



# Office of Government Relations Annual Report 2016

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OFFICE OF GOVERNMENT RELATIONS Overview

This annual report covers work by the Office of Government Relations from January 1 - December 31, 2016.

# **Mission**

The mission of the Office of Government Relations is to support the University of Colorado by building effective partnerships between the University and state and federal governments. This is achieved through representation and advocacy of CU's needs and interests with state and federal elected officials in Colorado and Washington, D.C.

# <u>Goals</u>

- Promote the University's interests at the state and federal level.
- Enhance the understanding of the role and value of CU.
- Achieve status as one of the top public university governmental relations offices in the United States.

# <u>Strategies</u>

- 1) Maintain visibility at both the state and federal level through testimony, tours, outreach events, Hill visits, and other activities to increase contact with state and federal policy makers.
- 2) Foster relationships between the president, chancellors and designated officers of the university with members of the General Assembly, Colorado Congressional Delegation, and Executive branch of both the state and federal government.
- 3) Engage the business community, CU Advocates, and alumni to help advocate for the university's initiatives.
- 4) Request federal funding for special projects at each campus.
- 5) Lobby for increases in funding by federal agencies. The following agencies are the primary sources of research funding for CU:
  - National Science Foundation (NSF)
  - National Institutes of Health (NIH)
  - National Aeronautics and Space Administration (NASA)
  - Department of Defense (DOD)
  - Department of Energy (DOE)
  - Department of Commerce (DOC)
  - National Oceanic and Atmospheric Administration (NOAA)
  - National Institute of Space and Technology (NIST)
- 6) Educate elected officials about the university through contact with faculty, students, and administrators from all three campuses.
- 7) Provide internal communication by:
  - Holding frequent legislative strategy meetings with top university officers;
  - Providing legislative updates at all three campuses and via email to the university community; and
  - Communicating with appropriate university faculty, administrators, and students regarding specific legislation and policy issues.

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Kirsten Schuchman Assistant Vice President of State Relations Phone: 303-831-9295 <u>kirsten.schuchman@cu.edu</u> The First Regular Session of the seventieth session of the Colorado General Assembly convened on January 13, 2016 and ended on May 11, 2016.

(Tate/Garnett)

# S.B. 16-121 Higher Education Tuition Pledged for Bonding

Under current law, a state institution of higher education or group of institutions may pledge up to 10% of tuition revenues of the institution for purposes of entering into contracts for the advancement of money. The bill allows an institution or group of institutions to pledge up to 100% of tuition revenue if the contract for the advancement of money for which it is pledging tuition is not subject to the higher education revenue bond intercept program and the institution is not a party to any existing contracts for the advancement of money that are subject to the higher education revenue bond intercept program.

**APPROVED** by Governor March 31, 2016 **EFFECTIVE** March 31, 2016

# H.B. 16-1459Submission Threshold for Higher Ed<br/>Cash Projects(Becker, K. &<br/>Brown/Sonnenberg & Kefalas)

Capital Development Committee. The bill:

\* Increases the dollar threshold for when the Colorado commission on higher education (CCHE) is allowed to except projects that are not for new construction from the requirements for program and physical planning;

\* Increases the dollar threshold for when CCHE has a duty to request from the governing board of each state institution of higher education a 2-year projection of projects that are not for new acquisitions of real property or new construction to be undertaken;

\* Increases the dollar threshold for the submission to the capital development committee of a 2year report for capital construction or capital renewal projects that are not for new acquisitions of real property or new construction for auxiliary and academic facilities to be funded solely from cash funds held by an institution of higher education; and

\* Makes conforming amendments and clarifies the reporting requirements.

APPROVED by Governor June 10, 2016

**EFFECTIVE** August 10, 2016



#### **<u>H.B. 16-1100</u>** Define Tuition Status Unaccompanied Homeless Youth

### (Pettersen & Esgar/Cooke)

The bill amends statutory provisions relating to the persons qualified to determine domicile for purposes of establishing in-state tuition at state institutions of higher education. The bill adds unaccompanied homeless youth to the list of persons who are qualified to determine their own domicile. An "unaccompanied homeless youth" is defined in the bill, consistent with the federal definition, as an individual who has not attained 22 years of age and who is either an unaccompanied youth who is a homeless child or youth or who has been verified as unaccompanied, at risk of homelessness, and self-supporting by one of four verifiers listed in the bill. The bill amends the definition of "qualified person" in the statutory provisions relating to tuition status to include unaccompanied homeless youth.

APPROVED by Governor May 17, 2016

EFFECTIVE May 17, 2016

# **<u>S.B. 16-161</u>** Regulate Athletic Trainers

#### (Crowder/Primavera)

The reengrossed bill requires athletic trainers to be registered with the Division of Professions and Occupations (DPO) in the Department of Regulatory Agencies (DORA), and reinstates the Athletic Trainer Practice Act as it existed prior to its 2015 repeal, by: • specifying educational background, certifications, and examination requirements; • providing DORA with the ability to set fees and schedule renewals of registrations; • establishing the grounds for disciplinary proceedings and authorizing the DPO director to take disciplinary actions; and • establishing a class 2 misdemeanor for conviction of the offense of practicing without an active registration, and a class 1 misdemeanor for a subsequent offense. In addition, the bill makes some changes to the act, including recodification, terminology modifications, and the following substantive changes: • adding title protection for the abbreviation A.T.C. (athletic trainer certified) to limit its use to registered athletic trainers; • requiring evidence of current national certification at registration and, if required by the DPO director, at renewal; and • adding as grounds for discipline the failure of an athletic trainer to practice pursuant to the direction of a Coloradolicensed or otherwise lawfully practicing health care professional and the failure to practice in a manner that meets generally accepted standards of athletic training practice. Entities involved with youth sports teams are not required to employ an athletic trainer and school coaches are not required to be athletic trainers. The bill repeals September 1, 2026, following a sunset review. APPROVED by Governor June 8, 2016 **EFFECTIVE** July 1, 2016

# S.B. 16-196 Inclusive Higher Education Pilot (Cooke & Cae Program

# (Cooke & Cadman/Landgraf & Young)

The reengrossed bill creates an inclusive higher education pilot program aimed at establishing higher education programs for students with intellectual and developmental disabilities. The program will operate from FY 2016-17 through FY 2020-21 at three institutions: the University of Northern Colorado, the University of Colorado-Colorado Springs, and Arapahoe Community College. Participating institutions must develop pilot programs, which may include: • conducting an assessment to determine needs related to inclusive higher education; • identifying state and institution regulations, polices, and practices that encourage or impede inclusive higher education; • offering programming and support for students with disabilities to take at least two on-campus undergraduate courses each semester in their area of interest and one course per

semester designed to meet the needs of students with disabilities; • integrating students socially and academically into the institution; • offering peer mentoring; • coordinating with vocational rehabilitation programs offered by the Department of Labor and Employment; • preparing students for gainful employment; • offering admissions standards that do not require a nationwide college entrance exam; • becoming a certified transition program to allow students to access federal financial aid, if the institution deems the pilot program sustainable; and • developing a five-year plan that includes enrollment projections for an inclusive higher education program. The bill specifies that the three participating institutions are not required to operate a pilot program if sufficient money is not appropriated by the General Assembly. Should an institution cease to operate the pilot program, DHE may request that the General Assembly reallocate funds among the participating institutions. In years in which the selected sites offer a pilot program and sufficient money is appropriated by the General Assembly, JFK Partners must annually evaluate the program from the perspective of multiple stakeholders listed in the bill, and provide a written report to the Department of Higher Education (DHE). As part of their annual presentation, DHE must report on the pilot program to the education committees of the House and Senate and the Joint Budget Committee and include the report from JFK Partners in years in which a pilot program is operating. The three participating institutions, JFK Partners, and Colorado Initiative for Higher Education (IN!) are encouraged to participate in an annual statewide summit on inclusive higher education in order to share best practices and promote the development of inclusive higher education programs. The bill transfers \$250,000 from the Intellectual and Developmental Disabilities Services Cash Fund to the General Fund in both FY 2015-16 and FY 2016-17 and appropriates \$250,000 for the program in FY 2016-17. The bill adds the pilot program as a purpose for which DHE can enter into fee-for-service contracts with participating institutions of higher education, and exempts the funding from provisions requiring that increases in higher education funding be matched by increases in funding to the College Opportunity Fund, or for financial aid.

**APPROVED** by Governor June 6, 2016 **EFFECTIVE** June 6, 2016

#### H.B. 16-1453 Colorado Cybersecurity Initiative

Joint Budget Committee. The Colorado cybersecurity council (council) is created in the department of public safety to operate as a steering group to develop cybersecurity policy guidance for the governor, develop comprehensive goals, requirements, initiatives, and milestones, and to coordinate with the general assembly and the judicial branch regarding cybersecurity. The council is comprised of specified officers from the governor's office, executive branch agencies, military organizations, institutions of higher education, the attorney general's office, and the state auditor's office. The department of public safety may coordinate with specified entities to define the operational requirements for in-state and interstate operational and training networks. The coordinating entities may:

\* Consider establishing memoranda of understanding or interstate compacts with entities that encourage the interstate sharing of information for cybersecurity;

\* Support the requirements for the fusion of cyber defense, cyber surveillance, and international and domestic intelligence and law enforcement operations;

\* Consider network infrastructures for interstate cyber training and operations;

\* Support secure Colorado requirements to identify threats and vulnerabilities, defend state cyber infrastructures, and investigate and enforce cyber-related crimes; and

\* Conduct training, inspections, and operational exercises. The university of Colorado at Colorado Springs (UCCS), in partnership with a nonprofit organization that supports national, state, and regional cybersecurity initiatives (nonprofit organization), may establish and expand cyber higher education programs and establish needed cyber education and training laboratories

(Hamner/Lambert)

in specified subject areas. UCCS and the nonprofit organization may:

\* Coordinate with the United States department of homeland security and the national security agency to certify cyber courses and curricula;

\* Coordinate planning for cyber education with appropriate institutions of higher education;

\* Identify appropriate curricula for community college and technical certification programs and for elementary and secondary education feeder programs;

\* Establish a public policy think tank as an academic research center of excellence for government, academic, and industrial communications, conferences, research, and publications; and

\* Establish education, training, and academic symposia for government leaders at all levels. UCCS and the nonprofit organization also may establish a secure environment for research and development, initial operational testing and evaluation, and expedited contracting for production for industrial cyber products and techniques and may consider:

\* Creating a business plan to develop a secure facility on the property of UCCS to allow physical, electronic, proprietary, and administrative security;

\* Exploring secure facility development and use at other Colorado universities and facilities; \* Establishing relationships with appropriate federally funded research and development corporations under the sponsorship of the United States department of defense and the United States department of homeland security;

\* Consider establishing relationships with certain existing federally funded research and development corporations, or consider creating a new organization to focus on defense and homeland security requirements;

\* Establishing cooperative relationships with Colorado cyber companies and other businesses, local governments, and other Colorado institutions with requirements for cybersecurity participation;

\* Establishing cooperative relations with civilian industrial producers; and

\* Linking to local and national military, homeland security, and intelligence community activities to support research and development, rapid test and evaluation, contracting, and production requirements. The cybersecurity cash fund (fund) is created in the state treasury. The fund consists of any money that the general assembly may appropriate or transfer to the fund. Subject to annual appropriation, the regents of the university of Colorado may expend money from the fund for the purposes of the bill. The cybersecurity gifts, grants, and donations account (account) is created in the fund. The regents of the university of Colorado may seek, accept, and expend gifts, grants, or donations from private or public sources for the purposes of the bill and are required to credit any such gifts, grants, or donations to the account. The moneys in the account are continuously appropriated to the department of higher education for use by the regents of the university of Colorado for the purposes of the bill.

#### **APPROVED** by Governor May 20, 2016 **EFFECTIVE** July 1, 2016

#### **H.B. 16-1423** Student Data Collection Use Security

#### (Lundeen/Hill)

Overview. The bill creates the Student Data Transparency and Security Act, and requires that the State Board of Education (SBE), the Colorado Department of Education (CDE), and schools, school districts, and Boards of Cooperative Educational Services (local education providers or LEPs) take actions to increase the transparency and security of student personally identifiable information (student PII). The bill imposes requirements on both the commercial entities that provide school services by formal contract with the CDE or an LEP (contract providers), and on the commercial entities that an LEP or employees of an LEP choose to use without entering into a formal, negotiated contract (on-demand providers). Contract providers. Each contract provider must give the CDE and LEPs clear information concerning the collection, use, and sharing of

student PII. A contract provider may only collect and use student PII for specified purposes authorized by the contract, and must obtain parental consent to use a student's data in any other way. Further, contract providers are prohibited from: • selling student PII; • using student PII for use in targeted advertising; or • using student PII to create a profile, except for purposes authorized by contract, or with parental consent. Student PII may only be shared with subcontractors, who are subject to the same restrictions and requirements imposed on the contract provider. Each contract provider must maintain a comprehensive information security program, and must destroy student PII in accordance with the terms of the contract. The bill creates some exceptions to the data restrictions and contract requirements imposed on contract providers. On-demand providers. Each LEP must post on its website a list of the on-demand providers in use by the LEP or its employees, and update the list twice each school year. If the LEP has evidence that an on-demand provider does not comply with its own privacy policy, or does not meet the restrictions and requirements imposed on contract providers, the LEP is encouraged to stop using the on-demand provider. The CDE must post on its website a list of the on-demand providers that LEPs stop using as a result of data privacy issues, and any written statements from those on-demand providers. Colorado Department of Education. The CDE is required to ensure that contracts the department enters into that share student PII include certain restrictions and requirements. The CDE must terminate the contract if a researcher commits a material breach of the contract involving the misuse or unauthorized release of student PII. The department must also maintain on its website a detailed list of the vendors, researchers, research organizations, and government agencies with which it has data sharing agreements involving student PII. The CDE must create a sample student information privacy and protection policy, and sample school service provider contract language that LEPs may choose to use. The department must make training materials and, upon request, training services, available to LEPs for training employees with regard to student information security and privacy. Local education providers. No later than December 31, 2017, each LEP must adopt a student information privacy and protection policy, make copies available to parents upon request, and post the policy on its website. Small rural school districts have until July 1, 2018, to adopt a policy. Each LEP is required to ensure that data sharing agreements with contract providers include the bill's restrictions and requirements. If the contract provider misuses data, or makes an unauthorized release of student PII, the LEP must either terminate the agreement or hold a public meeting to discuss the nature of the material breach, and to decide whether to terminate the agreement. Each LEP is required to post on its website a list of the student PII collected and maintained by the LEP, in addition to the student PII that the LEP submits to the CDE. Parents' rights. The bill recognizes a parent's right to inspect and review his or her child's student PII, request a paper or electronic copy of his or her child's student PII, and request corrections to factually inaccurate student PII that an LEP maintains. The governing board of each LEP must adopt a policy for hearing complaints from parents concerning the LEP's data policies.

**APPROVED** by Governor June 10, 2016 **EFFECTIVE** August 10, 2016

#### **S.B. 16-209** Authorize School District Property (1 Lease to Higher Education Institution

# (Todd & Holbert/Buckner & Priola)

The bill authorizes a school district board of education to lease school district property to a state institution of higher education and to accept in-kind services from the institution as all or part of the lease payments. The bill clarifies that a school district may issue bonds to construct a building for lease to a state institution of higher education.

APPROVED by Governor June 6, 2016

**EFFECTIVE** August 10, 2016

# H.B. 16-1142Rural and Frontier Health Care Preceptor<br/>Tax Credit(Buck & Ginal/Crowder<br/>& Cooke)

As amended in House Finance Committee, for tax years 2017, 2018, and 2019, this bill creates a state income tax credit for licensed Colorado health care professionals who provide uncompensated personalized instruction, training, and supervision to one or more graduate students seeking a medical degree at a Colorado institution for higher education. Instruction, training, and supervision must last at least four weeks during the income tax year in which the credit is claimed. The credit is limited to 200 qualifying taxpayers each year at \$1,000 per taxpayer. This credit is non-refundable, meaning it is limited to a taxpayer's income tax liability. Credits in excess of this amount may be carried forward for up to five years. A qualifying health care professional must be practicing in a designated rural or frontier county and must provide a certification form with their income tax return certifying that the he or she has satisfied the requirements for the tax credit. The certification form may be provided by an institution of higher education, hospital, or area health education center (AHEC) located in the jurisdiction of the health care professional's practice. AHECs may charge a reasonable fee for providing the certification form.

**APPROVED** by Governor June 6, 2016 **EFFECTIVE** August 10, 2016

# **<u>H.B. 16-1101</u>** Medical Decisions for Unrepresented Patients

#### (Young/Lundberg)

The reengrossed bill allows an attending physician to designate another willing physician to act as a patient's proxy decision-maker for health care treatment under certain conditions. The attending physician cannot act as the proxy decision-maker. A physician may be designated as a proxy decision-maker if: • after reasonable effort, the physician cannot locate any interested person, including the patient's spouse, a parent, an adult child, a sibling, a grandchild, or any close friend of the patient, who is willing and able to act as proxy decision-maker; • the physician has obtained an independent assessment of the patient's decision-making capacity from another health care provider confirming the patient's lack of decisional capacity; and • the physician has consulted with and obtained a consensus on the proxy designation with the medical ethics committee of the facility where the patient is receiving care. The designated physician's authority to act as proxy decision-maker terminates if: • an interested person is appointed to act as the proxy decision-maker; • a guardian is appointed for the patient; • the patient regains decisional capacity; • the proxy decision-maker no longer wishes to serve in that capacity; or • the patient is transferred or discharged from the facility where he or she is receiving care, unless the proxy decision-maker expresses his or her intention to continue acting in that capacity. The bill outlines procedures for decision-making by the attending physician, the proxy decisionmaker, and the facility's medical ethics committee, including for end-of-life treatment. A physician or his or her designee who is acting in good faith as a proxy decision-maker is not subject to civil or criminal liability or regulatory sanction, except that liability remains for any negligent acts or omissions in rendering care to an unrepresented patient. APPROVED by Governor May 18, 2016

APPROVED by Governor May 18, 2

EFFECTIVE August 10, 2016

### **H.B. 16-1408** Cash Fund Allocations for Healthrelated Programs

#### (Rankin/Steadman)

Recommend by the Joint Budget Committee, this rerevised bill establishes a new formula for the allocation of the annual payment received by the state as part of the Tobacco Master Settlement Agreement (Tobacco MSA). The new formula allocates all Tobacco MSA revenue by percentage shares, rather than the hybrid scheme of fixed dollar amounts and capped percentage shares in multiple tiers. The formula increases annual allocations to most programs receiving funding under the current distribution, while eliminating dedicated funding for the six purposes: • the Early Literacy Fund in the Department of Education; • the Public Health Services Support Fund in the Department of Public Health and Environment; • the Offender Mental Health Services Program in the Department of Human Services; • the Alcohol and Drug Abuse Prevention Program in the Department of Human Services; • the Children's' Mental Health Treatment Program in the Department of Human Services; and • the annual audit of Tobacco MSA-funded programs by the Office of the State Auditor. For all of these purposes listed above except the audit, the bill makes FY 2016-17 appropriations from the Marijuana Tax Cash Fund in the amounts that the programs are expected to receive under the current law allocation formula. The bill repeals the Public Health Services Support Fund and the Tobacco Litigation Settlement Trust Fund. It requires the State Treasurer to transfer any remaining balance in the Public Health Services Support Fund and the Offender Mental Health Services Fund to the Tobacco Litigation Settlement Cash Fund at the end of FY 2015-16. The bill creates a new Primary Care Provider Sustainability Fund in the Department of Health Care Policy and Financing to fund increased access to primary care office visits, immunization administration, health screening services, and newborn care, including neonatal critical care. On July 1, 2016, \$20.0 million is transferred from the Children's Basic Health Plan Trust to this new fund. The bill also modifies statute concerning higher education fee-for-service contracts paid to the University of Colorado for specialty education services, specifying that these contracts include care provided by faculty of the University of Colorado Health Sciences Center and are eligible for payment under the state's Medicaid provider reimbursement.

#### **APPROVED** by Governor May 4, 2016

#### EFFECTIVE July 1, 2016\*

\*The requirement that all money in the Public Health Services Support Fund and the Offender Mental Health Services Fund be transferred to the Tobacco Litigation Settlement Cash Fund at the end of FY 2015-16 takes effect upon signature of the Governor.

#### **<u>S.B. 16-062</u>** Veterinary Pharmaceuticals

#### (Marble/Becker J.)

This bill, as amended by the House State, Veterans, and Military Affairs Committee, creates the Veterinary Pharmaceutical Advisory Committee (advisory committee) in the Department of Regulatory Agencies (DORA) to hear matters concerning veterinary pharmaceuticals referred by the State Board of Pharmacy (board), specifically related to board action on an investigation or complaint, application review, and rules. The three-member advisory committee — whose qualifications, terms, succession, and meeting requirements are outlined in the bill — serve without compensation or expense reimbursement. DORA is to provide staff assistance to the advisory committee. The board, in consultation with the State Board of Veterinary Medicine, may promulgate rules to implement the advisory committee. The advisory committee repeals on September 1, 2026, following a sunset review. The board is prohibited from regulating the sale of disposable veterinary devices. It may exempt from regulation veterinary devices that are regulated by the federal Food and Drug Administration and other devices for which it determines regulation is unnecessary. Finally, the bill creates a reduced civil penalty between \$50 and \$500 for a single violation, and a maximum penalty of \$5,000 for multiple violations, for persons who

unlawfully distribute a veterinary drug; except that the board may issue a per violation fine between \$500 and \$5,000 if it determines that the registrant has committed one or more egregious violations. Before issuing a fine, the board must provide notice to the registrant and a hearing opportunity. The board must also consider the registrant's ability to pay the fine and waive the fine if it would cause the registrant undue hardship.

**APPROVED** by Governor June 10, 2016

**EFFECTIVE** July 1, 2016

# S.B. 16-135 Collaborative Pharmacy Practice Agreements

(Aguilar/Ginal)

The bill allows health insurance plans to provide coverage for health care services provided by a pharmacist as part of a collaborative pharmacy practice agreement if certain conditions are met. Specifically, the health plan must provide coverage for the same service if it is provided by a licensed physician or an advanced practice nurse and the pharmacist must be included in the insurers network of participating providers. The State Board of Pharmacy, the Colorado Medical Board, and the State Board of Nursing must jointly create rules governing collaborative pharmacy practice agreements. Collaborative pharmacy practice agreements are voluntary agreements between a licensed pharmacist and a physician or advanced practice nurse that allow a pharmacist to provide evidence-based health care services to one or more patients pursuant to a specific treatment protocol delegated to a pharmacist by a physician or advanced practice nurse. Collaborative pharmacy and the Department of Public Health and Environment for public health care services, including health care services for smoking cessation, travel health services, and self-administered hormonal contraception. **APPROVED** by Governor June 6, 2016

**EFFECTIVE** August 10, 2016

# GIVERNMENT RELATIONS Other Legislation

# H.B. 16-1405 2016-17 Long Appropriations Bill

(Hamner/Lambert)

(Roupe/Cooke)

Provides for the payment of expenses of the executive, legislative, and judicial departments of the state of Colorado, and of its agencies and institutions, for and during the fiscal year beginning July 1, 2016, except as otherwise noted.

**APPROVED** by Governor May 3, 2016 **EFFECTIVE** May 3, 2016

# **<u>H.B. 16-1114</u>** Repeal Employment Verification Standards (DelGrosso/Ulibarri)

As amended by the House Business Affairs and Labor Committee, this bill eliminates current employment verification standards that: • require each employer in Colorado to attest within 20 days that it has verified the legal work status of each employee, has not altered or falsified employee identification documents, and has not knowingly hired an unauthorized alien; • require each employer in Colorado to submit documentation to the director of the Division of Labor in the Colorado Department of Labor and Employment (CDLE) that demonstrates that the employer is in compliance with federal employment verification requirements; and • fine an employer for failing to provide required documentation or for providing fraudulent documentation.

**APPROVED** by Governor June 8, 2016 **EFFECTIVE** August 10, 2016

### **<u>H.B. 16-1048</u>** Expand Business Enterprise Program (Primavera/Lundberg)

This bill, as amended by the House Business Affairs and Labor Committee, establishes a working group in the CDLE consisting of various stakeholders and representatives from state agencies concerning the Business Enterprise Program (BEP). Specifically, the working group is required to study ways to expand opportunities for BEP vendors at the Department of Corrections, the Department of Natural Resources, institutions of higher education, and the Colorado State Fair. The working group will also consider the possibility of the BEP vendors expanding beyond food service and vending facilities. The working group is required to prepare a report and make recommendations to the relevant committees of the General Assembly by January 1, 2017. The bill also allows the CDLE to issue licenses to BEP vendors to operate businesses other than vending facilities.

**APPROVED** by Governor May 4, 2016 **EFFECTIVE** July 1, 2016

# **<u>H.B. 16-1104</u>** Summons in Lieu of Warrant for Non-violent Crimes

The reengrossed bill changes the rules and procedures for when a summons can be issued to a defendant in lieu of a warrant. The bill: • allows law enforcement officers, rather than the courts, to issue a summons in lieu of a warrant, based on the officer's discretion if certain conditions are met; • prohibits a summons in lieu of a warrant for class 4 felonies and crimes relating to victims' rights laws; and • allows for a summons in lieu of a warrant for level 1 and 2 drug felonies. A law enforcement officer may issue a summons if he or she believes there is a reasonable likelihood the defendant will appear, the local district attorney approves and has developed criteria for the procedure, the defendant has had no felony arrests in the past five years, there is

no allegation that the defendant used a deadly weapon, and there are no outstanding warrants for the defendant's arrest. Under the bill, a defendant receives the summons from the law enforcement officer rather than by mail, and it is signed by either the judge, the clerk of court, or the law enforcement officer. The law enforcement officer must deliver a copy to the court and the district attorney in the jurisdiction where the offense took place, no later than ten days after he or she issued the summons. The bill specifies that an information or complaint may be filed in open court on the date listed in the summons.

