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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](http://www.aap.org/subspecialty).

## Advocacy Training for Pediatric Subspecialists

### 2017 AAP Legislative Conference

The 2017 AAP Legislative Conference will take place April 23 – 25 in Washington, DC. Each year, the conference brings together pediatricians from across the country who share a passion for child health advocacy. Participants attend skills-building workshops, hear from guest speakers, learn about policy priorities impacting children and pediatricians and go to Capitol Hill to urge Congress to support strong child health policies. For the second year, the conference will include a **Pediatric Subspecialty Advocacy Track**. The track will feature specific workshops, advocacy and educational opportunities for specialists, including a skills-building workshop on how to frame specialty expertise to legislators and build relationships with congressional staff, advocacy on legislative priorities especially relevant to pediatric subspecialists and the patients they treat,

networking opportunities and more. For more information on the conference, including the pediatric subspecialty advocacy track, how to register and scholarship opportunities, please visit [aap.org/legcon](http://aap.org/legcon). Please send any questions to [LegislativeConference@aap.org](mailto:LegislativeConference@aap.org).

## 2016 Election Activities



### AAP Blueprint for Children

On September 19, the AAP unveiled its transition plan for the next presidential administration, *[Blueprint for Children: How the Next President Can Build a Foundation for a Healthy Future](#)*. The *Blueprint* includes a comprehensive overview of specific federal policy recommendations to promote healthy children, support secure families, build strong communities, and ensure that the United States is a leading nation for children. In addition, the transition plan offers [agency-by-agency recommendations](#) with detailed actions federal agencies and departments can take to improve the lives of children. As of October 1, the document has been endorsed by 10 leading medical and health organizations. For more information on the *Blueprint* and to read the full document, please visit [aap.org/blueprint](http://aap.org/blueprint). On the same day as the plan's release, the Academy hosted an expert panel discussion in Washington, DC, *Speaking Up for Children: A Conversation About Child Health in the Next Administration*. The archived video from the event can be found [here](#).

### AAP Solicits Responses from Presidential Candidates on Child Health

Earlier this summer, the Academy submitted four questions to the campaigns of Donald Trump and Hillary Clinton to better understand where they stand for children:

1. More than one in five children lives in poverty in this country, and its impacts on children's health can be severe and lifelong. How do you propose to help lift children and families out of poverty?

2. In 2014, there were 2,549 children under age 19 who were killed by guns. How do you plan to protect children from gun violence?
3. More children have health insurance in the United States than ever before. How will you continue to build on this trend and ensure access to affordable, high-quality health care for all children, no matter where in the country they live?
4. Children are 25% of the U.S. population and 100% of the future. How do you propose to provide for the future by investing in children?

Upon receiving them from both campaigns, the AAP published both campaigns' responses to these questions [here](#) on the AAP's [www.aap.org/votekids](http://www.aap.org/votekids) website and have disseminated them out to chapters, members, the public (through social media) and journalists. The responses will be an important part of AAP's get-out-the-vote efforts to provide pediatricians nationwide with better understanding of each candidates' plans and priorities for child health should he/she become president.

### AAP Launches #VoteKids Campaign

Earlier this summer, the AAP launched its #VoteKids campaign, encouraging pediatricians and the public to vote with children in mind and offering all of the tools and resources they need to make that possible. The campaign was announced in an open letter to all AAP members from AAP CEO/Executive Director Karen Remley, MD, MBA, MPH, FAAP, linking to the Academy's election portal [aap.org/votekids](http://aap.org/votekids). Pediatricians can engage in the #VoteKids campaign in many ways, including [writing an op-ed](#) to their local newspaper on why they #VoteKids, sharing [messages](#) on social media, changing their social media profile pictures using the [#VoteKids banner](#) and sharing a Prescription to Vote with their patients' families (in [English](#) and [Spanish](#)). Visit the Academy's one-stop-shop for the 2016 election to [learn](#) where the presidential candidates stand on children's health issues as well as for information on [voter registration](#) and state deadlines. In conjunction with the campaign, the AAP released a [video](#) featuring pediatricians and why they plan to #VoteKids this November. For the latest updates and information from the campaign, please visit [aap.org/votekids](http://aap.org/votekids).

## Access to Care

### Children's Health Insurance Program

The Children's Health Insurance Program (CHIP) is authorized through September 2019, however funding for CHIP is set to expire on Sept. 30, 2017. Although no specific proposals have been introduced in Congress, both members of Congress and child health advocates have begun to think through various options, including ending the program. In March, the Medicaid and CHIP Payment and Access Commission (MACPAC) staff told the AAP's Access to Care Subcommittee that potential options for CHIP reauthorization include the following:

1. Maintaining the current law and letting CHIP funding expire in 2017
2. Extend funding for CHIP
3. Enhance exchange coverage and implement policies to address benefit and affordability concerns
4. Replace CHIP with a bridge plan to smooth the transition between public and private coverage
5. Expand mandatory Medicaid levels

AAP staff has been working in conjunction with partner organizations and congressional committee staff to increase support for small, discrete fixes and reforms to CHIP. These smaller bills would potentially be introduced as marker bills this fall in order to create buy-in amongst committee members when a comprehensive package is developed in the next Congress. These bills include items such as making express lane eligibility permanent, auto-enrollment of newborns, parent mentor programs, incorporation of juvenile justice, eliminate waiting periods, and eliminating premiums in CHIP, among others. The AAP will continue to work with partner organizations to advocate for CHIP ahead of the 115<sup>th</sup> Congress.

