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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 which 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 suitable 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.

Physician Payment

Appropriate payment for services provided by pediatricians is essential to ensuring that all children have access to care. The Academy successfully advocated for increased Medicaid payment for pediatricians in the Affordable Care Act, and the AAP has advocated for the broadest possible applicability of this increase to pediatric subspecialists.

Medicaid Payment Increase

Pediatricians, including pediatric subspecialists, in a number of states are seeing increased Medicaid payments for certain primary care services, and physicians in additional states can expect increases soon.

The final regulation implementing the provision provides federal funding for an increase in Medicaid payment rates to at least Medicare rates for certain evaluation and management (E&M) and vaccine administration codes billed by qualifying providers in calendar years 2013 and 2014.

E&M codes 99201–99499 and vaccine administration codes 90460, 90461, 90471, 90472, 90473, and 90474 must be paid at rates that are at least equivalent to the Medicare rates for those services, as long as the state’s Medicaid program currently pays for the codes. The codes include primary care E&M codes not paid by Medicare, and the increase applies in fee-for-service as well as in managed care arrangements. The regulation also raises regional maximum vaccine administration fees in the Vaccines for Children (VFC) program.

The AAP maintains a chart detailing the state-by-state implementation of the payment increase. Many states have been slow to begin paying physicians, but eligible providers that signed up by the state deadline should receive retroactive payment back to January 1, 2013.

While progress is encouraging, the Academy recognizes that there still is work to do, especially in the Medicaid managed care context, to ensure that all eligible pediatricians in all states receive their increased Medicaid payments as soon as possible. The Academy continues to work at all levels to advocate for a more prompt implementation of the Medicaid payment increase.

The payment increase expires on December 31, 2014 and the Academy is currently working with congressional leaders to advocate for its extension.

Subspecialty Eligibility for Payment Increase

The AAP advocated strongly that the Medicaid payment increase apply to all pediatric subspecialists. Centers for Medicare and Medicaid Services (CMS) rules and accompanying guidance have been confusing and contradictory. As a result, states have variably drafted the forms that allow physicians to self-attest to eligibility for the increase.

Most states require subspecialty pediatricians to self-attest to (1) practicing in a subspecialty recognized by the American Board of Pediatrics, and (2) having either current board certification in that subspecialty, or having reached the 60-percent test (i.e., in prior year, 60 percent of Medicaid codes billed were eligible for the increase). Some states, however, have required pediatricians to self-attest to practicing primary care, while others have allowed any pediatrician that meets the 60-percent test to self-attest. The AAP recommends that all pediatricians check with their state Medicaid agency to determine eligibility.
Academic and Subspecialty Workforce

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

Pediatric Subspecialty Loan Repayment Program

The final fiscal year 2014 omnibus appropriations bill, signed into law on Jan. 17, 2014, included no new funding for programs authorized in the Affordable Care Act, leaving the Pediatric Subspecialty Loan Repayment Program unfunded for FY2014. The AAP will continue to pursue funding for the program in FY2015.

While the program will go unfunded again this year, 2013 marked the first time since the program’s creation that funding for the program was included in a committee-passed congressional appropriations bill. The Senate Appropriations Committee included $5 million for the program in their Labor-HHS-Education spending bill passed last July.

If ultimately funded at the initial $5 million level, as proposed in the President’ budget, the Pediatric Subspecialty Loan Repayment Program would be able to accommodate 64 recipients for two years. The President has included the program in his proposed budget each of the last two years.

The program, Section 775 of the Public Health Service Act (PHSA), was initially authorized by the Affordable Care Act. It is part of Title VII of the PHSA, which provides workforce funding for health professions. The Title VII programs are administered by the Health Resources and Services Administration (HRSA). The law allows 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.

In addition to advocating for its creation, the AAP has actively led an effort, joined by other pediatric subspecialty groups, to advocate for funding of the program.