**APPROVED** by Governor April 21, 2016 **EFFECTIVE** August 10, 2016

# **<u>H.B. 16-1438</u>** Employer Accommodations Related to Pregnancy

This reengrossed bill requires employers to engage in a timely, good-faith, interactive process when an employee or applicant requests reasonable accommodations related to pregnancy or physical recovery from childbirth. Reasonable accommodations may include the provision of more frequent or longer break periods; more frequent bathroom, food, or water breaks; acquisition or modification of equipment or seating; limitations on lifting; temporary transfer to a less strenuous or hazardous position or light duty, if available; assistance with manual labor; or modified work schedules, as long as certain conditions are met. Employers must provide these accommodations to an applicant for employment or to an employee, if requested, unless the accommodations place an undue hardship on the employer's business. "Undue hardship" is defined as an action requiring significant difficulty or expense to the employer and can include consideration of the following factors: • the nature and cost of the accommodations; • the overall financial resources of the employer or overall size of the business; and • the accommodation's effect on expenses, resources, or operations. In response to a request or need for reasonable accommodations related to pregnancy or childbirth, an employer may not: • take adverse actions against an employee; • deny employment opportunities to an applicant or employee; • require an applicant or employee to accept an accommodation that the applicant or employee has not requested or is unnecessary; or • require an employee to take leave if the employer can provide another reasonable accommodation. Employers must provide written notice of the right to be free from discriminatory or unfair employment practices related to these requirements to new employees and existing employees within 120 days of the bill's effective date, and they must post the notice in a conspicuous place. With the exception of posting the notice, any violation of these requirements constitutes a discriminatory or unfair employment practice. The bill clarifies that it neither increases nor decreases an employee's rights, under any other law, to paid or unpaid leave associated with the employee's pregnancy. The bill also specifies that a court must not award punitive damages in a civil action involving a claim of failure to make reasonable accommodations for conditions related to pregnancy or childbirth if the defendant demonstrated good faith efforts to comply with the requirement.

**APPROVED** by Governor June 1, 2016

EFFECTIVE August 10, 2016

### **S.B. 16-218** State Severance Tax Refunds

### (Lambert & Steadman/Hamner & Rankin)

(Winter/Martinez Humenik)

This reengrossed bill addresses a severance tax refund obligation arising as a result of the Colorado Supreme Court's April 25, 2016, decision in BP America v. Colorado Department of Revenue. The bill creates a mechanism for refunds of severance tax revenue to businesses, including businesses that revise their severance tax returns to claim additional tax deductions for tax years 2012 through 2015. It establishes a reserve from which all severance tax refunds are to be paid prior to the allocation of tax revenue to cash funds in the Department of Natural

Resources (DNR) and the Department of Local Affairs (DOLA). For FY 2015-16, income tax revenue is diverted from the General Fund to the reserve in amounts sufficient to pay any severance tax refunds that exceed severance tax revenue collected after the bill's effective date and before the end of the fiscal year. For FY 2016-17, income tax revenue is diverted each month from the General Fund to the reserve in amounts sufficient to pay any severance tax refund that exceeds 15 percent of severance tax revenue collected for that month. The bill imposes restrictions on \$19.1 million in the Severance Tax Perpetual Base Fund, \$10.0 million in the Severance Tax Operational Fund, and \$48.3 million in the Local Government Severance Tax Fund. While restrictions are in place, these moneys must remain in their respective cash funds and can not be expended for state purposes. Restrictions may be lifted in whole or in part upon a majority vote of the members of the Joint Budget Committee (JBC). The bill also extends a statutory repeal date, allowing severance tax revenue to continue to be allocated to the Severance Tax Trust Fund and the Local Government Severance Tax Fund between January 1, 2017, and July 1, 2017.

**APPROVED** by Governor June 10, 2016 **EFFECTIVE** June 10, 2016 GIVERNMENT RELATIONS Key Research Federal Legislation 114th Congress, 2nd Session

# S. 3084 American Innovation and Competitiveness Act (Ga

(Gardner)

This bill calls on the National Science Foundation (NSF) to maintain the intellectual merit and broader impacts criteria as the basis for evaluating grant proposals in the merit review process. The NSF shall issue and periodically update policy guidance for both NSF staff and other NSF merit review process participants, emphasizing the importance of transparency and accountability of the outcomes made through such process.

The bill renames the Experimental Program to Stimulate Competitive Research as the Established Program to Stimulate Competitive Research (EPSCoR) and revises program requirements.

The National Institute of Standards and Technology (NIST) shall: (1) research information systems for future cybersecurity needs; and (2) develop a process to research and identify, or if necessary, develop cryptography standards and guidelines for future cybersecurity needs, including quantum-resistant cryptography standards.

The bill renames the National High Performance Computing Program as the Networking and Information Technology Research and Development Program and revises program requirements. The National Science and Technology Council (NSTC) shall define and coordinate federal research in high-energy physics.

The NIST shall implement a comprehensive strategic plan for laboratory programs expanding interactions with academia, international researchers, and industry, and commercial and industrial applications.

The NSF shall:

- evaluate the existing and future needs, across all NSF-supported disciplines, for midscale projects; and
- strengthen oversight and accountability over the full life-cycle of large-scale research facility projects; and
- continue to review its efforts to sustain scientific efforts in the face of logistical challenges for the U.S. Antarctic Program.

The Department of Commerce Office of Security shall directly manage NIST's law enforcement and security programs through an assigned Director of Security for NIST.

The Office of Management and Budget shall establish an interagency working group to reduce administrative burdens of federally funded researchers while protecting the public's interest in the transparency of, and accountability for, federally funded activities.

The NSF, the Department of Education, the National Oceanic and Atmospheric Administration, and the National Aeronautics and Space Administration (NASA) shall establish the STEM Education Advisory Panel to advise the NSTC Committee on STEM Education on matters related to science, technology, engineering, and mathematics (STEM). The NSF shall award grants to:

- increase the participation of women and underrepresented groups in STEM fields,
- for research to advance the engagement of students in grades kindergarten through 8 in STEM, and
- for establishment of at least one Center of Excellence for the collection, maintenance, and dissemination of information to increase the participation of women and groups underrepresented in STEM fields.

The National Institute of Standards and Technology Act is amended to revise requirements for:

- the NIST post-doctoral fellowship program, and
- the Hollings Manufacturing Extension Partnership.

Federal agencies may use crowdsourcing and voluntary, collaborative citizen science to advance their missions.

The Office of Science and Technology Policy shall establish an interagency working group to:

- summarize available research and best practices on how to promote diversity and inclusions in STEM fields, and
- examine whether barriers exist to promoting diversity and inclusion within federal agencies employing scientists and engineers.

Each federal agency shall recommend to the President how it could expand research opportunities for undergraduate students attending institutions of higher education. The NSF shall award grants for:

- research on computer science education and computational thinking; and
- Innovation Corps entrepreneurship and commercialization education, training, and mentoring.

Discussed and expressed support for this bill. Status: 01/06/2017 Became Public Law No: 114-329.

# H.R. 1806America Competes Reauthorization Act of<br/>2015(Lamar)

# America Competes Reauthorization Act of 2015

TITLE I--NATIONAL SCIENCE FOUNDATION

(Sec. 101) Authorizes appropriations for FY2016-FY2017 for the National Science Foundation (NSF).

(Sec. 103) Specifies policy objectives for the NSF in allocating resources.

(Sec. 105) Expresses the sense of Congress that: (1) sustained, predictable federal funding is essential to U.S. leadership in science and technology; (2) building understanding of and confidence in investments in basic research are essential to public support for sustained, predictable federal funding; and (3) the NSF should commit itself fully to transparency and accountability and to clear, consistent public communication regarding the national interest for each NSF-awarded grant and cooperative agreement.

(Sec. 106) Directs the NSF to award federal funding for basic research and education in the sciences through a new research grant or cooperative agreement only if it makes an affirmative determination, justified in writing, that the grant or agreement promotes the progress of science in the United States, is worthy of federal funding, and meets certain other criteria.

(Sec. 107) Prohibits the obligation of funds for an NSF construction project that has not commenced before enactment of this Act until 30 days after transmittal to Congress of the annual report on major research equipment and facilities construction.

(Sec. 108) Directs the NSF to maintain a Large Facilities Office within the Office of the NSF Director to support the research directorates in the development, implementation, and assessment of major multi-user research facilities.

Requires the NSF Director to appoint a senior agency official within the Office of the Director responsible for oversight of major multi-user research facilities.

Requires the NSF to study reforming the NSF policies on financial management of major multiuser research facilities. Allows the NSF to provide management fees under an award only if the awardee has demonstrated that it has limited or no other financial resources available to cover the expenses for which the fees are sought.

Specifies prohibited uses of management fees.

(Sec. 109) Subjects the NSF to the prohibitions and requirements of the pilot program for the enhancement of contractor protection from reprisal for disclosure of certain information. Requires the NSF to provide education and training to the NSF managers and staff on such prohibitions and requirements and to give information on the law to all grantees, contractors, and their employees.

(Sec. 110) Expresses the sense of Congress that the NSF Research Traineeship Program, formerly the Integrative Graduate Education and Research Traineeship program, (or any successor to it) should be maintained.

Directs the NSF to enter into an agreement with the National Research Council (NRC) to convene a workshop or roundtable to examine models of federal support for STEM (science, technology, engineering, and mathematics) graduate students, including the NSF Graduate Research Fellowship Program and comparable fellowship programs at other agencies, traineeship programs, and the research assistant model.

(Sec. 111) Permits the use of a grant made by the Education and Human Resources Directorate to support informal education to: (1) support the participation of underrepresented students in nonprofit competitions, out-of-school activities, and field experiences related to STEM subjects; and (2) broaden underrepresented secondary school students' access to, and interest in, careers that require academic preparation in STEM subjects.

(Sec. 112) Directs the NSF, within the Education and Human Resources Directorate (or any successor to it), under existing programs targeting broadening participation, to provide grants on a merit-reviewed, competitive basis for research on programming that engages underrepresented students in grades kindergarten through 8 in STEM.

Requires the use of awarded grants for research to advance the engagement of underrepresented students in grades kindergarten through 8 in STEM through the implementation of innovative before-school, after-school, out-of-school, or summer activities.

(Sec. 113) Requires the NSF to review the NSF education programs in operation to determine: (1) whether any of these programs duplicates target groups, services provided, fields of focus, or objectives; and (2) how the programs are being evaluated and assessed for outcome-oriented effectiveness.

(Sec. 114) Instructs the NSF to ensure that the system for recompetition of Maintenance and Operations of facilities, equipment, and instrumentation is fair, consistent, and transparent and is applied in a manner that renews grants and awards in a timely manner.

(Sec. 115) Expresses the sense of Congress regarding industry's involvement in STEM education.

(Sec. 116) Prohibits any falsification, fabrication, or plagiarism in the findings and conclusions of any article authored by a principal investigator receiving an the NSF research grant, using the results of the research conducted under the grant, that is published in a peer-reviewed publication, otherwise made publicly available, or incorporated in an application for a research grant or grant extension.

Instructs the NSF Director to make publicly available any finding that research misconduct has been committed, including the name of the principal investigator, within 30 days of final administration action.

(Sec. 117) Expresses the sense of Congress regarding the reproduction and replication of published scientific research findings.

Requires the NSF Director to enter into an agreement with the NRC to assess research and data reproducibility and replicability issues in interdisciplinary research and make recommendations on how to improve rigor and transparency in scientific research.

(Sec. 118) Directs the NSF to establish procedures to ensure that specified requirements are met with respect to research grants awarded by the NSF.

(Sec. 119) Directs the Government Accountability Office (GAO) to study the use of scientific computing resources funded by the NSF at institutions of higher education.

(Sec. 120) Instructs the NSF to place a high priority on designing and administering pilot programs for scientific breakthrough prizes, in conjunction with private entities, for technological breakthroughs of strategic importance to the United States that have the capacity to

spur new economic growth. (Sec. 121) Requires NSF reports to Congress on individuals employed pursuant to the

Intergovernmental Personnel Act of 1970.

(Sec. 122) Expresses the sense of Congress regarding the NSF's Innovation Corps. Declares that the I-Corps should continue to promote a strong innovation system by investing in and supporting female entreprenuers, who are historically underrepresented in entrepreneurial fields, through mentorship, education, and training.

(Sec. 123) Directs the NSF to support research activities related to the Brain Research through Advancing Innovative Neurotechnologies Initiative, encouraging it to work with the Interagency Working Group on Neuroscience to determine how to use the NSF and other agency data infrastructures to help neuroscientists collect, standardize, manage, and analyze large amounts of data.

(Sec. 124) Amends the National Science Foundation Authorization Act of 2002 to allow the award of the NSF Master Teaching Fellowships to mathematics and science teachers who possess a bachelor's degree in their field (currently limited to those with a master's degree). Makes teachers with bachelor's degrees in their field and working towards a master's degree eligible for a one-year NSF Master Teaching Fellowship.

Makes elementary or secondary school computer science teachers eligible for teacher recruiting and training grants under the Robert Noyce Teacher Scholarship Program.

(Sec. 125) Requires the NSF Director to continue to award competitive, merit-reviewed grants to support: (1) research and development of innovative out-of-school STEM learning and emerging STEM learning environments, and (2) research that advances the field of informal STEM education.

(Sec. 126) Requires the NSF to continue to operate the Experimental Program to Stimulate Competitive Research (EPSCoR). Urges the NSF to make this program a high priority.

(Sec. 127) Directs the NSF, within 120 days of enactment of this Act, to establish the Hispanicserving institutions undergraduate program described in the America COMPETES Act for Hispanic-serving institutions of higher education.

TITLE II--SCIENCE, TECHNOLOGY, ENGINEERING, AND MATHEMATICS (Sec. 201) Expresses the sense of Congress regarding federal STEM programs.

(Sec. 202) Directs the President to establish or designate a 15-member STEM Education Advisory Panel, co-chaired by members of the President's Council of Advisors on Science and Technology.

(Sec. 203) Amends the America COMPETES Reauthorization Act of 2010 to require the Committee on STEM Education to: (1) collaborate with the STEM Education Advisory Panel and other outside stakeholders to ensure the engagement of the STEM education community, and (2) review evaluation measures used for federal STEM education programs.

(Sec. 204) Requires the NSF to establish within the Directorate for Education and Human Resources a STEM Education Coordinating Office to:

- give technical and administrative support to the Committee on STEM Education, the Advisory Panel, and federal agencies with STEM education programs;
- update periodically an inventory of federally sponsored STEM education programs and activities, and
- arrange dissemination of information on federal STEM education programs and activities to stakeholders in academia, industry, nonprofits with expertise in STEM education, state and local education agencies, and other STEM stakeholders.

TITLE III--OFFICE OF SCIENCE AND TECHNOLOGY POLICY

(Sec. 301) Authorizes appropriations for FY2016-FY2017 for the Office of Science and Technology Policy (OSTP).

(Sec. 302) Expresses the sense of Congress regarding the administrative burdens and costs in federal research administration.

Requires the OSTP Director to establish a working group under the authority of the National Science and Technology Council (NSTC) that includes the Office of Management and Budget. Makes this working group responsible for reviewing federal regulations affecting research and research universities and making recommendations on how to: (1) harmonize, streamline, and eliminate duplicative federal regulations and reporting requirements; (2) minimize the regulatory burden on U.S. institutions of higher education performing federally funded research while maintaining accountability for federal tax dollars; and (3) identify and update specific regulations to refocus on performance-based goals rather than on process while still meeting the desired outcome.

(Sec. 303) Requires the OSTP to establish under the NSTC a body, co-chaired by senior level officials from OSTP and the Department of State, to identify and coordinate international science and technology cooperation that can strengthen U.S. science and technology enterprise, improve economic and national security, and support U.S. foreign policy goals.

(Sec. 304) Directs specified federal science agencies to conduct pilot programs to validate alternative research funding models, including: (1) scientific breakthrough prize programs of strategic importance to the nation with the capacity to spur new economic growth; and (2) novel mechanisms of funding.

States that judges for prize competitions carried out under this section shall not be required to be federal employees.

Requires a judge for a prize competition with a total purse of \$10,000 or more, or for an aggregate of prize competitions with a total purse of \$50,000 or more, to disclose all personal financial interests.

(Sec. 305) Amends the Stevenson-Wydler Technology Innovation Act of 1980 regarding prize competitions, allowing an agency to waive liability insurance requirements for participants. Allows an agency to enter into a grant, contract, cooperative agreement, or other agreement with a private sector for-profit as well as a nonprofit entity (as under current law) to administer a prize competition.

Permits the use of funds from private sector for-profit entities to support a prize competition, as well as federal agency funds made available to the extent provided by appropriations acts. Prohibits an agency from giving special consideration to any private sector for-profit entity in return for a donation.

Limits the use of federal funds to those made available by appropriations Acts.

(Sec. 306) Authorizes the President to appoint a United States Chief Technology Officer, who shall be one of the Associate Directors of the OSTP, to:

• advise the President and the OSTP Director on federal information systems, technology, data, and innovation policies and initiatives;

- promote the use of innovative technological approaches across the federal government to ensure a modern information technology infrastructure; and
- work with the Chief Technology Officers and Chief Information Officers of all federal agencies to ensure the use of the best technologies and security practices for information systems.

(Sec. 307) Directs OSTP to arrange with the NRC to review technologies employed at institutions of higher education in order to provide notifications to students, faculty, and other personnel during emergency situations.

TITLE IV--NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

(Sec. 401) Authorizes appropriations for FY2016-FY2017 for the National Institute of Standards and Technology (NIST).

(Sec. 402) Amends the National Institute of Standards and Technology Act to authorize the NIST Director to: (1) serve as the President's principal advisor on standards policy pertaining to technological competitiveness and innovation ability, (2) facilitate standards-related information sharing and cooperation between federal agencies, (3) participate in and support scientific and technical conferences, and (4) perform pre-competitive measurement science and technology research with institutions of higher education and industry.

(Sec. 403) Revises the membership of the Visiting Committee on Advanced Technology, from a maximum of 15 to a minimum of 11, requiring that at least two-thirds of them (currently 10) to be from U.S. industry. Authorizes the Committee to consult with the NRC in making recommendations regarding general policy for NIST.

(Sec. 404) Authorizes the Department of Commerce to undertake activities to protect NIST buildings and other plant facilities, equipment, and property and persons located in them or associated with them.

(Sec. 405) Revises requirements for research fellowships. Authorizes the NIST Director to support, promote, and coordinate activities and efforts to enhance awareness and understanding of measurement sciences, standards, and technology. Requires the Post-Doctoral Fellowship Program to include no fewer than 20 fellows per fiscal year (currently, no fewer than 20 nor more than 120 new fellows per fiscal year). Eliminates the separate manufacturing fellowship and teacher science and technology enhancement programs.

(Sec. 406) Requires the three-year programmatic planning document for NIST to also describe how the NIST Director is addressing recommendations from the Visiting Committee on Advanced Technology.

(Sec. 407) Directs NIST to contract with the National Academy of Sciences to review NIST laboratory programs.

Directs NIST to contract with the NRC to assess the technical quality and impact of the work conducted at NIST laboratories. (Currently, NIST may contract with the NRC for advice and studies to serve industry and science.)

Allows NIST to contract with the NRC also to conduct additional assessments of NIST programs and projects that involve collaboration across NIST laboratories and centers and assessments of selected scientific and technical topics.

(Sec. 408) Revises requirements for the Hollings Manufacturing Extension Partnership and Hollings Manufacturing Extension Centers.

Includes as an objective of the Centers the promotion and expansion of certification systems offered through industry, associations, and local colleges.

Eliminates from the activities of Centers any loans, on a selective, short-term basis, of items of advanced manufacturing equipment to small manufacturing firms with less than 100 employees. Requires those activities instead to include facilitation of collaborations and partnerships between small and medium-sized manufacturing companies and community colleges and area

career and technical education schools to help: (1) the colleges and schools better understand the specific needs of manufacturers, and (2) manufacturers better understand the skill sets that students learn in the programs offered by those institutions.

Repeals the six-year limitation on financial support the Department of Commerce may give to any Center created under the Partnership.

Instructs Commerce to implement, review, and update regulations related to the Partnership at least once every three years.

Revises cost-sharing requirements for the receipt by an applicant of financial assistance under the Partnership.

Requires a Center to: (1) undergo an independent review in its eighth year of operation, and (2) be placed on probation for one year if the evaluation is not positive. Requires the Director, if a Center, upon reevaluation, has not shown a significant improvement in its performance, to conduct a new competition to select an operator for the Center. Permits the Director, as an alternative, to close the Center.

Requires the NIST to: (1) transmit to Congress a plan for how it will conduct reviews, assessments, and reapplication competitions; and (2) contract with an independent organization to assess the implementation of the reapplication competition process required for any Center after 10 consecutive years of financial assistance.

Applies the Freedom of Information Act (FOIA) to confidential information obtained by the government on the business operation of any participant in a Partnership program or of a client of a Center and trade secrets possessed by any client of a Center.

Requires each Center's advisory boards to institute a conflict of interest policy that ensures representation of local small and medium-sized manufacturers in the Center's region. Prohibits board members from serving or providing services to the Center or serving on more than one Center's oversight board simultaneously.

Changes the membership of the Manufacturing Extension Partnership Advisory Board from a maximum to a minimum of 10, at least one of whom represents a community college. Requires the Director, under the competitive grant program, to select proposals that will promote the transfer and commercialization of research and technology from institutions of higher education, national laboratories, and nonprofit research institutes.

Eliminates the separate innovative services initiative to assist small- and medium-sized manufacturers.

(Sec. 409) Eliminates the requirement for NIST, through the Technology Innovation Program (TIP), to continue providing support originally awarded under the Advanced Technology Program.

(Sec. 410) Amends the Stevenson-Wydler Technology Innovation Act of 1980 to repeal the limitation to 75% of the total cost of the program on the total amount of any grant or cooperative agreement to assist activities under the Act.

(Sec. 411) Removes the National Security Agency (NSA) from the list of agencies that NIST must consult in developing standards and guidelines for information systems.

(Sec. 412) Expresses the sense of Congress concerning U.S.-Israeli cooperation with regard to basic scientific research.

Calls on NIST to continue to facilitate scientific collaborations between Israel and the U.S. technical agencies working in measurement science and standardization.

TITLE V--DEPARTMENT OF ENERGY SCIENCE

(Sec. 501) Amends the Department of Energy Organization Act to declare that the mission of the Department of Energy (DOE) Office of Science shall be the delivery of scientific discoveries, capabilities, and major scientific tools to transform the understanding of nature and to advance the energy, economic, and national security of the United States.

Directs the Office of Science, in support of such mission, to carry out programs on basic energy sciences, advanced scientific computing research, high energy physics, biological and environmental research, fusion energy sciences, and nuclear physics through activities focused on:

- fundamental scientific discoveries through the study of matter and energy;
- science in the national interest; and
- national scientific user facilities to deliver the 21st century tools of science, engineering, and technology and provide U.S. researchers with the most advanced tools of modern science.

Requires the Under Secretary for Science and Energy to ensure the coordination of Office of Science activities and programs with other activities of DOE.

(Sec. 502) Directs the Office of Science to carry out a program in basic energy sciences, including materials sciences and engineering, chemical sciences, physical biosciences, and geosciences to support:

- fundamental research to understand, predict, and ultimately control matter and energy at the electronic, atomic, and molecular levels in order to provide the foundations for new energy technologies; and
- DOE missions in energy, environment, and national security.

Requires a subprogram for the development and operation of national user facilities, including xray light sources, neutron sources, nanoscale science research centers, and other appropriate facilities, to support the program in basic energy sciences.

Directs the Office of Science to:

- establish an initiative to sustain and advance global leadership of light source user facilities;
- carry out research and development on advanced accelerator and storage ring technologies relevant to the development of Basic Energy Sciences user facilities; and
- make awards, on a competitive, merit-reviewed basis, to multiinstitutional collaborations or other appropriate entities to conduct fundamental and use-inspired energy research to accelerate scientific breakthroughs.

Requires selection of a collaboration for a five-year period. Allows an existing Energy Frontier Research Center supported by the Office of Science to continue receiving that support for five years after its establishment.

(Sec. 503) Directs the Office of Science to carry out a research and development program to advance computational and networking capabilities to analyze, model, simulate, and predict complex phenomena relevant to the development of new energy technologies and U.S. competitiveness.

Requires the Office of Science to develop world-class computing and network facilities for science and deliver critical research in applied mathematics, computer science, and advanced networking to support DOE's missions.

Amends the Department of Energy High-End Computing Revitalization Act of 2004 with respect to: (1) exascale computing (computing system performance at or near 10 to the 18th power floating point operations per second), and (2) a high-end computing system with performance substantially exceeding that of systems commonly available for advanced scientific and engineering applications.

Directs the DOE to:

- coordinate the development of high-end computing systems across DOE;
- partner with universities, national laboratories, and industry to ensure the broadest possible application of the technology developed in the program to other challenges in science, engineering, medicine, and industry; and

• include among the multiple architectures researched, at DOE discretion, any computer technologies that show promise of substantial reductions in power requirements and substantial gains in parallelism of multicore processors, concurrency, memory and storage, bandwidth, and reliability.

Repeals authority for establishment of at least one High-End Software Development Center. Directs DOE to conduct a coordinated research program to develop exascale computing systems to advance DOE missions. Requires establishment through competitive merit review of two or more DOE national laboratory-industry-university partnerships to conduct integrated research, development, and engineering of multiple exascale architectures.

Requires DOE to conduct mission-related co-design activities in developing such exascale platforms. Defines "co-design" as the joint development of application algorithms, models, and codes with computer technology architectures and operating systems to maximize effective use of high-end computing systems.

Directs the DOE to develop any advancements in hardware and software technology required to realize fully the potential of an exascale production system in addressing DOE target applications and solving scientific problems involving predictive modeling and simulation and large-scale data analytics and management.

Directs DOE to submit to Congress an integrated strategy and program management plan. (Sec. 504) Directs the Office of Science to carry out a research program on the fundamental constituents of matter and energy and the nature of space and time.

Expresses the sense of Congress regarding particle physics.

Requires the Office of Science to carry out research activities on:

- rare decay processes and the nature of the neutrino;
- the nature of dark energy and dark matter; and
- advanced accelerator concepts and technologies, including laser technologies, to reduce the necessary scope and cost for the next generation of particle accelerators.

Instructs the Director of the Office of Science to ensure the access of U.S. researchers to the most advanced accelerator facilities and research capabilities in the world, including the Large Hadron Collider.

(Sec. 505) Directs the Office of Science to carry out a program of research and development in the areas of biological systems science and climate and environmental science to support the energy and environmental missions of DOE.

Directs GAO to identify climate science-related initiatives under this section that overlap or duplicate those of other federal agencies.

Prohibits the Office of Science from approving new climate science-related initiatives without first determining that such work is unique and not duplicative of work by other federal agencies. Requires the the Office to cease those overlapping or duplicative initiatives , unless justified as critical to achieving American energy security.

Requires the Office of Science to carry out a research program on low dose radiation to enhance the scientific understanding of and reduce uncertainties associated with the effects of exposure to low dose radiation.

Requires the Office of Science to enter into an agreement with the National Academies to assess the current status and development of a long-term strategy for low dose radiation research.

