related to human drug compounding in response to the nationwide meningitis outbreak, and strengthens the prescription drug supply chain. **State Issues** ▪ Pre-empts state drug pedigree laws. **Summary** **Compounding Quality Act** ▪ Creates a voluntary registration program for "outsourcing facilities[3]" ▪ Under the new framework outsourcing facilities voluntarily agree to subject themselves to certain requirements similar to those that currently govern traditional drug manufacturers. ▪ The language fails to differentiate the characteristics of an outsourcing facility and a compounding pharmacy. ▪ Creates an Advisory Committee on Compounding to consult with the secretary on the development of implementation of regulations. ▪ In fiscal year (FY) 2015, an assessment fee of $15,000 and an additional $15,000 (inflation adjusted) for inspections will be assessed on outsourcing facilities. ***Enhanced Communications Between State Boards of Pharmacy and the Food and Drug***	voice vote (09-28-2013).	▪ NCSL supports these efforts of Congress to improve the regulation of compounding pharmacies, but wants to ensure that the federal proposals will retain: state regulation of pharmacy compounding; will require the Food and Drug Administration (FDA) to address interstate regulation and the regulation of the non-traditional pharmacies that are compounding in a way that is closer to manufacturing, and; would require oversight and regulation beyond the authority of state pharmacy boards.

[3] The term "outsourcing facility means a facility at one geographic location or address that: (i) is engaged in the compounding of sterile drugs; (ii) has elected to register as an outsourcing facility; and complies with all of the requirements of this section. An outsourcing facility is not required to be a licensed pharmacy. An outsourcing facility may or may not obtain prescriptions from identified individual patients.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	Administration (FDA) ▪ Directs HHS to receive submissions from the State Boards of Pharmacy describing actions taken against compounding pharmacies or expressing concerns that a compounding pharmacy may be acting contrary to the provisions in the Federal Food, Drug, and Cosmetic Act pertaining to compounding pharmacies. ▪ Directs the secretary to immediately notify state boards of pharmacy when the secretary receives a submission or makes a determination that a pharmacy is acting contrary to the provisions of the Federal Food, Drug, and Cosmetic Act pertaining to compounding pharmacies. Government Accountability Office (GAO) Study ▪ Directs the GAO to within 36 months of enactment of this measure to submit a report to congress on the adequacy of state and federal efforts to assure the safety of compounded drugs. **Drug Supply Chain Security Act** ▪ Directs HHS to issue draft guidance that establishes standards for the interoperable exchange of transaction information, history, and statements. ▪ Creates a new framework for drug security, and establishes a 10-year transition to a unit-level tracking system that would increase security. ▪ In establishing standards, HHS will consider the feasibility of establishing standardized documentation to be used by members of the pharmaceutical distribution supply chain, and the standards established in relation to the provisions of law pertaining to pharmaceutical security		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	under the Federal Food, Drug, and Cosmetic Act. ***Waivers, Exceptions, and Exemptions*** ▪ Directs the secretary establish a process within two years of enactment by which: 1. A waiver of any requirements may be granted if it is determined that the requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration. 2. An exception may be granted related to the product identifier if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required. 3. The secretary may determine other products or transactions that will be exempt from the requirements. ***Manufacturer and Wholesale Distributor Requirements*** ▪ Creates new manufacturer and wholesale distributor requirements pertaining to product tracing to be implemented Jan. 1, 2015. ▪ Establishes new transaction reporting and product identifier requirements specific to manufacturers and wholesale distributor ▪ The term manufacturer with respect to a product means the person that holds an application approved under the Federal Food, Drug, and Cosmetic Act pertaining to new drugs, or a co-licensed partner or affiliate of the manufacturer. ▪ Requires manufacturers and wholesale		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	distributor to have in place by Jan. 1, 2015 a system by which they can us if they determine a product in their possession or control is a suspect product. ▪ The manufacturer or wholesale distributor must quarantine suspect products, and promptly investigate to determine if the product is an illegitimate product. ▪ If the manufacturer or wholesale distributor makes a determination that a suspect product is not an illegitimate product, the manufacturer will promptly notify the Food and Drug Administration (FDA) ▪ If a product is deemed illegitimate the manufacturer or wholesale distributor must quarantine the product and remove the product from the pharmaceutical distribution supply chain, retain a sample of the product for further physical examination, and make specified notifications. ▪ Provides for a process for saleable returns on products intended for further distribution. ▪ Requires manufacturers and wholesale distributors to respond to requests for information from federal or state officials in the event of a recall or for the purpose of investigating a suspect or illegitimate product no later than one business day and not to exceed 48 hours. ▪ Provides for similar requirements on dispensing entities defined as retail and hospital pharmacies, a group of chain pharmacy under common ownership and control that does not act as a wholesale distributer, and repackagers.		