A bill has also been introduced in the House to reauthorize the program through FY2018. H.R.1827, the Pediatric Subspecialty and Mental Health Workforce Reauthorization Act of 2013, was introduced on May 6, 2013 by Rep. Joe Courtney (D-Conn.). The bill currently has 33 co-sponsors.

Children’s Hospital GME Funding and Reauthorization

The omnibus appropriations bill signed into law Jan. 17 provides $265 million in funding for the Children’s Hospital Graduate Medical Education program, a nearly 6% increase from the FY2013 post-sequestration level of $251 million.

On Nov. 12, 2013, the Senate passed a bill to renew the authorization for the Children’s Hospital Graduate Medical Education (CHGME) program, which has lapsed. The CHGME Support Reauthorization Act of 2013 (S. 1557) had been introduced on Sept. 27 after several months of negotiation. The legislation had been stalled in the Senate amid concerns about the exclusion of freestanding psychiatric children’s hospitals from receiving funding through the bill.

The new legislation would allow the Secretary of Health and Human Services (HHS) to extend eligibility to certain institutions that were previously unable to benefit from the funding. The legislation would reauthorize the CHGME program at nearly $300 million per year for five years. The House of Representatives passed its own CHGME reauthorization legislation on Feb. 4 by a vote of 352-50 that would continue the program through FY2017 at $317.5 million per year.

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.

Next, the bill will move back to the House of Representatives where members will have the option of accepting the Senate’s compromise legislation and moving the bill on to the President for his signature. The AAP and other organizations including the Children’s Hospital Association are urging swift passage of the
Senate bill in the House. A copy of the AAP endorsement letter for the Senate bill can be found here.

**Title VII Training Grant Appropriations**
The omnibus spending bill signed by the President on Jan. 17, 2014 included $245 million in Title VII funding in this round of appropriations compared to the $220 million in funding after sequestration last fiscal year. 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 the Title VII workforce programs, of which the Pediatric Subspecialty Loan Repayment Program is a part.

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.

**Health Care Reform Implementation**
*Open enrollment in the Affordable Care Act (ACA) began on Oct. 1 and the Academy is working to help pediatricians discuss healthcare options with families.*

*The AAP also continues to work with the administration and the states to advocate for the needs of children in the implementation of the law. The Academy is also working to reauthorize the Children’s Health Insurance Program (CHIP).*

**AAP Outreach and Resources on Open Enrollment**
Starting on Oct. 1, 2013, as part of the implementation of the Affordable Care Act (ACA), a six-month open enrollment period began for individuals and families to sign up for health insurance in the new marketplaces (formerly known as Exchanges) in every state. The marketplaces will allow millions of people to compare options and choose which type of insurance plan will work best for their family. Public health insurance programs like Medicaid and the Children’s Health Insurance Program are still available before, during, and after open enrollment, and a single, streamlined application will make it easier for people to find out which plan will best meet their needs.

The AAP developed [state-specific resources](#) to help pediatricians and parents understand how to navigate the new health insurance marketplace and find the most appropriate health insurance plan for their families and employees. On [www.aap.org/ACAmarketplace](http://www.aap.org/ACAmarketplace), an interactive map contains state-specific, [printable flyers](#) for pediatricians to share with parents about what open enrollment means for them and how to navigate the marketplace.

On [www.healthychildren.org/ACAmarketplace](http://www.healthychildren.org/ACAmarketplace), parents will find even more information about open enrollment, including basic information about health insurance.

The ACA also provides health insurance coverage options for small business owners, including many pediatric practices. The AAP developed a [fact sheet](#) to help pediatrician small business owners understand their options for covering their employees. State-specific versions and additional resources can also be found on [www.aap.org/ACAmarketplace](http://www.aap.org/ACAmarketplace).

AAP members interested in talking to the media about the impact of ACA implementation on their patients and practices can also reference these media [speaking points](#) (login required).