### ACE Kids Act

On July 7, the House Energy and Commerce Subcommittee on Health held a hearing on the bipartisan *Advancing Care for Exceptional Kids (ACE Kids) Act of 2015* (H.R. 546/S. 298). The bill, which is pending in the House and Senate, would allow states the option of creating a Medicaid Children's Coordinated Care (MCCC) Program for children with medical complexity. The bill has 219 co-sponsors in the House and 37 in the Senate. The legislation was also included in a draft of the 21<sup>st</sup>

*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.

### Medical Foods Coverage

Each year, Congress must pass a *National Defense Authorization Act* (NDAA) in order to authorize all military programs. AAP has been very active in advocating on behalf of military children and pediatricians, particularly in trying to improve the program's benefits package, services, and access for children. The AAP and our TRICARE for Kids coalition have met with numerous congressional defense staffers on improving the overall program. This year, the Senate bill contains strong language requiring TRICARE to cover medically necessary foods. TRICARE had routinely been denying coverage of these foods, and families report being subject to arduous paperwork to get the foods that they needed.

The AAP has been actively engaging with members of congress to urge them to support the senate provision as the senate and house reconcile the differences between their NDAA bills.

## Academic and Subspecialty Workforce

*Shortages and maldistribution 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, Reps. Chris Collins (R-N.Y.) and Joe Courtney (D-Conn.) introduced the *Ensuring Children's Access to Specialty Care Act of 2015* (H.R. 1859). The legislation currently has 70 cosponsors. An identical Senate companion bill (S. 2782) was introduced on April 11 by Sens. Roy Blunt (R-Mo.) and Jack Reed (D-R.I.). 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 training for subspecialists. On June 7, the AAP and 71 other public health and medical organizations sent a [letter](#) to the bill's sponsors supporting the legislation.

Previously, the Affordable Care Act authorized a Pediatric Subspecialty Loan Repayment Program (PSLRP) 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's authorization expired in 2014 and has not since been reauthorized. However, a reauthorization of the PSLRP at a level of \$12 million per year for five years was included in the *Helping Families in Mental Health Crisis Act* (H.R. 2646), a sweeping mental health package that passed out of the House Energy and Commerce in mid-June. The reauthorization comes after the Senate Appropriations Committee approved language in its Labor-Health and Human Services-Education non-binding appropriations report addressing the need for additional support for pediatric subspecialists and directing that they be eligible for the National Health Service Corps loan repayment program. The AAP will continue to

strongly support both H.R. 1859/S. 2782 and the PSLRP during the lame duck session and in the next Congress.

### Children's Hospital GME Funding and Reauthorization

On Sept. 29, President Obama signed the House- and Senate-passed continuing resolution (CR) that will fund the federal government until Dec. 9, 2016. The CR funds the federal government for the next 10 weeks at Fiscal Year (FY) 2016 levels, with a 0.5 percent cut across all programs in order to comply with the budget caps set forth in the Balanced Budget Act of 2011. Thus, the CR will fund the Children's Hospital Graduate Medical Education (CHGME) at slightly less than the FY 2016 level of \$295 million.

The House and Senate Labor-Health and Human Services (HHS)-Education Subcommittees passed appropriations bills in early June and early July respectively that included \$300 million for the CHGME program, which represents full funding of the program's authorized funding level. This is a \$5 million increase over the President's Fiscal Year (FY) 2017 budget request, which requested mandatory rather than discretionary funding for the program, and the FY 2016 enacted level of \$295 million. Ultimately, this represents a \$30 million increase over the FY 2015 enacted level. 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.

### Defense Department Subspecialty Training

On June 15, the Senate overwhelmingly passed the *National Defense Authorization Act* (NDAA) in an 85-13 vote. Although the bill contains several provisions that the AAP advocated for and are important to children, including TRICARE coverage of medically necessary foods and improved child abuse reporting requirements, the Senate bill also contains language that directs the Secretary of Defense to implement a phased plan to eliminate graduate medical programs of the Department of Defense (DoD) that do not directly support combat readiness, which could ultimately affect pediatric training

programs. It also includes language that directs the Secretary to reduce or eliminate certain medical personnel, including many pediatric subspecialty fellowship programs. The AAP sent a [letter](#) to Sens. John McCain (R-Ariz.) and Jack Reed (D-R.I.), chairman and ranking member of the Senate Armed Services Committee, and Sens. Lindsey Graham (R-S.C.) and Kirsten Gillibrand (D-N.Y.), chairman and ranking member of the Personnel Subcommittee, expressing these concerns and encouraging them to remove these provisions.

The Senate formed a conference committee with the House in order to resolve the differences between its bill and the House bill. The AAP has joined with the American Congress of Obstetricians and Gynecologists (ACOG), as well as other specialty and subspecialty groups, to inform the conferees about the danger of this subspecialty provision, and the detrimental impacts that it, if implemented, would have on pediatric care in the Military Health System. The AAP and ACOG initiated a sign-on [letter](#) that almost 40 other medical groups signed on to. So far a conference report has not been released on the legislation.