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	Enhanced Drug Distribution Security ▪ Imposes interoperable, electronic tracing of product at the package level requirements to be implemented 10 years after enactment which includes: 1. The exchange of transaction information and statements in accordance with standards established by the secretary, 2. Transaction information inclusive of a product identifier at the package level, 3. A system and process for verification of product at the package level, including the standardized numerical identifier, 4. A system and process to promptly respond with to a product request by the secretary in the event of a recall or for the purposes of an investigation of a suspect product, and 5. A system and process in place to allow acceptance of a product and may accept a saleable returned products. ▪ Establishes requirements for information maintenance concerning agreements between dispensers and third parties. ▪ Establishes a process by which a small business, fewer than 25 full time employees, may receive a waiver of the requirements if they would result in an undue economic hardship and which will include a process for the biennial review and renewal of the waiver. ▪ Directs the secretary to within 180 days of enactment to publish guidance to aid trading partners in the identification of a suspect product.		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	Pilot Projects ▪ Directs the secretary to establish pilot projects in coordination with authorized manufacturers, repackagers, wholesale distributors, and dispensers, to explore and evaluate methods to enhance the safety and security of the pharmaceutical distribution chain. ▪ The pilot projects will be designed to utilize the product identifier for tracing of a product, improve technical capabilities, and identify system attributes that are necessary to implement security requirements. ***Provisions that Sunset*** ▪ Provision relating to: (1) receipt of transaction history, and; (2) saleable returned products; will sunset within 10 years of enactment. ***National Standards for Prescription Drug Wholesale Distributors*** ▪ Prohibits the distribution of a drug in any state unless the wholesale distributor is licensed by the state from which the dug is distributed, or if that state has not established a licensure requirement, is licensed by the secretary. ▪ If a drug is distributed interstate, the wholesale distributor must be licensed by the state into which the drug is distributed if the state requires the license for that purpose. ▪ Imposes new reporting requirements for wholesale distributors that begin Jan. 1, 2015 which the secretary will use in establishing a database of authorized wholesale distributors. ▪ The secretary is directed to coordinate with state officials who will have access to the information		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	provided. ▪ Authorizes the secretary to establish and collect fees if a state does not establish a licensing program to cover the costs associated with establishing and administering a licensure program and conducting periodic inspections. ▪ Nothing in the act prohibits states from collecting fees from wholesale distributors in connection with state licensing. ***Standards for Licensing of Drug Wholesale Distributors*** ▪ Directs the secretary to within two years of enactment to establish by regulation standards for their licensing. ▪ For the purposes of ensuring uniformity with respect to standards set, the standards will apply to all state and federal licenses concerning wholesale distributors which will include standards for the following: 1. Storage and handling of prescription drugs, including facility requirements, 2. The establishment and maintenance of records of the distributions of the drugs, 3. The furnishing of a bond or other equivalent means of security, inclusive of a $100,000 surety bond for nongovernmental entities or other equivalent means of security acceptable to the state, 4. Mandatory background checks and fingerprinting of facility managers or designated representatives, 5. The establishment and implementation of qualification for key personnel,		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	6. Mandatory physical inspection of the facility to be conducted by the licensing authority or the state, and 7. The prohibition of certain persons from receiving or maintaining licensure fro wholesale distribution. ▪ A federal or state licensing authority may conduct the inspection or may accept an inspection by the state in which the facility is located, or by third party accreditation or inspection service approved by HHS or the state. ***Third-Party Logistics Providers*** ▪ Requires the licensure of Third-Party Logistics Providers which is defined as an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product. ▪ Requires third-party logistics providers to report annually to the secretary the state, by which the facility is licensed, and the name and address of the facility and all trade names under which they conduct business. ▪ If the state does not establish a licensing program, the secretary will license the entity. ***Uniform National Policy-Preemption of State Law*** ▪ Prohibits states or their political subdivisions from establishing or continuing in effect any requirements for tracing products through the distribution system after enactment of this act.		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	▪ Prohibits states or their political subdivisions from establishing or continuing in effect any standards, requirements, or regulations with respect to wholesale prescription drug distributor or third-party logistics provider licensure, directly related to or covered by the standards and requirements as amended in this measure. ▪ Prohibits states from regulating third-party logistics providers as wholesale distributors. ▪ States may take administrative action including fines, to enforce a requirements promulgated by the state. ▪ States may provide for the suspension or revocation of licenses issued by the state.		