**Network Adequacy**
The AAP is closely watching what some see as a trend toward health insurers offering narrow network plans on the federal and state exchanges. Whether consumers will have adequate networks through which they can easily access providers depends on how conscientious state regulators are about enforcing the network adequacy standards set out in ACA regulations. These standards and issues surrounding their implementation by states is discussed in a [brief](#) prepared for the Robert Wood Johnson Foundation’s State Health Reform Assistance Network.

It is up to state regulators to assure that the insurers they oversee offer networks that provide reasonable access to a sufficient number of primary care and specialty care physicians, facilities, and other providers. Further, benefits must be delivered in a timely fashion within a
reasonable distance from the insured population. Networks that cannot fulfill these requirements should not be considered adequate by regulators.

While consumers with more modest incomes may be willing to trade lower premiums for a narrower choice of providers, if the networks are too narrow it may force consumers to access services outside of the network, with additional cost sharing. Additionally, if certain secondary or tertiary providers are excluded from the network to discourage those with chronic diseases from enrolling in a plan, the plan offering the network may not only be in violation of network adequacy standards, but also of the Affordable Care Act’s prohibition against discriminatory benefit design.

**Children’s Health Insurance Program**

Although the Affordable Care Act (ACA) authorized the Children’s Health Insurance Program (CHIP) through 2019, the program is only funded through September 2015. In order to keep CHIP strong for children, the AAP is urging Congress to fully fund the program through at least 2019. Since the program was first enacted in 1997, CHIP has grown to finance health coverage for nearly 8 million children in families with incomes too high to qualify for Medicaid but whose employers may not pay for health coverage for dependents.

In conjunction with the five-year anniversary of the Children’s Health Insurance Program Reauthorization Act (CHIPRA) on Feb. 4, the AAP is undertaking a robust advocacy effort to ensure that the program is kept strong to protect children’s health. These efforts included dissemination of a Jan. 27 revised policy statement on CHIP and social media outreach through Feb. 4 of CHIP-related facts and recommendations at #celebrateCHIP.

**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 last year, and continues to work to ameliorate shortages of important drugs for children.*

**Drug Shortages**

The AAP continues to receive regular reports about drug and vaccine shortages. AAP Washington and Elk Grove Village staff are in regular communication with the Food and Drug Administration (FDA) to alert them about these shortages. At every opportunity the AAP urges the FDA to not only address the immediate shortage but also to find a long-term solution to drug shortages.

**FDA Action on Reduce Drug Shortages**

On Oct. 31, 2013 the Food and Drug Administration (FDA) announced two steps toward addressing drug shortages and their impact on the nation’s public health.

First, the FDA provided Congress with strategic plan to enhance the agency’s efforts to prevent and mitigate drug shortages. This plan, required under *The Food and Drug Administration Safety and Innovation Act* (FDASIA), was developed by the FDA Drug Shortages Task Force, a panel of experts from across the agency, and contains two overarching goals: the first is to improve the agency’s response to imminent or existing shortages; and the second is to develop longer term approaches for addressing the underlying causes of drug shortages. The plan also highlights opportunities for drug manufacturers and others to prevent drug shortages by promoting and sustaining quality manufacturing. The AAP has worked closely with the FDA on the issue of drug shortages, and submitted comments to the task force to aid in the development of this plan earlier this year.

In addition to the Drug Shortages Strategic Plan, the agency also issued a proposed rule requiring all manufacturers of certain medically important prescription drugs to notify the FDA of a permanent discontinuance or a temporary interruption of manufacturing likely to disrupt their supply. The rule also extends this requirement to manufacturers of medically important biologic products.

