

**AMERICAN
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SOCIETY**

**ASSOCIATION OF MEDICAL
SCHOOL PEDIATRIC
DEPARTMENT CHAIRS**

**SOCIETY FOR
PEDIATRIC
RESEARCH**

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**Public Policy Council
Legislative Report**

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*Members of: Council of Academic Societies, Association of American Medical Colleges,
American Academy of Pediatrics Committee on Federal Government Affairs*

BUDGET AND APPROPRIATIONS

FY 2011 Budget

President Obama released his administration's proposed budget to Congress on February 1, 2010. In general, the President's budget calls for level funding with a few exceptions.

During his State of the Union speech, President Obama called for a three-year freeze in discretionary spending for most agencies, excluding defense, homeland security, veterans, and the State Department. However, the budget proposal reflects the administration's continued focus on health care as a priority. The Department of Health and Human Services (HHS) discretionary budget would increase by \$1.7 billion to \$81.3 billion in fiscal year 2011. Of special note, the budget proposes:

- \$32.3 billion for the **National Institutes of Health**, an increase of \$1 billion.
- \$194.4 million for the **National Children's Study**, up from \$193.8 million.
- \$20 million for a new CDC initiative to reduce the rates of morbidity and disability due to **chronic disease** in up to ten of the largest U.S. cities.
- \$10 million at CDC for a new **Health Prevention Corps**, which will recruit, train, and assign a cadre of public health professionals in State and local health departments, targeting disciplines with known shortages, such as epidemiology, environmental health, and laboratory science.
- An increase of \$10 billion in federal **child nutrition programs** to expand service to more children and improve the quality of food served in schools.
- Level funding of \$317.5 million for **Children's Hospitals Graduate Medical Education**.
- \$168 million for **National Health Service Corps**, up from \$142 million.
- Level funding for virtually all **Title VII health professions** programs, with the exception of an increase to \$8 million for workforce information and analysis.

- \$162 million for **CDC's Health Statistics**, an increase of \$23 million, to support electronic birth and death records in States and enhance national surveys.
- Modest increases in other programs, including the Title V Maternal and Child Health Block Grant; Child Care and Development Block Grant; and, Head Start and Healthy Start.

The presentation of the administration's budget represents the beginning of the annual budget and appropriations process. Congressional committees have begun to embark upon hearings in their areas of jurisdiction.

FY 2010 Summary

By the end of calendar year 2009, all appropriations bills had been passed and signed into law. Most passed as stand-alone legislation; however, in December, the remaining five bills were packaged into a modest omnibus bill and passed en masse. This final package, H.R. 3288, was signed into law by President Obama on December 16, 2009 as Public Law 111-117. The annual Labor, Health and Human Services, and Education Departments spending bill was included in that final package. In general, most accounts were funded level with the previous year or with small increases.

American Recovery and Reinvestment Act (ARRA) Update

In February 2009, Congress passed and the President signed into law the American Recovery and Reinvestment Act (ARRA), a package of over \$787 billion in spending meant to stimulate the economy toward recovery. Health-related provisions in ARRA included the following:

- \$10.4 billion for the **NIH**.
- \$87 billion for state **Medicaid** programs, increasing the Federal Medical Assistance Percentage (FMAP) by 6.2%.
- \$19 billion to incentivize the adoption of **electronic health records**.

- \$1 billion in funding for **wellness and prevention programs**, including \$300 million for the section **317 immunization** program; \$50 million for state health-associated infections reduction strategies; and \$650 million for evidence-based clinical and community-based prevention and wellness strategies.
- \$1.1 billion for **comparative effectiveness** research.
- \$500 million to primary health care provider training and **National Health Service Corps**.

HEALTH REFORM

In March 2010, President Obama signed into law *The Patient Protection and Affordable Care Act* (Public Law 111-148) and an accompanying package of modifications to the law, including Medicaid payment reform.

