BILL FLORES, CHAIRMAN

RSC THE REPUBLICAN STUDY COMMITTEE

Conference Report to Accompany S. 524: Comprehensive Addiction and Recovery Act of 2016 (Sheldon, D-RI)

CONTACT: Rebekah Armstrong, 202-226-0678

FLOOR SCHEDULE:

Scheduled for consideration on July 8, 2016, under closed rule providing for one hour of debate.

TOPLINE SUMMARY:

The Conference Report to Accompany S. 524 address opioid abuse through new grant programs administered by Secretary of Health and Human Services, the Secretary of Veterans Affairs and the Attorney General; programs to prevent drug abuse in the Medicare program; and, programs at the Department of Veterans Affairs to enhance patient advocacy, increase integrative approaches to mental health care for veterans, and increase oversight for providers at the VA.

This conference report did not receive the support Democrat conferees, because it did not contain the $920 million in additional funding they requested.

COST:

The Congressional Budget Office (CBO), which scored the draft conference agreement, estimates a net increase impact on the deficit of $125 million over the 2017-2021 period, while a net decrease of $47 million over the 2017-2026 period. The conference import includes provisions "parking" an additional $145 million in direct spending savings in the Medicare and Medicaid improvement funds.

The conference report would also authorize numerous new programs that would be subject to appropriation. No CBO analysis of this discretionary spending is available. The conference report does include $665 million reduction to discretionary spending for employee bonuses at the Department of Veterans Affairs, intended to offset any new discretionary spending included in the agreement.

CONSERVATIVE CONCERNS:

- **Expand the Size and Scope of the Federal Government?** Yes, this bill creates new grant programs to prevent and treat opioid abuse. The bill also provides new authorities for Medicare drug providers to restrict the availability of medications to potential drug abusers.
- **Encroach into State or Local Authority?** No.
- **Delegate Any Legislative Authority to the Executive Branch?** No.
- **Contain Earmarks/Limited Tax Benefits/Limited Tariff Benefits?** No.

DETAILED SUMMARY AND ANALYSIS:

Prevention and Education

A Pain Management Best Practices Inter-Agency Task Force would be established that would determine gaps in best practices for pain management adopted by federal agencies. The task force would propose updates to the best practices and submit them to relevant agencies and the public. This task force would sunset after three years.

The director of the Office of National Drug Control Policy and the administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA) could make grants to eligible entities to implement comprehensive, community-wide strategies that address local drug crises and emerging drug abuse. There is $5,000,000 authorized to be appropriated for this task force for each of fiscal years 2017 through 2021.

The secretary would be mandated to report on what information is available, and create new informational materials, directed to adolescents who play youth sports and health care providers on the effects and risks and potential misuse of prescribing opioids. Similar legislation, H.R. 4969, was passed out of the House by voice vote.

The secretary could establish a demonstration program to provide grants to states to streamline requirements and procedures for veterans with military emergency medical training to become civilian emergency medical technicians. Similar legislation, H.R. 1818, passed the House by a vote of 415-1.

This section would require new opioid medications to be referred to an advisory committee at the FDA prior to the approval. It would also seek recommendations on education programs for opioid prescribers. Similar legislation, H.R. 4976, passed the House by voice vote.

The secretary could award grants to eligible entities, such as a federally qualified health center, for the emergency treatment of known or suspected opioid overdose. Grants could be used to train and provide resources for health care providers on prescribing an emergency treatment for an overdose, to purchase the drugs for distribution, to offset copayments, or to connect patients who have experienced overdose with appropriate treatment. $5,000,000 is authorized to be appropriated for such grants for fiscal years 2017 through 2021.

This section would reauthorize funding for grants to states and territories to establish or maintain electronic database systems for monitoring and dispensing controlled substances. The secretary would have the authority to maintain and revise minimum program requirements for grantees. This would include a plan to apply the latest advances in health information technology in order to incorporate prescription drug monitoring program data directly in to the workflow of prescribers and dispensers to ensure timely access to patients' controlled prescription drug history. The conference report would authorize $10,000,000 for each of fiscal years 2017 through 2021 for these grants. A similar bill, H.R. 1725, passed the House by voice vote.