Pharmaceutical Quality, Security, and Accountability Act (S. 959) ***Sponsor: Senator Harkin (D-IA)***	**Description** ▪ Broadens the regulatory authority of the Food and Drug Administration (FDA) relating to the compounding of prescription drugs, and establishes national standards for monitoring the movement of prescription drugs through the "drug distribution system." **State Issues** ▪ Preempt some state laws. **Summary** ***Regulation of Human Drug Compounding*** ▪ Expands FDA's oversight role relating to compounded drugs. ▪ Clarifies that compounded drugs are new drugs, and therefore the Food and Drug, and Cosmetic Act (FFDCA) applies. ▪ Defines a *compounding manufacturer* as	▪ Reported to the Senate with an amendment in the nature of a substitute and without a written report by the Senate Health, Education, Labor and Pensions Committee (06/19/2013).	**NCSL Policy** ▪ NCSL supports these efforts of Congress to improve the regulation of compounding pharmacies, but wants to ensure that the federal proposals will retain: state regulation of pharmacy compounding; will require the Food and Drug Administration (FDA) to address interstate regulation and the regulation of the non-traditional pharmacies that are compounding in a way that is closer to manufacturing, and; would require oversight and regulation beyond the authority of state pharmacy boards.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	meaning a facility that compounds any sterile drug without receiving a prescription for an identified patient, and distributes or offers to sell the drug in interstate commerce, or; that repackages any preservative free sterile drug or engages in sterile pooling, ▪ Exemptions include a compounding nuclear pharmacy[4], infusion pharmacy[5], and hospitals and health systems. ▪ Creates a standard to allow traditional compounders to provide drugs to practitioners for their office use. Pharmacies that compound for office use will need to limit compounding to 10 percent of the products they dispense and will need to reconcile the names of patients who receive the office use product within 14 days. ***Drugs That May Not Be Compounded*** ▪ Authorizes the FDA to designate drugs that demonstrate difficulties for compounding that are reasonably likely to lead to an adverse effect. ▪ The secretary must seek public input every five years for the need for compounded drugs to be included or excluded from the list of drugs. ▪ Copies of marketed FDA-approved drugs may not be compounded for bulk except in the case of a drug shortage, in which case the compounder must submit a single notice to the secretary within three days of beginning compounding. ▪ Biologics may only be compounded starting with		

[4] A ***compounding nuclear pharmacy*** is a state-licensed pharmacy or federal facility; holds a licensed currently in effect from the Nuclear Regulatory Commission or from a state; does not compound non-radioactive drugs that would cause the entity to be a compounding manufacturer, and ; meets the requirements of a traditional compounder.

[5] An ***infusion pharmacy*** is a state-licensed pharmacy or a federal facility accredited to provide infusion pharmacy services by a national accreditation body approved by the secretary, and provides infusions pursuant to a prescription for an identified individual patient where the products are administered directly to the patient.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	a licensed biologic for a patient for whom the product produces a clinical benefit. ▪ Products subject to Risk Evaluation and Mitigation Strategies (REMS) with elements to assure safe use can only be compounded under these exceptions if the compounder shows the secretary it utilizes controls that are comparable to those in the REMS.		