Directs DOE to deliver to Congress a five-year research plan responding to the assessment's findings and recommendations.

Makes DOE's limitation on biomedical and human cell and human subject research inapplicable to research under this section.

(Sec. 506) Directs the Office of Science to carry out a fusion energy sciences research program to:

- expand the fundamental understanding of plasmas and matter at very high temperatures and densities, and
- build the scientific foundation necessary to enable fusion power.

Requires the Director of the Office of Science, in coordination with the Assistant Secretary for Nuclear Research, to carry out research and development activities to identify, characterize, and demonstrate materials that can endure the neutron, plasma, and heat fluxes expected in a fusion power system.

Requires DOE to assess:

- the need for a facility or facilities that can examine and test potential fusion and next generation fission materials and other enabling technologies relevant to the development of fusion power; and
- whether a single new facility that substantially addresses magnetic fusion and next generation fission materials research needs is feasible, in conjunction with the expected capabilities of facilities that are already operational.

Directs the Office of Science to support research and development activities and facility operations to optimize the tokamak approach to fusion energy.

Requires DOE to assess: (1) the most recent schedule of ITER approved by the ITER Council, and (2) the progress of the ITER Council and the ITER Director General toward implementing the recommendations of the Third Biennial International Organization Management Assessment Report.

Expresses the sense of Congress that the United States should support a robust, diverse fusion program.

Directs DOE to carry out a program of research and technology development in inertial fusion for energy applications, including ion beam, laser, and pulsed power fusion systems. Directs the Office of Science to support research and development activities and facility operations at U.S. universities, national laboratories, and private facilities for a portfolio of alternative and enabling fusion energy concepts that may provide solutions to significant challenges to the establishment of a commercial magnetic fusion power plant, prioritized based on the ability of the United States to play a leadership role in the international fusion research community.

Requires the Under Secretary for Science and Energy and the Director of the Office of Science to coordinate with the Director of the Advanced Research Projects Agency-Energy (ARPA-E) to assess the potential for any ARPA-E-supported fusion energy project to represent a promising approach to a commercially viable fusion power plant.

Directs DOE to assess opportunities in which the United States can provide world-leading contributions to advancing plasma science and non-fusion energy applications, and identify opportunities for partnering with other federal agencies both inside and outside DOE. (Sec. 507) Directs the Office of Science to carry out programs:

- of experimental and theoretical research, and support associated facilities, to discover, explore, and understand all forms of nuclear matter; and
- for the production of isotopes needed for research, medical, industrial, or other purposes.

(Sec. 508) Directs the Office of Science to carry out a program to improve the safety, efficiency, and mission readiness of infrastructure at the Office's laboratories.

(Sec. 509) Requires DOE to report to Congress on the current ability of domestic manufacturers to meet procurement requirements for major ongoing projects funded by the Office of Science. (Sec. 510) Authorizes appropriations for FY2016-FY2017 for the Office of Science.

TITLE VI--DEPARTMENT OF ENERGY APPLIED RESEARCH AND DEVELOPMENT

Subtitle A--Crosscutting Research and Development

(Sec. 601) Directs DOE, through the Under Secretary for Science and Energy, to utilize DOE capabilities to identify strategic opportunities for collaborative research and development of innovative science and technologies for:

- advancing the understanding of the energy-water-land use nexus;
- modernizing the electric grid by improving energy transmission and distribution systems security and resiliency;
- using supercritical carbon dioxide in electric power generation;
- subsurface technology and engineering;
- high performance computing;
- cybersecurity; and
- critical challenges identified through comprehensive energy studies, evaluations, and reviews.

Requires DOE to: (1) prioritize activities that promote the use of all affordable domestic resources; (2) develop a rigorous planning, evaluation, and technical assessment framework for setting objective, long-term strategic goals and evaluating progress that ensures the integrity and independence to insulate planning from political influence and the flexibility to adapt to market dynamics; and (3) identify programs that may be more effectively left to the states, industry, nongovernmental organizations, institutions of higher education, or other stakeholders. (Sec. 602) Amends the Energy Policy Act of 2005 to require the plan developed to improve coordination and collaboration in research, development, demonstration, and commercial application activities across DOE organizational boundaries to include:

- critical assessments of any ongoing programs that have experienced sub-par performance or has cost over-runs of 10% or more over one or more years;
- activities that may be more effectively left to the states, industry, nongovernmental organizations, institutions of higher education, or other stakeholders and
- proposals for innovation hubs, institutes, and research centers prior to establishment or renewal by DOE.

(Sec. 603) Amends the Energy Policy Act of 2005 to require DOE to submit to Congress along with the President's budget request for FY2018 a report on the strategy for facilities and infrastructure supported by certain DOE offices at all National Laboratories and single-purpose research facilities.

(Sec. 604) Directs DOE to make five-year (renewable) awards to consortia for establishing and operating Energy Innovation Hubs to conduct and support, whenever practicable at one centralized location, multidisciplinary, collaborative research, development, and demonstration of advanced energy technologies.

Requires the DOE to designate a unique advanced energy technology focus for each Hub. Instructs the DOE to ensure the coordination of, and avoid unnecessary duplication of, the activities of Hubs with those of other DOE research entities, including the national laboratories, the Advanced Research Projects Agency-Energy (ARPA-E), Energy Frontier Research Centers, and within industry.

Requires a consortium, to be eligible for such an award, to be composed of at least two qualifying entities and operate subject to an agreement entered into by its members that documents budget and certain measures, including a plan for managing intellectual property rights.

Requires each Hub to conduct or provide for multidisciplinary, collaborative research, development, and demonstration of advanced energy technologies within the technology development focus designated for it.

Requires Hubs to:

- maintain conflict of interest procedures to ensure that employees and consortia designees for Hub activities who are in decisionmaking capacities disclose all material conflicts of interest or face disqualification, and
- avoid such conflicts.

Prohibits the use of award funds, and of any funds that are part of the nonfederal share of a Hub cost-sharing agreement, for the construction of new buildings or facilities for Hubs.

Allows the DOE to terminate an underperforming Hub for cause during the performance period. Subtitle B--Electricity Delivery and Energy Reliability Research and Development (Sec. 611) Amends the Energy Policy Act of 2005 also to require DOE, in carrying out distributed energy resources and systems programs to seek to:

- leverage existing programs;
- consolidate and coordinate activities throughout DOE to promote collaboration and crosscutting approaches;
- ensure activities are undertaken in a manner that does not duplicate other activities within DOE or other federal government activities; and
- identify programs that may be more effectively left to the states, industry, nongovernmental organizations, institutions of higher education, or other stakeholders.

(Sec. 612) Requires the comprehensive research and development program to ensure the reliability, efficiency, and environmental integrity of electrical transmission and distribution systems to include technologies to enhance security for such systems.

Requires DOE, in carrying out this program, to seek to:

- leverage existing programs;
- consolidate and coordinate activities throughout DOE to promote collaboration and crosscutting approaches;
- ensure activities are undertaken in a manner that does not duplicate other activities within DOE or other federal government activities; and
- identify programs that may be more effectively left to the states, industry, nongovernmental organizations, institutions of higher education, or other stakeholders.

Subtitle C--Nuclear Energy Research and Development

(Sec. 621) Amends the Energy Policy Act of 2005 to require civilian nuclear energy research and development programs to take into consideration the following new objectives:

- reducing used nuclear fuel and nuclear waste products generated by civilian nuclear energy,
- supporting technological advances that industry by itself is not likely to undertake because of technical and financial uncertainty, and
- researching and developing technologies and processes to meet federal and state requirements and standards for nuclear power systems.

(Sec. 622) Directs GAO to study the scientific and technical merit of major federal and state requirements and standards, including moratoria, that delay or impede the further development and commercialization of nuclear power, and how DOE can assist in overcoming such delays or impediments.

(Sec. 623) Repeals the mandates for: (1) the Nuclear Power 2010 Program, (2) the Generation IV Nuclear Energy Systems Initiative, and (3) research to examine designs for high-temperature reactor production of hydrogen.

Directs DOE to carry out a research and development program to advance nuclear power systems as well as technologies to sustain currently deployed systems.

Requires DOE to examine advanced reactor designs and nuclear technologies, including those that:

- have higher efficiency, lower cost, and improved safety compared to reactors in operation;
- utilize passive safety features;
- minimize proliferation risks;
- substantially reduce production of high-level waste per unit of output;
- increase the life and sustainability of reactor systems currently deployed;
- use improved instrumentation;
- are capable of producing large-scale quantities of hydrogen or process heat;
- minimize water usage or use alternatives to water as a cooling mechanism; or
- use nuclear energy as part of an integrated energy system.

Requires DOE to seek opportunities to enhance program progress through international cooperation through such organizations as the Generation IV International Forum or any other international collaboration DOE considers appropriate.

Prohibits any funds authorized for these activities from being used to fund the activities authorized under the Next Generation Nuclear Plant Project.

(Sec. 624) Directs DOE to carry out a program to promote research and development of small modular reactors, including through cost-shared projects for commercial application of reactor systems designs.

Permits activities to include development of advanced computer modeling and simulation tools, by federal and non-federal entities, which demonstrate and validate new design capabilities of innovative small modular reactor designs.

(Sec. 625) Replaces the advanced fuel recycling technology research and development program with a research and development program on fuel cycle options that improve uranium resource utilization, maximize energy generation, minimize nuclear waste creation, improve safety, mitigate risk of proliferation, and improve waste management in support of a national strategy for spent nuclear fuel and the reactor concepts research and development program under section 623.

Authorizes DOE to consider developing:

- reactor fuels that increase energy generation, improve safety performance and margins, and minimize the amount of nuclear waste produced in an open fuel cycle;
- advanced recycling technologies;
- advanced storage technologies;
- an advanced reactor innovation testbed; and

• any other technology or initiative likely to advance the objectives of the program.

Permits DOE also to:

- investigate the potential research benefits of a fast test reactor user facility, and
- support certain additional advanced recycling and crosscutting activities.

(Sec. 626) Directs DOE to conduct a program to support the integration of activities undertaken through the reactor concepts research and development program and the fuel cycle research and development program, and support crosscutting nuclear energy concepts. Authorizes these activities to include research involving:

- advanced reactor materials,
- advanced reactor materials,
  advanced radiation mitigation methods,
- advanced proliferation and security risk assessment methods,
- advanced sensors and instrumentation,
- high performance computation modeling, and
- any crosscutting technology or transformative concept aimed at establishing relevant, appropriate, substantial, and revolutionary enhancements in the performance of future nuclear energy systems.

(Sec. 627) Directs NIST to establish a nuclear energy standards committee to facilitate and support the development or revision of technical standards for new and existing nuclear power plants and advanced nuclear technologies.

(Sec. 628) Directs DOE to prepare a database, accessible on the DOE website, of non-federal user facilities receiving federal funds that may be used for unclassified nuclear energy research. Subtitle D--Energy Efficiency and Renewable Energy Research and Development

(Sec. 641) Amends the Energy Policy Act of 2005 to require energy efficiency programs under that Act to prioritize activities that industry by itself is not likely to undertake because of technical challenges or regulatory uncertainty.

Modifies the objectives to be taken into consideration under such program, eliminating reduction of U.S. energy demand and improvement of U.S. energy security.

Revises the technologies that shall be included in the research and development of such programs, eliminating hybrid and electric propulsion systems and advanced control devices to improve the energy efficiency of electric motors, but adding advanced battery technologies and fuel cell and hydrogen technologies.

(Sec. 642) Eliminates the Next Generation Lighting Initiative, the grant and technical assistance program to support the development of voluntary consensus-based standards for high-performance buildings, and the secondary electric vehicle battery use program.

(Sec. 645) Authorizes the DOE to transfer to the NIST up to \$150 million through FY2017 from appropriations for advanced manufacturing research and development to carry out the Network for Manufacturing Innovation Program.

(Sec. 646) Revises certain requirements related to the Advanced Energy Technology Transfer Centers. Prohibits the use of any funds awarded under the Act for the deployment of commercially available technologies. Repeals the authorization of appropriations for such program.

(Sec. 647) Declares as an objective of renewable energy research and development programs decreasing U.S. dependence on foreign mineral resources (currently, on foreign energy supplies). Revises requirements regarding solar energy and wind energy programs.

Eliminates research on fish-friendly large turbines from hydropower programs.

Requires DOE analysis and evaluation activities in support of the renewable energy programs to include an assessment of domestic and international market drivers, including the impacts of any federal, state, or local grants, loans, loan guarantees, tax incentives, statutory or regulatory requirements, or other government initiatives.

(Sec. 648) Repeals the requirement that the bioenergy program include economic analysis. Revises the goals of the biofuels and bioproduct programs to include development of advanced conversion of biomass to biofuels and bioproducts as part of integrated biorefineries based on either biochemical processes, thermochemical processes, or hybrids of those processes.

Eliminates integrated biorefinery demonstration projects, the university biodiesel program, and the program for research, development, demonstration, and commercial application for increasing energy efficiency and reducing energy consumption in the operation of biorefinery facilities.

Prohibits any of funds authorized for carrying out provisions relating to the bioenergy program from being used to fund commercial biofuels production for defense purposes.

Redefines "biomass" to include solids derived from waste water treatment processes.

(Sec. 649) Eliminates the concentrating solar power research program and the demonstration program for renewable energy in public buildings.

Subtitle E--Fossil Energy Research and Development

(Sec. 661) Amends the Energy Policy Act of 2005 to repeal the requirement that fossil energy programs take into consideration the objective of improving U.S. energy security.

Requires DOE to seek to:

- leverage existing programs;
- consolidate and coordinate activities throughout DOE to promote collaboration and crosscutting approaches;
- ensure activities are undertaken in a manner that does not duplicate other activities within DOE or other federal government activities; and
- identify programs that may be more effectively left to the states, industry, nongovernmental organizations, institutions of higher education, or other stakeholders.

Eliminates the prohibition against using any funding authorized for such programs for Import/Export Authorization.

Prohibits the use of the results of any DOE fossil energy research, development, demonstration, or commercial application projects or activities for regulatory assessments or determinations by federal regulatory authorities.

Requires DOE to assess:

- the technical, institutional, policy, and regulatory constraints to bringing new domestic fossil resources to market; and
- existing and projected technological capabilities for expanded production from domestic unconventional oil, gas, and methane reserves.

(Sec. 662) Includes under the program for coal and related technologies programs to facilitate production and generation of coal-based power through:

- specific additional programs to address water use and reuse;
- the testing of high temperature materials for use in advanced systems for combustion or the use of coal; and
- innovations to application of existing coal conversion systems designed to increase efficiency of conversion, flexibility of operation, and other modifications to address existing usage requirements.

Authorizes DOE to enter into cost-sharing partnerships with private entities to carry out a specified transformational coal technology program.

Directs DOE to establish an advisory committee under the carbon capture and sequestration research and development program to review DOE progress in achieving the goals of this program, the coal and related technologies program, and the transformational coal technology program.

Directs DOE to assess the cost and feasibility of engineering, permitting, building, maintaining, regulating, and insuring a national system of carbon dioxide pipelines.

(Sec. 663) Directs DOE, through the Office of Fossil Energy, to carry out a multiyear, multiphase program of research and development to:

- support innovative engineering and detailed gas turbine design for megawatt-scale and utility-scale electric power generation;
- include technology demonstration through component testing, sub-scale testing, and full scale testing in existing fleets;
- make field demonstrations of the developed technology elements so as to demonstrate technical and economic feasibility; and
- assess overall combined cycle and simple cycle system performance. Specifies the goals of such multiphase program.

Specifies requirements for grants to and contracts with industry, small businesses, universities, and other appropriate parties to conduct activities under this program.

Subtitle F--Advanced Research Projects Agency-Energy

(Sec. 671) Amends the America COMPETES Act to revise ARPA-E goals to repeal specifications for:

- reductions of imports of energy from foreign sources;
- reductions of energy-related emissions, including greenhouse gases; and
- improvement in the energy efficiency of all economic sectors.

Bars ARPA-E from providing funding for a project unless the prospective grantee demonstrates sufficient attempts to secure private financing or indicates that the project is not independently commercially viable.

Requires DOE, once every six years after the sixth year ARPA-E has been in operation, to offer to contract with the National Academy of Sciences to evaluate how well ARPA-E is achieving its goals and mission.

Declares that specified categories of proprietary information collected by ARPA-E from recipients of financial assistance awards from ARPA-E shall be considered as privileged and confidential and not subject to disclosure pursuant to the FOIA.

Subtitle G--Authorization of Appropriations

(Sec. 681) Authorizes appropriations to DOE for FY2016-FY2017 for related technology activities of:

- the Office of Electricity,
- the Office of Nuclear Energy (but with no amounts derived from the Nuclear Waste Fund),
- the Office of Energy Efficiency and Renewable Energy,
- the Office of Fossil Energy, and
- ARPA-E.

Subtitle H--Definitions

Defines "Department" as Department of Energy and "Secretary" as Secretary of Energy. TITLE VII--DEPARTMENT OF ENERGY TECHNOLOGY TRANSFER

Subtitle A--In General

(Sec. 701) Defines terms used in this title.

(Sec. 702) Declares that nothing in this title or an amendment made by it abrogates or otherwise affects the primary responsibilities to DOE of any National Laboratory.

Subtitle B--Innovation Management at Department of Energy

(Sec. 712) Directs DOE to: (1) assess annually for Congress its ability to improve the technology transfer and commercialization of energy technologies, including the role and effectiveness of the Director of the Office of Technology Transitions; and (2) recommend policy and legislative changes to improve DOE ability to transfer new energy technologies successfully to the private sector.

(Sec. 713) Expresses the sense of Congress that DOE should encourage the nonmilitary National Laboratories (national laboratories) and federally funded research and development centers to inform small businesses of the opportunities and resources that exist pursuant to this title. (Sec. 714) Requires DOE to report on its capabilities to authorize, host, and oversee privately funded fusion and non-light water reactor prototypes and related demonstration facilities at DOE-owned sites. Instructs DOE, for purposes of this report, to consider DOE capabilities to facilitate privately-funded prototypes of up to 20 megawatts thermal output.

Subtitle C--Cross-Sector Partnerships and Grant Competitiveness

(Sec. 721) Directs DOE to carry out the Agreements for Commercializing Technology pilot program, in part by giving the contractors of the DOE nonmilitary national laboratories increased authority to negotiate contract terms and making every such facility eligible for the program. Permits the directors of the national laboratories to execute agreements with non-federal entities, provided that such funding is only used to carry out the purposes of the federal award. Subjects funding agreements to the requirements of the Bayh-Dole Act (concerning patent rights to inventions arising from federally-supported research and development).

Imposes contractor certification requirements for the avoidance of direct competition with the private sector and conflicts of interest.

Extends the pilot program until October 31, 2017.

(Sec. 722) Requires DOE to delegate to the directors of the national laboratories signature authority with respect to certain agreements (except those with a majority foreign-owned company) whose total cost is less than \$1 million.

(Sec. 723) Permits the directors of national laboratories to use funds authorized to support technology transfer within DOE to carry out early-stage and pre-commercial technology demonstration activities to: (1) remove technology barriers that limit private sector interest, and (2) demonstrate potential commercial applications of any research and technologies arising from national laboratory activities.

(Sec. 724) Amends the Energy Policy Act of 2005 to exempt, for six years after enactment of this Act, institutions of higher education and nonprofit institutions from the cost-sharing requirements for research and development.

(Sec. 725) Authorizes DOE to enter into an agreement with the NSF to enable the participation of DOE researchers in the National Science Foundation Innovation Corps program. Subtitle D--Assessment of Impact

(Sec. 731) Requires the GAO to report to Congress on the results of projects developed under subtitle C, and on DOE efforts to promote technology transfer and private sector engagement at the national laboratories.

TITLE VIII--SENSE OF CONGRESS

(Sec. 801) Expresses the sense of Congress that climate change is real.

Engaged on issues surrounding this bill.

# Status: 05/21/2015 Received in the Senate and Read twice and referred to the Committee on Commerce, Science, and Transportation.

# H.R. 6 21<sup>st</sup> Century Cures Act

### (Upton)

(Sec. 2) The NIH and Cures Innovation Fund is established and funds are appropriated: (1) for biomedical research, including high-risk, high-reward research and research conducted by early stage investigators; (2) to develop and implement a strategic plan for biomedical research; and (3) to carry out specified provisions of this Act.

# TITLE I--DISCOVERY

Subtitle A--National Institutes of Health Funding

(Sec. 1001) This bill amends the Public Health Service Act to reauthorize the National Institutes of Health (NIH) through FY2018.

(Sec. 1002) The NIH must establish an Innovation Prizes Program to fund areas of biomedical science that could realize significant advancements or improve health outcomes.

Subtitle B--National Institutes of Health Planning and Administration

(Sec. 1022) Directors of national research institutes and national centers have five-year terms in office.

(Sec. 1023) The NIH must reduce the administrative burdens of researchers funded by the NIH. (Sec. 1027) The support the National Center for Advancing Translational Sciences may provide to clinical trials is extended through a later clinical trial phase.

(Sec. 1028) Each national research institute must conduct or support high-risk, high-reward research.

Subtitle C--Supporting Young Emerging Scientists

(Sec. 1041) A loan repayment program is established for health professionals engaging in research. The maximum awards of other loan repayment programs are increased. Subtitle D--Capstone Grant Program

(Sec. 1061) Capstone Awards are established to support outstanding scientists in concluding research programs. Recipients cannot be principal investigators on subsequent NIH awards.

Subtitle E--Promoting Pediatric Research through the National Institutes of Health

(Sec. 1081) The Pediatric Research Initiative is revised to require establishment of a National Pediatric Research Network comprised of pediatric research consortia.

(Sec. 1083) The NIH must convene a workshop on appropriate age groupings and age exclusions in human research and must publish the number of children included in NIH research.

Subtitle F--Advancement of the National Institutes of Health Research and Data Access

(Sec. 1101) The NIH must standardize data in the clinical trial registry data bank.

Subtitle G--Facilitating Collaborative Research

(Sec. 1121) The NIH and the Food and Drug Administration (FDA) must implement a system that allows further research on clinical trial data.

(Sec. 1122) The Centers for Disease Control and Prevention (CDC) must expand surveillance of neurological diseases.

(Sec. 1124) The Department of Health and Human Services (HHS) must revise health information privacy rules to allow: (1) use of protected information for research purposes to be treated as use for health care operations, (2) remote access to information by researchers, and (3) individuals to authorize future use of their information for research.

Subtitle H--Council for 21st Century Cures

(Sec. 1141) The Council for 21st Century Cures, a nonprofit corporation, is established to accelerate the discovery, development, and delivery of innovative cures, treatments, and preventive measures.

TITLE II--DEVELOPMENT

Subtitle A--Patient-Focused Drug Development

(Sec. 2001) This bill amends the Federal Food, Drug, and Cosmetic Act to require the FDA to establish processes under which patient experience data may be considered in the risk-benefit assessment of a new drug.

Subtitle B--Qualification and Use of Drug Development Tools

(Sec. 2021) The FDA must establish a process to qualify drug development tools (methods, materials, or measures that aid drug development and regulatory review) as reliable for use in supporting approval or investigational use of a drug.

(Sec. 2022) The sponsor of a drug for a serious condition may request that the FDA agree to an accelerated approval development plan. The plan must include the design of the drug study. Subtitle C--FDA Advancement of Precision Medicine

(Sec. 2041) The FDA must define "precision" drugs and the evidence needed to support their use in a subset of patients. To expedite clinical development of precision drugs for the treatment of serious or rare conditions, the FDA may rely upon data previously submitted for a different approved drug or indication.

Subtitle D--Modern Trial Design and Evidence Development

(Sec. 2061) The FDA must issue guidance that addresses using alternative statistical methods in clinical trials and in the development and review of drugs.

(Sec. 2062) To support approval of a drug for a new indication, the FDA must evaluate the use of evidence from clinical experience (in place of evidence from clinical trials) and establish a streamlined data review program.

Subtitle E--Expediting Patient Access

(Sec. 2082) Manufacturers and distributors of investigational drugs for serious conditions must publish their policies on expanded access (also known as "compassionate use").

Subtitle F--Facilitating Responsible Manufacturer Communications

(Sec. 2101) The definition of, and requirements for, health care economic information that is provided to entities selecting drugs for coverage or reimbursement are revised.

Subtitle G--Antibiotic Drug Development

(Sec. 2121) At the request of the sponsor of an antibacterial or antifungal drug for treatment of a serious infection, the FDA may agree on a process for developing data to support approval of the drug for use in a limited population of patients.

HHS must monitor the use of antibacterial and antifungal drugs and resistance to these drugs. (Sec. 2122) The FDA must identify and publish susceptibility test interpretive criteria for antimicrobial drugs. (These criteria characterize the drug resistance of microbes.) The FDA may allow marketing of devices that use these criteria without premarket approval.

(Sec. 2123) This bill amends title XVIII (Medicare) of the Social Security Act (SSAct) to require the Centers for Medicare & Medicaid Services (CMS) to provide an additional payment to certain hospitals for providing certain new antimicrobial drugs (DISARM drugs) to inpatients. Total additional payments cannot exceed 0.02% of total payments to hospitals.

Subtitle H--Vaccine Access, Certainty, and Innovation

(Sec. 2141) The Advisory Committee on Immunization Practices must expedite review of certain vaccines. The CDC must provide a vaccine developer, upon request, with information on public health needs and priorities and certain epidemiological analyses or data.

Subtitle I--Orphan Product Extensions Now; Incentives for Certain Products for Limited Populations

(Sec. 2151) The marketing exclusivity period of a drug approved for a new indication that is a rare disease or condition is extended by six months.

(Sec. 2152) The priority review voucher program for rare pediatric diseases is extended through 2018 and revised to apply only to serious diseases.

Subtitle J--Domestic Manufacturing and Export Efficiencies

(2162) This bill amends the Controlled Substances Import and Export Act to allow unimpeded re-exportation of certain exported controlled substances within the European Economic Area. Subtitle K--Enhancing Combination Products Review

(Sec. 2181) The FDA must describe the responsibilities of each agency center charged with reviewing drugs, medical devices, or biological products when reviewing a product that is a combination of drug, medical device, or biological product.

Subtitle L--Priority Review for Breakthrough Devices

(Sec. 2201) The FDA must establish a program for priority review of breakthrough medical devices.

Subtitle M--Medical Device Regulatory Process Improvements

(Sec. 2221) The FDA must accredit third parties to certify device manufactures' quality systems as meeting FDA criteria. The FDA must rely on this certification when determining the safety and effectiveness of certain changes to medical devices.

(Sec. 2222) "Valid scientific evidence" is defined for purposes of the FDA determining the effectiveness of a medical device without clinical investigations.