This section would establish grants for states to develop standing orders for pharmacies regarding opioid overdose reversal medication and encourage pharmacies to dispense this medication pursuant to a standing order. It would authorize for appropriation $5,000,000 for fiscal years 2017 through 2019. A similar bill, H.R. 4586, passed the House by a vote of 415-4.

Law Enforcement and Treatment

This section would establish a comprehensive opioid abuse grant program within the Department of Justice using both new and existing programs, including providing training to first responders, investigating activities pertaining to the unlawful distribution of opioids, resident treatment centers, drug courts, and other purposes. Similar language passed the House through H.R. 5046, by a vote of 413-5.

Grant funds could be used broadly by states to address the opioid epidemic within their borders. Each program funded would be required to include a program assessment component. Applications for grant funding must comply with requirements, including a certification that federal funds would not be used to

supplant state and local funds, but would serve as additional resources, assurance that applicants will maintain and report data, as well as keep any records that the Attorney General may require, a certification that funded programs meet all requirements and are coordinated with relevant agencies; and assurance that applicants will work with the Drug Enforcement Administration in creating a strategy.

This section would also authorize grants to state and local entities, as well as Indian tribes and tribal organizations for first responder training and protocol establishment, to allow responders to administer drugs or devices approved for emergency treatment of opioids. Entities applying for grants would be required to provide a methodology to measure the program's impact, describe how it could be replicated, and explain coordination and cooperation with any governmental and community agencies.

It would also provide for the expansion of prescription drug take back. It would allow for the Attorney General, in coordination with the Administrator of the DEA, the Secretary for HHS, and the Director of the Office of National Drug Control Policy to coordinate with covered entities in expanding and establishing disposal sites for unneeded prescription medication.

Treatment and Recovery

The secretary could award grants to state substance abuse agencies, local governments or nonprofit organizations that have a high rate of heroin or other opioids in order to expand appropriate treatment options. It would authorize $25,000,000 to be appropriated for each of fiscal years 2017 through 2021. S. 524, which passed the House by a vote of 400-5, included similar language.

This section would amend the Controlled Substances Act to allow nurse practitioners and physicians assistants to dispense certain drugs for the treatment of an opioid use disorder for up to 30 patients. The number of patients treated could increase to 100 if the secretary approves the need. This section cannot preempt state law regarding a lower limit of patients a practitioner can treat.

Addiction and Treatment Services for Women, Families, and Veterans

This section would amend the Public Health Service Act to reauthorize residential treatment programs for pregnant and postpartum women. The bill would also establish a pilot program for states to develop models for treating women with substance abuse. This bill would authorize $16,900,000 for each of fiscal years 2017 through 2021 for residential treatment programs. Similar language was passed in H.R. 3691 by voice vote and in the House amendment to S.524.

The attorney general, in consultation with the secretary of Veterans Affairs (VA) could award grants to establish or expand veterans' treatment court programs or peer-to-peer services for qualified veterans.

This section would direct the secretary to maintain and disseminate information regarding the best practices related to the development of plans of self-care for infants born with substance and alcohol abuse withdrawal.

The GAO would be required to submit a report to Congress on the prevalence of neonatal abstinence syndrome (NAS) in the United States and the proportion of children born who are eligible for Medicaid services. It addition, it would examine the settings for treatment of infants with NAS, and the reimbursement methodologies and costs associated with treatments in such setting.

Incentivizing State Comprehensive Initiatives to Address Prescription Opioid Abuse

The secretary could award grants to states, or a combination of states, to implement an integrated opioid abuse response initiative. A state receiving such a grant must establish a comprehensive response plan that includes education efforts, treatment and addiction recovery. The conference report would authorize for appropriation $5,000,000 for each of fiscal years 2017 through 2021 for such grants.

Grant Accountability

Grants awarded by the Attorney General would be subject to increased accountability provisions including audits by the inspector general. Potential grantees would be ineligible to receive grant funds if an audit has an unresolved finding, and reimbursement of awarded grant funds would be required if they were received when an entity was barred from receiving funds. In addition, this section prohibits nonprofits that hold money in offshore accounts for the purpose of avoiding certain federal taxes from receiving subawards from grant recipients. Grant funds would also be limited in their use of conference expenditures. Finally, the attorney general would compare past grant awards with potential awards to ensure there is no duplication of grants awarded for the same purpose.