**GAO Report on Drug Shortages**

In accordance with a provision in the *Food and Drug Administration Safety and Innovation Act* (FDASIA), the Government Accountability Office (GAO) is currently preparing a report examining the causes of drug shortages and formulating recommendations to prevent or alleviate shortages. On Aug. 16, 2013 the GAO hosted a conference call with AAP leadership to discuss drug shortages. During the call, the AAP discussed with the GAO possible causes of drug shortages, common drugs in shortage, the challenges drug shortages present to clinical pediatric practice, ways pediatricians cope with drug shortages, and recommendations to the FDA to ameliorate or eliminate shortages altogether.
Daunorubicin

In Aug. 2013, Teva Pharmaceuticals announced that it had temporarily ceased production of the drug daunorubicin. Daunorubicin is a chemotherapeutic agent and is the primary treatment for children with acute myeloid leukemia (AML). Teva was the last active supplier of the drug. Pediatric hematologists-oncologists have reported that their institutions were unable to get daunorubicin from their suppliers and some institutions had very little supply left. In October, the FDA reported that Teva was releasing some supply of the drug directly, but the drug is still in shortage and it is unclear when it will be back in fully supply. The AAP and the American Society of Pediatric Hematology Oncology (ASPHO) sent a joint letter to Teva and the FDA asking for more information and urging production of the drug to begin as soon as possible. In addition, the co-chairs of the House Childhood Cancer Caucus, Reps. Chris Van Hollen (D-Md.) and Mike McCaul (R-Texas), sent letters to FDA and Teva inquiring about the shortage. In December, Teva replied to the AAP-ASPHO inquiry stating that the drug would be backordered through the first quarter of 2014.

Reporting a Drug Shortage

Pediatricians are encouraged to report drug shortages directly to FDA. To report a shortage of a drug product by email, please use drugshortages@fda.hhs.gov or to make a report by phone, please call (888) INFOFDA or (888) 463-6332. To report a shortage of a biological product (including blood, vaccines, tissue, allergens) by e-mail, please use CBERshortages@fda.hhs.gov or call (301) 827-4239.

Pediatricians may also wish to report a shortage to ASHP by completing this form: http://www.ashp.org/DrugShortages/Report/. ASHP maintains an up-to-date website with detailed information about ongoing and past shortages, alternative therapies, and information about when products are expected to be available.

Pharmaceutical Compounding

In the wake of the fungal meningitis outbreak caused by contaminated steroid injections, which sickened nearly 760 and caused the deaths of over 60 people in more than 20 states, Congress has been working to advance legislation giving the FDA authority over certain types of pharmaceutical compounding. On Sept. 28, 2013, the House of Representatives passed H.R. 3204, the Drug Quality and Security Act (DQSA), a bipartisan bill that would give the Food and Drug Administration more authority to regulate companies that compound sterile drugs. The legislation, which comes after months of negotiations to establish a bipartisan, bicameral solution to prevent a future outbreak like the fungal meningitis contamination caused by the New England Compounding Center, will now go to the Senate for final passage.

The legislation, introduced on Sept. 25, 2013 allows compounders who compound large volumes of sterile drugs without individual prescriptions to register as “outsourcing facilities”. Those compounders who choose to remain traditional pharmacies will continue to be regulated primarily by state boards of pharmacy, as they are in current law. Outsourcing facilities would be subject to oversight by the U.S. Food and Drug Administration (FDA) including registration and fee requirements, inspections, and adverse event reporting. Although the choice to be subject to stronger FDA oversight is voluntary, congressional sponsors hope that purchases will seek to buy compounded products only from those facilities who choose to become “outsourcing facilities.”

The AAP, along with the Children’s Hospital Association, has been working closely with congressional staff during negotiations to ensure the legislation strikes the appropriate balance between safety and access to compounded products for children.

BPCA and PREA Implementation

On July 9, 2012, President Obama signed into law legislation to permanently reauthorize the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA). These reauthorizations were included as part of the Food and Drug Administration Safety and Innovation Act (FDASIA, Public Law 112-144). The bill includes hard-fought pediatric provisions, negotiated after diligent advocacy by the Academy, including: encouraging earlier pediatric study planning by drug manufacturers to ensure expedited pediatric drug information to patients and providers; giving the FDA new authority to ensure PREA requirements are met on time; and increasing FDA expertise in neonatology and advancing drug studies in neonates.

