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Washington Report

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(CHIP) for two years, renewed the Maternal, Infant and Early Childhood Home Visiting Program (MIECHV), and permanently repealed the Sustainable Growth Rate (SGR) formula to avoid annual cuts to Medicare payments.

Prior to passage, 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 had only been 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 193 co-sponsors in the House and 30 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 2015. 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.

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 Ensuring Children's Access to Specialty Care Act.

Support for Pediatric Subspecialists

On April 16, 2015, Rep. Chris Collins (R-N.Y.) and 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 35 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. A Senate version of the legislation is expected to be introduced soon by Sens. Roy Blunt (R-Mo.) and Jack Reed (D-R.I.).

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 President's Fiscal Year (FY) 2017 budget, released on Feb. 9, included \$295 million for the Children's Hospital Graduate Medical Education (CHGME). This represents flat funding for the program from the FY 2016 enacted level and a \$30 million increase from the FY 2015 enacted level of \$265 million. In addition, the President's budget would make a major change by making the funding for the program mandatory rather than discretionary, which is an important recognition that this program deserves a consistent source of funding.

This is a major shift from the President's previous budgets, including his FY 2016 budget request, which proposed to cut the program's current funding level of \$265 million to \$100 million.

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. The CHGME program was reauthorized in April of 2014 at \$300 million through FY 2018.

Title VII Training Grant Appropriations

The President's Fiscal Year (FY) 2017 budget request, which was released on Feb. 9, included \$231.3 million for Title VII programs, a decrease of \$31.2 million from the FY 2016 enacted level. The FY 2016 Consolidated Appropriations Act (H.R. 2029), which was signed into law on Dec. 18, 2015, included \$262 million for Title VII programs. This represented a \$7 million increase over 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.

International Physician Legislation

On May 5, 2015, Sens. Amy Klobuchar (D-Minn.), Susan Collins (R-Maine), Jerry Moran (R-Kansas), and Heidi Heitkamp (D-N.D.) introduced the Conrad State 30 and Physician Access Act (S. 1189). The legislation would reauthorize and make permanent the Conrad State 30 J-1 visa waiver program, which expired on Sept. 30, 2015, and would allow waivers to be used by physicians whose specialties require them to practice at facilities that serve a medically underserved community rather than strictly applying to underserved geographic areas. The Conrad State 30 J-1 visa program was created in 1994 to allow each state's health department to sponsor up to a certain number of international medical graduates annually for a waiver of the two-year home residency requirement of a physician's J-1 visa. This would allow internationally trained physicians to remain in the United States for additional training in exchange for practicing in a medically underserved community. The AAP has endorsed the legislation.

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. No action has yet been taken on the bills.

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 2014. 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/Innovations for Healthier Americans

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 regulatory approval processes for drugs and medical devices, the legislation would provide a significant boost to National Institutes of Health (NIH)

funding, including a \$8.75 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:

- Requiring 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 as a whole. A summary and brief analysis of the provisions in the legislation relevant to pediatrics may be found [here](#).

In early 2015, Sens. Lamar Alexander (R-Tenn.) and Richard Burr (R-N.C.), both of the Senate Health, Education, Labor, and Pensions (HELP) Committee, announced the development of a corollary process to the 21st Century Cures Initiative in the Senate called the Innovations for Healthier Americans initiative. Following the announcement, the HELP Committee formed working

groups on medical innovation that have met throughout the past year.

On Feb. 9, the HELP Committee held the first of three proposed sessions to consider bills as part of its medical innovations efforts. One of the bills considered in this session was the *Next Generation Researchers Act* (S. 2014/H.R. 3466). The AAP-endorsed [legislation](#), introduced by Sens. Susan Collins (R-Maine) and Tammy Baldwin (D-Wis.) in the Senate and Rep. Mark Pocan (D-Wis.) in the House, would authorize an initiative at the National Institutes of Health (NIH) designed to encourage new researchers to enter the field, improve both diversity in the research workforce and mentorship opportunities for new researchers, and allow the NIH Director to coordinate with other federal agencies to improve tracking of research trainees and to develop additional new programs for young researchers. The legislation would also propose to expand existing loan repayment programs at the NIH for medical researchers. All pieces of legislation considered in the Feb. 9 session passed the committee by voice vote.

On March 9, the HELP Committee held its second session on medical innovations and considered larger pieces of legislation related to several issues including health information technology, pediatric rare diseases, and drug development for underserved populations. During the session, the committee passed the *Advancing Hope Act* (S. 1878), which would reauthorize the pediatric rare disease priority review voucher program, set to expire on March 17, as well as expand the program to include pediatric cancer and sickle cell disease.