### Title VII Training Grant Appropriations

On Sept. 29, President Obama signed the House- and Senate-passed continuing resolution (CR) that will fund the federal government until Dec. 9, 2016. The CR funds the federal government for the next 10 weeks at Fiscal Year (FY) 2016 levels, with a 0.5 percent cut across all programs in order to comply with the budget caps set forth in the Balanced Budget Act of 2011. Thus, the CR will fund the Children's Hospital Graduate Medical Education (CHGME) at slightly less than the FY 2016 level of \$262.5 million.

The House and Senate Appropriations Committees included \$294.2 million and \$297.2 million respectively for Title VII programs in its Fiscal Year (FY) 2017 Labor-Health and Human Services (HHS)-Education appropriations bill, which represents respective \$63 million and \$66 million increases over the President's Fiscal Year (FY) 2017 budget request of \$231.3 million. This would also be an increase of \$32 million and \$35 million respectively over the FY 2016 enacted level of \$262.5 million. 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.

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 Sept. 30, 2015, the Conrad State 30 J-1 visa program expired. Prior to its expiration, 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 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

The Medicaid payment equity (MPE) provision was authorized under the Affordable Care Act (ACA) that increased Medicaid payment rates for primary care services to at least those paid by Medicare. Currently, Medicaid payment rates are about 70% of Medicare payment rates. However, the ACA provision only applied to calendar years 2013 and 2014 and expired at the end of calendar year 2014.

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 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, 2015, 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.

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.

### Merit-Based Incentives Program (MIPS)

Last fall, the Centers for Medicare and Medicaid Services (CMS) issued a request for information (RFI) regarding the implementation of the new Medicare merit-based incentive payment system (MIPS), the promotion of alternative payment models, and incentive payments for participation in eligible alternative payment models. Although much of the RFI has no obvious relation to pediatrics, pediatricians have repeatedly experienced that changes in Medicare are often adopted and applied to Medicaid programs and in private payer arrangements. Thus, even though few children are enrolled in Medicare, the program has the potential to affect the nation's pediatric population. [Comments from the AAP](#) focus on quality and electronic health records. The most immediate way to improve the care for children through MIPS would be through the adoption of child-friendly quality measures since those measures could be applied to non-adult populations. The Academy has endorsed the *Children's Health Insurance Program Reauthorization Act (CHIPRA)* core set of pediatric quality measures and urges CMS to use that set when developing systems under MIPS that could impact children. The AAP also asked that CMS stratify quality measure data reporting not only by race, ethnicity and gender, but also by age. The AAP requested that any requirements pertaining to the use of electronic health records include pediatric specific requirements as current EHR systems are not pediatric friendly, and they miss pediatric functionalities such as weight-based dosing and immunization forecasting.

The final rule was released on April 27. Under the rule ([fact sheet here](#)), the current quality reporting programs in place will be streamlined and simplified into one MIPS. This will reduce the aggregate level of financial penalties physicians otherwise could have faced. Protections are also included so that medical liability cases cannot use Medicare quality program standards and measures as a standard or duty of care. Additionally, incentive payments will be available for physicians who participate in alternative payment models (APMs) and meet certain thresholds and technical support will be provided to help smaller practices participate in alternative payment models or the new fee-for-service incentive program.

Physicians can choose which program they want to participate in if they meet the requirements.

MIPS measures value over four areas: quality, cost, technology use, and practice improvement. Under MIPS the Meaningful Use program will be replaced with a new program called Advancing Care Information which is designed to increase physician flexibility and reduce burdens. The rule proposed two types of alternative payment models (APM): Advanced APMs and Other-Payer Advanced APMs. Providers must meet three requirements for each model to be considered eligible. For the two tracks of APMs, participants are required to use certified EHR technology and provide payment for covered professional services based on quality measures compared to those used in the quality category of MIPS.

In August, AAP leadership met with CMS staff to discuss the various ways in which children are impacted by Medicare policies and the exclusion from pediatrics in recent Medicare-centric programs like MIPS and CPC+, which is a five-year primary care medical home model beginning early next year that serves as a public-private partnership between Medicare, Medicaid, and private insurers to support primary care practices in 14 regions nationwide. The AAP will continue to advocate for the inclusion of pediatric friendly provisions in these programs.

### Pediatric Drugs and Devices

*The Academy is continuing efforts to advocate for policies that promote access to 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.*

### EpiPen Pricing

Beginning this past summer, there has been increased scrutiny over the pricing practices of pharmaceutical company Mylan N.V. for its EpiPen and EpiPen Jr. epinephrine auto-injector devices. In addition to the nearly 600% increase in price of EpiPen products since Mylan acquired the rights to the devices in 2007, EpiPen products on average carry an expiration date of one year post-purchase. In response, the AAP issued a [press statement](#) in August and sent letters on Sept. 7 to both the [Food and Drug Administration](#) (FDA) and [Mylan](#) requesting that they take action on the issue. The letters ask for an explanation of the data that justify the current

expiration dates. Such a short labeled stability window forces parents, first responders, and medical facilities to repeatedly repurchase these devices at great cost, an especially heavy burden for low-income families. More information can be found in this AAP News [article](#). On Oct. 4, FDA [replied](#) to AAP's letter indicating that the agency shared AAP's concerns about these issues. The agency also mentioned that they are prepared to review any supplement that is submitted by Mylan to extend the shelf-life of EpiPen and EpiPen Jr. and will work with any and all firms to review new applications for generic versions of epinephrine auto-injectors so that there are alternative epinephrine auto-injectors in the market.