The reauthorizations were championed in the House by Anna Eshoo (D-Calif.), Mike Rogers (R-Mich.), and Ed Markey (D-Ma.). The Senate champions were Jack Reed
Until BPCA and PREA were passed in 1997 and 2003 respectively, most medicines used to treat children had been tested for safety and efficacy only in adults. Under PREA, drug companies have been required to study adult drug indications in children, and the incentive under BPCA has been a successful mechanism to encourage drug companies to conduct pediatric studies requested by the FDA—especially for off-label drug uses—in return for an additional six months of marketing exclusivity. BPCA and PREA have been enormously successful laws and have recently resulted in 500 drug labels revised with new pediatric information. The AAP, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF), and the FDA recently issued a press release celebrating the milestone.

By making BPCA and PREA permanent, the law ensures that children will have a permanent seat at the table for drug research and development. The laws previously needed to be reauthorized every five years and were scheduled to expire on Sept. 30, 2012.

The bill also reauthorizes for five years an important BPCA program at the National Institutes of Health (NIH) that provides for pediatric studies of older drugs that no longer qualify for pediatric exclusivity, which can include some of the most commonly used drugs in children. In addition, the bill preserves the role of two FDA advisory committees in monitoring pediatric drug safety and advising the FDA on pediatric issues.

There are several publically-available documents that summarize and explain the final pediatrics laws. They can be found here. Among those documents is an implementation timeline. The AAP Washington Office is working closely with FDA and our congressional champions on the implementation of the laws.

**PREA Non-Compliance Letters**

In Aug. 2013, the FDA published the first PREA non-compliance letters and the sponsors’ responses. These letters mark an important step in the implementation of the pediatric drug testing provisions of the FDASIA. This provision requires FDA to send non-compliance letters to drug sponsors and publish the letters on the web if the sponsor has failed to submit deferred pediatric studies by the final due date agreed to with FDA and has failed to seek or obtain a deferral extension for good cause.

The provision was necessary because too many PREA commitments were being missed or submitted late and the FDA previously lacked any enforcement tools to ensure companies complied with their pediatric requirements. AAP staff will continue to work with the FDA to ensure that companies come into compliance with their PREA requirements.

**Pediatric Rare Diseases**

On Jan. 6-8, 2014, the FDA hosted a public meeting to discuss ways to encourage and accelerate the development of new therapies. The meeting, required by a provision in Food and Drug Safety and Innovation Act (FDASIA), featured two days of discussion on the development of drug and biological products and one day discussion on the development of medical devices. Within 180 days of the meeting, the FDA must issue a report that includes a strategic plan for encouraging and accelerating the development of new therapies for treating pediatric rare diseases.

FDASIA also created a demonstration project that provides priority review vouchers to companies that develop a drug for a pediatric rare disease. The voucher would be redeemed by the company for a subsequent application or could be sold to another company. There is a cap of three vouchers that can be issued by the FDA. Priority review requires that FDA review an application for approval of a drug or biologic within 6 months versus a standard review of 9 months or longer. AAP will be monitoring the new voucher project closely and its potential impact on advancing pediatric cancer therapies, in particular.

**FDA Expands Neonatal Focus**

To increase the understanding of drug products in neonates, FDASIA also required the FDA to hire a neonatologist for at least five years. The FDA recently hired Ronald Ariagno, MD, as a part time faculty fellow for 2 years under the Oak Ridge Institute for Science and Education (ORISE) fellowship program. Dr. Ariagno is Professor Emeritus, Pediatrics, Division of Neonatal and Developmental Medicine with Stanford University, and will develop programs within FDA to foster the appropriate study of drugs and biologics for use in neonates. Additionally, Dr. Ariagno will coordinate FDA outreach to other neonatal experts and external partners to participate in specific projects. The FDA also created a Neonatal Subcommittee to its Pediatric Advisory
Committee. This subcommittee met for the first time in March 2013.