The HELP Committee is expected hold its third session in early April. The AAP is working with members of the committee to include topics such as the inclusion of children in NIH research and NIH funding as part of the session agenda.

Pediatric Drug Laws

On March 25, 2015, 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, in early 2015 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. The working group is currently finalizing its comments to Congress on potential changes to the pediatric drug laws in anticipation of the FDA user fee negotiations to take place later this year.

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

The President's Fiscal Year (FY) 2017 budget requested \$3 million in funding for the Pediatric Device Consortia program, which represents flat funding from the FY 2016 enacted level. Although Congress has added AAP-supported report language to congressional appropriations bills for several years supporting the program, the program has yet to be funded beyond the \$3 million amount. The AAP is continuing to advocate for full funding for the program in the FY 2017 appropriations process.

Within the FY 2016 appropriations process, 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.

OxyContin Approval in Children

On Aug. 13, the Food and Drug Administration (FDA) approved new labeling for 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.

In early 2016, several Senators opposed the nomination of Robert Califf, MD, a cardiologist from Duke University, to be commissioner of the FDA over the agency's handling of opioids issues, including the aforementioned labeling change for OxyContin in the pediatric

population. The AAP sent a [letter](#) to Senate leadership on Feb. 4 supporting Dr. Califf's nomination and further emphasizing the AAP's support for the FDA's process for studying the safety and efficacy of drugs in children. Despite opposition, Califf, who previously served as deputy director of medical products and tobacco at the FDA, was confirmed by an 89-4 vote in the Senate as commissioner on Feb. 24.

Drug Shortages

On Nov. 10, the AAP Department of Federal Affairs widely distributed a ten-question survey to AAP members regarding the effects of drug shortages in their practice. The survey was generated to assist the Government Accountability Office (GAO), which is conducting a study on causes of and trends in drug shortages to supplement their previous work on drug shortages in 2011 and 2014 respectively. The survey responses from 365 members were summarized in an AAP-authored [report](#). The report concluded that nearly 75% of respondents saw the number of drug shortages increase in their practice over two years, and while some respondents saw an increase in the duration of shortages most respondents reported individual shortages to occur unpredictably and last a few months at a time.

In the spring of 2015, 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 basic and translational research activities at the National Institutes of Health.

National Institutes of Health Appropriations

The President's Fiscal Year (FY) 2017 budget request, which was released on Feb. 9, included \$33.1 billion for the National Institutes of Health (NIH), which is \$800 million above the FY 2016 enacted level. However, while the President's request is a funding increase, the increase is driven by \$1.8 billion in mandatory money for temporary projects and represents a net \$1 billion reduction in discretionary funding for the agency. The budget request also included \$1.338 billion for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), which is level funding from the FY 2016 enacted level, \$309 million for the Precision Medicine Initiative, and \$165 million for the "follow-on" to the National Children's Study, also known as the Environmental influences on Child Health Outcomes (ECHO). The AAP is currently supporting a funding level of \$34.5 billion for the NIH for FY 2017.

The FY 2016 *Consolidated Appropriations Act* (H.R. 2029), which was signed into law on Dec. 18, 2015, included \$32 billion for the National Institutes of Health (NIH), an increase of \$2 billion from FY 2015. The bill also included \$1.33 billion for the *Eunice K. Shriver* National Institute of Child Health and Human Development (NICHD), an increase of \$19 million from FY 2015. The bill also included \$165 million for the "follow-on" to the National Children's Study, which represents flat funding from FY 2015, \$200 million for the Precision Medicine Initiative (PMI), and \$150 million for the BRAIN Initiative, an increase of \$85 million over FY 2015.

Precision Medicine Initiative

The President's Fiscal Year (FY) 2017 budget request, released Feb. 9, requested \$309 million for the Precision Medicine Initiative, which represents a \$109 million increase over the FY 2016 level included in the *Consolidated Appropriations Act* (H.R. 2029), which was signed into law on Dec. 18, 2015.

On Dec. 10, Josie Briggs, MD, Acting Director of the PMI, and Kathy Hudson PhD, NIH Deputy Director for Science, Outreach, and Policy, gave an update to NIH Director Francis Collins, MD, PhD on the PMI. The update included several goals over the next four years, including an overall enrollment goal of 1.1 million people by 2019, starting with 79,000 enrollees in 2016. Currently, a formal search is underway for a permanent director of the PMI. Selection of the permanent director is expected in the spring of 2016.