Shortly thereafter, the U.S. House of Representatives Oversight and Government Reform Committee heard testimony on Sept. 21 from Heather Bresch, CEO of Mylan N.V., and Douglas Throckmorton, MD, FDA's Deputy Director for Regulatory Programs at the agency's Center for Drug Evaluation and Research. The two discussed Mylan's decision to increase the price of EpiPen products numerous times since acquiring rights to the device in 2007 as well as numerous topics related to the future approval and sale of generic epinephrine devices.

In response to a question from the committee's ranking member, Elijah Cummings (D-Md.), concerning Mylan's investments in research and development on epinephrine auto-injectors, Ms. Bresch announced that Mylan would soon be submitting an application to FDA to extend EpiPen's expiration date from 18 months to at least 24 months. The AAP will continue to work to ensure that children who need these life-saving devices are able to access them. On the issue of the high and rising price of drugs, several legislative proposals have been introduced and action on the issue is anticipated in 2017. The AAP is closely monitoring these proposals and evaluating them for their potential impact on children's access to medications.

## 21<sup>st</sup> Century Cures Initiative/Innovations for Healthier Americans

At the end of September, House and Senate leaders issued statements that passing a bicameral medical innovation package was one of their major priorities in the lame duck session of Congress following the elections in early November. Currently, the House and Senate are in negotiations concerning language contained in the

House-passed *21<sup>st</sup> Century Cures Act* (H.R. 6) and the Senate's Innovations for Healthier Americans initiative. Previous discussions of both House and Senate innovations packages have stalled over funding issues. Senate Democrats have promised to put a hold on the Senate package unless mandatory funding for the FDA and NIH is included. Although H.R. 6 passed the House overwhelmingly in July of 2015, the offsets originally used to pay for the legislation were shifted to pay for the *Bipartisan Budget Act of 2015*, which provided funding for the federal government in Fiscal Year (FY) 2016, stalling movement of the bill in the Senate.

One piece of legislation that the Senate Health, Education, Labor, and Pensions (HELP) Committee passed by voice vote last spring, the *Advancing Hope Act* (S. 1878), was signed into law by President Obama on Sept. 30. The legislation would extend the pediatric rare disease priority review voucher program, originally set to expire on Sept. 30, until Dec. 31. The legislation does not make the voucher program permanent, and Congress will likely consider similar legislation as it negotiates an omnibus appropriations package in early December.

On April 6, the HELP Committee held its final of three markups related to its Innovations for Healthier Americans initiative. The committee considered and passed several pieces of legislation to reform the FDA and the National Institutes of Health (NIH). Two bipartisan pieces of legislation, the *Advancing NIH Strategic Planning and Representation in Medical Research Act* (S. 2745) and the *Promoting Biomedical Research and Public Health for Patients Act* (S. 2742), included AAP-supported language that would mandate that the NIH collect, disaggregate and disseminate clinical research data on "relevant age categories," which would include children. The Senate language comes after the AAP-supported *Children Count Act* (H.R. 2436) was included in the *21<sup>st</sup> Century Cures Act* (H.R. 6).

In addition, the AAP, along with the March of Dimes, American Congress of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, successfully advocated for a provision in S. 2745 that would create a federal interagency task force to provide advice and guidance regarding research on safe and effective therapies for pregnant and lactating women.

Also passed in the markup was the AAP-supported Promise for Antibiotics and Therapeutics for Health

(PATH) Act (S. 185). The PATH Act establishes a new limited population antibacterial drug approval pathway for antibiotics to treat serious or life-threatening infections for which there exists an unmet medical need. The program would be crucial for children, whose treatment options are already limited, as antimicrobial resistance grows as a public health issue.

Previously, the HELP Committee held two of three proposed sessions in early 2016 to consider bills as part of its medical innovations efforts. The bills considered in this session included the *Next Generation Researchers Act* (S. 2014/H.R. 3466), an AAP-endorsed [legislation](#) that 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 sessions passed the committee by voice vote.

On July 10, 2015, the 21st Century Cures Act passed the House of Representatives by a vote of 344-77. The legislation included the aforementioned 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](#).

### Pediatric Drug Laws

On June 17, the Alliance for Childhood Cancer, a group of over 30 national patient advocacy and professional medical and scientific organizations dedicated to advocating on behalf of children with cancer, published a [white paper](#) entitled “Advancing Drug Development for Childhood Cancer: Policy Principles to Optimize the Pediatric Drug Laws,” which addresses improving the pediatric drug laws, the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA), to ensure that they maximize the development of cancer and other rare disease therapies for children. The white paper came out of a working group of the Alliance 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 Food and Drug Administration (FDA) bill negotiations to take place later this year and next year.

In late June, FDA released its [status report](#) to Congress on BPCA and PREA. The report, which was mandated to be transmitted to Congress before July 9 of this year under the Food and Drug Administration Safety and Innovation Act (FDASIA), was informed by a public stakeholder meeting held on March 25, 2015 FDA to discuss implementation of BPCA and 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 600 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.

