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Academic and Subspecialty Advocacy

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AAP Advocacy for Academic and Subspecialty Pediatrics

The American Academy of Pediatrics is actively engaged in federal advocacy for the needs of academic and subspecialist pediatricians and the children for whom they provide care. Through its Department of Federal Affairs and dedicated staff for academic and subspecialty issues, the Academy works to promote medical research for children, funding for medical education, child access to needed providers through appropriate payment, and a pediatric workforce able to meet the needs of children across the country.

The AAP has helped lead coalition efforts to pursue this agenda and partners with many pediatric subspecialty organizations to jointly advocate for shared issues. The Academy also works closely with the Pediatric Policy Council, which represents academic pediatric organizations: the Academic Pediatric Association, the American Pediatric Society, the Association for Medical School Pediatric Department Chairs, and the Society for Pediatric Research.

This report is available in electronic form, with clickable links, at www.aap.org/subspecialty.

Access to Care

Children’s Health Insurance Program

On April 14, in an overwhelmingly bipartisan vote of 92-8, the U.S. Senate passed the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015, which extended funding for the Children’s Health Insurance Program (CHIP) for two years, renewed the Maternal, Infant and Early Childhood Home Visiting Program (MIECHV), and permanently repealed the Sustainable Growth Rate (SGR) formula to avoid annual cuts to Medicare payments. Six amendments were offered on the Senate floor concerning the legislation and all were rejected. Failed amendments of note were Sen. Michael Bennet (D-Colo.)’s amendment 1115 that would have extended CHIP for four years (through 2019) and Sen. Patty Murray (D-Wash.)’s amendment 1117 that would have extended Medicaid payment equity through 2016. The Senate’s action followed a vote of 392-37 in the U.S. House of Representatives. The legislation was signed by President Obama on April 16.

Although the Affordable Care Act (ACA) authorized the Children’s Health Insurance Program (CHIP) through 2019, the program was only funded through September 2015. Since the program was first enacted in 1997, CHIP has grown to finance health coverage for nearly 8 million children in low-income families with incomes too high to qualify for Medicaid. Further, since CHIP’s creation, the percentage of uninsured children has been cut significantly, from 25% in 1997 to 6.2% in 2013, while improving health outcomes and access to care for children and pregnant women.

Despite the new benefits associated with coverage in the healthcare exchanges under the ACA, CHIP offers children several benefits that make continuation of the program crucial. CHIP typically provides more comprehensive benefits for children than plans listed in the marketplaces, which are predominantly created for adults. CHIP also preserves low out-of-pocket costs for families and includes appropriate pediatric providers that narrow networks in the marketplaces might not include. Finally, families that are unable to access tax credits to purchase coverage in the marketplaces will be able to get needed coverage for their children under CHIP.

ACE Kids Act

A bill is pending in the House and Senate that would allow states the option of creating a Medicaid Children’s Coordinated Care (MCCC) Program for children with medical complexity. The bill, called the Advancing Care for Exceptional (ACE) Kids Act of 2015 (H.R. 546/S. 298), has 158 co-sponsors in the House and 27 in the Senate. The legislation was also included in a draft of the 21st Century Cures Act (see below), although was ultimately removed from the version of the legislation that passed the House of Representatives in July. The AAP, the American Board of Pediatrics, and the Association of Medical School Pediatric Department Chairs support the legislation.

Under the bill, backed by the Children’s Hospital Association, eligible children with complex medical conditions in participating states would be prospectively enrolled in an MCCC program through initial assignment to a nationally designated children’s hospital network. Enrolled children would receive coordinated care through this network.

While the bill may ease the delivery of care across state lines, questions have been raised about the bill’s
potential impact on the primary care medical home, particularly given the automatic assignment of children to MCCC networks.

Medicaid Health Plans of America, a trade group representing for-profit Medicaid health plans, has raised concerns about the legislation and released a report arguing that the program would increase, rather than decrease, Medicaid costs.

King v. Burwell
On June 25, the Supreme Court upheld a ruling issued by the 4th Circuit Court of Appeals last July that tax credits are available to offset the cost of health insurance premiums for individuals enrolled in federally-run exchanges. Chief Justice John Roberts and Associate Justice Anthony Kennedy joined the four liberal Justices in the 6 – 3 ruling. The ruling preserved health insurance subsidies for as many as 13 million individuals in 34 states enrolled through federally-run healthcare exchanges.

Legislative language in the Affordable Care Act states that federal tax credits may go towards defraying the cost of monthly premiums for individuals who “were enrolled in [a plan] through an Exchange established by the State.” At issue in the King v. Burwell and related cases was whether the federal government may provide credits to defray the cost of an individual’s health insurance premiums if that individual was enrolled through a federally-run, rather than state-run, exchange.

The Supreme Court’s majority opinion argued that the tax credit provision in the ACA was necessary for the individual mandate to function and to prevent a State’s individual insurance market from descending into a “death spiral,” a situation that the majority argued was the ACA was fundamentally designed to avoid.

The AAP, in conjunction with American Academy of Family Physicians, Children’s Health Fund, Children’s Hospital Association, First Focus, March of Dimes, National Physicians Alliance, and individuals with pre-existing conditions, filed a brief with the Supreme Court on the King case. The brief can be viewed here.