(Sec. 2223) FDA employees that review premarket submissions of medical devices must receive training regarding the "least burdensome appropriate means" concept.

(Sec. 2225) The FDA must identify types of medical devices that do not require submission of a report prior to commercial marketing.

### H.R. 6 21st Century Cures Act, continued

(Sec. 2227) The FDA may exempt from effectiveness requirements certain medical devices intended to benefit fewer than 8,000 individuals.

Subtitle N--Sensible Oversight for Technology Which Advances Regulatory Efficiency (Sec. 2241) "Health software" is defined and, with specified exceptions, exempted from FDA regulation.

Subtitle O--Streamlining Clinical Trials

(Sec. 2262) Institutional Review Boards responsible for reviewing plans for clinical testing of a medical device no longer need to be local.

(Sec. 2263) Clinical testing of medical devices or drugs no longer requires the informed consent of the subjects if the testing poses no more than minimal risk and includes safeguards.

Subtitle P--Improving Scientific Expertise and Outreach at FDA

(Sec. 2281) The Silvio O. Conte Senior Biomedical Research Service is revised to remove the limit on the number of members and make other changes.

(Sec. 2283) Changes are made to the Reagan-Udall Foundation for the Food and Drug Administration to revise Board of Directors membership, Executive Director compensation, and accounting.

(Sec. 2285) The FDA is granted additional hiring authority for scientific, technical, or professional positions within certain centers.

Subtitle Q--Exempting from Sequestration Certain User Fees

(Sec. 2301) This bill amends the Balanced Budget and Emergency Deficit Control Act of 1985 to exempt from sequestration FDA administrative expenses funded through certain user fees. Subtitle R--Other Provisions

(Sec. 2321) This bill expresses the sense of Congress that recording unique medical device identifiers in electronic health records could enhance medical surveillance.

TITLE III--DELIVERY

Subtitle A--Interoperability

(Sec. 3001) Requirements are established for interoperability and certification of health information technology. Practices that discourage the exchange of electronic health information are prohibited.

Subtitle B--Telehealth

(Sec. 3021) The CMS and Medicare Payment Advisory Commission must provide information to Congress regarding telehealth.

Subtitle C--Encouraging Continuing Medical Education for Physicians

(Sec. 3041) Part A (General Provisions) of title XI of the SSAct is amended to remove the requirement that manufacturers of medical products report payments to physicians for certain educational activities.

Subtitle D--Disposable Medical Technologies

The CMS must pay home health agencies for certain disposable medical devices furnished to individuals receiving home health services under Medicare.

Subtitle E--Local Coverage Decision Reforms

(Sec. 3081) Medicare administrative contractors must publish local coverage determinations. Subtitle F--Medicare Pharmaceutical and Technology Ombudsman

(Sec. 3101) A pharmaceutical and technology ombudsman within the CMS must receive and respond to complaints from manufacturers of medical products regarding Medicare coverage of their products.

Subtitle G--Medicare Site-of-Service Price Transparency

(Sec. 3121) The CMS must publish estimated Medicare beneficiary prices for items and services provided by hospital outpatient departments or ambulatory surgical centers.

Subtitle H--Medicare Part D Patient Safety and Drug Abuse Prevention

(Sec. 3141) Medicare prescription drug plan sponsors may limit the access of certain beneficiaries to frequently abused drugs.

TITLE IV--MEDICAID, MEDICARE, AND OTHER REFORMS

Subtitle A--Medicaid and Medicare Reforms

(Sec. 4001) Aggregate Medicaid payments to states for durable medical equipment are limited to the amount that would be paid under Medicare, effective January 1, 2020.

(Sec. 4002) Generic drugs authorized by the brand name drug manufacturer are excluded from the calculation of average manufacturer price when determining rebates under Medicaid.

(Sec. 4003) Medicare payments are reduced for x-ray imaging that uses film or an imaging plate (instead of a digital sensor). After 2016, a multiple procedure payment reduction policy cannot be applied to a physician's imaging services until the CMS publishes an analysis of any efficiencies that may exist when more than one study is performed on the same patient on the same day.

(Sec. 4004) Medicare payments for infusion drugs and biologicals furnished through durable medical equipment are revised.

(Sec. 4005) CMS must expand and extend through August 31, 2018, the Prior Authorization of Power Mobility Devices Demonstration.

(Sec. 4006) For HHS grants, contracts, or other agreements, monetary penalties are established for fraudulent claims, fraudulent statements, and failure to provide timely access to the Inspector General of HHS.

Subtitle B--Other Reforms

(Sec. 4041) The Department of Energy must sell crude oil from the Strategic Petroleum Reserve. Subtitle C--Miscellaneous

(Sec. 4061) HHS must: (1) conduct or support research on Lyme disease and other tick-borne diseases, (2) establish the Interagency Lyme and Tick-Borne Disease Working Group, and (3) submit a strategic plan for tick-borne disease research.

Advocated in favor of this bill.

# Status: 7/13/2015 Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

# H.R. 34 21<sup>st</sup> Century Cures Act

### (Bonamici)

Shown Here:

Public Law No: 114-255 (12/13/2016)

(This measure has not been amended since the House agreed to the Senate amendment with amendment on November 30, 2016. The summary of that version is repeated here.)

21st Century Cures Act

DIVISION A--21ST CENTURY CURES

21st Century Cures Act

TITLE I--INNOVATION PROJECTS AND STATE RESPONSES TO OPIOID ABUSE (Sec. 1001) This bill provides funding for National Institutes of Health (NIH) Innovation Projects, which include the Precision Medicine Initiative and the BRAIN Initiative. The NIH must submit a work plan to Congress that describes and justifies the projects

(Sec. 1002) This bill provides funding for the Food and Drug Administration (FDA) activities required by this bill. The FDA must submit a work plan to Congress that describes and justifies the activities.

(Sec. 1003) This bill provides funding for Department of Health and Human Services (HHS) grants to states to address the opioid abuse crisis.

(Sec. 1004) The budgetary effects of this division of this bill are excluded from PAYGO scorecards.

TITLE II--DISCOVERY

Subtitle A--National Institutes of Health Reauthorization

(Sec. 2001) This bill amends the Public Health Service Act to reauthorize the NIH through FY2020.

(Sec. 2002) The NIH must support prize competitions to fund areas of biomedical science that could realize significant advancements or improve health outcomes.

Subtitle B--Advancing Precision Medicine

(Sec. 2011) HHS is encouraged to carry out a Precision Medicine Initiative to address disease prevention, diagnosis, and treatment. In implementing the initiative, HHS must implement secure data sharing and ensure inclusion of a broad range of participants.

(Sec. 2012) The bill revises provisions regarding disclosure by researchers of the identifiable, sensitive information of research subjects. HHS must prohibit researchers from disclosing such information from federally funded research to persons not connected to the research, with exceptions. Researchers may apply to have other research covered by this prohibition.

(Sec. 2013) HHS may exempt identifiable information collected for biomedical research from disclosure under the Freedom of Information Act.

(Sec. 2014) The NIH may require recipients of grants or cooperative agreements to share scientific data.

Subtitle C--Supporting Young Emerging Scientists

(Sec. 2021) The bill establishes the Next Generation of Researchers Initiative in the NIH to promote, provide, and improve opportunities for new researchers and earlier research independence.

(Sec. 2022) The bill revises loan repayment programs for health professionals conducting research to increase the maximum repayment amount and to give the NIH the authority to expand eligibility for the programs based on workforce and scientific priorities. Subtitle D--National Institutes of Health Planning and Administration

(Sec. 2031) NIH must publish a strategic plan that addresses research, training, the biomedical workforce, and collaboration with other agencies. The strategic plans of the national research institutes must ensure that future activities take into account women and minorities and are focused on reducing health disparities.

(Sec. 2032) The bill revises reporting requirements for the NIH and certain national research institutes.

(Sec. 2033) The Director of the NIH is given the authority to appoint the directors of the national research institutes. The term of office of these directors is set to five years, with no limit on the number of reappointments.

Before a national research institute awards a grant for a research project (R-series grant) the director of the institute must review and approve the award.

HHS must report on efforts to eliminate duplicative research that is scientifically unnecessary. (Sec. 2034) HHS and the NIH must review and revise policies, including policies on conflicts of interest and laboratory animals, to reduce the administrative burden on researchers while maintaining the integrity and credibility of research findings.

The Office of Management and Budget must establish a Research Policy Board to make recommendations to minimize the administrative burden of federal research policies while maintaining responsible oversight.

(Sec. 2035) The Paperwork Reduction Act does not apply to voluntary information collection during NIH research.

(Sec. 2036) The NIH may approve requests by national research institutes to fund research through transactions other than contracts, grants, or cooperative agreements. National research institutes must conduct and support high-risk, high-reward research.

(Sec. 2037) The National Center for Advancing Translational Sciences may support additional phases of clinical trials.

(Sec. 2038) In assessing research priorities, the NIH must publish data on certain clinical research study populations. The NIH must foster collaboration among clinical research projects that use human subjects and that collect similar data to increase the number and diversity of subjects.

Advisory council reports must include certain demographic data for clinical research subjects. The NIH must: (1) encourage efforts to improve research related to the health of sexual and gender minority populations; (2) develop policies for NIH-funded basic research projects to assess how differences between male and female cells, tissues, or animals may be examined and analyzed; (3) convene a workshop on age groupings and age exclusions in human research; (4) publish guidelines addressing consideration of age in human research; and (5) publish the number of children included in NIH research.

The National Institute on Minority Health and Health Disparities may foster partnerships among the national research institutes and encourage the funding of collaborative research projects to achieve NIH goals related to minority health and health disparities.

(Sec. 2039) The NIH must convene a working group to make recommendations to enhance the rigor and reproducibility of NIH-funded research.

(Sec. 2040) The bill revises requirements for medical rehabilitation research, including to revise the purpose of the National Center for Medical Rehabilitation Research (NCMRR) and to transfer responsibility for development of a comprehensive research plan for medical rehabilitation research to NCMRR from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

(Sec. 2041) HHS must establish the Task Force on Research Specific to Pregnant Women and Lactating Women to report on issues including development of safe and effective therapies for such women.

(Sec. 2043) Contractors making substances and living organisms available for research on behalf of HHS may collect payments on behalf of HHS for incurred costs.

Subtitle E--Advancement of the National Institutes of Health Research and Data Access (Sec. 2051) The bill revises provisions regarding the clinical trial registry data bank to permit earlier publication of certain data and to categorize clinical trials for combination products.

(Sec. 2052) The NIH and the FDA must report on information in the clinical trial registry data bank, activities undertaken to encourage compliance with data bank requirements, and actions to enforce compliance.

(Sec. 2053) The results of NIH-funded clinical trials that include women and minorities must be submitted to NIH's clinical trial data bank.

Subtitle F--Facilitating Collaborative Research

(Sec. 2061) The CDC must: (1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases, (2) incorporate obtained information into a National Neurological Conditions Surveillance System, and (3) ensure that the system facilitates further research on neurological diseases.

(Sec. 2062) HHS must: (1) continue to conduct or support research on vector-borne diseases, (2) establish the Tick-Borne Disease Working Group to review HHS efforts regarding tick-borne diseases.

(Sec. 2063) Researchers may remotely access protected health information if security and privacy safeguards are maintained and the information is not retained. HHS must: (1) issue

guidance regarding an individual's authorization to use protected health information for future research, and (2) convene a working group to study the use of protected health information for research.

Subtitle G--Promoting Pediatric Research

(Sec. 2071) In carrying out the Pediatric Research Initiative, NIH must (currently, may) support a National Pediatric Research Network and entities supporting pediatric research consortia. TITLE III--DEVELOPMENT

Subtitle A--Patient-Focused Drug Development

(Sec. 3001) This bill amends the Federal Food, Drug, and Cosmetic Act to require the FDA, after approving an application for a new medication, to publish a brief statement on any patient experience data or related information that was part of the application. Patient experience data is information about the impact of a medical condition or a related therapy on a patient's life and the patient's preferences for treatment.

(Sec. 3002) The FDA must issue guidance on the collection and use of patient experience data. (Sec. 3003) The Paperwork Reduction Act does not apply to voluntary collection of patient experience data.

(Sec. 3004) The FDA must report on its use of patient experience data in regulatory decision-making.

Subtitle B--Advancing New Drug Therapies

(Sec. 3011) The FDA must establish a process to qualify drug development tools (methods, materials, or measures that aid drug development and regulatory review) as reliable for use in supporting approval or investigational use of a drug.

(Sec. 3012) The FDA may permit the sponsors of new medications that target genes or variant proteins to treat rare, serious conditions to rely upon information submitted for an approved medication that uses the same technology. To rely upon submitted information, the sponsor must have developed, or have a right of reference to, the information.

(Sec. 3013) The priority review voucher program for rare pediatric disease medications is extended until the end of FY2020. (A priority review voucher is a transferable voucher that entitles the holder to have a new drug or biological product application acted upon by the FDA within six months.)

(Sec. 3014) The Government Accountability Office (GAO) must report on the effectiveness and impact of specified priority review voucher programs.

(Sec. 3015) This bill amends the Orphan Drug Act to authorize HHS to defray all the costs of development of orphan drugs (drugs for rare conditions), instead of only certain testing expenses. (Sec. 3016) HHS may award grants to institutions of higher education and nonprofits to study and recommend improvements to the process of continuous manufacturing of medications. (Currently, most medications are manufactured in batches.)

Subtitle C--Modern Trial Design and Evidence Development

(Sec. 3021) The FDA must issue guidance addressing the use of novel clinical trial design in the development and review of drugs.

(Sec. 3022) The FDA must evaluate and issue guidance on the use of evidence from sources other than clinical trials to support approval of a drug for a new indication.

(Sec. 3023) HHS must revise the HHS Human Subject Regulations, the FDA Human Subject Regulations, and the vulnerable populations rules to: (1) reduce regulatory duplication and unnecessary delays; (2) modernize the provisions; and (3) protect vulnerable populations, incorporate local considerations, and support community engagement.

(Sec. 3024) Clinical testing of investigational medical devices and drugs no longer requires the informed consent of the subjects if the testing poses no more than minimal risk to the subjects and includes safeguards.

Subtitle D--Patient Access to Therapies and Information

(Sec. 3031) For certain indications, the FDA may rely upon a summary of clinical data to approve a supplemental application for a medication.

(Sec. 3032) The manufacturer or distributor of an investigational drug for a serious condition must publish a policy for compassionate use of the drug.

(Sec. 3033) Upon request, the FDA must facilitate development and expedite review of regenerative advanced therapies, including cell therapies, therapeutic tissue engineering products, and human cell and tissue products. For a therapy to be eligible, there must be preliminary clinical evidence that the therapy has the potential to address an unmet medical need for a serious condition.

(Sec. 3034) The FDA must issue guidance on its evaluation of medical devices used in the recovery, isolation, or delivery of regenerative advanced therapies.

(Sec. 3036) HHS must facilitate the development of standards to support development and review of regenerative medicine and advanced therapies.

(Sec. 3037) Health care economic information provided to an entity selecting medications for coverage or reimbursement, such as the formulary committee of a health insurer, must describe any differences between the information provided regarding a medication and the FDA-approved labeling for that medication.

(Sec. 3038) The bill revises provisions regarding combination products, which are a combination of a drug, medical device, or biological product.

The FDA may not determine that a combination product is a drug or biological product solely because the product has a chemical action. (Combination products are regulated based on their primary mode of action.) If the sponsor of a combination product disagrees with the FDA's determination of the primary mode of action of the product, the FDA must provide the rationale for its determination and the sponsor and the FDA may agree to studies to inform a reevaluation of the product.

The FDA's Office of Combination Products must coordinate reviews of combination products and oversee feedback regarding such reviews.

The FDA must: (1) issue guidance that describes the process and best practices for review of combination products, and (2) propose that certain types of combination products may adopt good manufacturing practices that vary from requirements in regulations.

Subtitle E--Antimicrobial Innovation and Stewardship

(Sec. 3041) HHS must encourage the health care facilities of the Department of Defense, the Department of Veterans Affairs, and the Indian Health Service to report on antimicrobial drug use, microbial resistance to antimicrobial drugs, and antimicrobial stewardship programs. HHS must: (1) annually publish information on antimicrobial resistance and antimicrobial stewardship; (2) disseminate guidance and materials regarding antimicrobial stewardship; (3) continue working with state and local public health departments on antimicrobial resistance programs; and (4) collect, evaluate, and publish data from the antimicrobial stewardship activities of health care facilities.

(Sec. 3042) The FDA may, at the request of the drug's sponsor, approve an antibiotic or antifungal drug for use in a limited population if the drug is intended to treat a serious infection in a limited population of patients with unmet medical needs. The FDA's determination of the safety and effectiveness of such a drug must reflect the drug's use in the intended limited population.

The label and prescribing information of such a drug must indicate that the drug has been approved for use only in a limited population. The sponsor of such a drug must submit promotional materials for the drug to the FDA prior to dissemination. The FDA may remove these requirements for such a drug that is approved for broader use.

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(Sec. 3044) The FDA must identify and publish susceptibility test interpretive criteria for antimicrobial drugs. (These criteria characterize the drug resistance of microbes.) Under specified conditions, the FDA may waive certain requirements for medical devices that characterize the drug resistance of microbes using these criteria.

Subtitle F--Medical Device Innovations

(Sec. 3051) The bill revises requirements regarding priority review of breakthrough medical devices.

Upon a sponsor's request, the FDA must determine whether a device meets the criteria for designation as a breakthrough device. To expedite the development and review of designated medical devices, the FDA must:

•assign a team of staff for each device,

•adopt an efficient process for dispute resolution,

•provide for interactive and timely communication with the device sponsor,

•expedite review of manufacturing and quality systems compliance,

•disclose to the sponsor in advance the topics of any consultation between the FDA and external experts or an advisory committee and provide the sponsor the opportunity to recommend external experts,

•assign staff to address questions by institutional review committees concerning investigational use of the device.

The FDA may take additional steps to expedite the development and review of designated medical devices.

(Sec. 3052) The humanitarian device exemption is expanded to allow the FDA to exempt from effectiveness requirements certain medical devices intended to benefit up to 8,000 individuals. (Currently, a device must be intended to benefit fewer than 4,000 individuals to qualify for this exemption.)

(Sec. 3053) The bill revises provisions related to medical device performance standards.

(Sec. 3054) The bill revises provisions related to medical device reporting requirements.

(Sec. 3055) The bill revises provisions related to medical device classification panels.

(Sec. 3056) The bill eliminates the requirement for the Institutional Review Board supervising the clinical testing of an investigational or humanitarian medical device to be local.

(Sec. 3057) The FDA must revise the guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices."

(Sec. 3058) The FDA must ensure that employees who review premarket submissions of medical devices receive training on least burdensome means requirements. (Currently, the FDA is required to consider the least burdensome appropriate means for a sponsor to demonstrate the effectiveness of a medical device or demonstrate a device's substantial equivalence to an approved medical device.)

The FDA must consider the least burdensome means requirements when requesting additional information from a medical device sponsor to support a premarket approval application. The FDA's documented rationale for a significant decision regarding a medical device must include a statement on how the least burdensome means requirements were considered and applied.

(Sec. 3059) The FDA must: (1) identify types of medical devices for which premarket notification must include validated instructions for cleaning, disinfection, and sterilization; and (2) issue final guidance regarding when a premarket notification is required for a modification to a medical device.

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(Sec. 3060) Certain software is exempted from requirements for medical devices, including software that provides medical recommendations and the basis for those recommendations to health care professionals. Software remains subject to regulation as a medical device if: (1) the software acquires, processes, analyzes, or interprets medical information; or (2) the FDA identifies use of the software as reasonably likely to have serious adverse health consequences. When assessing a medical device that includes a software function exempted from medical device requirements, the FDA may assess the impact of the software on the functioning of the device.

The FDA must classify a medical device accessory based on its intended function, not based on the classification of the medical device with which it is used.

Subtitle G--Improving Scientific Expertise and Outreach at FDA

(Sec. 3071) The bill revises the Silvio O. Conte Senior Biomedical Research Service to: (1) increase the limit on the number of members, (2) expand eligibility for appointment, (3) set a maximum pay rate, and (4) remove the option for members to contribute to the retirement system of an institution of higher education.

(Sec. 3072) The bill grants the FDA additional hiring authority for scientific, technical, or professional positions that support the development, review, and regulation of medical products. (Sec. 3073) The FDA must establish one or more Intercenter Institutes. Each institute must coordinate activities applicable to a major disease area among the FDA centers that review products.

(Sec. 3074) Scientific meetings directly related to the duties of a HHS professional must not be considered conferences for purposes of certain reporting requirements and restrictions on conference travel.

(Sec. 3075) The bill revises provisions regarding: (1) FDA screening of the Adverse Event Reporting System, and (2) evaluation of elements to assure safe use of drugs.

(Sec. 3076) The bill revises provisions regarding the Reagan-Udall Foundation for the FDA's Board of Directors membership, Executive Director compensation, and accounting. Subtitle H--Medical Countermeasures Innovation

(Sec. 3081) HHS must ensure the issuance of timely and accurate guidelines regarding the use of medical products for countering public health emergencies or material threats. HHS must report on funding for procurement of medical countermeasures when available funds are below a specified amount.

(Sec. 3082) The Biomedical Advanced Research and Development Authority's (BARDA's) contracting authority for procurement of medical countermeasures under Project BioShield is codified.

(Sec. 3083) The Office of the Assistant Secretary for Preparedness and Response must annually publish its budget plan for medical countermeasures.

(Sec. 3084) BARDA may enter an agreement with an independent, nongovernmental nonprofit to foster and accelerate the development and innovation of medical countermeasures and related technologies. BARDA must direct and oversee the nonprofit's work and ensure transparency and accountability.

(Sec. 3085) BARDA's procurement of medical countermeasures no longer requires Presidential approval or an agreement between HHS and the Department of Homeland Security.

(Sec. 3086) The FDA must award, upon approval, a priority review voucher to the sponsor of a drug or biological product that: (1) is a significant improvement in the prevention, diagnosis, or treatment of a serious condition; and (2) can be used as a medical countermeasure to a material threat. The transferable voucher entitles the holder to have an application for a new medication acted upon by the FDA within six months. The FDA may not issue vouchers after FY2023.

(Sec. 3087) The Paperwork Reduction Act does not apply to voluntary collection of information during a public health emergency or while determining whether there is a public health emergency.

(Sec. 3088) The bill revises provisions regarding FDA authorization of emergency use of unapproved products to include animal drugs and veterinary feed directive drugs.

Subtitle I--Vaccine Access, Certainty, and Innovation

(Sec. 3091) The Advisory Committee on Immunization Practices must: (1) consider the use of newly licensed vaccines at each regularly scheduled meeting, and (2) make timely recommendations for vaccines designated as breakthrough therepies and vaccines that could be

recommendations for vaccines designated as breakthrough therapies and vaccines that could be used in a public health emergency.

(Sec. 3092) The CDC must review the processes of the Advisory Committee on Immunization Practices.

(Sec. 3093) HHS must: (1) report on ways to promote innovation in the development of vaccines, and (2) revise the Vaccine Injury Table to include information on vaccines recommended by the CDC for pregnant women. A mother and child are individually considered

for compensation for a vaccine injury from a vaccine administered during pregnancy.

Subtitle J--Technical Corrections

(Sec. 3101) The bill revises provisions regarding:

•movement of impounded drugs,

•pediatric study plans,

•reporting on drug shortages,

•reporting on inspections of establishments manufacturing drugs or medical devices,

•requests to classify medical devices,

•priority review of qualified infectious disease products,

•use of clinical investigation data from outside the United States, and

•medical gasses.

The bill makes technical changes to various provisions regarding medical products. TITLE IV--DELIVERY

(Sec. 4001) This bill amends the Health Information Technology for Economic and Clinical Health Act to require HHS to establish a goal, develop a strategy, and make recommendations to reduce regulatory or administrative burdens relating to the use of electronic health records (EHR).

The Office of the National Coordinator for Health Information Technology (ONC) must encourage, keep, or recognize the certification of health information technology (IT) for use in medical specialties. HHS must adopt certification criteria to support health IT for pediatrics. HHS must publish attestation statistics for the Medicare and Medicaid EHR Incentive Programs. (Health care providers in these programs must attest to meaningful use of EHR to avoid a penalty.)

(Sec. 4002) The bill requires developers of health IT, for their health IT to be certified, to meet certain requirements, including that the developer not engage in information blocking, which is preventing, discouraging, or interfering with the access, exchange, or use of information.

A health care provider whose adopted health IT is decertified is exempted from penalties under the Medicare EHR Incentive program.

HHS must support the convening of stakeholders to develop reporting criteria for health IT developers.

(Sec. 4003) The ONC must: (1) convene stakeholders to develop or support a framework and agreement for the secure exchange of health information between networks, (2) provide for testing of the framework and agreement, and (3) publish a list of networks that adopt the agreement.

HHS must establish an index of digital contact information for health professionals, health facilities, and others to encourage the exchange of health information.

The bill replaces the Health IT Policy Committee and the Health IT Standards Committee with the Health IT Advisory Committee. The ONC must periodically convene the Health IT Advisory Committee to report on priority uses of health IT and standards and implementation specifications that support the use and exchange of electronic health information.

(Sec. 4004) Developers of health IT and health care providers may be penalized for engaging in information blocking.

The ONC must issue guidance on the secure exchange of electronic health information. (Sec. 4005) To be certified, EHR must be capable of transmitting to and receiving from data registries certified by the ONC.

HHS must report on best practices and current trends provided by patient safety organizations to improve the integration of health IT into clinical practice.

(Sec. 4006) HHS must: (1) encourage partnerships between health information exchanges and others to offer patients access to their electronic health information, (2) educate providers on health information exchanges, (3) issue guidance to health information exchanges on best practices, and (4) promote policies to facilitate patient communication with providers.

The ONC must ensure patient access to health information in a convenient form.

The HHS Office for Civil Rights must assist individuals and health care providers in understanding a patient's rights to access and protect their personal health information. The ONC may require health IT certification criteria support certain usability features.

(Sec. 4007) The GAO must review the policies and activities of the ONC and stakeholders to ensure correct matching of a patient to electronic health information.

(Sec. 4008) The GAO must report on patient access to their protected health information, including difficulties providers experience in providing such access.

(Sec. 4009) Medicare administrative contractors must publish local coverage determinations.

(Sec. 4010) A pharmaceutical and technology ombudsman within the Centers for Medicare and Medicaid Services (CMS) must receive and respond to complaints from manufacturers of medical products regarding Medicare coverage of their products.

(Sec. 4011) The CMS must publish estimated Medicare beneficiary prices for items and services provided by either hospital outpatient departments or ambulatory surgical centers.