**Pediatric Medical and Surgical Devices**

FDASIA also reauthorized the *Pediatric Medical Device Safety and Improvement Act of 2007*, extending the pediatric device development incentive first passed in the 2007 bill.

Devices for small populations (under 4,000 patients) can be approved by the FDA under the Humanitarian Device Exemption (HDE), which is not subject to the same requirements as large-market devices. HDE-approved devices are generally not allowed to make profit, but manufactures can recoup their research and development costs. The 2007 law lifted the profit restriction for pediatric devices.

As a result, three pediatric devices have been approved since 2007 under this program and more are expected in the coming years. Since passage, five times as many pediatric devices have confirmed eligibility for the program.

The success of this program prompted rare disease advocates to push for this profit allowance to apply to adults as well. Initial legislation introduced to expand the program to adults did so in a way that would have seriously harmed the pediatric incentive. The AAP worked with Sen. Al Franken (D-Minn.) to craft a compromise that was ultimately included in the final bill. It expands the program to adults while preserving the strength of the pediatric incentive.

The innovative Pediatric Device Consortia (PDC) program was also reauthorized for five years. The PDC has assisted in 135 proposed pediatric medical device projects, and several of these devices have either been approved for pediatric patients in the U.S. or have been able to remain on the U.S. market. On Sept. 12, 2013 the FDA awarded grants to consortia which advance the development of pediatric medical devices for the third time since 2009. This year’s awards will be granted to consortia that each bring together teams with excellence and expertise in delivering business, regulatory, legal, scientific, engineering, and clinical services for children. The program was funded at $3 million for fiscal year 2014.

**Pediatric Device Tracking**

On Jan. 10, 2014, the Food and Drug Administration (FDA) published a final rule implementing the pediatric tracking provisions of the *Pediatric Medical Devices Safety and Improvement Act of 2007*. Despite comments by the AAP – joined by the Elizabeth Glaser Pediatric AIDS foundation – on the proposed rule, the FDA again failed to include a provision requiring the submission of readily-available information on potential pediatric uses.

An earlier version of these regulations required the submission of pediatric prevalence data not only for the labeled indication, but also for foreseeable “potential” or “off-label” uses of devices in children. The AAP strongly supported this requirement but the FDA was forced to withdraw the proposal after industry opposition.

After the FDA withdrew the initial proposal, it delayed proceeding with the rulemaking for several years. As a result, the AAP successfully advocated for language to be included in the recently passed Food and Drug Administration Safety and Innovation Act of 2012 that required the FDA to publish a new proposal to implement the 2007 provision. The FDA published such a proposal last February, but it did not include a requirement for the submission of data on potential pediatric uses. The previously mentioned AAP comments strongly opposed the change made to the rule and urged the FDA to require the submission of readily available information for potential uses in pediatrics in the final rule.

**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 translational research activities at the National Institutes of Health.

**Inclusion of Children in Human Subjects Research**

The AAP has continued advocacy efforts to improve reporting on the number of children included in human subjects research funded by the National Institutes of Health (NIH). Currently, NIH has no systematic mechanism to accurately track the numbers and ages of children included in NIH trials, leaving pediatric research advocates with no data to judge whether children are being appropriately included in clinical research that may be relevant to pediatrics. NIH currently only requires that investigators report on whether or not any children...
under the age of 21 were included in a given trial, which fails to offer useful information about the total number and age ranges of any included children.

The Academy has consistently engaged with officials at NIH to urge the institutes to revise their process for reporting on pediatric inclusion. The NIH is currently engaged in a broader process to reevaluate clinical trial participation based on age, race, gender, and sexual orientation.

**National Children’s Study**

In response to a request from Congress, the Institute of Medicine (IOM) is currently conducting a review of the design of the National Children’s Study (NCS). Congressional appropriators asked for the review after the National Institutes of Health (NIH)—which runs the study—proposed significant changes to the study in recent years.