BPCA and PREA, originally signed into law in 2002 and 2003 respectively, were permanently reauthorized in 2012 as part of 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.

### Pediatric Device Consortia Program Appropriations

On April 19, the House Appropriations Committee passed the House Agriculture, Rural Development, Food and Drug Administration (FDA), and Related Agencies appropriations bill. Nonbinding report language accompanying the bill included \$2.5 million for the Pediatric Device Consortia program, a \$500,000 decrease for the Fiscal Year (FY) 2016 enacted level. The counterpart appropriations bill in the Senate, which passed the Senate Appropriations Committee on May 18, contained report language that recommended \$5 million for the program, a \$2 million increase over the FY 2016 enacted level and the fully authorized amount for the program. The President's 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 language is nonbinding and the program has yet to be funded beyond the \$3 million amount.

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.

### Opioids and Children

On Sept. 15 and 16, the Food and Drug Administration (FDA) held a joint meeting of its Anesthetic and Analgesic Drug Products Advisory, Drug Safety and Risk Management Advisory, and Pediatric Advisory Committees to discuss establishing the safety and efficacy of prescription opioid analgesics for pediatric patients. Rohit Sheno, MD, FAAP, a pediatric emergency medicine specialist and a member of AAP's Committee on Drugs, spoke on behalf of the AAP and spoke about the importance of FDA-approved labeling on medications used in children and a balanced approach to treating pain in children and preventing opioid dependence. The FDA meeting was informed by a previously held meeting of FDA's Pediatric Advisory Committee (PAC) in April. Chris Feudtner, MD, PhD, MPH, FAAP, Chair of AAP's Section on Hospice and Palliative Care, presented on behalf of the AAP regarding the treatment of refractory pain in the pediatric population.

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 approving labeling for the use of 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. Prior to Califf's nomination, the FDA announced in early February the development of an opioids [action plan](#) to reexamine the risk-benefit framework currently used to approved opioids for use by the public. Notably, the plan required the FDA to consult with advisory committees of external experts with opportunity for public input before approval of any new pediatric opioid labeling.

In the summer of 2015, 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.

### Drug Shortages

On Nov. 10, 2015, 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, 2015, 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, 2015 to the CEO of Amphastar Pharmaceuticals requesting resolution of the Vitamin K1 shortage as soon as possible. Both drugs remain in shortage. On Aug. 30, FDA employees and other stakeholders, including the AAP, held a discussion concerning the ongoing Aristospan shortage and whether there existed viable alternate sources for hexacetonide solutions. Among possible options discussed included utilizing FDA's Personal Important Policy (PIP), which

allows a physician to suspend FDA's enforcement discretion on a patient-by-patient basis for a short supply of an imported drug.

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 Environmental influences on Child Health Outcomes (ECHO) program and the basic and translational research activities at the National Institutes of Health.*

### National Institutes of Health Appropriations

On Sept. 29, President Obama signed the House- and Senate-passed continuing resolution (CR) that will fund the federal government until Dec. 9, 2016. The CR funds the federal government for the next 10 weeks at Fiscal Year (FY) 2016 levels, with a 0.5 percent cut across all programs in order to comply with the budget caps set forth in the Balanced Budget Act of 2011. Thus, the CR will fund the Children's Hospital Graduate Medical Education (CHGME) at slightly less than the FY 2016 level of \$32.3 billion.

On June 9 and July 14, the Senate and House Appropriations Committees passed their respective Fiscal Year (FY) 2017 Labor-Health and Human Services (HHS)-Education, and Related Agencies appropriations bills. The Senate Labor-HHS bill represents the first committee-passed bill of its kind in seven years, and provided \$34.1 billion for the National Institutes of Health (NIH), an increase of \$2 billion over the FY 2016 enacted level. The bill also includes \$1.396 billion for the *Eunice K. Shriver* National Institute of Child Health and Human Development (NICHD), a \$57.5 million increase over the FY 2016 level. The House Labor-HHS bill included slightly less than the Senate bill in both categories, with \$33.3 billion and \$1.373 billion going to the NIH and NICHD respectively. Both Senate and House bills provided \$165 million for the Environmental influences on Child Health

Outcomes (ECHO) program and \$300 million for the Precision Medicine Initiative, a \$100 million increase of FY 2016.

The President's 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 was driven by \$1.8 billion in mandatory money for temporary projects and represented 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 ECHO program. The AAP is currently supporting a funding level of \$34.5 billion for the NIH for FY 2017.

### Precision Medicine Initiative

The House and Senate Labor-Health and Human Services (HHS)-Education appropriations bills, which were passed by the House and Senate Appropriations committees earlier this summer, each included \$300 million for the Precision Medicine Initiative (PMI). This represents a \$100 million increase over the Fiscal Year (FY) 2016 levels. Previously, the President's 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 April 11, National Institutes of Health (NIH) Director Francis Collins announced that Eric Dishman was selected as director of the PMI cohort program. Dishman will lead the agency's effort to build the million-person longitudinal cohort study and was instrumental in helping to design the program last year as part of the PMI Working Group. Prior to being named PMI cohort director, Dishman served as Vice President and Intel Fellow of Intel Corporation's Health and Life Sciences Group, where he was responsible for global strategy, platform development, research, and care coordination technologies, and developed numerous platforms and technologies to measure the effects of a variety of illnesses and diseases from movement disorders to cancer.