Academic and Subspecialty Workforce

Shortages and misdistribution among pediatric subspecialists create access problems for children with special health care needs. The Academy strongly advocates for funding programs to improve the subspecialty workforce, including the Children’s Hospital Graduate Medical Education Program (CHGME) and the Pediatric Subspecialty Loan Repayment Program.

Loan Repayment for Pediatric Subspecialists
On April 16, Rep. Chris Collins (R-N.Y.) along with Rep. Joe Courtney (D-Conn.) introduced the Ensuring Children’s Access to Specialty Care Act of 2015 (H.R. 1859). The legislation would amend the Public Health Service Act to include pediatric subspecialists in the National Health Service Corps (NHSC) loan repayment program. Currently, the NHSC is unable under existing law to meaningfully fund pediatric subspecialty loan repayment. The legislation was the product of work by the AAP along with a coalition of stakeholders to explore new ways to fund education for subspecialists. The legislation currently has 24 bipartisan cosponsors. On June 23, the AAP along with 40 other public health and medical organizations sent a letter to Reps. Collins and Courtney supporting the legislation.

Previously, the Affordable Care Act authorized a Pediatric Subspecialty Loan Repayment Program as part of the Title VII, or workforce, section of Public Health Service Act (PHSA). It would have allowed for up to $35,000 in loan repayment per year for up to three years for pediatric subspecialists or child mental health providers who agree to practice in underserved areas. The program expired in 2014 and was not reauthorized.

Children’s Hospital GME Funding and Reauthorization

The House and Senate Labor-Health and Human Services (HHS)-Education appropriations bills, which passed their respective committees in late June, included $265 million and $270 million respectively for the Children’s Hospital Graduate Medical Education (CHGME). This represents flat funding for the program in the House and a $5 million increase in the Senate bill from the FY 2015 enacted level of $265 million. The continuing resolution (CR) signed by President Obama on Sept. 30 will
temporarily fund the CHGME program at slightly less than the FY 2015 enacted level through Dec. 11.

The President’s FY 2016 budget request released on Feb. 2 proposed to cut the program’s current funding level of $265 million to $100 million. In addition, the President requested the creation of a competitive Targeted Graduate Medical Education program that would incorporate the Teaching Health Center Graduate Medical Education program and be funded at $400 million in mandatory funding, or $5.25 billion over 10 years, through a transfer from the Medicare Insurance Trust Fund. Pediatric hospitals would qualify to compete for this funding. This proposal would require congressional approval, and so far Congress has shown little enthusiasm. The CHGME program was reauthorized in April of 2014 at $300 million through FY 2018.

CHGME provides funding to free-standing children’s hospitals to support pediatric residency and fellowship positions. The AAP has worked to maintain this invaluable funding stream for pediatric residents and fellows, more than half of whom train at CHGME-eligible children’s hospitals.

Title VII Training Grant Appropriations
The House and Senate Labor-Health and Human Services (HHS)-Education appropriations bills, which passed their respective committees in late June, included $246 million and $230 million respectively for Title VII programs. The President’s FY 2016 budget request, released February 2, included $237 million for Title VII programs, a decrease of $18 million from the FY 2015 enacted level. The AAP, in conjunction with the Health Professions and Nursing Education Coalition (HPNEC), has encouraged Congress to continue prioritizing funding for health care workforce through essential programs such as Title VII. On Sept. 17, the AAP signed a HPNEC coalition letter advocating for stable funding for Title VII programs.

Title VII of the Public Health Services Act provides federal funding for training and development to bolster the public health workforce, including support to pediatric residency training and faculty development programs throughout the country. Grants provided under the Title VII program support individuals and institutions in a wide-variety of ambulatory and community-based sites, improve racial and ethnic diversity of health care workforce, promote training in fields of primary medical and dental care, and improve geographic distribution of the healthcare workforce. Funding for Title VII is appropriated annually, requiring ongoing and concerted support from the AAP.

The Consolidated and Further Continuing Appropriations Act of 2015 (H.R. 83), signed into law Dec. 16, included $255 million for Title VII programs for FY 2015, an increase of $10 million over the FY 2014 figure.

Physician Payment
Appropriate payment for services provided by all pediatricians is essential to ensuring that all children have access to care. The Academy is continuing to advocate for increased Medicaid payment for pediatricians with the broadest possible applicability to pediatricians and pediatric subspecialists.

Medicaid Payment Equity
On March 12, 2015, Sens. Sherrod Brown (D-Ohio) and Patty Murray (D-Wash.) introduced Ensuring Access to Primary Care for Women and Children Act (S. 737). This bill would extend the Medicaid payment equity (MPE) for an additional two years following enactment. Additionally, the bill would expand MPE to nurse practitioners, physician assistants, certified nurse-midwives, and obstetricians/gynecologists who deliver primary care services. On May 12, Rep. Kathy Castor (D-Fla.) introduced H.R. 2253, the House companion bill to S. 737.

Sen. Murray also introduced Amendment 1117 to the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. The amendment would have extended MPE from 2015 through 2016. Unfortunately, the amendment failed to pass along party lines by a vote of 43 to 57. MPE expired at the end of calendar year 2014.