(Sec. 4012) The CMS and the Medicare Payment Advisory Commission must provide information to Congress regarding Medicare telehealth services.

TITLE V--SAVINGS

(Sec. 5001) The bill increases the funds available to the Medicare Improvement Fund for services provided during and after FY2021.

(Sec. 5002) The effective date of the limit on Medicaid reimbursement to states for durable medical equipment, to Medicare payment rates, is changed from January 1, 2019, to January 1, 2018.

(Sec. 5003) For HHS agreements, monetary penalties are established for fraudulent claims, fraudulent statements, and failure to provide timely access to the Inspector General of HHS. (Sec. 5004) The bill revises Medicare payments for infusion medications delivered through durable medical equipment. These medications are excluded from Medicare competitive bidding programs.

(Sec. 5005) The bill amends titles XIX (Medicaid) and XXI (Children's Health Insurance Program [CHIP]) of the Social Security Act to prohibit Medicaid payment for nonemergency services furnished by providers whose participation in CHIP has been terminated. (Currently, states must exclude from Medicaid participation any provider that has been terminated under any state's Medicaid program or under Medicare.) States must exclude from CHIP participation any provider that has been terminated under Medicaid or Medicare.

States must require Medicaid and CHIP providers to submit identifying information to the state. States must submit this information when notifying HHS that a provider has been terminated under a state plan.

The bill prohibits federal payment under Medicaid or CHIP for services provided by a managed care organization (MCO) unless: (1) the state notifies MCOs when a provider is terminated under Medicaid, Medicare, or CHIP; and (2) any contract between the state plan and an MCO requires such providers be excluded from participation in the MCO provider network.

(Sec. 5006) A state must publish and annually update a directory of physicians participating in its Medicaid program if the program provides assistance on a fee-for-service basis or through a primary care case-management system.

(Sec. 5007) The supplemental needs trust exemption, which excludes a supplemental needs trust from treatment as resources available to an individual for purposes of Medicaid eligibility, is extended to supplemental needs trusts established by individuals for themselves.

(Sec. 5008) The bill eliminates federal payment under Medicaid for drugs used for cosmetic purposes or hair growth, unless medically necessary.

(Sec. 5009) The bill reduces funding for the Prevention and Public Health Fund for FY2018-FY2024.

(Sec. 5010) The Department of Energy must sell crude oil from the Strategic Petroleum Reserve. The bill reduces the minimum amount of oil that must be kept in the reserve under certain circumstances that allow for a drawdown.

(Sec. 5011) The bill rescinds a specified amount of funding related to health insurance exchanges for U.S. territories.

(Sec. 5012) Medicare coverage is expanded to include home infusion therapy, including training and monitoring.

DIVISION B--HELPING FAMILIES IN MENTAL HEALTH CRISIS

Helping Families in Mental Health Crisis Reform Act of 2016

TITLE VI--STRENGTHENING LEADERSHIP AND ACCOUNTABILITY

Subtitle A--Leadership

(Sec. 6001) This bill amends the Public Health Service Act to rename the position of Administrator of the Substance Abuse and Mental Health Services Administration (SAMHSA) to Assistant Secretary for Mental Health and Substance Use.

(Sec. 6002) The bill revises SAMHSA authorities, including to expand SAMHSA's authority to develop educational materials and intervention strategies to reduce the risks of communicable diseases among individuals with mental or substance use disorders.

The bill establishes new requirements for SAMHSA, including that SAMHSA must: (1) improve mental and substance use disorder services provided by the Department of Defense (DOD) and the Department of Veterans Affairs, (2) improve mental and substance use disorders services for chronically homeless individuals and individuals who have been arrested or incarcerated, and (3) develop and support activities to recruit and retain a workforce addressing mental and substance use disorders.

(Sec. 6003) The bill creates the position of Chief Medical Officer within SAMHSA.

(Sec. 6004) SAMHSA must maintain a Center for Behavioral Health Statistics and Quality to: (1) carry out existing data collection requirements, (2) provide statistical and analytical support for SAMHSA activities, (3) recommend performance metrics to evaluate SAMHSA activities, and (4) coordinate with others to improve SAMHSA services and evaluation of SAMHSA activities.

(Sec. 6005) Every four years, SAMHSA must develop, publish, and carry out a strategic plan.

#### H.R. 34 21st Century Cures Act, continued

(Sec. 6006) The bill revises requirements regarding SAMHSA's biennial report on its activities. (Sec. 6007) The bill revises provisions regarding SAMHSA's Center for Mental Health Services, Center for Substance Abuse Prevention, and Center for Substance Abuse Treatment, including to require the centers to ensure consistent documentation of the application of grant criteria. (Sec. 6008) The bill revises membership requirements for SAMHSA advisory councils. (Sec. 6009) The bill revises membership requirements for SAMHSA peer review groups.

Subtitle B--Oversight and Accountability

(Sec. 6021) The Office of the Assistant Secretary for Planning and Evaluation must ensure efficient and effective planning and evaluation of mental and substance use disorders prevention and treatment programs and related activities.

(Sec. 6022) This bill amends the Protection and Advocacy for Individuals with Mental Illness Act to require state protection and advocacy systems to publish their annual reports. The Department of Health and Human Services (HHS) must include in its biennial reports detailed accounting for each system.

(Sec. 6023) The Government Accountability Office (GAO) must report on protection and advocacy systems for individuals with mental illness.

Subtitle C--Interdepartmental Serious Mental Illness Coordinating Committee

(Sec. 6031) HHS must establish the Interdepartmental Serious Mental Illness Coordinating Committee to report on research, evaluate the effect of federal programs, and recommend agency actions to better coordinate administration of mental health services.

TITLE VII--ENSURING MENTAL AND SUBSTANCE USE DISORDERS PREVENTION, TREATMENT, AND RECOVERY PROGRAMS KEEP PACE WITH SCIENCE AND TECHNOLOGY

(Sec. 7001) SAMHSA's Office of Policy, Planning, and Innovation is renamed the National Mental Health and Substance Use Policy Laboratory. The bill specifies responsibilities for the laboratory, including that the laboratory must: (1) facilitate the implementation of policy changes likely to have a significant effect on mental health; (2) collect information from SAMHSA grantees to evaluate and disseminate information on evidence-based practices; and (3) identify SAMHSA activities that are duplicative or that are not evidence-based, effective, or efficient. SAMHSA may award grants for the development of evidence-based interventions for mental illness, serious emotional disturbances, substance use disorders, and co-occurring illness or disorders.

(Sec. 7002) SAMHSA must review and publish information on evidence-based programs and practices.

(Sec. 7003) The bill revises and extends through FY2022 SAMHSA support for addressing regionally and nationally significant needs regarding mental health, substance use disorder treatment, and substance use disorder prevention.

TITLE VIII--SUPPORTING STATE PREVENTION ACTIVITIES AND RESPONSES TO MENTAL HEALTH AND SUBSTANCE USE DISORDER NEEDS

(Sec. 8001) The bill revises and extends through FY2022 block grants for community mental health services. States must use at least a specified amount of a block grant to support evidence-based programs for individuals with early serious mental illness. The bill revises the block grant requirement that a state maintain spending on community mental health services.

(Sec. 8002) The bill revises and extends through FY2022 block grants for prevention and treatment of substance abuse. The bill eliminates the block grant requirements for states to: (1) maintain spending on services for individuals with tuberculosis or HIV, and (2) submit an assessment of need for a block grant. The bill revises the block grant requirement for a state to maintain spending on prevention and treatment of substance abuse.

(Sec. 8003) In the case of a public health emergency, HHS may grant extensions or waive requirements for block grants for transition from homelessness, community mental health services, and prevention and treatment of substance abuse.

SAMHSA must permit states to apply jointly for block grants.

(Sec. 8004) SAMHSA must report on the funding formulas for block grants for community mental health services and prevention and treatment of substance abuse.

TITLE IX--PROMOTING ACCESS TO MENTAL HEALTH AND SUBSTANCE USE DISORDER CARE

Subtitle A--Helping Individuals and Families

(Sec. 9001) The bill revises and extends through FY2022 grants for mental health and substance abuse services for homeless individuals.

(Sec. 9002) The bill revises and extends through FY2022 grants to divert individuals with a mental illness from the criminal justice system to community-based services. In awarding grants, SAMHSA must give special consideration to entities proposing to support services for veterans. Grant funding may be used to develop programs to divert individuals prior to booking or arrest. (Sec. 9003) SAMHSA may provide support for improvement of integrated primary care and behavioral health care.

(Sec. 9004) The bill revises and extends through FY2022 block grants for transition from homelessness. SAMHSA must report on the funding formula for these block grants.

(Sec. 9005) SAMHSA must maintain the existing National Suicide Prevention Lifeline program. (Sec. 9006) SAMHSA must maintain the existing National Treatment Referral Routing Service to assist individuals and families in locating treatment providers for mental and substance use disorders.

(Sec. 9007) SAMHSA must award grants to enhance community-based crisis response systems or for a database of available beds at inpatient psychiatric facilities, crisis stabilization units, and residential community mental health and residential substance use disorder treatment facilities. (Sec. 9008) The bill revises and extends through FY2022 a technical assistance resource center to prevent suicides. The center's focus is expanded from youth suicides to suicides among all ages, particularly among groups that are at high risk for suicide.

A program to provide support for youth suicide early intervention and prevention strategies is also revised and extended through FY2022.

(Sec. 9009) SAMHSA must award grants for suicide prevention and intervention programs for adults.

(Sec. 9010) The bill revises and extends through FY2022 SAMHSA's training grant program. The program is expanded to include additional categories of trainees.

(Sec. 9012) SAMHSA must provide technical assistance and disseminate information regarding mental health and substance use disorders among geriatric populations.

(Sec. 9013) The Centers for Disease Control and Prevention is encouraged to improve the National Violent Death Reporting System.

(Sec. 9014) This bill amends the Protecting Access to Medicare Act of 2014 to extend through FY2022 a pilot program for assisted outpatient treatment programs for individuals with serious mental illness.

(Sec. 9015) SAMHSA must award grants for assertive community treatment programs for adults with a serious mental illness. (Patients in assertive community treatment programs receive care in their community from a multidisciplinary team of providers.)

(Sec. 9016) The bill extends SAMHSA programs to reduce underage drinking through FY2022 and expands the programs to permit SAMHSA to award grants to pediatric health care providers. (Sec. 9017) The bill repeals various expired SAMHSA programs.

Subtitle B--Strengthening the Health Care Workforce

(Sec. 9021) The bill revises and extends through FY2022 mental and behavioral health education and training grants. Grantees must be able to place students in areas with a high need and high demand population.

(Sec. 9022) HHS must establish a training demonstration program for mental and substance use disorders to award grants for: (1) training medical residents and fellows to practice psychiatry and addiction medicine in underserved, community-based settings with integrated care; (2) training other providers to provide services in such settings; and (3) academic units or programs that train students or faculty or develop practices or recommendations for the design of such units or programs.

(Sec. 9023) The Health Resources and Services Administration (HRSA) must clarify the eligibility of pediatric psychiatrists for the National Health Service Corps Loan Repayment Program.

(Sec. 9024) HHS must maintain a Minority Fellowship Program for mental and substance use disorder treatment professionals to improve services for racial and ethnic minority populations. (Sec. 9025) A health professional volunteer providing primary health care to an individual at a community health center or through programs or events carried out by a center is deemed to be an employee of the Public Health Service for purposes of any civil action that may arise from providing services to patients. For a volunteer to be covered by this liability protection, HHS must approve the center's application to sponsor the volunteer.

(Sec. 9026) HRSA must publish a report on the adult and pediatric mental health and substance use disorder workforce.

Subtitle C--Mental Health on Campus Improvement

(Sec. 9031) The bill revises and extends through FY2022 SAMHSA grants for mental and behavioral health services at institutions of higher education.

(Sec. 9032) HHS must establish a College Campus Task Force to discuss mental and behavioral health concerns at institutions of higher education.

(Sec. 9033) SAMHSA must convene a working group regarding a public education campaign focused on mental and behavioral health at institutions of higher education.

TITLE X--STRENGTHENING MENTAL AND SUBSTANCE USE DISORDER CARE FOR CHILDREN AND ADOLESCENTS

(Sec. 10001) The bill revises and extends through FY2022 a grant program to provide comprehensive community mental health services to children with a serious emotional disturbance.

(Sec. 10002) HRSA must award grants to promote integration of behavioral health with pediatric primary care.

(Sec. 10003) The bill revises and extends through FY2022 SAMHSA support for substance use disorder treatment services for children. The program is expanded to include support for early identification and services for children at risk of substance use disorders and assistance to pregnant and parenting women with substance use disorders.

(Sec. 10004) The bill revises and extends through FY2022 a grant program to address violencerelated stress. The program must support the continued operation of the National Child

Traumatic Stress Initiative (NCTSI). The NCTSI coordinating center must report on child treatment and outcomes and facilitate training in evidence-based and trauma-informed treatments, interventions, and practices.

(Sec. 10005) HHS must award grants to states for screening, assessment, and treatment services for maternal depression.

(Sec. 10006) HHS must award grants for infant and early childhood mental health promotion, intervention, and treatment programs.

#### H.R. 34 21st Century Cures Act, continued

#### TITLE XI--COMPASSIONATE COMMUNICATION ON HIPAA

(Sec. 11002) After finalizing regulations on the confidentiality of alcohol and drug abuse patient records, HHS must convene stakeholders to determine the effect of the regulations on patient care, health outcomes, and patient privacy.

(Sec. 11003) The HHS Office for Civil Rights must ensure that entities involved in mental or substance use disorder treatment, including patients and their families, have adequate, accessible, and easily comprehensible resources regarding use and disclosure of protected health information under the Health Insurance Portability and Accountability Act. HHS must issue guidance clarifying the circumstances under which an entity may use or disclose protected health information.

(Sec. 11004) HHS must identify, or recognize entities to develop and disseminate, model programs and materials for training: (1) health care providers regarding the use and disclosure of the protected health information of patients seeking or undergoing mental or substance use disorder treatment, and (2) patients and their families regarding their rights to protect and obtain such information.

#### TITLE XII--MEDICAID MENTAL HEALTH COVERAGE

(Sec. 12001) The bill declares that current law allows a state Medicaid plan to pay for a primary care service and a mental health service furnished to an individual on the same day by providers at the same facility.

(Sec. 12002) The Centers for Medicare and Medicaid Services (CMS) must report on Medicaid coverage of services provided through Medicaid managed care organizations or prepaid inpatient health plans to certain enrollees receiving treatment in institutions for mental diseases.

(Sec. 12003) The CMS must notify state Medicaid programs regarding opportunities to design innovative service delivery systems for adults with a serious mental illness or children with a serious emotional disturbance.

(Sec. 12004) The CMS must collect and report specified information from states with Medicaid emergency psychiatric demonstration projects, including the extent to which there is a reduction in spending under demonstration projects.

(Sec. 12005) This bill amends title XIX (Medicaid) of the Social Security Act to provide for federal payment under Medicaid for early and periodic screening, diagnostic, and treatment services for children in inpatient psychiatric hospitals, effective January 1, 2019.

(Sec. 12006) Federal payment under Medicaid for in-home personal care services or home health care services is reduced for states that do not require the use of an electronic visit verification system for such services, effective January 1, 2019. The CMS must pay a specified share of state expenditures attributable to such a system.

HHS must disseminate to states best practices for electronic visit verification systems, including training for users.

#### TITLE XIII--MENTAL HEALTH PARITY

(Sec. 13001) HHS, the Department of Labor, and the Department of the Treasury must: (1) issue guidance to improve the compliance of group health plans and health insurance coverage with requirements for parity between mental health and substance use disorder benefits and medical and surgical benefits, (2) publish feedback from the public on the disclosure request process for documents regarding parity requirements, and (3) audit the plan documents of group health plans and health insurers that repeatedly violate parity requirements.

(Sec. 13002) HHS must convene stakeholders to produce an action plan for improved federal and state coordination regarding enforcement of parity requirements.

(Sec. 13003) The Employee Benefits Security Administration must report on closed federal investigations that found serious violations of parity requirements.

(Sec. 13004) The GAO must report on the extent to which group health plans, health insurers, Medicaid managed care organizations, and Children's Health Insurance Program (CHIP) health plans comply with parity requirements.

(Sec. 13005) The HHS Office on Women's Health may: (1) update published information on eating disorders, (2) incorporate public resources into its obesity prevention programs, and (3) advance public awareness of eating disorders.

(Sec. 13006) HHS may facilitate the identification of model programs and materials for educating and training health professionals regarding eating disorders.

TITLE XIV--MENTAL HEALTH AND SAFE COMMUNITIES

Subtitle A--Mental Health and Safe Communities

(Sec. 14001) This bill amends the Omnibus Crime Control and Safe Streets Act of 1968 to expand the Edward Byrne Memorial Justice Assistance Grant Program to support mental health programs and related law enforcement and corrections programs.

The public safety and community policing grant program is expanded to support training and programs for law enforcement and corrections officers regarding individuals with mental illness. This bill amends the Federal Fire Prevention and Control Act of 1974 to expand Federal Emergency Management Agency (FEMA) grants for fire and emergency response to support training for first responders regarding individuals with mental illness.

(Sec. 14002) The bill revises the Department of Justice (DOJ) mental health courts program to require grantees to support court-ordered assisted outpatient mental health treatment.

(Sec. 14003) DOJ must establish a pilot program to determine the effectiveness of diverting certain offenders with mental illness or intellectual disabilities from federal prosecution, federal probation, or federal prison and placing the offenders in drug or mental health courts.

(Sec. 14004) DOJ may award grants for: (1) pretrial mental health screening of defendants and supervision of defendants on pretrial release, and (2) criminal justice system behavioral health assessments and intervention programs.

(Sec. 14005) DOJ may award grants for forensic assertive community treatment programs that provide services in the community for individuals with mental illness involved with the criminal justice system to prevent future incarcerations.

(Sec. 14006) The bill revises priority considerations for DOJ reentry demonstration project grants, including to prioritize applications that provide mental health treatment and transitional services to individuals with mental illness.

(Sec. 14007) The bill revises grants for drug courts and training for drug court personnel and officials to specify that the programs include activity regarding individuals with co-occurring substance abuse and mental health problems.

(Sec. 14008) HHS, DOD, the Department of Homeland Security, and the Department of Commerce must provide the uniformed services with training, technology, and programs for responding to individuals with mental illness.

(Sec. 14009) The bill revises priority considerations for DOJ reentry demonstration project grants, including to prioritize applications that target offenders with histories of homelessness, substance abuse, or mental illness.

The bill specifies that DOJ grants for transitional services may be used for mental health care. (Sec. 14010) Grants awarded by the Office of Community Oriented Policing Services for improving school security may be used for crisis intervention teams.

(Sec. 14011) DOJ may provide safety training and technical assistance to local law enforcement agencies as part of the Preventing Violence Against Law Enforcement and Ensuring Officer Resilience and Survivability Initiative.

(Sec. 14012) DOJ grants for residential substance abuse treatment programs for state prisoners may be used for programs for inmates with co-occurring mental health and substance abuse disorders or challenges.

(Sec. 14013) The bill revises a grant program for drug treatment alternatives to incarceration, including to expand the program to include mental health treatment alternatives.

(Sec. 14014) DOJ may award grants to establish a National Criminal Justice and Mental Health Training and Technical Assistance Center to conduct activities including: (1) training of law enforcement officers and others regarding individuals with mental illness, and (2) providing support for individuals with mental illness at risk of involvement with the criminal justice system.

(Sec. 14015) Data prepared by, or submitted to, the DOJ or the Federal Bureau of Investigation on homicides, law enforcement officers killed, seriously injured, and assaulted, or individuals killed or seriously injured by law enforcement officers must include data on the involvement of mental illness in the incident.

(Sec. 14016) The GAO must report on the cost of imprisonment of individuals with serious mental illness and include: (1) the number and type of crimes committed by such individuals, and (2) strategies or ideas for preventing crimes by such individuals.

(Sec. 14017) The Department of Veterans Affairs, prior to determining a beneficiary is mentally incompetent, must provide the beneficiary with notice of the proposed determination and opportunities to request a hearing, be represented at the hearing, and present evidence.

(Sec. 14018) The bill extends though FY2021 the Justice and Mental Health Collaboration Program.

Subtitle B--Comprehensive Justice and Mental Health

(Sec. 14021) DOJ may award grants for sequential intercept mapping, which is aimed at minimizing criminal justice involvement for individuals with mental illness.

(Sec. 14022) DOJ may award grants to assist correctional facilities in addressing the needs of inmates with mental illness and training employees to respond to incidents involving inmates with mental illness.

(Sec. 14023) Justice and Mental Health Collaboration Program implementation grants may be used to support multidisciplinary teams that address frequent users of crisis services.

(Sec. 14024) DOJ grants to improve law enforcement response to mentally ill offenders may be used to support academy training and other programs that teach law enforcement personnel. Priority for these grants is given to programs that are administered cooperatively by law enforcement personnel and mental health and substance abuse professionals.

(Sec. 14025) Regarding response to individuals with mental illness, DOJ must provide direction and guidance on: (1) training programs for federal first responders and tactical units, and (2) systems to provide timely information to federal law enforcement agencies and criminal justice agencies.

(Sec. 14026) The GAO must report on: (1) the practices used by federal first responders, tactical units, and corrections officers in responding to individuals with mental illness, (2) the application of evidence-based practices in criminal justice settings to better address individuals with mental illnesses, and (3) how DOJ can expand and improve information sharing and dissemination of best practices.

(Sec. 14027) The bill revises priority considerations for Justice and Mental Health Collaboration Program grants to prioritize applications that: (1) propose interventions that reduce recidivism, and (2) target certain offenders with a moderate or high risk of recidivism and a need for treatment and services.

(Sec. 14028) The bill revises the Justice and Mental Health Collaboration Program to include certain veterans and violent offenders as preliminarily qualified offenders.

(Sec. 14029) The bill revises the Justice and Mental Health Collaboration Program to make grants subject to audits, prohibit certain nonprofits with offshore accounts from receiving grants, limit spending on conferences, and prevent duplicative grants.

DIVISION C--INCREASING CHOICE, ACCESS, AND QUALITY IN HEALTH CARE FOR AMERICANS

Increasing Choice, Access, and Quality in Health Care for Americans Act TITLE XV--PROVISIONS RELATING TO MEDICARE PART A

(Sec. 15001) The bill amends title XVIII (Medicare) of the Social Security Act to require the Centers for Medicare & Medicaid Services (CMS) to develop, with respect to claims for hospital services, codes under the Healthcare Common Procedure Coding System (HCPCS) for similar inpatient and outpatient hospital services.

(Sec. 15002) The bill establishes processes for adjusting a hospital's Medicare payments based on the hospital's overall proportion of inpatients who are dually eligible for Medicare and Medicaid.

(Sec. 15003) The bill extends for five years the Rural Community Hospital Demonstration Program, through which Medicare pays certain rural hospitals on the basis of reasonable incurred costs rather than under the standard prospective payment system.

(Sec. 15004) With respect to long-term care hospitals (LTCHs), the bill lifts a moratorium on bed increases. The bill reduces rates for high-cost outlier payments, which are additional Medicare payments made in extraordinarily high-cost cases.

(Sec. 15005) The bill reduces the amount by which hospital payment rates for inpatient services increase in FY2018.

(Sec. 15006) The bill amends the Medicare, Medicaid, and SCHIP Extension Act of 2007 to revise the applicability of certain Medicare payment rules exempting LTCHs from negative payment adjustments for admissions from certain co-located hospitals beyond specified thresholds. These rules shall apply for an additional period beginning on October 1, 2016.

(Sec. 15007) In addition, the bill amends the Pathway for SGR Reform Act of 2013 to expand to all LTCHs the application of a payment rule that requires the exclusion of certain patients for purposes of calculating length of stay. Under current law, the payment rule applies only to a hospital that was classified as an LTCH as of a specified date.

(Sec. 15008) The bill removes certain hospitals specializing in neoplastic disease from their classification as LTCHs for purposes of Medicare payment.

(Sec. 15009) With specified exceptions, current law applies certain payment limits to inpatient services for LTCHs that do not meet specified discharge requirements. The bill: (1) establishes a new temporary exception to these limits for certain spinal cord specialty hospitals, and (2) expands an existing temporary exception with respect to certain discharges involving severe wounds.

# TITLE XVI--PROVISIONS RELATING TO MEDICARE PART B

(Sec. 16001) The bill excludes certain off-campus outpatient departments (OPDs) from specified rules that mandate lower Medicare payments. Specifically, the exclusion applies to: (1) cancer hospitals in off-campus OPDs, and (2) mid-build OPDs. A "mid-build" OPD is one for which the provider had, before a certain date, a binding written agreement with an outside party for construction.

(Sec. 16003) With respect to payment reductions for failing to meet requirements for the meaningful use of electronic health records, the bill exempts eligible professionals who are based in ambulatory surgical centers.

(Sec. 16004) The bill requires CMS to continue to instruct Medicare contractors not to enforce requirements for direct physician supervision of outpatient therapeutic services in critical access and small rural hospitals through 2016. The Medicare Payment Advisory Commission must report on the effect of extending this instruction on: (1) Medicare beneficiaries, and (2) hospital staffing needs.

(Sec. 16005) The bill amends the Patient Access and Medicare Protection Act to delay by six months the implementation of specified Medicare fee schedule adjustments with respect to certain accessories and seating systems used with complex rehabilitation technology wheelchairs.

(Sec. 16006) The bill allows physical therapists to utilize "locum tenens" arrangements (through which a substitute practitioner is retained when the regular practitioner is absent for a reason such as illness or pregnancy) under Medicare in the same manner as physicians are allowed to use utilize such arrangements under current law.

(Sec. 16007) CMS shall: (1) delay by six months the full implementation of new Medicare payment rates for durable medical equipment (DME), and (2) study and report on the impact of applicable payment adjustments on the availability of DME to Medicare beneficiaries. (Sec. 16008) Under current law, CMS must use payment information from competitive acquisition programs to make payment adjustments for DME items furnished in areas outside of such programs. Current law also allows, but does not require, CMS to make such adjustments with respect to certain orthotics (such as splints and braces) and parenteral and enteral nutrients, equipment, and supplies (such as feeding tubes). The bill requires CMS, in making these adjustments, to account for stakeholder input. In addition, CMS must account for a comparison of competitive acquisition areas and other areas with respect to the following factors: •average travel distance and cost associated with furnishing items and services, •average volume of items and services furnished by suppliers, and •number of suppliers.