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 took up AAP's [recommendation](#) 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 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 based on data collected from a national research cohort. 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 President's Fiscal Year (FY) 2017 budget request, as well as the *Consolidated Appropriations Act* (H.R. 2029) signed into law in December, included \$165 million for the follow-on to the National Children's Study, also known as the Environmental influences on Child Health Outcomes (ECHO). This represents flat funding from the FY 2015 enacted level. In addition, both the House and Senate Labor-Health and Human Services (HHS)-Education appropriations bills, which were passed by the House and Senate Appropriations committees last June, included \$165 million for an alternative to the National Children's Study as well as AAP-supported report language accompanying the bills that 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. 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.

On Dec. 7, National Institutes of Health (NIH) Principal Deputy Director Lawrence Tabak, DDS, PhD announced the publication of seven funding opportunity announcements (FOAs) for the Environmental influences on Child Health Outcomes (ECHO) program. The FOAs relate to several aspects of the program including the proposed data analysis and coordinating centers for the program as well as the pediatric cohorts to be formed for the program. The application deadline for the FOAs is April 15. Additional information on the ECHO program FOAs may be found [here](#).

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 advocating for this policy in the context of the aforementioned Innovations for Healthier Americans initiative 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. This language was incorporated into the *Consolidated Appropriations Act* (H.R. 2029) signed into law in December 2015.

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, and submitted [comments](#) on the proposed rule on Jan. 4.

NIH-Wide Five-Year Strategic Plan

On Dec. 16, the National Institutes of Health (NIH) unveiled its agency-wide strategic plan for Fiscal Years (FYs) 2016-2020. Soliciting the input of more than 450

community stakeholders and 21 NIH advisory councils, the plan includes several broad objectives over the next five years, including to:

1. advance opportunities in biomedical research in fundamental science, treatment and cures, and health promotion and disease prevention;
2. foster innovation by setting NIH priorities to enhance nimbleness, consider burden of disease and value of permanently eradicating a disease, and advance research opportunities presented by rare diseases;
3. enhance scientific stewardship by recruiting and retaining an outstanding biomedical research workforce, enhancing workforce diversity and impact through partnerships, ensuring rigor and reproducibility, optimizing approaches to inform funding decisions, encouraging innovation, and engaging in proactive risk management practices; and
4. excel as a federal science agency by managing for results by developing the “science of science,” balancing outputs with outcomes, conducting workforce analyses, continually reviewing peer review, evaluating steps to enhance rigor and reproducibility, reducing administrative burden, and tracking effectiveness of risk management in decision making.

The strategic plan will serve as a living document for the agency as it carries out its goals, and may be amended as priorities shift over the next five years. More information on the strategic plan may be found [here](#). Although the NIH chose not to focus on specific populations in the strategic plan, in August, the AAP drafted a [response](#) to a Request for Information (RFI) during the drafting phase of the NIH five-year strategic plan that urged the agency to focus on childhood development in the context of its research.

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.

President's FY 2017 Budget

On Feb. 9, President Obama released his budget request for Fiscal Year (FY) 2017, the final budget request of his presidency. The budget request included \$33.1 billion for the National Institutes of Health (NIH), which is \$800 million above the FY 2016 enacted level. However, while the President's request is a funding increase, the increase is driven by \$1.8 billion in mandatory money for temporary projects and represents a net \$1 billion reduction in discretionary funding for the agency. Unlike previous budgets that cut or eliminated the program, the President provided \$295 million for the Children's Hospital Graduate Medical Education (CHGME) program, representing the same funding level as the FY 2016 enacted level and a \$30 million increase over FY 2015. The budget also included a \$4 million boost to the Teen Pregnancy Prevention Program (TPPP) and a \$14 million increase to the Title X family planning program.

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

- \$165 million for a "follow-on" to the National Children's Study, also known as the Environmental influences on Child Health Outcomes (ECHO).
- \$309 million for the Precision Medicine Initiative, a \$109 million increase over the FY 2016 enacted level.
- \$363 million for the Agency for Healthcare Research and Quality (AHRQ), a \$29 million increase from the FY 2016 enacted level (flat funding compared to the FY 2015 level). This increase came after the House proposed to eliminate the agency in its FY 2016 appropriations bill.

However, several programs were level-funded or cut:

- \$1.338 billion for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), which is level funding from the FY 2016 enacted level.
- \$7.014 billion for the Centers for Disease Control and Prevention (CDC), which is \$164 million below the FY 2016 enacted level.

- \$39 million for Title VII primary care funding under the Health Resources and Services Administration (HRSA), level funding from FY 2016.