Although there has been a great deal of anecdotal evidence on the importance of MPE, several new studies help quantify the MPE’s impact on access to care. The Urban Institute released its finding from a study of Medicaid physician fees in December. The study concluded once the MPE expires, that Medicaid payments for primary care services would decrease by 42.8% on average. This figure varies from state to state with payments cut by over 50% in seven states and no payment reduction in four states.
In February, 2015, the New England Journal of Medicine released a study on the impact MPE made on appointment availability. Although the study did not include pediatricians, the resulting were encouraging. The researchers posed as new Medicaid enrollees and privately insured patients seeking new patient primary care appointments. The study found that the availability of primary care appointments for Medicaid patients increased by 7.7 percentage points from the time period at the beginning of the MPE program in late 2012/early 2013 to May-July 2014 after payments were consistently made at the higher rate.

Pediatric Drugs and Devices

The Academy is continuing efforts to advocate for policies that promote safe and effective drugs and medical and surgical devices for children. The AAP is working on the implementation of three pediatric drug and device laws reauthorized in 2012.

21st Century Cures Initiative

On July 10, the 21st Century Cures Act passed the House of Representatives by a vote of 344-77. In addition to modifications to the development processes for drugs and medical devices, the legislation would provide a significant boost to National Institutes of Health (NIH) funding, including a $10 billion increase in mandatory funding over the next five years to create an NIH Innovation Fund and an annual $1.5 billion per year increase in NIH discretionary spending for the next three years. In addition, the legislation included the AAP-championed Children Count Act (H.R. 2436), that would direct the NIH to disclose biennially the number of children included in research performed or supported by the NIH and breakdown the data by age-group, race, and gender. While NIH policy has required the inclusion of children in its research, the NIH has consistently failed to track the number of children included in NIH-supported research, preventing pediatric researchers from understanding gaps in current research. Other pediatric-specific provisions in the legislation include:

- Requires the NIH to complete a strategic plan that requires the NIH to ensure that rare and pediatric diseases remain a priority of the agency;
- Increases and indexes for inflation the maximum annual support from the NIH pediatric loan repayment program from $35,000 to $50,000;
- Requires the NIH to implement the National Pediatric Research Network Act;
- Establishes a sense of Congress that the NIH and FDA should support the development of a global pediatric clinical trials network, and;
- Reauthorizes the rare pediatric disease priority review voucher program through Dec. 31, 2018 and requires a Government Accountability Office (GAO) report to evaluate the effectiveness of the program at spurring the development of new drugs.

The AAP has not taken a formal position on the legislation. A summary and brief analysis of the provisions in the legislation relevant to pediatrics may be found here.

Announcing a similar initiative in the Senate, Sens. Lamar Alexander (R-Tenn.) and Richard Burr (R-N.C.), both of the Senate Health, Education, Labor, and Pensions (HELP) Committee, released a document on Jan. 29 that details broad ideas for ways the NIH and FDA may be reformed to expand medical research initiatives and product development at the agencies. Senator Alexander has announced the formation of a HELP Committee working group on medical innovation that will meet throughout this year. A legislative proposal is possible this fall.

Pediatric Drug Laws

On March 25, the U.S. Food and Drug Administration (FDA) held a public stakeholder meeting to discuss implementation of the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). Kathleen Neville, MD, MS, FAAP, a pediatric hematologist/oncologist and chair of the AAP Committee on Drugs, provided comments on behalf of the Academy at the meeting and applauded the agency’s implementation of the laws, which have resulted in more than 580 pediatric label changes on drugs. In addition, Dr. Neville urged the FDA to increase research on drugs in newborns, a population in which more than 90% of drugs are still used off-label, and encouraged the agency to look critically at issues related to drug development for children with cancer.
In addition, earlier this year the Alliance for Childhood Cancer, a group of over 20 national patient advocacy and professional medical and scientific organizations dedicated to advocating on behalf of children with cancer, formed a working group co-led by the AAP to examine how the pediatric drug laws may better promote the future development of therapies for children with cancer.

BPCA and PREA, originally signed into law in 2002 and 2003 respectively, were permanently reauthorized in 2012 as part of the Food and Drug Administration Safety and Innovation Act (FDASIA), giving children a permanent seat at the drug development table. In addition to making BPCA and PREA permanent, FDASIA also mandated that the FDA hold a public stakeholder meeting for open comment on the implementation of the laws. Comments at the stakeholder meeting on March 25 will help inform an FDA report to Congress on BPCA and PREA that will be submitted in July of next year.

Pediatric Device Consortia Program Appropriations

Last October, the AAP led a sign-on letter to the Food and Drug Administration (FDA) requesting it include $5.25 million in funding for the PDC program in its FY 2016 budget proposal. Report language accompanying the FY 2016 Agriculture/Food and Drug Administration funding bill that was passed by the Senate Appropriations Committee on May 22 praised the program and recommended full funding for the program. Despite this, the President Obama’s FY 2016 budget request released Feb. 2 ignored the congressional directive and included only $3 million in funding for the program instead of the authorized level of $5.25 million that the AAP and others advocated for in the fall.

The PDC grant program, established in 2009 and reauthorized under the Food and Drug Administration Safety and Improvement Act (FDASIA) in 2012, supports nonprofit consortia that promote the development of pediatric medical devices. Since their inception in 2009, the PDC have been remarkably successful – nine consortia have assisted in advancing the development of more than 440 proposed pediatric medical devices. Most of the devices supported by the consortia are in the early stages of development, including concept formation, prototyping, and preclinical (animal and bench testing) stages, though several devices are now available to patients.