Compounding Clarity Act of 2013 (H.R.3089) ***Sponsor: Representative Griffith (R-VA)***	**Description** ▪ Broadens." **State Issues** ▪ Preempt some state laws. **Summary** ▪ Defines the term "*traditional compounding*" as meaning a drug product compounded by a licensed pharmacist in a state-licensed pharmacy or federal facility, or licensed physician, for an identified individual patient based on the receipt of a valid prescription. ▪ Permits anticipatory compounding by a licensed pharmacist in limited quantities before the receipt of a valid prescription for an identified individual patient based on: 1. historical demand for the drug product; 2. a history of prescriptions for the drug product for the individual patient, or 3. For the physician or other licensed practitioner who wrote the prescription. ***Compounding for Office Use*** ▪ Requires drug products produced for office use to be reconciled back to the pharmacy within 7 days. ▪ Restricts to five percent the sterile drug products that are compounded and or shipped interstate. ▪ Requires that records of the compounding are to	▪ In traduced (9/12/2013)	**<u>NCSL Policy</u>** ▪ NCSL supports these efforts of Congress to improve the regulation of compounding pharmacies, but wants to ensure that the federal proposals will retain: state regulation of pharmacy compounding; will require the Food and Drug Administration (FDA) to address interstate regulation and the regulation of the non-traditional pharmacies that are compounding in a way that is closer to manufacturing, and; would require oversight and regulation beyond the authority of state pharmacy boards.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	be kept for not less than three years. ▪ The statement "Office Use Only" and the statement "Not for resale" must appear on the compounded drug products. ***Quality Standards*** ▪ Requires all compounded products to be compounded, stored, and dated in compliance with the U.S. Pharmacopoeia[6] chapters that are applicable to pharmaceutical compounding. ▪ Provides standards for the use of bulk substances in drug compounding. ▪ Prohibits the compounding of drug products which are essentially the copy of a marketed and approved drug product. ▪ Prohibits the use of drug products which present demonstrable difficulties for compounding. ▪ Prohibits the sale of compounded drug products by an entity other than the pharmacy or physician that compounded the drug products. ***State Authority and Reporting*** ▪ Upholds the authority of states to impose restrictions on compounding on top of the restrictions imposed in this measure, and enforcing requirements or restrictions or standards imposed by this measure. ▪ Directs the secretary to develop and implement a system for receiving and reviewing submissions from state boards of pharmacy concerning actions taken against compounding pharmacies in their jurisdictions including: violations; warning letters; sanctions or penalties, and; revocation of a state-issued pharmacy license or certification.		

[6] The U.S. Pharmacopeial Convention (USP) is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide. USP's drug standards are enforceable in the United States by the Food and Drug Administration, and these standards are developed and relied upon in more than 140 countries.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	▪ The secretary will review submissions and determine if the pharmacy is in violation of this act. ▪ The secretary may inspect a pharmacy's records to determine whether the pharmacy is in violation of one or more requirements. ▪ The inspection is to be conducted in coordination with the relevant state board or boards of pharmacy. ***Outsourcing Facilities***[7] ▪ Clarifies FDA's authority over the large-scale compounding entities, or outsourcing facilities, by outlining new federal requirements. ▪ Requires outsourcing pharmacies to register annually with the secretary and indicate if they plan to compound drugs. ▪ The outsourcing facility must submit to the secretary a report identifying the drugs products compounded by that facility during the previous six month period. ▪ Outsourcing facilities will be subject to inspection and will not be eligible for exemption. Inspections will be made based on a risk-based schedule established by the secretary. ▪ Risk factors considered in determining the risk-based schedule include compliance history, records, inherent risk of the drug product, and history of past inspections. ***Fees Relating to Outsourcing Facilities*** ▪ Beginning in fiscal year (FY) 2015 and thereafter, the secretary will collect an annual establishment fee from each outsourcing facility, and re-inspection fee from each outsourcing facility subject to re-inspection during that fiscal year.		