On Sept. 17, 2015, 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 the 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."

### Environmental influences on Child Health Outcomes (ECHO)

On Sept. 21, the National Institutes of Health (NIH) announced awards totaling \$157 million to launch the seven-year Environmental influences on Child Health Outcomes (ECHO) program. The awards were given in response to several FOAs published earlier this year for the pediatric cohorts, and clinical sites for the IDEa States Clinical Pediatric Trials Network, which aims to provide medically underserved and rural populations with access to clinical trials.

The House and Senate Labor-Health and Human Services (HHS)-Education appropriations bills, which were passed by the House and Senate Appropriations committees earlier this summer, included \$165 million for ECHO program. This represents level funding from Fiscal Years (FYs) 2015 and 2016. In addition, the House Labor-HHS appropriations bill included report language urging the NIH to ensure that ECHO grantees and other ECHO-related activities collect data on the impacts of the environment on children's health as well as requesting a report to Congress on the establishment of a federal advisory committee to oversee the project.

On April 25, NIH Director Francis Collins, MD, PhD announced that the agency selected Matthew Gillman, MD as program director of the ECHO program, the follow-on to the now-shuttered National Children's Study. Dr. Gillman has experience in epidemiology, pediatrics, and internal medicine, and has been affiliated with a number of large research studies including Project Viva, the Framingham Heart Study, and the aforementioned National Children's Study. Dr. Gillman

also serves as a member of the U.S. Preventive Services Task Force.

## Inclusion of Children in NIH-Funded Research

On April 27, [49 representatives](#) and [26 senators](#) sent bipartisan letters to National Institutes of Health (NIH) Director Francis Collins, MD, PhD, requesting that the agency begin collecting data on the inclusion of children in NIH studies. Although the NIH has had a formal policy since 1998 requiring the appropriate inclusion of children in its research, the agency has failed to track and publish data on the numbers of children actually enrolled. Such data is needed to inform NIH officials and the public about possible gaps in pediatric research. A response to the letter from the NIH indicated that the agency would initiate a pilot project to investigate the possibility of cataloguing deidentified genetic data to inform a wide variety of inquiries in addition to the ages of trial participants. Further details on this pilot program have not yet been released.

On July 10, 2015, 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.), which 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. 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.

On April 6, the HELP Committee held its final of three markups related to its Innovations for Healthier Americans initiative. The committee considered and passed several pieces of legislation to reform the FDA and the National Institutes of Health (NIH). Two bipartisan pieces of legislation, the *Advancing NIH Strategic Planning and Representation in Medical Research Act* (S. 2745) and the *Promoting Biomedical Research and Public Health for Patients Act* (S. 2742), included AAP-supported language that would mandate

that the NIH collect, disaggregate and disseminate clinical research data on “relevant age categories,” which would include children.

Report language accompanying the House and Senate FY 2017 Labor-Health and Human Services (HHS)-Education appropriations bills, which were passed by the House and Senate Appropriations Committees respectively earlier this summer, 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.

## Fetal Tissue Research

The federal government and Congress have launched multiple investigations into fetal tissue procurement and research. The investigations were sparked by a series of videos released in July 2015 by David Daleidan, the CEO of the anti-abortion group Center for Medical Progress.

Currently, under federal law the National Institutes of Health (NIH) may provide funding for research using fetal tissue and may allow grant recipients to receive compensation for the costs associated with collecting and shipping fetal tissue, although fetal tissue providers are strictly barred from receiving profit from such transactions.

The AAP has been actively engaging with multiple stakeholders to respond to investigations into fetal tissue research. In response to an initial hearing of the Select Investigative Panel on Infant Lives, which was formed on Oct. 7, 2015, the AAP sent a [letter](#) to Chairwoman Marsha Blackburn (R-Tenn.) and Panel Ranking Member Janice Schakowsky (D-Ill.) strongly supporting continued federal funding for fetal tissue research and citing numerous examples of vaccines produced from cell lines derived from fetal tissue including vaccines for chicken pox, polio, rabies, and rubella. The letter was cited in a March 2 Washington Post article about the hearing. On March 30, Rep. Blackburn sent a reply to the AAP’s letter asking clarifying questions about the AAP’s position on fetal tissue research and why the research is necessary for the development of effective therapies. The AAP replied to the letter in late April providing further information on how fetal tissue research has led to the development of several vaccines, including research currently underway that will be used to develop a vaccine for the Ebola and Zika viruses, and advances related to fetal tissue research.

## Cancer “Moonshot” Initiative

On Sept. 7, the National Cancer Advisory Board approved a draft [report](#) developed by the Cancer “Moonshot” Blue Ribbon Panel and its seven working groups that describes a series of recommendations for accelerating cancer research to achieve “a decade’s worth of cancer research progress in five years” and to increase access to promising clinical developments for those currently diagnosed with cancer. The panel has been developing the report since the announcement of the moonshot initiative in January in an effort to assess the state of science in specific areas of cancer treatment development and to identify research opportunities that could benefit the most from the moonshot initiative. Among the ten recommendations outlined in the report, the panel had several recommendations related to children including developing a cancer immunotherapy clinical trials network, developing preclinical models improve understanding of fusion oncoproteins in pediatric cancer, and developing three-dimensional human tumor atlases to improve understanding of various cancers. The report has been forwarded to Vice President Joe Biden’s Moonshot Task Force for consideration.