Pediatric Extrapolation Draft Guidance

On April 30, the FDA posted draft guidance entitled “Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices.” The draft guidance provides a framework for potentially evaluating a device’s performance in pediatric patients in premarket approval applications (PMAs) and humanitarian device exemptions (HDEs) by extrapolating existing clinical medical device data. On Aug. 4, the AAP along with several other public health and medical associations submitted comments on the draft guidance.

OxyContin Approval in Children

On Aug. 13, the FDA approved OxyContin (oxycodone) in children ages 11 and up for daily, long-term pain relief for which there is no alternative. Previously, OxyContin carried an indication to treat patient ages 18 and up. Although the approval added new information to the drug label about how it works in children, FDA’s action sparked a backlash from members of Congress concerned about the addictive nature of the drug and its potential adverse effects in children. On Sept. 9, nine Senators wrote a letter to Sens. Lamar Alexander (R-Tenn.) and Patty Murray (D-Wash.), Chair and Ranking Member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, urging the FDA to hold public hearings on the approval decision and on the opioid epidemic in general citing, among other things, a quadrupling in the number of opioid prescriptions written annually since 1999. The AAP has been educating members of Congress about the importance of the FDA’s process for studying the safety and efficacy of drugs in children.

Drug Shortages

In the spring, the AAP was made aware of two drug shortages with potentially serious implications for children. The shortages were for the drugs triamcinolone hexacetonide (Aristospan), which is used to treat juvenile idiopathic arthritis (JIA), and preservative-free, injectable Vitamin K1 (Phytonadione), which is used to treat Vitamin K deficiency bleeding in newborns. On Sept. 10, the AAP sent a letter to the FDA requesting the agency’s help in resolving the Aristospan shortage. A similar letter was sent on Sept. 24 to the CEO of Amphastar Pharmaceuticals requesting resolution of the Vitamin K1
shortage as soon as possible. Both drugs remain in shortage.

The AAP has worked for years to ensure that drugs for children, especially therapies for which there are few or no alternative therapies, remain in supply for the pediatric patients that need them, and support FDA policies mandating that drug manufacturers send adequate notice of shortage with clear timelines for resolution of shortages.

**Pediatric Research**

The Academy continues to advocate for basic and translational pediatric research funding, as well as the importance of including children in clinical research. The AAP closely tracks the National Children’s Study and the basis and translational research activities at the National Institutes of Health.

**National Institutes of Health Appropriations**

The continuing resolution (CR) signed by President Obama on Sept. 30 (see below) will fund the National Institutes of Health (NIH) through Dec. 11 at 0.21% less than the Fiscal Year (FY) 2015 enacted level of $30.3 billion in order to stay under FY 2016 budgetary cap set by the Budget Control Act. On June 24, the House Appropriations Committee passed its Fiscal Year (FY) 2016 spending bill. The bill included $31.2 billion for the NIH, which is $1.1 billion above the FY 2015 enacted level, and $1.305 billion for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), which is $19 million above the FY 2015 enacted level. On June 25, the Senate Appropriations Committee passed its own Labor-HHS-Education appropriations bill. The bill included $32 billion for the National Institutes of Health (NIH), an increase of $2 billion from the FY 2015 enacted level and nearly $1 billion above the House appropriations bill, and also included $1.345 billion for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), a $59 million increase from the FY 2015 enacted level.

The President’s FY 2016 budget requested $31.3 billion for the National Institutes of Health (NIH), an increase of $1 billion over the enacted FY 2015 level. This includes $1.318 billion for the **Eunice Kennedy Shriver** National Institute of Child Health and Human Development (NICHD), an increase of $31 million from the FY 2015 enacted level. The AAP supported a statement made by the Ad Hoc Group for Medical Research, a biomedical research funding advocacy coalition run by the Association of American Medical Colleges (AAMC), advocating for $32 billion in funding for the NIH in FY 2016.

The **Consolidated and Further Continuing Appropriations Act of 2015**, signed into law on Dec. 16, 2014, provided $30.3 billion for the NIH, an increase of $150 million from FY 2015. Despite increasing bipartisan consensus supporting additional funding for the NIH, the cap imposed by the **Budget Control Act** continues to put significant downward pressure on NIH funding and purchasing power.

**Precision Medicine Initiative**

The House and Senate Labor-Health and Human Services (HHS)-Education Appropriations Committees passed their respective appropriations bills in late June. Both bills included $200 million for FY 2016 for the Precision Medicine Initiative. This represents a slight decrease from the President’s FY 2016 budget request, released Feb. 2, that included $215 million in funding for the Initiative and provided further details about the program.

On May 7, the AAP sent a letter to Francis Collins, MD, PhD, Director of the NIH, in response to a Request for Information (RFI) on the Precision Medicine Initiative (PMI) cohort requesting that children specifically be included in the national cohort in order to determine the effect of environmental and genetic influences on children as they grow and develop. On Sept. 17, the Precision Medicine Initiative (PMI) Working Group of the National Institutes of Health (NIH), the advisory group tasked with providing recommendations on the design and implementation of the PMI, released its final report. In the report, the working group recommended that the PMI national cohort include all life stages, including children. Further, the report recommended that the NIH carefully examine issues related to the inclusion of children among other populations, and that the agency should develop “specific approaches to address the needs of these individuals so that they may be included and retained in the cohort.”