#### TITLE XVII--OTHER MEDICARE PROVISIONS

(Sec. 17001) Until plan year 2019, CMS may not terminate a Medicare Advantage (MA) plan solely because the plan failed to achieve a specified minimum quality rating.

(Sec. 17002) CMS must annually report on specified Medicare enrollment data.

(Sec. 17003) CMS shall: (1) request information and recommendations from stakeholders on information included in the Welcome to Medicare package, and (2) update the information included in the package accordingly.

(Sec. 17004) Current law allows CMS to impose a temporary moratorium on the enrollment of new providers under Medicare, Medicaid, or the Children's Health Insurance Program (CHIP) if necessary to combat fraud, waste, or abuse. With specified exceptions, the bill prohibits payment under these programs to new providers in areas subject to such temporary moratorium. (Sec. 17005) The bill expands and modifies enrollment and disenrollment options for MA-eligible individuals. Specifically, the bill extends the annual period in which an individual enrolled in MA may elect to instead receive benefits under the original Medicare fee-for-service (FFS) program as well as elect to change qualified prescription drug coverage. Furthermore, any MA-eligible individual (whether or not enrolled in MA) may once per period change a previous election with respect to receiving benefits through MA or Medicare FFS, including changing from one MA plan to another. Unsolicited marketing during this period is prohibited. (Sec. 17006) The bill allows individuals with end-stage renal disease (ESRD) to be eligible for MA. Under current law, only individuals who develop ESRD while already enrolled in an MA plan may be considered eligible.

With respect to payment, the bill: (1) shifts responsibility for the cost of kidney acquisitions from MA plans to Medicare's FFS program, and (2) excludes such costs from the calculation of certain benchmarks that form the basis for payment under MA plans.

CMS must conduct, and post online the results of, an evaluation of whether to include in a plan's quality rating a measure specifically related to care for MA enrollees with ESRD.

The bill also modifies risk adjustment with respect to MA plans. Specifically, in making such adjustments, CMS must:

•take into account an MA enrollee's total number of diseases or conditions,

•use at least two years of diagnostic data,

•provide separate adjustments for individuals dually eligible for Medicare and Medicaid, and •evaluate whether other specified factors should be included in the risk adjustment model. (Sec. 17007) The bill establishes additional requirements for assigning Medicare FFS

beneficiaries to accountable care organizations (ACOs) under the Medicare shared savings program. (The program enables ACOs to receive payments for savings stemming from care coordination and management.)

Specifically, the bill requires the basis for assignment to reflect beneficiaries' utilization of not only primary care services provided by ACO physicians, but also those furnished in federally qualified health centers or rural health clinics.

TITLE XVIII--OTHER PROVISIONS

(Sec. 18001) This bill amends the Internal Revenue Code, the Patient Protection and Affordable Care Act (PPACA), and other laws to exempt qualified small employer health reimbursement arrangements (HRAs) from certain requirements that apply to group health plans.

A qualified small employer HRA is offered by employers that have fewer than 50 full-time employees and do not offer group health plans to any of their employees. A qualified small employer HRA must:

•be provided on the same terms to all eligible employees of the employer;

•be funded solely by the employer without salary reduction contributions;

•provide, after an employee provides proof of coverage, for the payment or reimbursement of medical expenses of the employee and family members; and

•limit annual payments and reimbursements to specified dollar amounts.

HRAs that meet these requirements are not considered group health plans and are exempt from various requirements that apply to group health plans, including coverage and cost-sharing requirements. (Under current law, employers that sponsor group health plans that do not meet specified requirements are subject to an excise tax.)

Coverage and payments under a qualified HRA are excluded from gross income, unless the employee does not have minimum essential coverage for the month in which the medical care was provided.

Employers offering a qualified HRA must notify employees in advance regarding permitted benefits and report benefit information on W-2 forms and to health exchanges.

The bill sets forth requirements for determining whether an employee covered under an HRA is also eligible for premium subsidies under PPACA.

Advocated in favor of this bill.

Status: 12/13/2016 Became Public Law No: 114-255.

# S.2817 Space Weather Research and Forecasting Act

(Sec. 2) This bill directs the Office of Science and Technology Policy (OSTP) to:

- coordinate the development and implementation of federal government activities to improve the nation's ability to prepare, avoid, mitigate, respond to, and recover from potentially devastating impacts of space weather events;
- and coordinate the activities of the National Space Weather Program members.

The National Science and Technology Council shall establish an interagency working group on space weather, including representatives of the federal agencies participating in the National Space Weather Program, and of other federal agencies, as appropriate.

In order to understand and respond to the adverse effects of space weather, such program shall leverage capabilities across participating federal agencies, including the:

National Oceanic and Atmospheric Administration (NOAA); National Aeronautics and Space Administration (NASA); National Science Foundation (NSF); Department of Defense (DOD); Department of the Interior; Department of Homeland Security (DHS); Department of Energy; Department of Transportation, including the Federal Aviation Administration (FAA); and Department of State.

It is the sense of Congress that the interagency collaboration between NASA and NOAA on terrestrial weather observations provides:

- an effective mechanism for improving weather and climate data collection while avoiding unnecessary duplication of capabilities across federal agencies, and
- an agency collaboration model that could benefit space weather observations.

NASA and NOAA shall enter into at least one interagency agreement that provides for cooperation and collaboration in the development of space weather spacecraft, instruments, and technologies.

It is U.S. policy to establish and sustain a baseline capability for space weather observations. The OSTP, in coordination with NOAA, NASA, NSF, and DOD, shall develop an integrated strategy for solar and solar wind observations beyond the lifetime of current assets that considers the provision of:

- solar wind measurements and other measurements essential to space weather forecasting, and
- solar and space weather measurements important for scientific purposes.

In developing such strategy, the OSTP shall consider small satellite options, hosted payloads, commercial options, international options, and prize authority.

In order to sustain current space-based observational capabilities, NASA shall

- in cooperation with the European Space Agency, maintain operations of the Solar and Heliospheric Observatory/Large Angle and Spectrometric Coronagraph (SOHO/LASCO) for as long as it continues to deliver quality observations, and
- prioritize the reception of LASCO data.

NOAA shall secure reliable secondary capability for near real-time coronal mass ejection imagery.

NOAA, in coordination with DOD and NASA, shall develop options to build and deploy one or more instruments for near real-time coronal mass ejection imagery.

In developing such options, NOAA shall consider commercial solutions, prize authority, academic and international partnerships, microsatellites, ground-based instruments, and opportunities to deploy the instrument or instruments as a secondary payload on an upcoming planned launch.

In securing reliable secondary capability for near real-time coronal mass ejection imagery, NOAA shall make it a priority to achieve a cost-effective solution.

NOAA shall develop an operational contingency plan to provide continuous space weather forecasting in the event of a SOHO/LASCO failure.

Within 120 days of the enactment of this bill, NOAA shall brief Congress on the options for building and deploying the instrument or instruments and the operational contingency plan.

NOAA, in coordination with DOD, shall develop requirements and a plan for follow-on spacebased observations for operational purposes.

The OSTP shall report to Congress on the integrated strategy, including the plans for follow-on space-based observations.

The NSF the Air Force, and where practicable in support of the Air Force, the Navy shall each:

- maintain and improve, as necessary and advisable, ground-based observations of the Sun; and
- provide space weather data by means of ground-based facilities, including radars, lidars, magnetometers, radio receivers, aurora and airglow imagers, spectrometers, interferometers, and solar observatories.

The NSF shall:

- provide key data streams from such platforms for research and to support space weather model development,
- develop experimental models for scientific purposes, and
- support the transition of such models to operations where appropriate.

NOAA, the Air Force, and where practicable in support of the Air Force, the Navy, in conjunction with other relevant federal agencies, shall conduct a survey to identify and prioritize the needs of space weather forecast users, including space weather data and space weather forecast data needed to improve services and inform research priorities and technology needs. In conducting such survey, NOAA, the Air Force, and where practicable in support of the Air Force, the Navy, at a minimum, shall:

- consider the goals for forecast lead time, accuracy, coverage, timeliness, data rate, and data quality for space weather observations;
- identify opportunities to address the identified needs of space weather forecast users through collaboration with academia, the private sector, and the international community;
- identify opportunities for new technologies and instrumentation to address those needs; and
- publish a report on the findings regarding such goals and opportunities.

NOAA, the Air Force, and where practicable in support of the Air Force, the Navy, shall:

- make the survey's results publicly available; and
- notify Congress of making those results available to the public.

As part of the program, the NSF, NASA, and DOD shall continue to carry out basic research activities on heliophysics, geospace science, and space weather and support competitive, meritbased, peer-reviewed proposals for research, modeling, and monitoring of space weather and its impacts, including science goals outlined in Solar and Space Physics Decadal surveys conducted by the National Academy of Sciences (NAS).

As part of such program, the NSF, NOAA, and NASA shall pursue multidisciplinary research in subjects that further our understanding of solar physics, space physics, and space weather. It is the sense of Congress that NASA and the NSF should support competitively awarded Heliophysics Science Centers.

NASA shall seek to implement missions meeting science objectives identified in NAS Solar and Space Physics Decadal surveys.

NASA, the NSF, NOAA, and the Air Force, and where practicable in support of the Air Force, the Navy shall:

- develop a mechanism to transition NASA, NSF, Air Force, and Navy research findings, models, and capabilities to NOAA and DOD space weather operational forecasting centers; and
- enhance coordination between research modeling centers and forecasting centers.

NOAA and DOD, in coordination with NASA and the NSF, shall develop a mechanism to communicate the operational needs of space weather forecasters to the research community.

NASA and the NSF shall support the development of technologies and instrumentation to improve space weather forecasting lead-time and accuracy to meet needs identified by NOAA. NASA and the NSF shall:

- make space weather related data obtained for scientific research available to space weather forecasters and operations centers, and
- support model development and applications to space weather forecasting.

NOAA shall make space weather related data obtained from operational forecasting available for scientific research.

The provisions relating to space weather under the National Aeronautics and Space Administration Authorization Act of 2010 are repealed.

(Sec. 3) The Space Weather Interagency Working Group shall:

- assess existing data, the historical record, models, and peer-reviewed studies on space weather; and
- develop preliminary benchmarks for measuring solar disturbances.

Within 18 months of the development of the preliminary benchmarks, the working group shall publish final benchmarks and NASA shall contract with the NAS to review them.

The working group shall update and revise the final benchmarks as necessary, based on:

- the results of the review by the NAS,
- any significant new data or advances in scientific understanding that become available, or
- the evolving needs of entities impacted by solar disturbances.

(Sec. 4) NOAA shall inform DHS about space weather hazards to protect national critical infrastructure from space weather events.

DHS shall:

- include, in meeting national critical infrastructure reporting requirements, an assessment of the vulnerability of such infrastructure to space weather events; and
- support critical infrastructure providers in managing the risks and impacts associated with space weather.

(Sec. 5) The National Security Council shall:

- assess the vulnerability of the national security community to space weather events, and
- develop mechanisms to protect national security assets from space weather threats.

DOD shall inform the National Security Council, the Director of National Intelligence, and the heads of the defense agencies about space weather hazards for purposes of the protection of those assets.

(Sec. 6) The FAA shall assess:

- the safety implications and vulnerability of the national aerospace system by space weather events;
- methods to mitigate the safety implications and effects of space weather on aviation communication systems, aircraft navigation systems, satellite and ground-based navigation systems, and potential health effects of radiation exposure; and

• options for incorporating space weather into operational training for pilots, cabin crews, dispatchers, air traffic controllers, meteorologists, and engineers.

The FAA shall develop methods to increase the interaction between the aviation community and the space weather research and service provider community.

Engaged on issues surrounding this act. Discussed the bill.

Status: 11/28/2016 Placed on Senate Legislative Calendar under General Orders. Calendar No. 689

#### <u>S. 3346</u> National Aeronautics and Space Administration Transition Authorization Act of 2016

(Cruz)

#### TITLE I--AUTHORIZATION OF APPROPRIATIONS

(Sec. 101) This bill authorizes appropriations to the National Aeronautics and Space Administration (NASA) for FY2017 for:

- exploration;
- space operations;
- science;
- aeronautics;
- space technology;
- education;
- safety, security, and mission services;
- construction and environmental compliance and restoration; and
- the NASA Inspector General.

### TITLE II--SUSTAINING NATIONAL SPACE COMMITMENTS

(Sec. 201) Expresses the sense of Congress that NASA is and should remain a multimission agency with a balanced and robust set of core missions in science, space technology, aeronautics, human space flight and exploration, and education.

# TITLE III--MAXIMIZING UTILIZATION OF THE ISS AND LOW-EARTH ORBIT (Sec. 301) The bill expresses the sense of Congress that:

- NASA should continue to support the development of the Commercial Crew Program as planned to end reliance upon Russian transport of U.S. astronauts to the International Space Station (ISS); and
- the ISS should continue to provide a platform for fundamental, microgravity, discoverybased space life and physical sciences research.

Congress reaffirms that it shall be U.S. policy, in consultation with its international partners in the ISS program, to support full and complete utilization of the ISS through at least 2024. (Sec. 302) The bill declares that it is U.S. policy that, in order to foster the competitive development, operation, improvement, and commercial availability of space transportation services, services for federal government access to and return from the ISS shall be procured by fair and open competition for well-defined, milestone-based, Federal Acquisition Regulation-based contracts.

The Commercial Orbital Transportation Services Program is renamed as the Commercial Resupply Services Program.

NASA shall protect the safety of U.S. space crews by ensuring that commercial crew systems meet all applicable human rating requirements under specified federal law.

(Sec. 303) NASA shall develop a plan for transitioning the ISS from the current regime that relies heavily on NASA sponsorship to a regime where NASA is one of many customers of a low-Earth orbit commercial human space flight enterprise.

NASA shall submit triennial reports until 2023 which include:

- identification of the low-Earth orbit capabilities necessary to meet its deep space human flight exploration objectives and mission requirements beyond the period of operation and use of the ISS;
- steps NASA is taking and will take, including demonstrations that could be conducted on the ISS, to stimulate and facilitate commercial demand and supply of products and services in low-Earth orbit;
- an assessment of current and projected commercial activities in low-Earth orbit, including on the ISS, and their potential for meeting the capabilities identified;
- identification of barriers preventing the commercialization of low-Earth orbit;
- evaluation of the feasible and preferred service life of the ISS beyond September 30, 2024, through at least 2028, as a unique scientific, commercial, and exploration-related facility;
- evaluation of the functions, roles, and responsibilities for the management and operation of the ISS; and
- a description of the progress on meeting human exploration research objectives on the ISS and prospects for accomplishing future exploration and other research objectives on future commercially supplied low-Earth orbit platforms or migration of those objectives to cis-lunar space.

The bill defines "cis-lunar space" as the region of space from the Earth out to and including the region around the surface of the Moon.

(Sec. 304) Any contract between NASA and a provider (a person that provides domestic launch or domestic reentry services to the federal government) may provide that the United States will indemnify that provider against successful claims (including reasonable expenses of litigation or settlement) by third parties for death, bodily injury, or loss of or damage to property resulting from launch services and reentry services carried out under the contract that are defined in it as unusually hazardous or nuclear in nature, but only to the extent the total amount of successful claims related to the activities under that contract:

- is more than the amount of insurance or demonstration of financial responsibility, and
- is not more than \$1.5 billion (plus additional amounts necessary to reflect inflation occurring after January 1, 1989) above such insurance or financial responsibility amount.

A contract made under this section that provides indemnification shall provide for:

- notice to the United States of any claim or suit against the provider for death, bodily injury, or loss of or damage to property; and
- control of or assistance in the defense by the United States, at its election, of such claim or suit and approval of any settlement.

A provider that has a contract with NASA under this section shall obtain liability insurance or demonstrate financial responsibility in amounts to compensate for the maximum probable loss from claims by:

- a third party for death, bodily injury, or property damage or loss resulting from a launch service or reentry service carried out under the contract; and
- the federal government for damage or loss to government property resulting from a launch service or reentry service carried out under such contract.

NASA shall determine maximum probable losses within 90 days of the provider requesting such a determination and submitting all of the information that NASA requires. NASA may revise such a determination if the revision is warranted based on new information.

For the total claims related to one launch or reentry, a provider shall not be required to obtain insurance or demonstrate financial responsibility of more than:

- \$500 million with respect to a third party, or \$100 million with respect to the federal government; or
- the maximum liability insurance available on the world market at reasonable cost.

An insurance policy or demonstration of financial responsibility regarding this section shall protect to the extent of their potential liability for involvement in launch services or reentry services:

- the federal government,
- federal government personnel,
- related entities of the federal government,
- related entities of the provider, and
- government astronauts (as defined in federal law).

NASA may not indemnify a provider under this section until there is a cross-waiver between NASA and the provider.

The bill states that NASA shall reciprocally waive claims with a provider under which each party agrees to be responsible for damage or loss to its property, or for losses resulting from any injury or death sustained by its employees or agents. Such a waiver shall apply only to the extent that the claims are more than the amount of insurance or demonstration of financial responsibility. Indemnification under this section may exclude claims that result from the willfull misconduct of the provider or its related entities.

No payment may be made under this section unless NASA or its designee certifies that the amount is just and reasonable.

NASA may not provide indemnification under this section for an activity requiring a license or permit under provisions relating to commercial space launch activities.

#### TITLE IV--ADVANCING HUMAN DEEP SPACE EXPLORATION

Subtitle Human Exploration Goals and Objectives

(Sec. 411) The bill states that the long-terms goals for the human space flight and exploration efforts of NASA shall be:

- to expand permanent human presence beyond low-Earth orbit with the involvement of international, academic, and industry partners; and
- the peaceful settlement of a location in space or on another celestial body and a thriving space economy in the 21st century.

(Sec. 412) The key U.S. objectives for human expansion into space shall include achieving human exploration of Mars, including the establishment of a capability to extend human presence, including potential human habitation, on the surface of Mars.

(Sec. 413) NASA shall manage human space flight programs, including the Space Launch System (SLS) and the Orion multipurpose crew vehicle, to enable humans to explore Mars and other space destinations.

(Sec. 414) NASA shall implement an exploration research and technology development program for enabling human and robotic operations.

(Sec. 415) The bill declares that in order to maximize the cost-effectiveness of the long-term exploration and utilization activities of the United States, NASA shall take all necessary steps, including engaging international, academic, and industry partners, to ensure that activities in NASA's human exploration program balance how those activities might also help meet the requirements of future exploration and utilization activities leading to human habitation on the surface of Mars.

Within budgetary considerations, once an exploration-related project enters its development phase, NASA shall seek to complete such project without any undue delays.

Subtitle B--Assuring Core Capabilities for Exploration

(Sec. 421) NASA shall continue the development of:

- an uncrewed exploration mission to demonstrate the capability of the SLS and Orion as an integrated system by 2018;
- a crewed exploration mission to demonstrate the SLS, including the core stage and exploration upper stages, and a crewed Orion mission by 2021;
- subsequent missions beginning with the EM-3 using the SLS and Orion to extend into cis-lunar space and eventually to Mars; and
- a deep space habitat as the next element in a deep space exploration architecture along with the SLS and Orion.

NASA shall assess the utility of the SLS for use by the science community and for other federal government launch needs, including considering the overall cost and schedule savings from reduced transit times and increased science returns enabled by the capabilities of the SLS. Subtitle C--Journey to Mars

(Sec. 431) The bill states it is U.S. policy that NASA shall develop propulsion technologies to support:

- its core missions in science, aeronautics, and human space flight and exploration; and
- sustained investments in early stage innovation and fundamental research and technologies to expand the boundaries of the nation's aerospace enterprise.

Furthermore, a goal of such technologies shall be to significantly reduce the amount of time it takes for human travel to Mars.

(Sec. 433) NASA shall develop a strategic framework, including a critical decision plan, for expanding human presence beyond low-Earth orbit, including to cis-lunar space, the surface of Mars, the moons of Mars, and beyond.

The strategic framework shall include:

- an integrated set of exploration, science, and other goals and objectives of a U.S. human space exploration program with the long-term goal of human missions near to or on the surface of Mars in the 2030s;
- precursor missions in cis-lunar space and other missions or activities necessary to meet the exploration objectives developed under the human space exploration program; and
- a description of how cis-lunar elements, objectives, and activities advance the human exploration of Mars.

As part of the strategic framework, NASA shall include a critical decision plan that:

- identifies and defines key decisions to guide human space exploration priorities and plans that need to be made by June 30, 2020;
- define decisions needed to maximize efficiencies and resources for reaching the near, intermediate, and long-term goals and objectives of space exploration; and
- identifies and defines timelines and milestones for a sustainable cadence of missions beginning with EM-3 for the SLS and Orion to extend human exploration from cis-lunar space to the surface of Mars.

NASA shall submit an initial strategic framework, including a critical decision plan, by December 1, 2017, and updated frameworks biennially thereafter.

(Sec. 434) NASA shall submit a plan for achieving an advanced space suit capability that aligns with crew needs for exploration enabled by the SLS and Orion, including an evaluation of the merit of delivering the planned suit system for use on the ISS.

(Sec. 435) NASA shall evaluate:

- those alternative approaches to the Asteroid Robotic Redirect Mission that demonstrate the technologies and capabilities needed for a human mission to Mars;
- the scientific and technical benefits of those approaches; and

• the commercial benefits of those approaches, including their impact on the development of domestic solar electric propulsion technology to bolster U.S. competitiveness in the global marketplace.

Subtitle D--Scott Kelly Human Spaceflight and Exploration Act

Scott Kelly Human Spaceflight and Exploration Act

(Sec. 443) NASA may provide for medical monitoring, diagnosis, and treatment of current and former U.S. government astronauts and former payload specialists for conditions associated with human space flight.

NASA may not:

- provide for medical monitoring, diagnosis, or treatment of such astronauts and payload specialists for any psychological or medical condition not associated with human space flight; or
- require a former U.S. government astronaut or payload specialist to participate in the medical monitoring authorized by this section.

The Administrator of NASA shall protect the privacy of all medical records generated with respect to such medical monitoring, diagnosis, and treatment and accessible to NASA. TITLE V--ADVANCING SPACE SCIENCE

(Sec. 502) In accordance with the priorities established in the most recent decadal survey for planetary science, NASA shall ensure the completion of a balanced set of Discovery, New Frontiers, and flagship missions.

Consistent with such set of missions and while maintaining the continuity of scientific data and steady development of capabilities and technologies, NASA may seek, if necessary, adjustments to mission priorities, schedule, and scope as a result of changing budget projections.

(Sec. 503) NASA should continue robust surveillance of the performance of the James Webb Space Telescope project and continue to improve the reliability of cost estimates and contractor performance data and other major spaceflight projects so as to enhance its ability to deliver such telescope on-time and within budget.

(Sec. 504) NASA should make progress on the technologies and capabilities needed to position it to meet the objectives concerning the Wide-Field Infrared Survey Telescope (WFIRST), as outlined in the 2010 National Academies' Astronomy and Astrophysics Decadal Survey, in a way that maximizes the scientific productivity of meeting those objectives for the resources invested.

(Sec. 505) The bill expresses the sense of Congress that the Mars 2020 mission, to develop a Mars rover and to enable the return of samples to Earth, should remain a priority for NASA. Such mission should also:

- significantly increase our understanding of Mars,
- help determine whether life previously existed on that planet, and
- provide opportunities for gathering knowledge and demonstrating technologies that address the challenges of future human expeditions to Mars.

(Sec. 506) The bill expresses the sense of Congress that a scientific, robotic exploration mission to Europa (a moon orbiting Jupiter), as prioritized in the previous and current Planetary Science Decadal Surveys, should be supported.

TITLE VI--MAXIMIZING EFFICIENCY

Subtitle A--Agency Information Technology and Cybersecurity

(Sec. 611) NASA shall take specified actions governing its information technology operations and investments, including those that:

- ensure the NASA Chief Information Officer has a significant role in the management, governance, and oversight processes related to information technology operations and investments and information security programs for the protection of NASA systems;
- arrange for the NASA Chief Information Officer to directly report to the NASA Administrator;
- provide an information technology program management framework;
- establish a monetary threshold for all agency information technology investments and related contracts; and
- improve the operational linkage between the NASA Chief Information Officer and each NASA mission directorate, center, and mission support office.

(Sec. 612) NASA shall develop a specified information technology strategic plan to guide NASA information technology management and strategic objectives. The plan shall include:

- near and long-term goals and objectives for leveraging information technology,
- a plan on how NASA will submit a list of information technology projects to Congress,
- an implementation overview for an agency-wide centralized approach to information technology investments and operations,
- a plan to increase the efficiency and effectiveness of information technology investments,
- a plan for improving the information security of NASA information and NASA information systems, and
- submission by NASA to Congress of information regarding high risk projects and cybersecurity risks.

NASA shall submit such plan and any plan updates to Congress.

(Sec. 613) NASA shall implement a specified agency-wide information security plan to enhance information security for NASA information and information infrastructure.

The Chief Information Officer shall submit the plan to the NASA Administrator for approval prior to its implementation.

The plan shall include:

- an overview of the requirements for the information security system;
- an agency-wide risk management framework for information security;
- an identification and assignment of the roles, responsibilities, and management commitment for information security at NASA; and
- heightened consideration of the need to protect the information security of missioncritical systems and activities and high-impact and moderate-impact information systems.

NASA shall include in biennial reports on the implementation of its information security system an update on its efforts to apply additional information security protections to secure high-impact and moderate-impact information systems and mission-critical systems and activities, including those systems that control spacecraft and maintain critical data sources.

(Sec. 614) Until the information security plan is developed and implemented agency-wide, NASA shall update Congress on the progress it is making toward implementation of or response to:

- such plan; and
- the information security-related recommendations made by the NASA Inspector General and the Government Accountability Office in the five years preceding the enactment of this bill.

(Sec. 615) NASA shall:

• develop a strategic plan for transitioning NASA from legacy software;

- implement an agency-wide software license management policy to improve centralization, lifecycle management, and procurement education; and
- direct an agency-wide inventory of NASA's total software licenses and spending.

(Sec. 616) NASA shall notify Congress when it has implemented the information security recommendations from the National Academy of Public Administration on foreign national access management, based on reports from January 2014 and March 2016. (Sec. 617) NASA shall:

- develop a plan to fully remediate security vulnerabilities in NASA web applications, and
- implement the recommendations from the NASA Inspector General in a specified audit report to remove from the Internet or secure with a web application firewall all of NASA's web applications in development or testing mode.

Subtitle B--Collaboration Among Mission Directorates and Other Matters (Sec. 621) NASA shall encourage an interdisciplinary approach among all NASA mission directorates and divisions for projects or missions to:

- improve coordination, and encourage collaboration and early planning on scope;
- determine areas of overlap or alignment;
- leverage across divisional perspectives to maximize outcomes; and
- be more efficient with resources and funds.