[7] The term "outsourcing facility" means a facility at one geographic location or address that compounds sterile drug products for office use in excess of the limitation set in law.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
PUBLIC HEALTH			
Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Reauthorization Act (S. 252) ***Sponsor: Senator Alexander (R-)TN***	**Description** ▪ Reauthorizes the PREEMIE Act which provides funding for research, education to reduce preterm labor through fiscal year 2018. **State Issues** ▪ Grant awards for telemedicine and demonstration projects aimed at improving treatment of pregnant women and outcomes for babies born prematurely. ▪ Funding for public and health care provider education. **Summary** ▪ Reauthorizes funding for the PREEMIE Act though FY 2018. ▪ Directs HHS, acting through the Centers for Disease Control and Prevention to conduct an epidemiological study on the factors relating to prematurity, subject to the availability of appropriations, and to continue efforts to prevent preterm birth. ▪ Authorizes the Health Resources and Services Administration (HRSA) to award telemedicine grants and demonstration projects aimed at improving treatment of pregnant women and outcomes for babies born prematurely. ▪ Appropriates funding for public and health care provider education related to the factors and behaviors associated with premature birth. ▪ Authorizes HHS to establish an Advisory Committee on Infant Mortality to provide	▪ Adopted in the Senate by voice vote (09-25-2013).	**NCSL Policy** ▪ NCSL has no policy

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	recommendations to the secretary regarding reducing infant mortality, preterm birth and improving the health status of pregnant women and infants.		
HIV Organ Policy Equity Act (H.R. 698; S. 330) ***Sponsors: Representative Lois Capps (D-CA); Senator Barbara Boxer (D-CA)***	**Description** ▪ Amends current law prohibiting the acquisition and procurement of donated organs that are infected with the virus that causes acquired immune deficiency syndrome, and requires the Secretary to develop guidelines for conducting research relating to organ transplants from donors who are infected with the human immunodeficiency virus (HIV). **State Issues** ▪ None **Summary** ▪ Amends the Public Health Service Act to repeal the requirement that the Organ Procurement and Transplantation Network adopt and use standards of quality for the acquisition and transportation of donated organs that include standards for preventing the acquisition of organs infected with the etiologic agent for acquired immune deficiency syndrome (AIDS). ▪ Replaces this requirement with authorization for the Network to adopt and use such standards with respect to organs infected with human immunodeficiency virus (HIV), provided that any such standards ensure that organs infected with HIV may be transplanted only into individuals who are infected with such virus before receiving such an organ.	▪ Placed on the House calendar. (07/30/2013) ▪ Discharged by the House Judiciary Committee. (07/30/2013) ▪ Reported by the House Energy and Commerce Committee. (07/30/2013) [See H Rpt. 113-181 Part 1] ▪ Senate bill was referred to the Subcommittee on Crime, Terrorism, Homeland Security and Investigations. (07/30/2013)	**NCSL Policy** ▪ NCSL has no policy.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	▪ Revises similarly the requirement that organ procurement organizations arrange for testing to prevent the acquisition of organs infected with the AIDS etiologic agent to require that they arrange for testing to identify organs infected with HIV. ▪ Directs the Secretary of Health and Human Services (HHS) to develop and publish guidelines for the conduct of research relating to transplantation of organs from HIV-infected donors. ▪ Requires the Network to revise its standards of quality regarding HIV-infected organs and the Secretary to revise any related regulations. ▪ Requires the Secretary to: (1) review annually the results of scientific research in conjunction with the Network to determine whether they warrant revision of quality standards relating to donated HIV-infected organs and to the safety of cross-strain transplantation; and (2) direct the Network, if the review so warrants, to revise its standards in a way that ensures the changes will not reduce the safety of organ transplantation. ▪ Amends the federal criminal code to declare that an organ donation does not violate the prohibition against a knowing organ donation by an HIV-infected individual, if the donation is made in accordance with this Act.		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