The proposed Initiative would enroll 1 million volunteers to form a research collaborative with the National Institutes of Health (NIH) to increase data needed to understand the causes of and to develop effective...
therapies for diseases. On Sept. 2, the AAP and the March of Dimes, along with 32 other public health and medical organizations, sent a letter to the leaders of the PMI working group urging the inclusion of children in the PMI national cohort. More information on the Initiative may be found here.

**National Children’s Study**

Both the House and Senate Labor-Health and Human Services (HHS)-Education appropriations bills, which were passed by the House and Senate Appropriations committees in late June, included $165 million for an alternative to the National Children’s Study. Report language accompanying the bills provided further requests concerning the scope of the NCS alternative, including an emphasis on the environmental and social influences that affect child health and development. The appropriations bills expand upon information included in the President’s FY 2016 budget request, which budgeted $158 million in FY 2016 for “Strategic Pediatrics Research” in place of the National Children’s Study as well as $7 million in FY2016 funding for maintaining NCS specimens and data. As the NCS has for several years now, this money would continue to come out of the base budget for the NIH Office of the Director. The FY2016 budget also detailed the FY 2015 close-down costs for the NCS, which total $20 million, leaving $145 million of the total $165 million FY 2015 appropriation for “Strategic Pediatrics Research.” On Aug. 25, the AAP and the March of Dimes organized a letter signed by 34 other public health and medical organizations thanking congressional appropriators for including funding for an alternative to the NCS in the FY 2016 appropriations bills.

In late June, in response to the inclusion of an NCS alternative in the FY 2016 appropriations bills, the NIH announced that planning for the next phase of the NCS had begun as the Environmental influences on Child Health Outcomes (ECHO) program. As part of the planning process, the NIH issued a Request for Information (RFI) soliciting public input on the proposed core elements and focus areas of the ECHO program. On Aug. 14, the AAP, along with several other academic pediatric organizations, sent a response to the RFI providing feedback and offering suggestions that, among other things, urged a stronger focus on the social influences of child health and development.

**Inclusion of Children in NIH-Funded Research**

On July 10, the 21st Century Cures Act passed the House of Representatives by a vote of 344-77. The legislation included the AAP-supported Children Count Act (H.R. 2436), sponsored by Reps. Marsha Blackburn (R-Tenn.) and Lois Capps (D-Calif.), that would direct the NIH to disclose biennially the number of children included in research performed or supported by the NIH and breakdown the data by age-group, race, and gender. While NIH policy has required the inclusion of children in its research, the NIH has consistently failed to track the number of children, preventing pediatric researchers from understanding gaps. The legislation would also direct the NIH to hold a workshop of experts in pediatrics and geriatrics to determine which appropriate age groups should be included in human subjects research and the criteria for excluding any age groups from similar research and make the results of the workshop public. The legislation comes after years of consistent advocacy on the issue by the AAP. The AAP is currently working to find a champion for this provision in the Senate.

In addition, report language accompanying the House and Senate FY 2016 Labor-Health and Human Services (HHS)-Education appropriations bills, which were passed by the House and Senate Appropriations Committees respectively in late June, emphasized the importance of the inclusion of children in federal research and directed the NIH to collect and report publicly on the numbers of children in NIH research studies broken down by age.

**Proposed Updates to Common Rule**

On Sept. 8, the National Institutes of Health (NIH) published a notice of proposed rulemaking (NPRM) that would update the “Common Rule” for the Protection of Human Subjects (45 C.F.R. Part 46(A)). The Common Rule, last revised and adopted by federal agencies in 1991, represents the uniform body of federal regulations that promotes the protection of research subjects in federal scientific research. The NPRM proposes several changes and clarifications including requiring informed consent for secondary research with a biospecimen, the use of a web-based “decision tool” that would allow researchers to determine whether a study is exempt from further Institutional Review Board (IRB) review, and the use of a single IRB for research that is performed at multiple sites. The NPRM was published nearly four years after the NIH published an advanced notice of proposed
rulemaking soliciting public feedback for the creation of a proposed rule to update the Common Rule. The AAP provided comments on the ANPRM in October of 2011. The comment deadline for the NPRM is Dec. 7. The AAP will be working to provide comments on the NPRM.

Budget and Appropriations

The AAP is working hard to support funding for important child health funding which is particularly vulnerable to budget cuts as the U.S. economy rebounds from recession. The Budget Control Act of 2011 enacted sequestration placing strict caps on discretionary spending, which continue to constrain federal funding on non-entitlement spending.

FY 2016 Appropriations

On Sept. 30, President Obama signed a short-term continuing resolution (CR) that will temporarily fund the government through Dec. 11 at 0.21% less than the Fiscal Year (FY) 2015 enacted level in order to stay under FY 2016 budgetary cap set by the Budget Control Act. The CR was signed hours before government funding would have expired at the end of FY 2015. The House passed the CR by a vote of 277-151 after the Senate approved the resolution 78-20. Leading up to the deadline, conservative Republicans displayed a willingness to shut down the federal government by threatening to block and spending bills that contained funding for Planned Parenthood. Although a previous version of the CR was introduced with a provision to defund the women’s health organization in both the House and Senate, votes on these bills failed allowing a “clean” CR to pass and be signed by the President. AAP continues to urge Congress to raise the budget caps to adequately fund non-defense discretionary programs important to child health and recently signed onto a coalition letter to Congress, which was signed by more than 2,500 organizations.