Although the President's budget is one of the main resources that the Administration uses to communicate its spending and policy priorities to Congress, the recommendations are nonbinding and do not heavily influence the congressional budget and appropriations process.

Administration Proposes New Emergency Funding Measures

The Obama Administration has recently made emergency funding requests related to several urgent public health situations that affect children. On Feb. 9, President Obama requested \$1.8 billion for a federal response to the recent emergence of the Zika virus in the western hemisphere, which would include funding for initiatives such as mosquito control programs, rapid response teams to virus outbreak sites, and containment efforts in countries currently affected by the virus. \$828 million of the request would go to the Centers for Disease Control and Prevention (CDC) to research the virus and establish protocols to treat those infected by it. Congress is currently investigating the issue to determine how much new funding should be dedicated to the efforts and the source of the funding.

In addition, the President's Fiscal Year (FY) 2017 budget requested \$1.1 billion in new funding to address the prescription opioid and heroin use epidemic. The request included \$1 billion in new mandatory funding, most of which will go to support cooperative agreements to expand state-level medication-assisted treatment programs for opioid use disorders, with additional funding going towards both the evaluation of existing medication-assisted treatment programs and to the National Health Service Corps to expand substance use treatment programs in areas with behavioral health provider shortages. The request also included a \$90 million increase in discretionary funding for the departments of Health and Human Services (HHS) and Justice (DOJ) to implement overdose prevention strategies. Congress has recently engaged on the issue as just last week, the Senate Judiciary Committee passed the *Comprehensive Addiction and Recovery Act* (S. 524), introduced by Sen. Sheldon Whitehouse (D-R.I.), by voice

vote. Although the legislation would expand prescription drug monitoring programs and access to the opioid overdose drug naloxone, the bill does not include new money for the provisions. Congressional leaders are currently at an impasse over new funding to tackle the opioid use epidemic.

Finally, the President's budget included \$157 million in additional funding for state-based low-interest loans to help repair and replace water infrastructure. However, the budget included no direct funding for the ongoing water crisis in Flint, Mich., where dangerously high lead levels have led to a curfew, and in some cases a halt, of the use of city water by residents. The House of Representatives has recently passed the *Safe Drinking Water Act Improved Compliance Awareness Act* (H.R. 4470) to directly address the water crisis in Flint.

There are currently ongoing discussions between congressional leaders about combining these emergency spending requests into one emergency supplemental appropriations bill, which would isolate the requests from other discretionary funding priorities. However, the most recent emergency supplemental spending bill was passed by Congress in 2014, and there remains uncertainty moving forward especially among calls by some members of Congress to offset the spending requests.

FY 2016 Appropriations

Congressional Action on Appropriations

On Dec. 18, Congress voted to approve the Fiscal Year (FY) 2016 *Consolidated Appropriations Act* (H.R. 2029) negotiated by both chambers of Congress, with the House voting 316-113 and the Senate voting 65-33 in favor. The President signed the bill later that day. The appropriations bill came after Congress passed continuing resolutions (CRs) on Sept. 30, Dec. 11, and Dec. 16 to fund the federal government at slightly less than FY 2015 enacted levels in order to avoid a shutdown of the government before the final bill could be negotiated. The bill included a significant \$2 billion (6.6%) increase for the National Institutes of Health (NIH), as well as a \$53 million increase for the *Eunice K. Shriver* National Institute of Child Health and Human Development (NICHD). In addition, funding for the National Children's Study Follow-on (ECHO program) was also continued and the Children's Hospital Graduate Medical Education (CHGME) program received a \$30

million increase. The Agency for Healthcare Research and Quality (AHRQ) got an unfortunate \$29 million cut, but was spared more dramatic cuts proposed earlier in the year. Unfortunately, efforts by Democrats to lift the ban on federal funding for gun violence research were unsuccessful.

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

- \$32 billion for the National Institutes of Health (NIH), which is a nearly \$2 billion above the FY 2015 enacted level.
- \$1.33 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 "follow-on" to the National Children's Study.
- \$7.23 billion for the Centers for Disease Control and Prevention (CDC), which is \$300 million above the FY 2015 enacted level.
- \$295 million for the Children's Hospital Graduate Medical Education (CHGME) program. This is a \$30 million increase from the FY 2015 enacted level.

However, these increases in funding resulted in several programs receiving level funding or being cut:

- \$334 million for the Agency for Healthcare Research and Quality (AHRQ), a \$29 million decrease from the FY 2015 enacted level. The House of Representatives had proposed to eliminate the program in its FY 2016 appropriations proposal over the summer.
- \$286 million for the Title X Family Planning program, level funding from FY 2015.
- \$39 million for Title VII primary care funding under the Health Resources and Services Administration (HRSA), level funding from FY 2015.