Grants awarded by the secretary of Health and Human Services (HHS) would also be subject to new accountability requirements. Grantees would be required to report on the effectiveness of the activities carried out and the number of persons served by the grant. Grantees would also be limited in the amount of funds used to hose conferences. The secretary would be required to complete an evaluation of any program administered by the secretary included in this legislation.

Partial Fills of Schedule II Controlled Substances

This section would allow for partial fills for Schedule II controlled substance if it is not prohibited by state law, is requested by the patient of the practitioner, and the total quantity dispensed does not exceed the total quantity prescribed. In emergency situations, remaining portions of a partially filled prescription could be filled not later than 72 hours after the prescription was issued. Similar legislation, H.R. 4599, was passed by the House by voice vote.

Programs to Prevent Prescription Drug Abuse under Medicare Parts C and D

This section would allow prescription drug plans (PDP) under Medicare Part D and Medicare Advantage plans to establish a drug management program for at-risk beneficiaries. The PDP may limit a beneficiary's access to coverage for frequently abused drugs that are prescribed by one or more prescriber and dispensed by one or more pharmacies. A PDP cannot limit access until it provides the beneficiary notice and verifies with the providers that the beneficiary is at-risk for prescription drug abuse. Exemption to this would be granted for those receiving hospice care and residents of long-term care facilities.

$140,000,000 would be made available to the Medicare Improvement Fund for fiscal year 2021 and beyond. This fund and its Medicaid counterpart have been used as "parking spots" to bank savings to offset future spending. Should these savings not be reappropriated by future action, the funds would be available as a slush fund at the secretary's discretion.

Exempting Abuse-Deterrent Formulations of Prescription Drugs

This section would exempt the abuse-deterrent formulation of a drug from the definition of line extension when calculating Medicaid rebates. This would increase the net cost of such medications to the Medicaid system.

To offset the costs of the rebate exemption, this bill would limit the disclosure of predictive modeling technologies and other analytics technologies to identify and prevent waste, fraud, and abuse with respect to Medicare, Medicaid, and the Children's Health Insurance Program. This would prevent fraudsters from utilizing the information to circumvent detection and would result in lower fraud rates.

$5,000,000 would be made available to the Medicaid Improvement Fund for fiscal year 2021 and beyond. This fund and its Medicare counterpart have been used as "parking spots" to bank savings to offset future spending. Should these savings not be reappropriated by future action, the funds would be available as a slush fund at the secretary's discretion.

Kingpin Designation Improvement

This section would amend section 804 of the Foreign Narcotics Kingpin Designation Act (21 U.S.C. 1903) to allow classified information to be submitted to a reviewing court ex parte (without the defendant or counsel present) or in camera (in a judge's chambers or other off-the-record hearing), in any judicial review of a presidential determination based on classified information, if a foreign person is subject to sanctions as a significant foreign narcotics trafficker. It would clarify that it would not confer or imply any right to judicial review. Similar legislation, H.R. 4985, passed the House by voice vote.

Department of Veterans Affairs

Jason Simcakoski Memorial and Promise Act

This section is similar to House passed legislation, H.R 4063, which passed the House by voice vote.

This section would expand and improve opioid safety measures at the VA. The secretary would be directed to expand the Opioid Safety Initiative to all VA medical facilities and require health care providers to use the Opioid Therapy Risk Report tool prior to initiating opioid therapy to treat a patient. In carrying this out, the secretary would ensure access by health care providers to VA information on controlled substances prescribed to veterans outside of the VA through the prescription drug monitoring program.

VA providers who prescribe opioids would be required to receive training and education on pain management and safe prescribing practices. This would include the use of evidence-based pain management therapies and screening and identifying patients with substance use disorders. Each medical facility would also have a pain management team to prevent the prescription of analgesics by a provider without expertise in the drug or who has not completed the required education and training. The computerized patient record system at the VA would be modified to ensure that any health care provider that accesses a veteran's record will be immediately notified if there is a history of substance abuse or a risk of becoming an opioid abuser.