President Obama’s FY 2017 budget request, released Feb. 9, included \$1 billion for the cancer moonshot initiative. The funds would be split between several agencies, with \$195 million proposed to go to new cancer activities at the National Institutes of Health (NIH) immediately, with \$755 million in additional mandatory funds for cancer-related research activities at the NIH and the Food and Drug Administration (FDA) the following fiscal year. \$680 million of the total funds would specifically go to the National Cancer Institute at the NIH. The House and Senate Labor-Health and Human Services (HHS)-Education appropriations bills did not include specific entries for the moonshot initiative.

## 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 programs that are particularly vulnerable to cuts as a result of the strict discretionary budget caps set forth in the Budget Control Act of 2011, which continue to constrain federal funding on non-entitlement spending.*

## Congressional Action on Appropriations

On Sept. 29, President Obama signed the House and Senate passed Continuing Resolution (CR) that will fund the federal government until Dec. 9, 2016. The CR funds

the federal government for the next 10 weeks at Fiscal Year (FY) 2016 levels, with a 0.5 percent cut across all programs in order to comply with the budget caps set forth in the Balanced Budget Act of 2011. The CR also included \$1.1 billion in funding to respond to the Zika virus, \$500 million for flood damaged areas including Louisiana, West Virginia, and Maryland, and the full-year FY 2017 Military Construction-Veterans Affairs appropriations bill. Importantly, the Zika package does not contain any restrictions on funding for Planned Parenthood or lift restrictions on pesticide spraying.

Prior to passage, the AAP sent a [letter](#) to Congressional leadership thanking them for including the Zika funding in the CR but also encouraging them to include assistance for the residents of Flint, Michigan. In fact, Senate Democrats had held up passage of the bill to protest the absence of funds for addressing lead poisoning in Flint, but the House leadership agreed to allow a vote in the House on an amendment to the Water Resource Development Act (WRDA) to include \$170 million in assistance for Flint. With this agreement in hand, and thus with an assurance that federal assistance for Flint would be contained in the WRDA bill, Senate Democrats lifted their objection to the CR and the bill passed by a 72-26 margin. The House also passed the CR by a 342-85 vote.

As mentioned above, the House did adopt an amendment providing assistance to Flint and passed the WRDA bill 399-25. The Senate version of WRDA was passed earlier this year and already included \$220 million in assistance for Flint. Because of this difference in dollar amount, and other differences between the two bills, there will need to be a conference report to resolve the differences and final passage will take place in the lame-duck session after Congress returns. In the debate on the Senate floor prior to the vote on the CR, Sens. Barbara Boxer (D-Calif.) and James Inhofe (R-Okla.) declared that they had received assurances that the final conference report will contain the larger Senate amount of \$220 million for Flint.

With these votes completed, Congress will adjourn until after the November elections, likely returning on Nov. 14, when they will have to complete work on funding the rest of the FY 2017 fiscal year and vote on the conference report for the WRDA bill.

On June 9, the Senate Appropriations Committee passed its Fiscal Year (FY) 2017 Labor, Health and Human Services (HHS), Education, and Related Agencies appropriations bills, which is the first committee-passed Labor-HHS appropriations bill in seven years. The bill provides \$161.9 billion in total funding for labor-HHS programs, a \$270 million cut from FY 2016.

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

- \$34.1 billion for the National Institutes of Health (NIH), an increase of \$2 billion over the FY 2016 enacted level.
- \$165 million for a “follow-on” to the National Children’s Study, also known as the Environmental influences on Child Health Outcomes (ECHO).
- \$300 million for the Precision Medicine Initiative, a \$100 million increase over the FY 2016 enacted level.
- \$1.396 billion for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), a \$57.5 million increase from the FY 2016 enacted level.
- \$300 million for the Children’s Hospital Graduate Medical Education (CHGME) program, a \$5 million increase over the FY 2016 enacted level.

However, several programs were level-funded or cut:

- \$324 million for the Agency for Healthcare Research and Quality (AHRQ), a \$10 million decrease from the FY 2016 enacted level.
- \$7.115 billion for the Centers for Disease Control and Prevention (CDC), which is \$118 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 bill provided solid funding for many programs affecting child health, it cut \$2 million from the Health Resources and Services Administration (HRSA)’s universal newborn screen program and did not include

additional funds for the Centers for Disease Control and Prevention (CDC)'s lead poisoning prevention program. The bill must now be considered by the full Senate.

On July 7, the House Labor-HHS Appropriations Subcommittee passed its own FY 2017 appropriations bill, which included \$161.6 billion in total funding, a \$569 million cut from the FY 2016 enacted level.