(Sec. 622) NASA shall pursue a strategy for acquiring crewed transportation services and noncrewed launch services that continues to enhance communication, collaboration, and coordination between the Launch Services and Commercial Crew programs.

(Sec. 623) NASA may enter into agreements with covered entities to provide them with space transportation infrastructure support and services, including to:

- maximize use of such infrastructure by the private sector, and
- encourage commercial space activities.

Also, at such an entity's request, NASA may include in such an agreement that support and services in the contracted space launch and reentry range support requirements of NASA if:

- NASA determines that including that support and services in those requirements is in the best interest of the federal government, does not interfere with NASA requirements, does not compete with commercial space activities of other covered entities, and does not result in NASA retaining ownership of assets which are no longer needed to meet a programmatic mission of NASA; and
- any commercial requirement included in the agreement has full nonfederal funding before the implementation of the agreement.

NASA may enter into an agreement with a covered entity on a cooperative and voluntary basis to accept funds, services, and equipment to carry out the purposes of this section.

Any funds, services, or equipment accepted by NASA under this section:

- may be used only for the objectives specified in this section according to the terms of use set forth in the agreement, and
- shall be managed by NASA.

An agreement entered into with a covered entity under this section shall:

- address the terms of use, ownership, and disposition of the funds, services, or equipment contributed under the agreement;
- include a provision that the covered entity will not recover the costs of its contribution through any other agreement with the United States; and
- include a provision that the contribution of the covered entity will not preclude access to or use by another covered entity.

NASA shall submit annual reports to Congress on the process used to establish such agreements.

The bill defines "covered entity" as a nonfederal entity that:

- is organized under U.S. law or of any jurisdiction within the United States and is engaged in commercial space activities; or
- an entity that controls, is controlled by, or is under common control with, such a nonfederal entity.

(Sec. 624) The bill expresses the sense of Congress that the presence of counterfeit electronic parts in NASA's supply chain poses a danger to astronauts, crew, and other NASA personnel and a risk to NASA overall.

NASA shall revise specified regulations so as to improve the detection and avoidance of counterfeit electronic parts in its supply chain.

(Sec. 625) NASA shall continue engagement with the public and educational opportunities for students using all NASA mission directorates.

NASA shall report on its near-term outreach plans for advancing space law education.

(Sec. 626) NASA shall identify orbital assets in specified mission directorates that could benefit from satellite servicing-related technologies and shall work across all NASA mission directorates to evaluate opportunities for the private sector to perform these services or advance technical capabilities by leveraging the technologies and techniques developed by NASA programs and other industry programs.

(Sec. 627) In order to conduct necessary research, NASA shall continue, and as appropriate, consider expanding the development of technology payloads for scientific research and the investigation of new or improved capabilities.

To carry out such purpose, NASA shall make funds available for flight testing, payload development, and hardware related to such research and investigation.

Congress reaffirms that NASA should provide flight opportunities for payloads to microgravity environments and suborbital altitudes.

(Sec. 628) The bill expresses the sense of Congress on specified small class launch missions.

Discussed the bill. Discussed issues related to this bill.

# Status: 12/12/2016 Held at the desk.

# S. 2689 REGROW Act

This bill amends the Public Health Service Act to require the Food and Drug Administration (FDA) to conditionally approve certain cellular therapeutic products without initiation of largescale clinical trials. A conditionally approved cellular therapy may be marketed if certain conditions are met, including conditions on the source, processing, and function of the cells in the product.

The sponsor of a conditionally approved cellular therapy must apply for approval of the product as a biological product within five years. Unless the FDA has decided not to approve the product, the product may be marketed during this five-year period and the FDA may permit continued marketing while the application is being reviewed.

An individual administering a conditionally approved cellular therapy must inform the recipient regarding conditional approval.

The premarket report for a medical device used for cellular therapy must include specified information regarding the preparation or delivery of the cellular therapy.

The approval of a medical device that is a cellular therapy must be based on laboratory performance testing and not clinical trials.

(Kirk)

A medical device used for cellular therapy is subject to medical device classification. The FDA must not limit the use of these devices to only specific cell types unless unique to the use of the device.

The Center for Biologics Evaluation and Research has primary jurisdiction for premarket review of combination products that act primarily through cellular components.

The Department of Health and Human Services must work with stakeholders to promote the development of standards for regenerative medicine products.

Expressed concerns with regenerative medicine legislation.

# Status: 03/16/2016 Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

# <u>H.R. 4762</u> REGROW Act

(Coffman)

(Alexander)

Reliable and Effective Growth for Regenerative Health Options that Improve Wellness or the REGROW Act

This bill amends the Public Health Service Act to require the Food and Drug Administration (FDA) to conditionally approve certain cellular therapeutic products without initiation of largescale clinical trials. A conditionally approved cellular therapy may be marketed if certain conditions are met, including conditions on the source, processing, and function of the cells in the product.

The sponsor of a conditionally approved cellular therapy must apply for approval of the product as a biological product within five years. Unless the FDA has decided not to approve the product, the product may be marketed during this five-year period and the FDA may permit continued marketing while the application is being reviewed.

An individual administering a conditionally approved cellular therapy must inform the recipient regarding conditional approval.

The premarket report for a medical device used for cellular therapy must include specified information regarding the preparation or delivery of the cellular therapy.

The approval of a medical device that is a cellular therapy must be based on laboratory performance testing and not clinical trials.

A medical device used for cellular therapy is subject to medical device classification. The FDA must not limit the use of these devices to only specific cell types unless unique to the use of the device.

The Center for Biologics Evaluation and Research has primary jurisdiction for premarket review of combination products that act primarily through cellular components.

The Department of Health and Human Services must work with stakeholders to promote the development of standards for regenerative medicine products.

Expressed concerns with regenerative medicine legislation.

# Status: 03/18/2016 Referred to the Subcommittee on Health.

# **S.2713** Advancing Precision Medicine Act of 2016

(Sec. 2) This bill encourages the Department of Health and Human Services (HHS) to carry out a Precision Medicine Initiative to address disease prevention, diagnosis, and treatment. The initiative may include collection of health information from a diverse cohort of individuals. HHS may carry out specified activities relating to the initiative, including coordinating with the Department of Energy to address supercomputing needs.

In implementing the initiative, HHS must: (1) collaborate with the National Institutes of Health (NIH), the Food and Drug Administration, and the Office of the National Coordinator for Health

Information Technology; (2) implement secure data sharing; and (3) ensure inclusion of a broad range of participants, considering factors that contribute to health disparities.

(Sec. 3) This bill amends the Public Health Service Act to revise provisions regarding disclosure by researchers of the identifiable, sensitive information of research subjects. HHS must prohibit researchers from disclosing such information from federally funded research to persons not connected to the research. Researchers may apply to have other research covered by this prohibition.

Disclosures of such information are permitted if required by law, necessary for the medical treatment of the research subject, made with the consent of the subject, or made for the purposes of other research that is in compliance with regulations regarding protection of subjects. (Sec. 4) HHS may exempt identifiable information collected for biomedical research from disclosure under the Freedom of Information Act.

(Sec. 5) The NIH may require recipients of grants or cooperative agreements to share scientific data.

(Sec. 6) The NIH may approve requests by national research institutes to fund high-impact, cutting-edge research through transactions other than contracts, grants, or cooperative agreements. National research institutes must conduct and support high-risk, high-reward research.

Expressed support for this bill.

Status: 04/18/2016 Placed on Senate Legislative Calendar under General Orders. Calendar No. 428.

# S.2742Promoting Biomedical Research and Public(Alexander)Health for Patients Act

(Sec. 2) This bill amends the Public Health Service Act to revise reporting requirements for the National Institutes of Health (NIH) and certain national research institutes.

(Sec. 3) The Department of Health and Human Services (HHS) must revise policies related to the disclosure of financial conflicts of interest to reduce the administrative burden on researchers while maintaining the integrity and credibility of research findings.

The NIH must reduce administrative burdens related to monitoring subrecipients of grants. HHS must revise expenditure reporting policies to avoid duplication and minimize burden for recipients of NIH funding.

The NIH, in collaboration with the Department of Agriculture and the Food and Drug Administration (FDA), must revise policies regarding laboratory animals to reduce administrative burdens while maintaining the integrity and credibility of research findings and protection of research animals.

HHS must clarify the applicability of regulations regarding documentation of personnel expenses by grant recipients.

The Office of Management and Budget must establish the Research Policy Board to make recommendations to minimize the administrative burden of federal research policies while maintaining responsible oversight. The board is terminated at the end of FY2020.

(Sec. 4) Contractors making substances and living organisms available for research on behalf of HHS may collect payments on behalf of HHS for incurred costs.

(Sec. 6) HHS must revise the Vaccine Injury Table to include information on vaccines recommended by the Centers for Disease Control and Prevention for pregnant women. A mother and child are individually considered for compensation for a vaccine injury from a vaccine administered during pregnancy.

(Sec. 7) HHS must report on ways to promote innovation in the development of vaccines.

(Sec. 8) The bill revises provisions regarding the clinical trial registry data bank to permit earlier publication of certain data and to categorize clinical trials for combination products.

(Sec. 9) The NIH and the FDA must report on information in the clinical trial registry data bank, activities undertaken to encourage compliance with data bank requirements, and actions to enforce compliance.

(Sec. 10) The Director of NIH is given the authority to appoint the directors of the national research institutes. The term of office of these directors is set to five years, with no limit on the number of reappointments.

(Sec. 11) The National Center for Advancing Translational Sciences may support additional phases of clinical trials.

Expressed support for this bill.

Status: 04/18/2016 Placed on Senate Legislative Calendar under General Orders. Calendar No. 429.

# GFFICE OF GOVERNMENT RELATIONS Key Health Care Federal Legislation 114th Congress, 2nd Session

#### <u>S. 2873</u> ECHO Act

Public Law No: 114-270 (12/14/2016)

(This measure has not been amended since it was passed by the Senate on November 29, 2016. The summary of that version is repeated here.)

Expanding Capacity for Health Outcomes Act or the ECHO Act

(Sec. 3) This bill requires the Department of Health and Human Services (HHS) to report on technology-enabled collaborative learning and capacity building models, which connect specialists to primary care providers through videoconferencing to facilitate case-based learning, dissemination of best practices, and evaluation of outcomes.

The report must include: (1) an analysis of the use, integration, and impact of such models; (2) a list of such models recently funded by HHS; (3) recommendations to reduce barriers to adoption of such models; (4) opportunities for adoption of such models into HHS programs; and (5) recommendations regarding the role of such models in continuing medical education.

Advocated in favor of this bill.

# Status: 12/14/2016 Became Public Law No: 114-270.

# S.3483 Midnight Rules Relief Act of 2016

This bill amends the Congressional Review Act to allow Congress to consider a joint resolution to disapprove multiple regulations that federal agencies have submitted for congressional review within the last 60 legislative days of a session of Congress during the final year of a President's term. Congress may disapprove a group of such regulations together (i.e., "en bloc") instead of the current procedure of considering only one regulation at a time.

Expressed support for the delay of the "Two-Midnight" rule at the Center for Medicare & Medicaid Services

# Status: 11/29/2016 Read twice and referred to the Committee on Homeland Security and Governmental Affairs.

# H.R. 5982 Midnight Rules Relief Act of 2016

(Sec. 2) This bill amends the Congressional Review Act to allow Congress to consider a joint resolution to disapprove multiple regulations that federal agencies have submitted for congressional review within the last 60 legislative days of a session of Congress during the final year of a President's term. Congress may disapprove a group of such regulations together (i.e., "en bloc") instead of the current procedure of considering only one regulation at a time. Expressed support for the delay of the "Two-Midnight" rule at the Center for Medicare & Medicaid Services

# Status: 11/28/2016 Received in the Senate and Read twice and referred to the Committee on Homeland Security and Governmental Affairs.

(N/A)

(Johnson)

(Issa)

# H.R. 5273 Helping Hospitals Improve Patient Care Act of 2016

TITLE I--PROVISIONS RELATING TO MEDICARE PART A

(Sec. 101) The bill amends title XVIII (Medicare) of the Social Security Act to require the Centers for Medicare & Medicaid Services (CMS) to develop, with respect to claims for hospital services, codes under the Healthcare Common Procedure Coding System (HCPCS) for similar inpatient and outpatient hospital services.

(Sec. 102) The bill establishes processes for adjusting a hospital's Medicare payments based on the hospital's overall proportion of inpatients who are dually eligible for Medicare and Medicaid. (Sec. 103) The bill extends for five years the Rural Community Hospital Demonstration Program, through which Medicare pays certain rural hospitals on the basis of reasonable incurred

Program, through which Medicare pays certain rural hospitals on the basis of reasonable incurred costs rather than under the standard prospective payment system.

(Sec. 104) With respect to long-term care hospitals, the bill lifts a moratorium on bed increases. The bill reduces rates for high-cost outlier payments, which are additional Medicare payments made in extraordinarily high-cost cases.

(Sec. 105) The bill reduces the amount by which hospital payment rates for inpatient services increase in FY2018.

# TITLE II--PROVISIONS RELATING TO MEDICARE PART B

(Sec. 201) The bill excludes certain off-campus outpatient departments (OPDs) from specified rules that mandate lower Medicare payments. Specifically, the exclusion applies to: (1) cancer hospitals in off-campus OPDs, and (2) mid-build OPDs. A "mid-build" OPD is one for which the provider had, before a certain date, a binding written agreement with an outside party for construction.

(Sec. 203) With respect to payment reductions for failing to meet requirements for the meaningful use of electronic health records (EHRs), the bill exempts eligible professionals who are based in ambulatory surgical centers.

TITLE III--OTHER MEDICARE PROVISIONS

(Sec. 301) Until plan year 2019, CMS may not terminate an MA plan solely because the plan failed to achieve a specified minimum quality rating.

(Sec. 302) CMS must annually report on Medicare enrollment data, as specified by the bill. (Sec. 303) CMS shall: (1) request information and recommendations from stakeholders on information included in the Welcome to Medicare package, and (2) update the information included in the package accordingly.

Expressed support for this bill.

Status: 06/08/2016 Received in the Senate and Read twice and referred to the Committee on Finance.

# GIVERNMENT RELATIONS Key Education Federal Legislation 114th Congress, 2nd Session

#### H.R. 3238 Cuba Trade Act of 2015

(Emmer)

This bill repeals or amends current laws restricting trade with Cuba. The prohibition on assistance to Cuba, and the President's authority for the embargo on Cuba, under the Foreign Assistance Act of 1961 are eliminated.

The Cuban Democracy Act of 1992 is amended to eliminate:

- presidential authority to impose sanctions against Cuban trading partners,
- restrictions on transactions between U.S.-owned or controlled firms and Cuba,
- limitations on direct shipping between Cuban and U.S. ports, and
- restrictions on remittances.

# The Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996 is amended to eliminate:

- the enforcement of an economic embargo of Cuban provisions, and
- the prohibition on indirect financing of Cuba.

The Trade Sanctions Reform and Export Enhancement Act of 2000 is amended to:

- remove Cuba from the list of state sponsors of terrorism subject to agricultural and medical export restrictions;
- eliminate the prohibition on U.S. assistance, including foreign assistance, export assistance, and any credit or guarantees being made available for exports to Cuba;
- eliminate the prohibition against a U.S. person's providing payment or financing terms for sales of agricultural commodities or products to Cuba;
- prohibit the United States from providing any foreign assistance to Cuba or any financial assistance, loans, loan guarantees, extension of credit, or other financing for exports to Cuba; and
- eliminate the prohibition on the U.S. entry of merchandise that is of Cuban origin, is or has been located in or transported from or through Cuba, or is made or derived in whole or in part of any article which is the growth, produce, or manufacture of Cuba.

The federal government may not obligate or expend any funds to promote trade with or develop markets in Cuba, except through certain commodity promotion programs.

#### Expressed support of this bill.

#### Status: 08/05/2015 Referred to the Subcommittee on Trade.

#### **<u>S.1543</u>** Cuba Trade Act of 2015

#### (Moran)

This bill repeals or amends current laws restricting trade with Cuba.

The prohibition on assistance to Cuba, and the President's authority for the embargo on Cuba, under the Foreign Assistance Act of 1961 are eliminated.

The Cuban Democracy Act of 1992 is amended to eliminate:

- presidential authority to impose sanctions against Cuban trading partners,
- restrictions on transactions between U.S.-owned or controlled firms and Cuba,
- limitations on direct shipping between Cuban and U.S. ports, and
- restrictions on remittances.

The Cuban Liberty and Democratic Solidarity (LIBERTAD) Act of 1996 is amended to eliminate:

• the enforcement of an economic embargo of Cuban provisions, and

• the prohibition on indirect financing of Cuba.

The Trade Sanctions Reform and Export Enhancement Act of 2000 is amended to:

- remove Cuba from the list of state sponsors of terrorism subject to agricultural and medical export restrictions;
- eliminate the prohibition on U.S. assistance, including foreign assistance, export assistance, and any credit or guarantees being made available for exports to Cuba;
- eliminate the prohibition against a U.S. person's providing payment or financing terms for sales of agricultural commodities or products to Cuba;
- prohibit the United States from providing any foreign assistance to Cuba or any financial assistance, loans, loan guarantees, extension of credit, or other financing for exports to Cuba; and
- eliminate the prohibition on the U.S. entry of merchandise that is of Cuban origin is or has been located in or transported from or through Cuba, or is made or derived in whole or in part of any article which is the growth, produce, or manufacture of Cuba.

The federal government may not obligate or expend any funds to promote trade with or develop markets in Cuba, except for certain commodity promotion programs.

# Expressed support of this bill.

# Status: 06/10/2015 Read twice and referred to the Committee on Banking, Housing, and Urban Affairs.

#### S.299 Freedom to Travel to Cuba Act of 2015

(Flake)

This bill states that:

- the President may not prohibit or otherwise regulate travel to or from Cuba by U.S. citizens or legal residents, or any of the transactions incident to such travel, including banking transactions;
- any regulation in effect on the date of enactment of this Act prohibiting or otherwise regulating such travel or transactions incident to such travel shall cease to have any force or effective; but
- the prohibitions and requirements of this Act shall not apply if the United States is at war with Cuba, armed hostilities between the two countries are in progress, or there is imminent danger to the public health or the physical safety of U.S. travelers.

Expressed support for this bill.

# Status: 01/29/2015 Read twice and referred to the Committee on Foreign Relations

#### <u>H.R. 664</u>

# Freedom to Travel to Cuba Act of 2015

#### (Sanford)

This bill states that:

- the President may not prohibit or otherwise regulate travel to or from Cuba by U.S. citizens or legal residents, or any of the transactions incident to such travel, including banking transactions;
- any regulation in effect on the date of enactment of this Act prohibiting or otherwise regulating such travel or transactions incident to such travel shall cease to have any force or effective; but
- the prohibitions and requirements of this Act shall not apply if the United States is at war with Cuba, armed hostilities between the two countries are in progress, or there is imminent danger to the public health or the physical safety of U.S. travelers.

Expressed support for this bill.

#### Status 03/20/2015 Referred to the Subcommittee on the Western Hemisphere.

#### <u>S.2506</u>

### **CREATE Graduates Act**

Introduced in Senate (06/19/2014)

Correctly Recognizing Educational Achievements To Empower Graduates Act or the CREATE Graduates Act - Amends the Higher Education Act of 1965 to direct the Secretary of Education to award competitive grants to states and, through them, subgrants to institutions of higher education (IHEs) or systems of higher education to:

- identify current or former students who have earned at least 60 postsecondary credit hours (or the state-required minimum for earning an associate's degree) at the IHE or at an IHE within the system but have not been issued a postsecondary degree by such IHE or an associate's or bachelor's degree elsewhere;
- perform a degree audit on each of those students to identify those who are eligible to obtain an associate's degree and those who are eligible to obtain such a degree upon the completion of 12 or fewer postsecondary credit hours (or the equivalent);
- provide outreach and award an associate's degree to each of those students identified as eligible to obtain an associate's degree unless the student declines the degree; and
- provide outreach to those students identified as eligible to obtain such a degree upon the completion of 12 or fewer postsecondary credit hours, including guidance on the steps they can take to attain such a degree.
- Allows states to use up to: (1) 15% of their grant for administrative purposes, including the purchase of the technology to carry out grant requirements; and (2) 5% of their grant to create articulation agreements between 2-year and 4-year IHEs to facilitate the transfer of students between such schools.

#### Provided feedback on this bill.

# Status: 06/19/2014 Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

# (Hagan)

# Given States of GOVERNMENT RELATIONS Key Immigration Federal Legislation 114th Congress, 2nd Session

### S.3542 BRIDGE Act

#### (Graham)

Bar Removal of Individuals who Dream and Grow our Economy Act or the BRIDGE Act This bill amends the Immigration and Nationality Act to provide that the Department of Homeland Security (DHS): (1) shall grant a three-year provisional protected presence to a qualifying alien, (2) may not remove the alien from the United States unless such protected presence is rescinded, and (3) shall provide such alien with employment authorization. An alien is eligible for such protected presence and employment authorization if the alien: (1) was born after June 15, 1981; (2) entered the United States before attaining 16 years of age; (3) continuously resided in the United States since June 15, 2007; (4) was physically but unlawfully present in the United States on June 15; (5) on the date the alien files an application the alien is present in the United States, is enrolled in school or in an education program assisting students in obtaining a high school diploma, has graduated or obtained a certificate of completion from high school or a general educational development certificate, or is an honorably discharged U.S. Coast Guard or Armed Forces veteran; (6) has not been convicted of a felony, a significant misdemeanor, or three or more misdemeanors not occurring on the same date and not arising out of the same act; and (7) does not otherwise pose a threat to national security or a threat to public safety.

The bill: (1) provides for confidentiality of application information, with certain national security and law enforcement exceptions; and (2) sets forth the criteria under which DHS may rescind such protected presence.

An alien granted protected presence is not considered to be unlawfully present in the United States during such period.

An alien must be at least 15 years old, unless in removal proceedings, to apply for protected presence.

DHS may provide for an application fee and for fee exemptions.

DHS may not: (1) remove an alien who appears prima facie eligible for protected presence while the alien's application is pending, or (2) refer individuals whose cases have been deferred pursuant to the Deferred Action for Childhood Arrivals Program (DACA) or who have been granted protected presence to U.S. Immigration and Customs Enforcement.

A DACA alien is deemed to have protected presence through the expiration date of his or her deferred action status.

Discussed support for this bill.

Status: 12/09/2016 Read twice and referred to the Committee on the Judiciary. (Sponsor introductory remarks on measure: CR S7034)

Given State and Federal Meetings, Events and Tours

As a service to the University of Colorado, the Office of Government Relations coordinates and staffs many state and federal meetings, events and tours on the Hill in Washington, DC, at the Colorado State Capitol, and on each of the university's four campuses. Highlighted below are a few of the many activities we participated in during the year.

## **State Relations**

The State Relations team met with many university groups to give legislative updates during the state session and during the interim. The activities for these meetings included securing state elected and appointed officials and legislators to speak with the groups; providing tours of the State Capitol; and talking with them about advocacy on behalf of the university and higher education; and providing legislative updates at their meetings on campus.

• The groups who came to the capitol included, but were not limited to: UCCS Senior Vice Chancellor for University Advancement, Martin Wood presented to the Legislature's Aerospace and Defense Caucus about Cybersecurity; UCHealth Advanced Care Close to Home Day; Aerospace Day at the Capitol; Staff Council from all four campuses and system; Excellence in Leadership Program.

Highlighted below are some of the meetings and events we helped facilitate or where we staffed legislators:

- On January 19th, the CU Advocates program partnered with the CU Denver Business School to showcase its industry-relevant program partnerships with businesses such as Encana, J.P. Morgan and Pinnacol Assurance. Special guests included CU Denver Chancellor Dorothy Horrell, industry representatives and Colorado legislators. Over 9 legislators were in attendance including, Senators John Cooke (R-Greeley), Jack Tate (R-Centennial), Randy Baumgardner (R-Cowdry), Bill Cadman (R-Colorado Springs), Representatives Susan Lontine (D-Littleton), Kevin Priola (R-Henderson), Paul Rosenthal (D-Denver), Angela Williams (D-Denver), and Dan Thurlow (R-Grand Junction), among others.
- UCCS Senior Vice Chancellor for University Advancement, Martin Wood presented to the Legislature's Aerospace and Defense Caucus about Cybersecurity on February 26th.
- March 21, 2016 Aerospace Day at the Capitol.
- March 29, 2016 CU-Boulder Aerospace Summit with Senator Baumgardner (R-Cowdrey), Representatives Brown (R-Ignacio), Rankin (R-Carbondale), Klingenschmitt (R-Colorado Springs), Willett (R-Grand Junction), and Thurlow (R-Grand Junction).
- April 8, 2016 "It's On Us" Event with Vice President Joe Biden at CU-Boulder. Lt Governor Joe Garcia attended.
- April 13, 2016 UCHealth Advanced Care Close to Home Day, featuring the Pink Life Saver Mobile Mammography Van and the Mobile Stroke Treatment Unit. This event was sponsored by Senator Mary Hodge (D-Brighton), and Representatives Kevin Priola (R-Henderson) and Dianne Primavera (D-Broomfield).
- University of Colorado Denver Chancellor Dorothy Horrell presented State Senator Lucia Guzman (D-Denver) with the 2016 CU Denver Alumni Legislative Award at CU Denver's May 14th graduation ceremony.
- Governor John Hickenlooper signed HB 16-1456: Sale of State Land for Fort Logan National Cemetery and HB 16-1277: Appeal Process Changes to Medicaid Benefits on

June 1st at Sheridan Health Services. State Representative Susan Lontine (D-Denver) was in attendance.