The NCS is the largest and most comprehensive study of children’s health and development ever planned in the United States. If fully implemented, this study will follow a sample of 100,000 children from across the country from before birth until age 21. The study will examine the effects of the environment—including factors like air, water, diet, family dynamics, and community influences—on the growth and development of children.

A pilot phase of the study, known as the “Vanguard Study,” has been in operation for several years. The experience with the Vanguard Study led NCS planners to back away from the initially planned household-based recruitment strategy due to higher-than-expected costs. In its place, the NIH has recommended a mixed recruitment model that incorporates a birth cohort and provider-based recruitment. This has led to criticism that the study will be less representative of the population as a whole and that environmental factors early in pregnancy may be missed. The NCS also came under fire for scrapping its initial structure that utilized academic medical centers as hubs for recruitment, data collection, and hypothesis development in favor of a less costly "data repository" model where recruitment and data collection are performed by a small number of regional contractors.

The final public meeting of the IOM NCS panel took place on Oct. 31. The President-Elect of the AAP, James Perrin, MD, offered comments to the group supporting the continuation of the NCS. The comments expressed the Academy’s longtime support of the study without weighing in specifically on the scientific issues the IOM committee is now grappling with. The AAP acknowledged increasing congressional frustration with delays in the study and urged the committee to develop scientifically-sound recommendations that would allow the NIH to begin the main arm of the study as quickly as possible. Dr. Perrin’s remarks maybe found here. The IOM plans to make recommendations by July on the revised NIH plan for NCS.

The omnibus spending bill signed into law on Jan. 17 includes $165 million (flat funding) for the National Children’s Study in FY2014. The major stipulation attached to this funding is that any funding not used for the study will be divided among the other institutes and centers at NIH.

**National Pediatric Research Network Bill**

On Nov. 27, 2013 the President signed the Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Reauthorization Act into law. Also included in the package bill was the National Pediatric Research Network Act of 2013 (S. 252), which would authorize consortia at medical and research institutions for basic and translational pediatric research efforts. The Senate approved the House amended bill (S. 252) on Nov. 14, 2013 by unanimous consent.

The bill amends the Public health Service Act to authorize the Director of the National Institutes of Health (NIH) to establish a National Pediatric Research Network. The bill also allows the NIH to give grants and develop cooperative agreements with public or private non-profit agencies for (1) planning, establishing, or strengthening pediatric research consortia; and (2) providing basic operating support for such consortia, including for pediatric research needs and training.

While the pediatric network bill signed into law gives the National Institute of Child Health and Human Development (NICHD) greater flexibility than previous versions of the proposal, it does not include any funding authorization levels for research networks. Alan Guttmacher, MD, Director of the NICHD and Francis Collins, MD, PhD, Director of the National Institutes of Health will have to decide how to implement the bill in the absence of new funding.
Preemie Reauthorization Act

On Nov. 27, 2013, the President signed the Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Reauthorization Act into law. The PREEMIE Act was sponsored in the House (H.R. 541) by Reps. Anna Eshoo (D-Calif.) and Leonard Lance (R-N.J.) and in the Senate (S. 252) by Sens. Lamar Alexander (R-Tenn.) and Michael Bennett (D-Ohio). The law aims to reduce preterm birth, its associated disabilities, and deaths of babies born preterm, expand research into the causes of preterm birth, and promote the development, availability and use of evidence-based standards of care for pregnant women at risk of preterm labor or other serious pregnancy-related complications and for infants born preterm. The AAP joined a letter supporting the PREEMIE Reauthorization Act in February.

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 works to rebound from recession. The Budget Control Act of 2011 enacted sequestration and placed strict caps on discretionary spending. Many crucial programs for children were impacted in fiscal year 2013, but those impacts have been lessened in part due to the omnibus appropriations bill passed in January 2014.