Access to Emergency Epinephrine Act (H.R. 2094) ***Sponsors: Representative David Roe (R-TN); Representative Steny Hoyer (D-MD)***	**Description** ▪ Amends the Children's Asthma Treatment Grants Program and other asthma programs to encourage schools to plan for severe allergic reactions. **State Issues** ▪ Provides financial incentives to states to permit trained school personnel to administer epinephrine to students. **Summary** ▪ Amends the Children's Asthma Treatment Grants Program and other asthma programs administered by the Department of Health and Human Services (HHS) to aid in preparing schools to treat allergic reactions. ▪ States would receive a preference for funding if they: ▪ Certify to HHS that they have reviewed their civil liability protection laws and determined that the laws provide adequate protection to school personnel who administer epinephrine; and ▪ Require the States' schools to maintain a supply of epinephrine in a secure location and have trained personnel to administer the epinephrine.	▪ Adopted by voice vote in the House and referred to the Senate Committee on Health, Education, Labor and Pensions (HELP). (07/30/2013)	**NCSL Policy** ▪ NCSL urges Congress to continue to support initiatives that promote the management of chronic conditions such as asthma. Early diagnosis, treatment and management is key to helping children with chronic conditions such as asthma and diabetes to stay on grade level at school and to become healthier adults
TEMPORARY ASSISTANCE FOR NEEDY FAMILIES (TANF)			
Preserving the Welfare Work Requirement and TANF Extension Act of 2013 (H.R. 890)	**Description** ▪ Extends the authorization for the Temporary Assistance for Needy Families (TANF) program	▪ Referred to the Senate Finance Committee. (03/14/2013)	**NCSL Policy** ▪ NCSL supports the reauthorization of the Temporary Assistance for Needy Families (TANF) program and supports the state

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
Sponsor: Representative David Camp (R-MI)	through December 31, 2013. ▪ Prohibits the HHS Secretary from implementing certain state flexibility options authorized under current law. (Section 407 requirements[8]) **State Issues** ▪ Provides funding to states to provide assistance to certain low-income families. The current authorization expires September 30, 2013. **Summary** ▪ Prohibits the Secretary of Health and Human Services (HHS) from finalizing, implementing, enforcing, or otherwise taking any action to give effect to the Information Memorandum dated July 12, 2012[9] (Transmittal No. TANF-ACF-IM-2012-03), or to any administrative action relating to the same subject matter or that reflects the same or similar policies. ▪ Prohibits the Secretary also from authorizing, approving, modifying, or extending any experimental, pilot, or demonstration project under the Social Security Act (SSA) that: (1) waives compliance with mandatory work requirements of SSA title IV part A (Temporary Assistance for Needy Families) (TANF), or (2) authorizes an expenditure not otherwise allowable under a state TANF program with respect to compliance with such work requirements. ▪ Rescinds and nullifies any waiver relating to the subject matter of the Information Memorandum granted before the enactment of this Act.	▪ Adopted by the House by recorded vote 246 yeas – 181 nays. (03/13/2013)	flexibility waivers. **Publications** ▪ Statement of Administrative Policy, H.R. 890-Preserving Work Requirements for Welfare Programs Act of 2013, March 12, 2013.

[8] Mandatory Work Requirements, http://www.law.cornell.edu/uscode/text/2/607 .
[9] Office of Family Assistance Guidance TANF-ACE-IM-2012-03, http://www.acf.hhs.gov/programs/ofa/resource/policy/im-ofa/2012/im-ofa/2012/im201203/im201203.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	▪ Extends through December 31, 2013, in the manner authorized for FY2012, the Temporary Assistance for Needy Families (TANF) Program under part A of title IV of the Social Security Act (except for the Contingency Fund for State Welfare Programs), including the entitlement of Puerto Rico, the Virgin Islands, Guam, and American Samoa to matching TANF grants. ▪ Makes appropriations for TANF activities through calendar 2013.		
VETERANS			
A bill to improve the processing of disability claims by the Department of Veterans Affairs, and for other purposes. (H.R. 2189) ***Sponsor: Representative Miller (R-FL)***	**Description** ▪ Extends VA pensions for veterans covered by Medicaid plans for services furnished in a nursing facility. **State Issues** ▪ Extends the expiration date for reduction of VA pensions for beneficiaries with no dependents who are covered by Medicaid plans for services furnished by nursing facilities. **Summary** ▪ Extends through Sept. 30, 2018, the expiration date for the reduction of VA pensions for certain beneficiaries with no dependents who are covered by Medicaid plans for services furnished by nursing facilities. ▪ The $90 pension benefit may not be counted in determining eligibility for Medicaid or the patient's share of cost.	▪ Reported as amended by the House Veterans Affairs Committee (09/27/2013).	**NCSL Policy** ▪ NCSL has no policy.
Women Veterans and Other Health Care Improvements Act of 2013	**Description** ▪ Includes the provision of fertility counseling and	▪ S. 131 was favorably reported to the Senate with an amendment in	**NCSL Policy** ▪ NCSL has no policy.