The new law contains many strong child health provisions, a direct result of decades-long efforts by the pediatric community to urge Congress to prioritize children's health needs on the national policy agenda. PPC members advocated throughout the health reform debate to amplify the voices of children and pediatricians, and the resulting new law will improve the quality, affordability and accessibility of health care services for children and families.

Throughout the health reform process, pediatric advocates have been focused on "the ABC's" of fundamental priorities for children and pediatricians:

- appropriate payment rates and workforce improvements to allow real **A**ccess to covered services
- age-appropriate **B**enefits in a medical home
- health care **C**overage for all children in the United States

The current law addresses these issues in the following ways:

- **Access:** The law provides pediatric primary and subspecialty workforce improvements, including a new loan repayment program (\$35,000 per year) for pediatric subspecialists who practice in subspecialty shortage areas. In addition, for the first time ever, a new \$8.3 billion federal investment will bring parity to Medicaid and Medicare payments for primary care doctors. The increase applies to payments for evaluation and management codes recognized by Medicare starting in 2013, and is available to physicians with a specialty designation of internal medicine, family medicine or pediatrics.
- **Benefits:** All *Bright Futures* services will now be covered for children with private and public insurance as an immediate benefit for no co-pay. The law also includes new funding for Medicaid medical home demonstration projects.
- **Coverage:** The law projects that nearly thirty-two million children, parents and individuals will now gain insurance coverage. The law also prevents children from being denied health insurance due to pre-existing conditions, and allows young adults to remain on their parents' insurance until the age of 26; both provisions will take effect in 2010. In addition, the law preserves the Children's Health Insurance Program (CHIP) with funding until the end of fiscal year 2016 and includes a renewed federal funding commitment to states through 2019.

In addition to these reforms, the current law also reauthorizes the Emergency Medical Services for Children program, which provides grants to all 50 states to support activities and efforts related to pediatric emergency care.

In the weeks and months ahead, the pediatric community will work with Congress and the Administration to ensure that the health reform

law is appropriately implemented to provide the best possible outcomes for children and the pediatricians who care for them.

PEDIATRIC RESEARCH

National Institutes of Health (NIH) Leadership

The Public Policy Council, along with the American Academy of Pediatrics and the Ad Hoc Group for Medical Research, supported President Obama's nomination and the Senate's confirmation of Francis S. Collins, MD, PhD, to be the new director of the National Institutes of Health (NIH). The Public Policy Council sent a letter to congratulate Dr. Collins.

The National Institute of Child Health and Human Development (NICHD) had some leadership changes in 2009. In October, Duane Alexander, MD, director of NICHD took a new position as the senior scientific advisor to the director of the NIH's Fogarty International Center. Alan Guttmacher, M.D., assumed the duties of NICHD acting director. Dr. Guttmacher was the acting director of the National Human Genome Research Institute (NHGRI) since August 2008 and its deputy director since 2002.

The search for a permanent director for NICHD is underway. A search committee has been formed, which includes Public Policy Council member Elena Fuentes-Afflick, MD. The search committee is in the process of interviewing qualified candidates. The Public Policy Council and pediatric community will stay involved throughout the transition process.

NIH Appropriations

The president's FY 2011 budget requested \$2 billion for the National Institutes of Health (NIH), an increase of \$1 billion over the previous fiscal year. The National Institute of Child Health and Human Development are slated for a \$40 million increase, to \$1.369 billion. A modest increase was

requested for the National Children's Study, from \$193.8 million to \$194.4 million.

NIH Economic Stimulus

The Public Policy Council, working together with the Ad Hoc Group on Medical Research Funding, an umbrella coalition with over 300 organizations, supported additional funding in the stimulus package for the NIH. Collective advocacy efforts resulted in \$10.4 billion for the NIH to be available until September 30, 2010.

National Children's Study (NCS)

Appropriations

President Obama's FY 2011 budget proposed \$194.4 million for the National Children's Study, up from \$193.8 million.