Because the CR was passed funding the government at the FY 2015 enacted level, the following bills passed by the House and Senate Appropriations Committees have not yet become law. In late June, the House and the Senate Appropriations Committees held respective votes on their proposed Labor-Health and Human Services (HHS)-Education appropriations bills. On June 24, the House Appropriations Committee passed its Fiscal Year (FY) 2016 spending bill by a party-line vote of 30 to 21. The bill passed the House Labor-HHS-Education Appropriations Subcommittee on June 17. The legislation would provide $153 billion in discretionary funding, $3.7 billion less than the FY 2015 enacted level. Of the $3.7 billion in proposed discretionary spending cuts, $2.8 billion would come from the Department of Education budget and $206 million would come from Department of Labor budget. The Department of Health and Human Services, however, would see a $298 million increase over the FY 2015 enacted level for a total funding amount of $71.3 billion. While there are good provisions in the bill including a $1 billion increase to NIH and $165 million for an alternative to the National Children’s Study (see below), the bill would completely eliminate funding for the Agency for Healthcare Research and Quality (AHRQ).

The bill included several provisions related to research and child health. Positive provisions in the legislation included:

- $31.2 billion for the National Institutes of Health (NIH), which is $1.1 billion above the FY 2015 enacted level.
- $1.305 billion for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), which is $19 million above the FY 2015 enacted level.
- $165 million for a “National Children’s Study alternative.”
- $7 billion for the Centers for Disease Control and Prevention (CDC), which is $140 million above the FY 2015 enacted level.
- $265 million for the Children’s Hospital Graduate Medical Education (CHGME) program. This is flat-funding from the FY 2015 enacted level.

However, these increases in funding resulted in several programs being cut or eliminated. In addition to containing several provisions to defund or prevent implementation of the Affordable Care Act, the legislation included:

- $3.3 billion for the Centers for Medicare and Medicaid Services (CMS), which is $344 million below the FY 2015 enacted level.
- $6 billion for the Health Resources and Services Administration (HRSA), which is $299 million below the FY 2015 enacted level.
- Eliminating funding for the Title X Family Planning program and over a 90% cut to the
On June 25, the Senate Appropriations Committee passed its own Labor-HHS-Education appropriations bill by a party-line vote of 16 to 14. The bill would provide $153.2 billion in discretionary funding, $3.6 billion less than the FY 2015 enacted level. Unlike the increase seen in the House appropriations bill, the Senate bill would provide $70.4 billion for the Department of Health and Human Services, a $646 million decrease from FY 2015. Despite this decrease, the bill included $32 billion for the National Institutes of Health (NIH), an increase of $2 billion from the FY 2015 enacted level and nearly $1 billion above the House appropriations bill. In addition, the bill contained several positive provisions related to child health including:

- $165 million for a “follow-on to the National Children’s Study.
- $1.345 billion for the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), $59 million above the FY 2015 enacted level.
- $270 million for the Children’s Hospital Graduate Medical Education (CHGME) program, a $5 million increase over the FY 2015 enacted level.

However, despite these additions, the large increase to NIH funding combined with a reduction in the Department of Health and Human Services appropriations level resulted in cuts to several programs including:

- $6.7 billion for the Centers for Disease Control and Prevention (CDC), a $215 million reduction from the FY 2015 enacted level.
- Defunding of Affordable Care Act provisions.
- $236 million for the Agency for Healthcare Research and Quality (AHRQ), a $127 million decrease from the FY 2015 enacted level. The House eliminated AHRQ in their appropriations recommendation.
- $6.241 billion for the Health Resources and Services Administration (HRSA), a $105 million decrease from the FY 2015 enacted level.
- $257 million for the Title X Family Planning program, a $29 million cut from the FY 2015 enacted level, as well as an 80% cut to the Teen Pregnancy Prevention Program.

The full House and Senate must now vote on the respective appropriations bills before they move to conference, where both chambers will resolve differences in the legislation. Although Congress reported all 12 appropriations bills for the first time in six years, a continuing resolution to fund the government past the end of FY 2015 is likely given a political impasse over the discretionary budget caps mandated under the Budget Control Act.

In late March, both chambers passed their FY 2016 Budget Resolutions. These non-binding documents are symbolic pieces of legislation that do not become law, but instead outline the majority in each chamber’s priorities for how money should be spent by the federal government.

The House Budget (H Con Res 27), which passed by a vote of 228-199 on March 25, maintains statutory caps on discretionary spending for FY 2016—$523 billion for defense and $495.5 billion for non-defense discretionary spending—while adding funding to defense outside of the budget caps dictated in the Budget Control Act of 2011 (BCA). The Budget agreed upon by the full House adds $96 billion in the war funding account, known as the Overseas Contingency Fund (OCO), without offsets. The resolution also repeals the Affordable Care Act, including reconciliation instructions to allow this to happen, and converts both Medicaid and SNAP into block grant programs. Beyond FY 2016, the budget resolution also plans to balance the budget within ten years and includes spending cuts totaling $5.5 trillion, including $759 billion to non-defense discretionary spending, which is 14 percent below the current caps out lined in the BCA. The vote was largely along party lines with 182 Democrats voting “no” and 17 Republicans also voting “no.”