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
(S. 131, H.R. 958) ***Sponsors: Senator Murry (D-WA), Representative Larsen (D-WA)***	treatment within authorized Department of Veterans Affairs (VA) medical services. **State Issues** ▪ Provides health care and supportive assistance to women veterans and their families. **Summary** ▪ Includes fertility counseling and treatment within authorized Department of Veterans Affairs (VA) medical services. ▪ Directs the Secretary of Veterans Affairs to furnish counseling and treatment, including the use of assisted reproductive technology, to a spouse or surrogate of a severely wounded, ill, or injured veteran who has an infertility condition incurred or aggravated in the line of duty and who is enrolled in the VA health care system, as long as the spouse and veteran apply jointly for such counseling and treatment. ▪ Authorizes the Secretary to pay to assist in the adoption of one or more children. ▪ Directs the Secretary to: (1) report annually to the congressional veterans committees on the counseling and treatment provided under this Act; (2) prescribe regulations on the furnishing of counseling, treatment, and adoption assistance; and (3) coordinate the furnishing of counseling and treatment with that provided by the Department of Defense (DOD). ▪ Directs the Secretary to facilitate research conducted collaboratively by the Secretaries of Defense and Health and Human Services (HHS) to improve the VA's ability to meet the long-	the nature of a substitute by the Senate Veterans' Affairs Committee. S Rept 113-106.(09/17/2013) ▪ The House bill, H.R. 958 was referred to the House Subcommittee on Military Personnel. (03/14/2013)	

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	term reproductive health care needs of veterans who have a service-connected genitourinary disability or a condition that was incurred or aggravated in the line of duty, such as a spinal cord injury, that affects the veterans' ability to reproduce. ▪ Requires the Secretary to enhance the capabilities of the VA women veterans contact center: (1) to respond to requests for assistance with accessing VA health care and benefits, and (2) for referral to community resources to obtain assistance with services not furnished by the VA. ▪ Amends the Caregivers and Veterans Omnibus Health Services Act of 2010 relating to a pilot program of group retreat reintegration and readjustment counseling for women veterans recently separated from service to: (1) increase from at least 3 to at least 14 the number of locations for counseling, and (2) extend the pilot program for an additional 2 years. ▪ Directs the Secretary to carry out a pilot program of providing child care assistance to veterans receiving or in need of VA readjustment counseling and related mental health services. ▪ Directs the Secretary to impose, as a contract condition, a contractor user fee with respect to each contract entered into by the VA for a good or service. Provides for the determination of fee amounts. Authorizes the Secretary to waive the fee if the contractor is an individual or a small business. ▪ Establishes within the Treasury, the Department of Veterans Affairs Fertility Counseling and Treatment Fund and provides for all contractor		

LEGISLATION	DESCRIPTION/STATE ISSUES/SUMMARY	LEGISLATIVE ACTION	NCSL POLICY, CORRESPONDENCE & PUBLICATIONS
	user fee amounts to be deposited into the Fund.		
Veteran Emergency Medical Technician Support Act of 2013 (H.R. 235) ***Sponsor: Representative Kinzinger (R-IL)***	**Description** ▪ Amends the Public Health Service Act to provide demonstration grants to states with Emergency Medical Technician (EMT) shortages. **State Issues** ▪ Grant funding for states. **Summary** ▪ Amends the Public Health Service Act to provide demonstration grants to states with EMT shortages. ▪ Facilitates the creation of a streamlined EMT certification process to support returning veterans who have already completed military EMT training to enable them to enter the civilian workforce without unnecessary duplication of their training.	▪ Adopted in the House by voice vote under suspension of the rules (02-12-2013).	**NCSL Policy** **Federal Funding to Assist States to Improve Services to Underserved People and Areas to Address Health Profession Shortages** ▪ **HRSA Health Professions Grants and Cooperative Agreements** The Health Resources and Services Administration (HRSA), through a number of grants and cooperative agreements, supports innovations and targeted expansions in health professions education and training. Most of these programs focus on: (1) increasing the diversity of the health care workforce; (2) preparing health care providers to serve diverse population; and (3) preparing health care providers to practice in the nation's medically underserved communities. NCSL urges Congress to continue to support these important programs.