Next, the Pain Management Working Group of the Health Executive Committee of the Department of Veterans Affairs-Department of Defense (DoD) Joint Executive Committee would focus on the opioid prescribing practices of health care providers at each department, the ability to manage pain, and coordination in coverage and constant access to medications prescribed for patients transitioning from receiving care from the Department of Defense to the VA. The Secretary of the VA and the Secretary of Defense would be instructed to update the Clinical Practice Guidelines for Management of Opioid Therapy for Chronic Pain.

The comptroller general is directed to submit to Congress a report on the Opioid Safety Initiative of the VA and the opioid prescribing practices of health care providers at the VA. In addition, the secretary would submit to Congress a report on the opioids prescribed by health care providers at the each VA health care facility.

This section would require the secretary to disclose information about a veteran or the dependent of a veteran to a state controlled substance monitoring program if necessary to prevent the misuse and diversion of prescription medications. States implement and maintain drug monitoring program databases on controlled substances prescribed and filled with their borders. The VA had the authority, but was not required, to disclose information on veterans and their dependents about prescriptions of controlled substances.

This section would eliminate copayments for veterans receiving opioid antagonists or education on the use of opioid antagonists.

Patient Advocacy

This section would ensure each VA medical facility hosts community meetings open to the public on improving health care furnished through the VA. In addition, the comptroller general would be required to

submit to Congress a report on the Patient Advocacy Program at the VA. This report would include the purpose and activities carried out by the program and recommendations for improvement.

In addition, an Office of Patient Advocacy would be established within the Office of the Under Secretary for Health. The purpose of this office would be to advocate on behalf of veterans including resolving complaints with respect to health care furnished by the VA.

Complementary and Integrative Health
This section would establish a commission known as the Creating Options for Veterans' Expedited Recovery (COVER) Commission. The ten-member commission would examine the evidence-based therapy treatment model used by the VA for treating mental health conditions of veterans and integrative health treatments available at non-department facilities. The commission would submit reports on its recommendations and an analysis of the evidence-based therapy model used by the VA for treating veterans with mental health issues. The commission would also submit an action plan for implementing its recommendations for improving wellness-based outcomes for veterans and a timeframe for when it can be implemented department wide.

This section would establish a three-year pilot program to assess the feasibility of using complementary and integrative health and wellness-based programs to complement the provision of pain management and related health care services for veterans. The secretary would assess how to improve the coordination between federal, state and local health care providers for pain management services and how to use complementary and integrative health programs and whether they are effective in enhancing a veteran's quality of life.

Fitness of Health Care Providers
As part of the hiring process for a health care provider at the VA, the secretary would require the medical board for each state in which the provider has a license provide information on any violation of the requirements of the medical license during the 20-year preceding period and information on whether the providers had entered into any settlement agreement for a disciplinary charge. If a VA health care provider violated a requirement of medical licensure, the secretary would provide the medical board of the state where the provider is licensed detailed information regarding the violation.

Limitation on Awards and Bonuses
This section would limit the awards and bonuses paid to VA employees to not exceed $230,000,000 for fiscal years 2017 and 2018, $225,000,000 for fiscal years 2019 through 2021 and $360,000,000 for fiscal years 2022 through 2024. Current law caps the aggregate amount of awards and bonuses paid by the secretary in each of fiscal years 2015 through 2024 at $360,000,000.

A sense of Congress is also included to state the limitation on bonuses should not disproportionately impact lower-wage employees, and the VA is encouraged to used bonuses to incentive high-performing employees in areas in which retention is challenging.

OUTSIDE SUPPORT:

- Click here for a list of 115 organizations supporting the conference report provided by the Energy and Commerce Committee.

COMMITTEE ACTION:

S.524 was introduced by Senator Sheldon and passed the Senate on March 9, 2016. On May 13, 2016, the House voted on the House amendment to S. 524 which passed with a vote of 400-5. On June 6, 2016, there was motion in the Senate to disagree with the House amendments, but to agree to the request for a conference. On July 6, 2017, the conferees agreed to file the conference report.

ADMINISTRATION POSITION:

No Statement of Administration Policy is available at this time.

CONSTITUTIONAL AUTHORITY:

According to the sponsor, Congress has the power to enact this legislation pursuant to the following: Article I, Section 8, Clause 3 of the United States Constitution