The Senate Budget Resolution (S Con Res 11) passed in a 52-46 vote, which followed the lengthy “vote-a-rama” process during which close to 800 amendments were filed. Of these amendments, 49 were considered, and 35 were approved. The Senate Budget, like the House, maintained FY 2016 budget caps, and also added an additional $96 billion to OCO. The Senate resolution also includes reconciliation instructions to allow for the repeal of the Affordable Care Act and would also
transform Medicaid and SNAP into a block grant programs. Beyond FY2016, the Senate resolution gradually reduces non-defense discretionary funds by at least $263 billion until FY 2025, which is 4% below current caps. The final vote was also largely along partisan lines with all Democrats voting against the resolution, and two Republicans, Sens. Ted Cruz (R-TX) and Rand Paul (R-KY) voting against it as well.

In late April, the budget conference committee signed off on their final budget (S. Con. Res. 11). The budget, which was negotiated by a selection of legislators from both the House and Senate, locks the sequestered discretionary caps in place and doubles the impact of sequester cuts over the next decade. Starting in 2016, non-defense discretionary spending would be cut by an average of $37 billion per year, on top of the Budget Control Act’s spending caps. The conferenced budget was passed by both chambers.

President’s FY 2016 Budget
On Feb. 2, President Obama released his Fiscal Year 2016 Budget Proposal. Although the President’s Budget is a symbolic gesture, and it is not passed in its entirety by Congress, it outlines the president’s priorities for the nation. In his $3.99 trillion budget, the President lifted the spending caps set forth in the 2011 Budget Control Act and restored more than $70 billion in sequestration cuts.

The President’s budget:

- Increased Head Start and preschool development grants
- Included funding for federal research on gun violence prevention, as well as investments in mental health programs for children
- Increased Summer Electronic Benefit Transfer Demonstrations, which are providing monthly food assistance to low-income children in the summer, increased school meal equipment grants, and funding for the Special Supplemental Nutrition Program for Women, Infants and Children (WIC), that is level with FY 2015.
- Supported the Affordable Care Act, extended the Children’s Health Insurance Program (CHIP) for four more years, and proposed to extend Medicaid payment equity through 2016.
- Included level funding from FY 2015 for the National Center on Birth Defects and Developmental Disabilities and the Emergency Medical Services for Children program

Though these important priorities for children were included in the budget, it also cut Children’s Hospital Graduate Medical Education (CHGME) funding. Instead of maintaining the full amount of dedicated CHGME funding, the president proposed piloting a new initiative: Targeted Graduate Medical Education. This program would provide competitive grants for GME and would include pediatric opportunities. The budget proposal also did not follow through with funding to support the goals of the National Children’s Study (NCS) which was terminated last year. The President also proposed a $50 million cut to the Section 317 vaccine program.

A comprehensive summary of the President’s Budget can be found here. Upon release of the budget, the AAP issued a press release urging Congress to take up the important proposals for children that the budget included. The press release can be found here.

FY 2015 Appropriations
On Dec. 11, the House passed the Consolidated and Further Continuing Appropriations Act of 2015 (H.R. 83) by a vote of 219 – 206. The bill provided $1.1 trillion to fund the federal government in what remains of Fiscal Year 2015. Following the passage of a two-day continuing resolution (J.J. Res. 130) to avert government shutdown and allow the Senate to consider the House bill, the Senate passed the measure the evening of Dec. 13 by a vote of 56 – 40. President Obama signed the measure into law on Dec. 16. The measure included 11 of 12 full appropriations bills with the homeland security appropriations funded under a continuing resolution until Feb. 27, a result of controversy regarding the President’s executive action on immigration. Action on FY 2015 appropriations came after the House of Representatives passed a Continuing Resolution (CR) on Sept. 17 by a vote of 319-108 that funded the government through Dec. 11, 2014 (H.J. Res. 124). The Senate took up the resolution on Sept. 18, and it passed 73-27. The President signed the measure on Sept. 19, thus averting a government shutdown.

The resolution also contained $88 million in funding to fight the Ebola outbreak, as well as an extension of the
Export-Import Bank charter until June 30, 2015. The $88 million to fight the Ebola virus is to be divided between $30 million for the Center for Disease Control and Prevention’s efforts to trace the spread of the disease in Africa and $58 million to the Biomedical Advanced Research and Development Authority to accelerate the production of promising drugs to fight the disease. In addition, below are funding for several key programs and agencies important to children’s health within the FY 2015 omnibus appropriations bill:

- $265 million in flat funding for the Children’s Hospital Graduate Medical Education program.
- $1.287 billion for the Eunice Kennedy Shriver National Institutes of Child Health and Human Development, an increase of $3.977 million from FY 2014.
- $255 million for Title VII programs, an increase of $10 million from FY 2014.
- $8.6 billion for the Head Start program.
- $6.5 billion for the Health Resources and Services Administration (HRSA), an increase of $23.76 million from FY 2014.
- $30.3 billion for the National Institutes of Health (NIH), and incrase of $150 million from FY 2014.

Emergency Medical Services for Children

Federal Aviation Administration Emergency Medical Kits

In July, Reps. Sean Patrick Maloney (D-N.Y.) and Richard Hanna (R-N.Y.) introduced the bipartisan Airplane Kids in Transit Safety (KITS) Act. This AAP-championed legislation would require the Federal Aviation Administration (FAA) to update the emergency medical kits on airplanes to ensure that they contain appropriate medication and equipment to meet the emergency medical needs of children, including an epinephrine auto-injector. In advance of introduction, the AAP sent a support letter with several other health organizations.