- On June 2<sup>nd</sup>, outgoing Representative Janak Joshi (R-Colorado Springs) hosted a town hall meeting at the University of Colorado, Colorado Springs to discuss Cyber Security. Retired General Ed Anderson, UCCS Executive Director of Strategic Military, Science, Space and Security Initiatives presented on the National Cyber Intelligence Center. Senators Kent Lambert (R-Colorado Springs), and Owen Hill (R-Colorado Springs), and Representative Dan Nordberg (R-Colorado Springs) were in attendance.
- On August 24th, Dr. Huntington Potter and his staff hosted a tour of the Rocky Mountain Alzheimer's Disease Center at the University of Colorado Anschutz Medical Campus. The event highlighted Dr. Potter's important new research to find a cure for Alzheimer's Disease. Staff members from Senators Michael Bennet, and Cory Gardner, Congressmen Jared Polis, Ken Buck, Doug Lamborn and Ed Perlmutter were in attendance. State Representatives Janet Buckner (D-Aurora), JoAnn Ginal (D-Fort Collins), Dianne Primavera (D-Broomfield), Kim Ransom (R-Littleton), Joann Windholz (R-Commerce City), and Senator Nancy Todd (D-Aurora) were in attendance. Several candidates for state seats were also in attendance including, Jeff Bridges (D-HD 3), James Coleman (D-HD 7), Philip Covarrubias (R-HD 56), Leslie Herod (D-HD 8), Dominique Jackson (D-HD 42), and Kevin Priola (R-SD 25).
- CU Advocates hosted "CU Celebration" events this July in Grand Junction and Pueblo to welcome new and incoming students from the Western Slope and southern Colorado who plan to attend a CU campus. To help welcome the new students and their families to the CU family, State Representative Yeulin Willett's (R-Grand Junction) wife Rose, a CU Boulder alumna, attended the Grand Junction event. Rep. Willett is also a CU Boulder alumnus. State Representative Daneya Esgar (D-Pueblo) and state Senator Leroy Garcia (D-Pueblo) attended the Pueblo event.
- At the September 10<sup>th</sup> CU football game, State Senator Jack Tate (R-Centennial) and State Representative Alec Garnett (D-Denver) were honored as 2016 Legislators of the Year for sponsoring a CU initiated bill, Senate Bill 16-121, which allows CU to realize tens of millions of dollars in savings when bonding for construction through better interest rates. Just this year, the change in state law saved CU over 13 million dollars and has the potential to save many millions more in future years.
- On September 12<sup>th</sup>, business leaders from the Colorado Investment Services Coalition, state legislators and stakeholders from our CU business schools, connected at the CU South Denver Campus for a reception highlighting the economic imperative of workforce talent development partnerships with higher education and industry. Representative Kevin Van Winkle (R-Highlands Ranch), Kim Ransom (R-Littleton), and SD 4 candidate Jim Smallwood were in attendance.
- On September 22<sup>nd</sup>, Colorado State University, the One Cure Initiative at the CSU Flint Animal Cancer Center and Rocky Mountain PBS presented a special pre-screening of "The Answer to Cancer May Be Walking Right Beside Us." The film highlighted the unique and critical collaboration between scientists at the University of Colorado Cancer Center and CSU Flint Animal Cancer Center. Representative Dianne Primavera (D-Broomfield) and HD8 candidate Leslie Herod were in attendance.
- Kirsten staffed a CU Boulder Unmanned Aerial Systems lunch hosted by Senator Randy Baumgardner (R-Cowdry) in Winter Park on September 23<sup>rd</sup>.
- On October 6<sup>th</sup>, the Carson J. Spencer Foundation held an event on the CU Denver campus with Dafna Michaelson Jenet, candidate for HD 30. Connie and Heather staffed.

- On November 12<sup>th</sup>, Senators-elect Dominick Moreno (D-Commerce City) and Jim Smallwood (R-Parker) served as judges at a case competition at Anschutz Medical Campus.
- On December 17th, Representative Chris Hansen (D-Denver) joined Chancellor Dorothy Horrell, President Benson, Regents and Faculty at the CU Denver commencement ceremony. Representative Cole Wist (R-Centennial) attended the Anschutz Medical Campus graduation on December 17th.
- Representative Bob Rankin (R-Carbondale), Representative Alec Garnett (D-Denver), CU Office of Government Relations VP Tanya Kelly-Bowry, and Chief of Staff to Gov. Hickenlooper Doug Friednash served as panelists at the December 2nd First Friday Breakfast sponsored by CU Denver School of Public Affairs. The panelists discussed their insights into Colorado's upcoming 2017 legislative session and answered some great audience questions. The panel was moderated by Dr. Tony Robinson.
- Legislative Delegation Luncheons were held with campus leaders and legislators serving near their respective campuses.

### 2016 CU Advocates Events

CU Advocacy Day at the Capitol was held on January 26, 2016. There were more than 100 attendees at the event including CU Advocates, alumni, donors, legislators, regents and friends. The program included remarks from Senators Jessie Ulibarri (D-Denver), Rollie Heath (D-Boulder) Representatives Jovan Melton (D-Aurora) and Joe Salazar (D-Thornton) Bob Rankin (R-Carbondale), U.S. Senator Cory Gardner, CU Vice President of Government Relations Tanya Kelly-Bowry, CU Vice President of Budget and Finance Todd Saliman, and CU President Bruce Benson, among others. Following the event at the Capitol, legislators and advocates were invited to Benson Mineral Group for a reception. Legislators in attendance included Senators Jack Tate (R-Centennial), Vicki Marble (R-Fort Collins), Matt Jones (D-Louisville), Larry Crowder (R-Alamosa), Representatives Jeni Arndt (D-Fort Collins), Terri Carver (R-Colorado Springs), Yeulin Willett (R-Grand Junction), JoAnn Windholz (R-Commerce City), Dave Young (D-Greeley), Gordon Klingenschmitt (R-Colorado Springs), Janet Buckner (D-Aurora), and Kevin Van Winkle (R-Highlands Ranch).

### **Federal Relations**

The Federal Relations team arranged, facilitated and staffed meetings with congressional members, federal agency officials, and staffers both in Washington, DC and on all four CU campuses throughout the year. We also set up and staffed Hill visits for University of Colorado leadership including Chancellors Elliman, DiStefano, and Horrell. In addition, we set up and staffed Hill visits for key campus professionals including John Reilly, CU Anschutz Medical Campus Dean of School of Medicine; Chris Koehler, Director of the Colorado Space Grant Consortium at CU Boulder; Terri Fiez, Vice Chancellor for Research at CU Boulder; Sarah Thompson, Dean of the College of Nursing; and other key faculty from all four campuses. We set up and staffed meetings and tours at the four campuses throughout the year for staff from various congressional committees and from the Colorado congressional delegation. Tanya Kelly-Bowry, Abby Benson, David Sprenger, Jack Waldorf, Kent Springfield, and Heather Bené represented CU at several of these events in DC and Colorado throughout the year. David also staffed Conservative Scholar Francis Beckwith while he was in DC.

Abby and Heather actively participated in federal relations briefings and conferences hosted by the Association of American Universities (AAU), and Kent attended the Association of American Medical Colleges (AAMC) Government Relations Representatives meetings. Heather

attended National Humanities Alliance (NHA) and Consortium of Social Science Association (COSSA) meetings. Abby and Heather attended the UCCS Women Succeeding Symposium. Abby attended the Women in Innovation summit, the Government Aerospace Affairs Forum, and the Space Symposium Reception. Dave attended a cybersecurity conference in Kansas City. Kent attended the Friends of Cancer Research Biopharma Congress conference and the Association of American Cancer Institutes (AACI) spring government relations forum.

The federal team attended and staffed several briefing on the Hill in 2016. Abby attended space weather briefings with CU Boulder faculty, and arranged and staffed the CU Aerospace in DC event, which was attended by Senator Cory Gardner, Congressman Scott Tipton, and NASA Deputy Administrator Dava Newman. Heather and Kent attended several briefings on the Hill with faculty from the CU Boulder and CU Anschutz Medical campuses, including a briefing on the National Institute of Health (NIH) funded Adolescent Brain Cognitive Development (ABCD) Study, in which CU Boulder is participating as a study site.

Abby served as the co-chair of the Science Authorization Task Force with the Association of Public and Land-grant Universities (APLU) Council of Government Affairs (CGA) and attended their winter, spring, and summer meetings. Kent served as the chair of the APLU CGA's Biomedical Authorization Task Force. Heather served as the chair of Immigration Task Force for AAU's Council of Federal Relations (CFR). Heather attended the APLU Annual Meeting in Austin, TX where the sessions revolved around the theme of "Institutional Issues" and focused on topics such as innovation and economic prosperity, project degree completion, sexual assault on campuses, and crisis communication in the community.

The federal team worked with the Colorado congressional delegation, especially Senator Cory Gardner, on S. 3084, the American Innovation and Competitiveness Act (AICA). The Senate approved the AICA by unanimous consent and the House followed suit passing the bill in pro forma session. The legislation became Public Law No. 114-329 in January 2017. The AICA is the latest iteration of the America COMPETES Act, which establishes the policies governing the National Science Foundation (NSF), the National Institute of Standards and Technology (NIST), and federal programs on innovation, manufacturing, and science, technology, engineering and math (STEM) education. Senator Gardner co-led the bipartisan reauthorization effort in the Senate over an 18 month period. The Senator worked closely with CU as he drafted the bill - including hosting roundtable discussions in Colorado and DC - as well as during negotiations with the House Science Committee, and incorporated many university recommendations in the final legislation.

Another important legislative success was the 21st Century Cures Act, originally conceived by Congresswoman Diana DeGette along with House Energy and Commerce Committee Chairman Fred Upton (MI). The two worked for years to craft a bill that would improve research and care delivery – taking input from thousands of outside groups and advocates. Congresswoman DeGette worked closely with faculty members and leadership at CU Anschutz Medical Campus and CU Boulder to ensure that our ideas were considered in the process. The final legislation will provide an additional \$4.8 billion in new funding for the National Institutes of Health (NIH) over the next ten years outside of the traditional appropriations process. Those NIH funds include \$1.8 billion for cancer research and \$1.56 billion for mapping the human brain through the NIH Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. Additionally, the bill includes \$1 billion to help states fight the opioid abuse epidemic over the next two years. The final 21st Century Cures legislation includes a number of other important provisions meant to bring reform and innovation to research and clinical care delivery. These include efforts to harmonize regulations governing research in order to reduce the amount of "red tape" faced by researchers, reform the federal approach to mental healthcare, and a streamlining of the Food and Drug Administration (FDA) oversight of drugs and medical devices. Other members of the Colorado congressional delegation collaborated to add their input to 21<sup>st</sup> Century Cures – many of which were included in the final bill. Senator Michael Bennet worked with his Senate colleagues to add provisions improving electronic health records, developing a pathway for "breakthrough" medical devices at the FDA, incentivizing drugs to combat antibiotic-resistant bacteria, and adding patient focus into drug development. Congressman Mike Coffman worked hard to see provisions included in the bill that would provide incentives to get regenerative medicine therapies to market faster. Still other members – including Senator Cory Gardner, Congressman Scott Tipton, Congressman Doug Lamborn, Congressman Jared Polis, and Congressman Ed Perlmutter supported the legislation in its final form. Kent was an important part of the collaboration with the delegation and the University of Colorado.

Highlighted below are just a few of the many events our office helped to arrange and/or participated in in 2016:

- Abby arranged for a Polis staffer to be a guest speaker at a "Climate Controversies" class
- Kent staffed College of Nursing Dean Sarah Thompson
- Abby and Heather helped arrange and staffed the CU Aerospace in DC Event. CU Boulder Chancellor DiStefano, Senator Cory Gardner, Congressman Scott Tipton, Vice Chancellor for Research Terri Fiez, and NASA Deputy Administrator Dava Newman attended and gave remarks.
- Abby helped arrange and staff U.S. Senator Cory Gardner when he spoke at a "Headliner Breakfast" for The Science Coalition, a non-profit, nonpartisan group of the nations leading research universities, including CU Boulder. Senator Gardner described his interest in science policy and updated the group on his efforts to reauthorize the America COMPETES Act
- Dan Baker, Professor and Director of CU Boulder's Laboratory for Atmospheric and Space Physics (LASP) moderated a panel discussion entitled "Space Weather: What Is It, What Can We Do About It, and Why Should You Care?" on Capitol Hill. Abby and Heather organized and staffed the event.
- CU Boulder Professor Noah Finkelstein presented at the Coalition for National Science Funding's (CNSF) 22nd annual reception in Washington, DC. The theme was "Investments in STEM Research and Education: Fueling American Innovation." Finkelstein presented on a shared CU Boulder/APLU/UMass National Science Foundation (NSF) award to support a first-of-its-kind national network of STEM education centers. He was joined by project co-director Kacy Redd from APLU and met with NSF Director France Córdova and Assistant Director Joan Ferrini-Mundy of NSF's Education and Human Resources Directorate. He also had separate meetings with the Colorado congressional delegation. Heather staffed the meetings and event.
- Congressman Jared Polis visited CU Boulder for two roundtables with university administrators and CU Student Government. During the first roundtable, which included officials from CU Boulder, Colorado State University, and Front Range Community College, Congressman Polis gave a brief update on congressional efforts to reauthorize the Higher Education Act (HEA).

- David staffed U.S. Senator Cory Gardner and Regent Kyle Hybl for a roundtable discussion on multiple cybersecurity efforts in the Colorado Springs community, held at UCCS. These efforts include creating the new National Cyber Intelligence Center (NCIC) and UCCS' Cyber Private Public Partnership (Cyber P3) consortium, a partnership with the US Army Reserve and 7 other universities to provide cyber education and training. UCCS is the designated lead university for the P3i consortium and is a key founding member of the NCIC. While these are two separate cybersecurity efforts, UCCS is privileged to play a leadership role in working with the State of Colorado, the federal government and the local community to support intensive cyber education, training and research priorities. Those in attendance included UCCS Vice Chancellor Martin Wood, and NCIC Interim Director Gen. Ed Anderson (Ret).
- Kent helped arrange a roundtable with U.S. Senator Michael Bennet and Robert Califf, MD, Commissioner of the Food and Drug Administration (FDA) at the CU Anschutz Medical Campus that included CU faculty members as well as Colorado BioScience Association members. Senator Bennet and Commissioner Califf also toured the Barbara Davis Center and joined a roundtable discussion to discuss treatment options such as FDA-approved artificial pancreas (AP) system.
- Jack staffed Congresswoman Diana DeGette, Congressman Jared Polis, and Congressman Eric Swalwell (CA) at a conversation centered on college affordability and entrepreneurship among millennials. The discussion, which took place at CU Denver's School of Public Affairs and the Jake Jabs Center for Entrepreneurship (part of the CU Denver Business School), included both faculty and students on their experiences, and highlighted the work taking place in congress to address college affordability and promote entrepreneurship among younger Americans.
- Vice President Joe Biden spoke to a crowd of over 1,500 during his CU Boulder visit as part of the "It's On Us Week of Action." During his speech, Biden spoke about the importance of involving all members of the campus community in curbing sexual assault and supporting victims. The event featured several speakers and was attended by Lt. Gov. Joe Garcia, U.S. Senator Michael Bennet, Boulder Mayor Suzanne Jones, and CU Boulder Chancellor Philip P. DiStefano. Abby staffed the event.
- Heather staffed CU Boulder Vice Chancellor for Research and Innovation Terri Fiez when she participated in a media roundtable for Senior Research Officers (SRO) in Washington, DC titled "All Things Research 2016." The AAU and The Science Coalition (TSC) sponsored the event. At this national forum, Dr. Fiez discussed several important campus initiatives including the CU Boulder "Our Space, Our Future" Grand Challenge and the Inclusive Excellence initiative. She also discussed some of the research and creative work underway at CU Boulder, including the development of next generation, low-cost HPV vaccines by Robert Garcea and others at CU Boulder's BioFrontiers Institute that will save women's lives in the developing world.
- Kent staffed U.S. Senator Cory Gardner during an educational tour of the CU Anschutz Medical Campus led by CU School of Medicine Dean John J. Reilly. The visit included stops at the Beginning to Advanced Radiology (BAR) Lab, the Center for Advancing Professional Excellence (CAPE) simulation site, and a conversation with experts on rural healthcare and education. Senator Gardner also met with faculty members who are leaders in rural medical training and care at CU Anschutz Medical Campus and discussed a number of important issues related to the healthcare workforce and innovations in care in rural areas.
- Jack staffed Congresswoman Diana DeGette when she gave the keynote speech for the Robert Reynolds Distinguished Lecture and International Executive Roundtable at CU

Denver's Center for International Business Education and Research (CIBER). Her talk focused on U.S./Japanese relations amid recent changes in the Japanese economy and politics.

- Jack staffed Congressman Jared Polis when he visited CU Boulder's Science Discovery summer camps and joined kids having fun while learning. Polis was briefed on the broader Science Discovery program by camp Director Stacey Forsyth, and was able to observe the Girls in *STEM: Maker Space* class at the Idea Forge and the *Making Miniatures* class in the engineering center.
- Jack staffed Congressman Jared Polis when he toured the Alliance for Technology, Learning, and Society (ATLAS) on the CU Boulder campus. The Congressman, joined by his Colorado chief of staff and district education staffer, was shown the Blow Things Up (BTU) lab, where students experiment with new technologies; the Interactive Robotics and Novel Technologies (IRON) Lab, which focuses on developing humanrobot interaction; and the Laboratory for Playful Computation, where fun programmable learning technologies are designed. CU Boulder Vice Chancellor for Research and Innovation Terri Fiez, ATLAS Institute Director Mark Gross, and ATLAS Institute Associate Director Jill Van Matre Dupre briefed the Congressman on the growth of the Technology, Arts and Media (TAM) program and its bachelor's, minor, and certificate tracks.
- Jack staffed Congressman Jared Polis when he toured the CU Boulder Intermountain Neuroimaging Consortium (INC) to learn more about the facility. The visit was prompted by his interest in the Adolescent Brain Cognitive Development (ABCD) Study, the largest long-term study of brain development and child health in the United States. Dr. Marie Banich, lead principal investigator for ABCD, met with Congressman Polis on the Hill in 2016 to discuss the study. Dr. Banich and Nicole Speer, Director of Operations, updated Polis on INC's role in the ABCD study and local community outreach.

## 2016 Colorado Capital Conference

The 2016 Colorado Capital Conference was hosted by CU Denver Chancellor Dorothy Horrell, U.S. Senators Cory Gardner and Michael Bennet, and Colorado Mesa University President Tim Foster, in Washington, DC, June 8-10. Participants included Coloradoans from all across the state, and we were honored to have CU Regents Steve Bosley and Sue Sharkey among this year's attendees. The great lineup of speakers included Charlie Cook, Cool Political Report; Chuck Todd, NBC News; U.S. Senator Marco Rubio (R-FL); Denis McDonough, President Obama's Chief of Staff; U.S. Senator Tim Scott (R-SC); and U.S. Senator Chuck Schumer (D-NY), to name a few. This annual event is a great example of one of our successful partnerships between CU and other Colorado institutions of higher education.





## Tanya Kelly-Bowry Vice President

Tanya Kelly-Bowry was selected by President Benson and confirmed in October, 2008 by the Board of Regents, as vice president of government relations. She was chosen to lead the university's efforts to increase funding at the state and federal levels. Kelly-Bowry has more than 20 years of advocacy experience, having lobbied on behalf of higher education, human services and health care issues in both Colorado and Washington, D.C. She earned bachelor's degrees in international affairs and political science at CU-Boulder and a master's degree in nonprofit management from Regis University as a Colorado Trust Fellow. Kelly-

Bowry also studied at Harvard University's John F. Kennedy School of Government as a member of the senior executives in state and local government.



#### Abby Benson

#### **Associate Vice President of Government Relations**

Abby Benson is the Associate Vice President of Government Relations. In this role, Abby ensures the flow of information between the university and relevant stakeholders in Colorado and Washington, DC, and advocates for increased support for CU priorities, including research and higher education funding and policies, at both the state and federal levels. Abby has served in several leadership roles in the higher education government relations community, including as a past Chair of the Association of American Universities (AAU) Council on Federal Relations and as a member of the Association of Public and Land Grant

Universities (APLU) Council on Government Affairs Executive Committee. In 2012, Abby also served as President of the Science Coalition, an organization dedicated to strengthening the federal government's investment in university-based scientific, medical, engineering and agricultural research. Prior to joining CU, Abby held the position of Assistant Director of the Massachusetts Institute of Technology's (MIT) Washington, DC Office. Abby also served for over nine years as an officer in the U.S. Coast Guard, with specialties in maritime safety, security, environmental protection, planning, and budgeting. Earlier in her career, Aby worked as an earth scientist for Tetra Tech and Arthur D. Little. Abby earned a BS in geology and geophysics from Yale University; earned a MS and MEng in transportation and logistics from MIT; and served as a Marshall Memorial Fellow in 2009.



### **Heather Bené**

#### **Assistant Director of Federal Relations**

Heather Bené is the Assistant Director of Federal Relations for the University of Colorado and represents CU in Washington, DC. Bené specializes in higher education policy, which encompasses issues such as student financial aid, accreditation, campus safety, graduate education, etc. Other policy focuses in her portfolio include immigration, humanities, and the National Institutes of Health (NIH). Bené currently serves as co-chair on immigration issues for the Association of American Universities' (AAU) Council on Federal Relations (CFR). Previously, Bené worked for eight years in the Government Relations Office at her alma mater Oregon State University (OSU) on state and federal policy and advocacy. Bené managed legislative affairs for Oregon's Higher Education Coordinating Commission (HECC) during the 2014 legislative session and served as administrator to two HECC subcommittees. Bené has a master of public policy degree from OSU. Her graduate thesis analyzed university student voting behavior over six diverse election cycles. She also has bachelor of arts degrees from OSU in English and Political Science. As an undergraduate, Bené was recognized as student employee of the year by both OSU and the State of Oregon. She is the recipient of numerous scholastic awards for academic excellence, most notably the Waldo-Cummings Outstanding Student Award and the Oregon Laurels Graduate Scholarship.



### Natalie Ellis

#### **Executive Assistant of Federal Relations**

Natalie Ellis is the Executive Assistant of Federal Relations. She supports a broad range of administrative, research, writing, and analytical duties that are designed to support CU's federal relations efforts. She prepares and sends out the quarterly Government Relations department newsletter. She also works closely with each congressional office to schedule Hill visits and assists with constituent requests

regarding issues on campus. Natalie helps plan and coordinate federal events on CU campuses. Additionally, she makes travel arrangements, drafts correspondence, and prepares department expense system reports. Natalie has a Bachelor of Arts in Communications from University of Nevada, Las Vegas.



## Heather Retzko

#### **Director of State and Federal Relations**

Heather Fields is the Associate Director of State and Federal Relations. She is responsible for analyzing and tracking legislation during the state session, as well as preparing fact sheets for use with legislators. She also organizes state legislator tours and events and works with state legislative offices on constituent issues. Additionally, helps prepare correspondence and updates to the university community on legislation. She assists the lobby team with coverage of committee hearings and floor work at the Capitol. Heather worked in the office as a student assistant for three years. She also served as Executive Assistant to our state and federal

lobbyists, and Special Assistant to the Executive Director and Policy Analyst of State Relations. She has a Bachelor of Arts in Political Science from the University of Colorado at Boulder and a Master in Public Administration from the University of Colorado Denver School of Public Affairs. In FY 2012, Heather was a fellow in the CU Emerging Leaders Program.



# Connie Johnson Chief of Staff

In 2007, Connie Johnson joined the Office of Government Relations as the Senior Policy Analyst and Assistant Director. She is responsible for managing the day-to-day office operations, managing the department's budget and website, providing support to the Vice President and supporting state and federal activities. She monitors the healthcare legislation during the State session, and coordinates the Colorado Capital Conference for CU. Prior to CU, Connie served for over 18 years in higher education in Washington State. She has a B.S. in Accounting from Central Washington University, a Master of Public Administration from

the Daniel J. Evans School of Public Affairs at the University of Washington, and was a fellow in the 2008 CU Emerging Leaders Program.



### **Angela Rennick**

### **Executive Assistant of State Relations**

Angela Rennick is the Executive Assistant for State Relations. She supports a broad range of administrative duties that are designed to support CU's state relations efforts. She also assists with the state legislative session by drafting and updating legislator biographies, running reports on legislation being tracked, filing lobby reports and assisting with research requests. Angela has a Bachelor of Arts in International Studies from Colorado State University and a Master in Public Administration from the University of Colorado Denver School of Public Affairs.



## Kirsten Schuchman

## **Assistant Vice President of State Relations**

Kirsten Schuchman serves as Assistant Vice President of State Relations for the University of Colorado. She serves all four institutions in the CU system by taking the lead on much of the legislation affecting CU, as well as being the lead on system-wide capital construction funding and health care policy issues for the UCHealth, University of Colorado Denver School of Nursing, and the CU Colorado Springs Beth El College of Nursing and Health Sciences. She also takes special interest in CU's issues related to research, technology transfer, academic programs and administration. Kirsten is an alumnus of the 50 for Colorado 2005

program and is active in the Denver metro community. In her free time she enjoys spending time with her husband, daughters, family and friends, hiking, camping, traveling to exotic places and enjoying Denver. Kirsten has a Bachelor of Arts from the University of Virginia and a Master of Arts in Higher Education from the University of Michigan, Ann Arbor.



### David Sprenger Assistant Vice President of Federal Relations

David Sprenger, Assistant Vice President for Federal Relations is based in Washington, DC, and has expanded the presence of the University of Colorado by developing strong and effective relationships with Congressional offices, legislative staff, federal departments, professional organizations, industry and key advocacy groups within the federal departments and with the Congressional offices. He brings over 10 years of firsthand professional experience in Washington, D.C. both from both Capitol Hill and in federal relations consulting with an extensive background on public policy and direct advocacy. David, represents

several interest at the University of Colorado on both a system and campus level. David, a Colorado-native, received Bachelor degrees in Political Science and History from Regis University, and holds a Master degree in Public Policy from George Mason University.



### Kent Springfield

### Assistant Vice President of Research and Federal Relations

Kent serves as Assistant Vice President of Research and Federal Relations. He is the lead on all federal issues for the University of Colorado Anschutz Medical Campus and the University of Colorado Hospital. Kent represents Anschutz and UCH on issues including biomedical and healthcare research funding and policy, student financial aid, healthcare workforce issues, and healthcare delivery. He represents the University of Colorado System on issues related to intellectual property. Kent is active in the AAMC Government Relations

Representatives, the AAU Council on Federal Relations, the AAHC Steering Committee and the American Association of Cancer Institutes. Kent serves at the Biomedical Task Force lead for the APLU Council on Governmental Affairs. Prior to joining the University of Colorado, he spent five years as the Director of Government Relations for the George Washington University. He has a Bachelor of Arts in Political Communications and Master of Business Administration from GW.



#### Jack Waldorf Director of Federal Relations

Jack Waldorf serves as Associate Director of Federal Relations. Based in Denver, Jack is responsible for federal activities here locally and works with our Washington, DC-based team on federal policy issues impacting the University of Colorado System and its campuses, as well as the hospital. Prior to joining CU, Jack worked in both the United States House of Representatives and the United States Senate serving as a policy advisor for both education and health care issues, and comes to CU with a deep understanding in public policy and the legislative process

at the federal level. Jack holds a Bachelor's degree in Political Science from the University of Colorado at Boulder. A Colorado native, Jack enjoys spending time with his wife, enjoying Colorado's outdoors, and cheering on Colorado's sports teams.