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

- \$33.3 billion for the National Institutes of Health (NIH), an increase of \$1.25 billion over the FY 2016 enacted level.
- \$165 million for a “follow-on” to the National Children’s Study, also known as the Environmental influences on Child Health Outcomes (ECHO).
- \$300 million for the Precision Medicine Initiative, a \$100 million increase over the FY 2016 enacted level.
- \$1.373 billion for the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), a \$34.5 million increase from the FY 2016 enacted level.
- \$300 million for the Children’s Hospital Graduate Medical Education (CHGME) program, a \$5 million increase over the FY 2016 enacted level.
- \$7.8 billion for the Centers for Disease Control and Prevention (CDC), which is \$605 million below the FY 2016 enacted level.

However, several programs were level-funded or cut:

- \$280 million for the Agency for Healthcare Research and Quality (AHRQ), a \$54 million decrease from the FY 2016 enacted level.
- \$6.1 billion for the Health Resources and Services Administration (HRSA), a \$218 million cut from the FY 2016 enacted level.
- Elimination of the Title X Family Planning Program, which provides health services to millions of women across the country.

The bill will now move to be considered by the full House, potentially later this month before summer recess and the party conventions.

### 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), a \$14 million increase to the Title X family planning program, and \$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.

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

Earlier this year, the Obama Administration 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.

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 this past summer, Congress passed the *Comprehensive Addiction and Recovery Act* (S. 524), which was signed into law by President Obama on July 22. 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, Michigan, where dangerously high lead levels have led to a curb, 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.

## Emergency Medical Services for Children

### Federal Aviation Administration Emergency Medical Kits

In July, before the authorization of the Federal Aviation Administration (FAA) lapsed and Congress left for summer recess, both the House and Senate voted to reauthorize the FAA through September 2017. Unfortunately, the short-term extension of FAA does not include a requirement to review and update the

contents of Emergency Medical Kits (EMKs) on airplanes to ensure their appropriateness for children. Positive language was included, however, in the Senate's Transportation Appropriations report that strongly encourages the FAA to examine current EMK regulations.

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.

In July 2015, 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 came 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 will continue working with the House and Senate to require FAA to update the contents of the kits, whether in an appropriations package or as part of the long term FAA reauthorization package that will be considered next year.

## Protecting Patient Access to Emergency Medications Act

Recently, the DEA began notifying emergency medical services (EMS) agencies that it believed they were in violation of the Controlled Substances Act by allowing EMS providers to receive, store, transport and administer controlled substances to patients pursuant to standing orders issued by the EMS agency's medical director. In the absence of a change in law or change in DEA interpretation, an individual patient prescription would have to be provided by a properly licensed and credentialed medical provider prior to dispensing a controlled substance.

AAP is [supporting](#) the bipartisan *Protecting Patient Access to Emergency Medications Act of 2016* (H.R. 4365/S. 2932) introduced by Reps. Richard Hudson (R-N.C.) and G.K. Butterfield (D-N.C.) and Sen. Bill Cassidy (R-La.) that would amend the Controlled Substances Act to clarify that EMS providers can administer controlled substances pursuant to a standing order issued by one or more medical directors of a registrant EMS agency.

On Sept. 21, the full House Energy and Commerce Committee voted unanimously to advance the *Protecting Patient Access to Emergency Medications Act of 2016* (H.R. 4365). The week prior, the bill was passed unanimously by the House Energy and Commerce Committee's Subcommittee on Health. Following the bill's passage through subcommittee, the Academy issued a [statement](#) thanking its sponsors Rep. Richard Hudson (R-N.C.) and Rep. G.K. Butterfield (D-N.C.) for their work on the issue. The AAP worked to secure senate passage of the bill before the November elections but time on the congressional calendar ran out. We anticipate further consideration of the bill in the lame duck session.

## CMS Finalizes Emergency Preparedness Rule

In September, the Centers for Medicare & Medicaid Services (CMS) finalized a [rule](#) establishing emergency preparedness requirements for certain healthcare providers participating in Medicare and Medicaid. The rule applies to most health care facilities, but not private physician offices. AAP had previously submitted [comments](#) on the proposed rule released in 2013, which were highlighted in a New York Times [article](#). The finalized requirements will require certain participating providers to plan for disasters and coordinate with

federal, state, tribal, regional and local emergency preparedness systems to ensure that facilities are adequately prepared to meet the needs of their patients during disasters and emergency situations. Specifically, the rule requires providers to meet the four following best practice standards:

- 1. Emergency plan:** Based on a risk assessment, develop an emergency plan using an all-hazards approach focusing on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters specific to the location of a provider or supplier.
- 2. Policies and procedures:** Develop and implement policies and procedures based on the plan and risk assessment.
- 3. Communication plan:** Develop and maintain a communication plan that complies with both Federal and State law. Patient care must be well-coordinated within the facility, across health care providers, and with State and local public health departments and emergency systems.
- 4. Training and testing program:** Develop and maintain training and testing programs, including initial and annual trainings, and conduct drills and exercises or participate in an actual incident that tests the plan.

Unfortunately, the rule falls short on the recommendations for pediatric preparedness that the AAP had urged for. However, the AAP has been advocating for pediatric-specific provisions in the revisions to the capabilities and performance measures for the Hospital Preparedness Program run by the Assistant Secretary for Preparedness and Response.

## 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](mailto: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](http://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, Helene Holstein, at [hholstein@aap.org](mailto:hholstein@aap.org).

## AAP 7 Great Achievements Campaign

In April 2015 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](http://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](http://AAP.org/7Achievements).

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