On the day of the bill’s introduction, Brian Moore, MD, FAAP, member of the AAP Committee on Pediatric Emergency Medicine, joined a press call to discuss children’s unique vulnerabilities during emergencies and the importance of the Airplane KITs Act in helping to ensure air travel is safe for children. Dr. Moore’s remarks were later picked by The Hill.

The legislation comes after resolutions calling for an update to the contents of emergency medical kits were approved at the 2014 and 2015 Annual Leadership Forums. The AAP Washington Office is working with the House and Senate to ensure the bill will be included in a larger reauthorization of the FAA that is currently under consideration. In the Senate, Senators Brian Schatz (D-HI) and Jerry Moran (R-KS) sent a letter to the Senate Commerce Committee leadership calling for inclusion of an identical provision in the senate’s FAA reauthorization bill.
Grassroots Advocacy: AAP Key Contact Program

Key Contacts are AAP members who are interested in receiving advocacy opportunities and timely policy updates from the AAP Department of Federal Affairs on federal legislation and other issues important to the Academy.

Through regular e-mail communication with specific requests for action, the Department of Federal Affairs keeps Key Contacts informed of the latest legislative developments affecting children and pediatricians.

How to Become a Key Contact

E-mail kids1st@aap.org with your name, AAP ID if known, and your preferred e-mail address. If you have questions about federal advocacy, contact AAP Department of Federal Affairs at 800-347-8600.

FederalAdvocacy.aap.org: Dept. of Federal Affairs Online Resource Center

Visit the AAP Department of Federal Affairs website at FederalAdvocacy.aap.org to find federal advocacy resources and tools, including:

- Contact and biographical information for your federal legislators
- An Action Center where you can call and e-mail federal legislators directly on current federal child health policy priorities
- A media center where you can read recent opinion pieces written by pediatricians and learn how to submit your own
- Background information on current AAP federal child health issues advancing in Congress

Engage with AAP on Social Media

Twitter is a powerful tool that allows individuals and organizations to amplify messages, connect with new and diverse networks, and gain access to local-, state- and federal-level decision-makers. As a pediatrician, Twitter also offers you the opportunity to be part of a community that encourages the exchanging of ideas around child health, while not being constrained by time or geography.

To stay up-to-date on child health news, follow and engage with AAP on social media via @AmerAcadPeds, @AAPPres, @AAPNews and @healthychildren. You also can subscribe to AAP’s official #tweetiatrician list on Twitter by visiting https://twitter.com/AmerAcadPeds/lists/tweetiatricians. Request to be added to the list by emailing AAP’s social media community manager, Cassandra Blohowiak, at cblohowiak@aap.org.

AAP 7 Great Achievements Campaign

In April at the Pediatric Academic Societies (PAS) meeting in San Diego, the Academy announced a new campaign to celebrate the successes in pediatric research. The campaign, 7 Great Achievements in Pediatric Research, highlights seven key discoveries over the past 40 years that have saved millions of children’s lives worldwide, from groundbreaking treatments for deadly chronic diseases to life-saving interventions for babies who are born premature.

In order to help educate the public and members of Congress about the importance of sustained investment in pediatric research, the AAP also unveiled a video from the podium at PAS, which outlines each of the following achievements and spotlights real-life success stories:

1. Preventing disease with life-saving immunizations
2. Reducing SIDS with "Back-to-Sleep"
3. Curing a common childhood cancer
4. Saving premature babies by helping them breathe
5. Preventing mother-to-baby HIV transmission
6. Increasing life expectancy for children with chronic disease
7. Saving lives with car seats and seat belts

Following the announcement, all of these achievements were featured by CBS News.

Join the effort by sharing the importance of pediatric research to children’s health with your federal legislators: Visit federaladvocacy.aap.org and click on the following links in the Advocacy Action Center:
• **Support Funding for the Next Great Achievements in Pediatric Research:** Share your own compelling stories about the successes of pediatric research with policymakers, and urge for sustained funding for pediatric research.

• **Get a Grant, Send Your Thanks:** Highlight the importance of pediatric research with a thank you note to your members of Congress each time you are awarded a federal grant.

For more information and a brochure on the 7 Great Achievements in Pediatric Research, please visit AAP.org/7Achievements.

### Advocacy Training Opportunities in Washington, DC

**2016 AAP Legislative Conference**

Mark your calendars-- the 25th AAP Legislative Conference will take place April 3-5, 2016, in Washington, DC. Join us next spring to learn more about how to become a strong advocate for children’s health.

For more information, please visit aap.org/legcon. If you are interested in attending and would like to be notified when registration opens, please email LegislativeConference@aap.org.

**“Speak Up for Kids” Capitol Hill Rally at the AAP National Conference & Exhibition**

If you plan to attend the AAP National Conference & Exhibition on Oct. 24-27 in Washington, DC, bring your white coat and join your fellow pediatricians on **Tuesday, October 27, at 12:00 p.m.** for the “Speak Up for Kids: White Coat Rally at the Capitol.” AAP leaders and members of Congress will share updates about strong federal policies needed to protect child health, and participants will attend the event on the east front lawn of the U.S. Capitol.

A session to prepare for the rally, “Getting Ready to Rally,” will be held on Monday, October 26. There, you will learn all the details involved with the rally: why we are here in Washington, DC, what to expect from the rally, and why advocacy is so important.

For more information or questions on the rally, please email the AAP Washington Office at kids1st@aap.org.
AAP Washington Office

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