On Nov. 2, the President signed the Bipartisan Budget Agreement of 2015 (H.R. 1314). The budget agreement, released by congressional leadership and the White House on October 26, was a product of weeks-long negotiations between President Barack Obama, Senate Majority Leader Mitch McConnell (R-Ky.), House Speaker

John Boehner (R-Ohio), and other Democratic leaders. The House passed the budget agreement on Oct. 28 by a 266-167 vote, with Senate passage coming on Oct. 30 by a 64-35 vote. The two-year agreement provides \$33 billion in non-defense discretionary (NDD) sequestration relief for Fiscal Year (FY) 2016, and \$23 billion in FY 2017. In addition to lifting the budget caps, the deal also maintained the parity principle between defense and non-defense discretionary spending, with both spending categories received the same amount of increases. The deal also extends the debt ceiling until March 5, 2017. The increase in budget caps provides Congress the opportunity to increase funding for the National Institutes of Health (NIH), which was included in differing amounts in the House and Senate Labor-Health and Human Services (HHS)-Education appropriations bills that passed their respective chambers in June. The AAP strongly advocated for Congress to raise the budget caps to adequately fund non-defense discretionary programs important to child health. The AAP signed onto a [coalition letter](#) to Congress earlier this fall advocating for increasing the budget caps.

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 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) and the Title X Family Planning program as well as cut \$299 million from the Health Resources and Services Administration (HRSA).

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, and would include \$1.345 billion for the *Eunice K. Shriver* National Institute of Child Health and Human Development (NICHD). The bill would also include a \$5 million boost to the Children's Hospital Graduate Medical Education (CHGME) program. 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 a \$215 million cut from the Centers for Disease Control and Prevention (CDC), a defunding of Affordable Care Act provisions, a \$127 million cut to AHRQ, and a \$29 million cut to the Title X Family Planning program.

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. In February, Senators Brian Schatz (D-HI) and Jerry Moran (R-KS) introduced companion legislation in the Senate.

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 February, the U.S. House of Representatives Transportation and Infrastructure Committee passed the *Aviation, Innovation, Reform, and Reauthorization (AIRR) Act*, legislation that reauthorizes the Federal Aviation Administration (FAA), out of committee. During the markup, a bipartisan amendment was adopted that would begin a process for considering updates to the kits, but does not achieve AAP's goal of requiring FAA to initiate a rulemaking process to update the contents of the emergency medical kits within a reasonable date.

The Academy issued a [press statement](#) following the markup and the introduction of the Senate bill, and will continue to work with both the House and Senate to ensure that children have access to appropriate medication and devices when traveling by plane. The Senate is expected to markup their FAA reauthorization bill in March.

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
- 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](https://twitter.com/AmerAcadPeds), [@AAPPres](https://twitter.com/AAPPres), [@AAPNews](https://twitter.com/AAPNews) and [@healthychildren](https://twitter.com/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

The 25th AAP Legislative Conference will take place **April 3-5, 2016**, in Washington, DC. Join us to learn more about how to become a strong advocate for children's health. For more information and how to register, please visit aap.org/legcon.

In addition, the 2016 Legislative Conference is piloting a new **Pediatric Subspecialty Advocacy Track** of specific legislative and skills building workshops uniquely focused on the interests and needs of pediatric medical and surgical subspecialists.

This year's pilot will feature a group of participants from the AAP Section on Developmental and Behavioral Pediatrics who are joining the conference, but participation in the pilot is open to all pediatric subspecialty fellows and clinicians.

All attendees who participate in the track will attend the events and workshops on the full conference agenda, with the below modifications/additions:

- **A skills-building workshop** on how to educate legislators and their staff about your field of expertise, how to credential yourself as a resource to legislators on issues related to your specialty when there isn't legislation moving on that topic, and how to adapt broader legislative priorities to meet your focus and interest
- **At least one legislative priority workshop** on a subspecialty topic related to an issue impacting specialists and subspecialists (for example,

sustaining a robust and specialized pediatric workforce)

- **Networking opportunities** to meet other pediatricians in other fields and compare advocacy challenges and achievements

To apply for the track:

- 1) register for the conference at www.aap.org/legcon, and
- 2) email with your name, title, subspecialty to LegislativeConference@aap.org and indicate you interest in the Pediatric Subspecialty Advocacy Track.

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