FY 2014 Appropriations

On Jan. 17, 2014, the President signed an omnibus spending bill for fiscal year 2014 into law, which passed the House and Senate on Jan. 15 and Jan. 16 respectively. The bill, which makes funding allocations for the remainder of FY 2014, marks the first time since FY 2012 that Congress has been able to come to an agreement on all 12 appropriations bills. It is important to note, however, that funding levels are still lower than they were in FY 2010. Since a deal to end to end a government shutdown was signed into law on Oct. 16, 2013, the government has been operating on the FY2013 post-sequestration funding level of $986.3 million. The FY2014 omnibus spending bill is based on a discretionary spending topline of $1.012 trillion established on Dec. 12, 2013 by a budget conference committee led by House Budget Chair Rep. Paul Ryan (R-Wisc.) and Senate Budget Chair Sen. Patty Murray (D-Wash.). The compromise topline would replace roughly 40% of discretionary funds cut by sequestration. The budget committee also established a discretionary spending topline of $1.014 trillion for FY2015.

A comprehensive breakdown of FY2014 children’s health funding is available here, and below are several key programs and agencies important to children and their funding within the Consolidated Appropriations Act:

- $29.9 billion for the National Institutes of Health; a $1 billion increase from FY 2013 (post-sequestration), which will allow for approximately 385 additional research studies and trials.
- $1.3 billion for the Eunice K. Shriver National Institute of Child Health and Human Development (NICHD), an increase of $37 million
- $634 million for the Title V Maternal and Child Health Block Grant, an increase of $29 million from FY 2013.
- $193.2 million for the Centers for Disease Control and Prevention’s (CDC) Global Immunization Program, an increase of $41 million from FY 2013.
- $11.2 million for the CDC National Violent Death Reporting System, an increase of $7.9 million from FY 2013.
- $115 million in new funding for “Now is the Time” violence prevention initiative, including $15 million for mental health first aid grants, grants to state education authorities, and $20 million for programs targeting young adults at high risk of mental illness.
- $165 million in flat funding for the National Children’s Study, pending mid-year review.
- $265 million for the Children’s Hospital Graduate Medical Education (CHGME), and an increase of $13.8 million.

Despite these child health gains, there were some setbacks. Due to the fact that omnibus bill did not include any new spending for the Affordable Care Act, the Pediatric Subspecialty Loan Repayment Program, which provides loan reimbursement to qualified pediatricians, pediatric specialists and other eligible physicians who practice in underserved areas, remained unfunded. The loan repayment program has been recommended three times to be funded at $5 million—twice by the president and in the latest Senate health
spending bill. This year also marks the 30th anniversary of the Emergency Medical Services for Children (EMSC) program, the only federal program that focuses specifically on improving how the emergency medical services system meets children’s needs. It is disappointing that the omnibus bill cut EMSC funding when significant gaps in quality emergency care for children still remain. In addition, the CDC National Center on Birth Defects and Developmental Disabilities saw a $7.7 million decrease in its funding from the prior fiscal year.

AAP President James M. Perrin, MD, FAAP, released a statement on behalf of the Academy, noting that while the FY 2014 omnibus bill was a step in the right direction, further work needs to be done by Congress in FY 2015 and future fiscal years to eliminate the policy of sequestration to fully restore funding to programs important to children.
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
- Information on how to submit timely opinion pieces to local media outlets
- Fact sheets on health reform implementation and other timely topics
- All recent federal testimony given by AAP experts before the U.S. government on various child health topics
- Additional online resources such as PowerPoint presentations, videos, and other documents on current federal child health policy priorities.

Advocacy Training Opportunities in Washington, DC

Save the Date: Legislative Conference 2014

Mark your calendar! The 2014 Legislative Conference will be held June 15, 2014 – June 17, 2014, in Washington, DC. Join pediatricians from across the country and learn how you can become a strong advocate for the children you care for. During the three-day conference, participants will have the opportunity to develop their federal advocacy skills around a timely child health issue, hear from several guest speakers, attend tailored advocacy workshops and visit with their legislators on Capitol Hill. Please visit www.aap.org/legcon for more information about the conference, including a brochure, scholarships, and how to register.
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