The Public Policy Council, in collaboration with the American Academy of Pediatrics, March of Dimes and others, supported the next installment in funding for FY 2010 - \$194.4 million. Over 50 organizations signed onto a letter supporting funding the NCS at that level. The President's budget requested \$194.4 million for the NCS in FY 2010. Although the House approved \$194.4 million, the Senate did not specify a funding amount for FY 2010. The Senate language expressed strong concerns about the overall cost of the study and requested additional information in costs in the coming year. The final omnibus appropriations bill for FY 2010 provides the National Children's Study \$193.8 million.

Leadership

In August 2009, Steven Hirschfeld, MD, PhD, NICHD's associate director for clinical research, was appointed acting director of the National Children's Study. Dr. Hirschfeld is board certified in general pediatrics and pediatric hematology-oncology. He worked at the National Cancer Institute as a clinical investigator and then at the Food and Drug Administration (FDA) in the Center for Drug

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Evaluation and Research and the Center for Biologics Evaluation and Research.

Pediatric Research Consortia Establishment Act (S. 353/ H.R. 758):

Senators Sherrod Brown (D-OH) and Kit Bond (R-MO) reintroduced S. 353, to amend Title IV of the Public Health Service Act to establish the National Pediatric Research Consortia. The Public Policy Council, as well as the members of the Federation of Pediatric Organizations all provided their collective support to this important legislative effort in the 110th Congress and will continue to do so. In addition to Senators Brown and Bond, the bill is cosponsored by Senators Mark Begich (D-AK), Jeff Sessions (R-AL), and Sheldon Whitehouse (D-RI.) The House companion bill, H.R. 758 was introduced by Rep. Dianna DeGette (D-CO) and has 33 co-sponsors.

The *Pediatric Research Consortia Establishment Act* authorizes up to 20 National Pediatric Research Consortia at institutions throughout the country. The consortia will conduct both basic and translational research. Each consortium will partner with satellite facilities. The peer reviewed awards will be made for five years with each consortium receiving initially no more than \$2.5 million per year and renewable for another five years contingent on evaluations by a peer review panel.

Agency for Healthcare Research and Quality (AHRQ) Appropriations

The President's FY 2011 budget proposes \$611 million in funding for AHRQ, an increase of \$214 million over the current FY 2010 level. The FY 2010 Consolidated Appropriations Act passed by the House and Senate, approved \$397 million for AHRQ. The pediatric advocacy community will continue working with the Friends of AHRQ to support this funding increase to preserve AHRQ's current and new initiatives.

Although there was some interest expressed by the Senate Health, Education, Labor and Pensions Committee (HELP) on the reauthorization of AHRQ, no action was taken but renewed interest is anticipated in the 111th Congress.

PEDIATRIC WORKFORCE/GRADUATE MEDICAL EDUCATION

GME Financing for Children's Hospitals (CHGME), Title VII Health Professions Program and Title VIII Nursing Professions Program

Appropriations

President Obama's FY 2011 budget outline proposes \$318 million in funding for CHGME. The Public Policy Council and the American Academy of Pediatrics continued its collaboration with the National Association of Children's Hospitals (NACH) last year to urge the House and Senate Appropriations committees to include funding for the CHGME at the authorized level of \$330 million in FY 2011. The House and Senate both passed the FY 2010 Consolidated Appropriations Act which approved \$317 million for CHGME.

The President's FY 2011 budget released on February 1, 2010, proposes \$503.9 million for Titles VII and VIII funding. This is a 1.2% increase over the FY 2010 enacted funding. The Public Policy Council continues to work closely with the Health Professions and Nursing Education Coalition (HPNEC), led by the AAMC, to urge Congress to increase funding for the Title VII and Title VIII programs. The coalition requested \$600 million for both Titles VII and VIII for FY 2011.

The final FY 2010 Omnibus conference agreement passed by the House and Senate, included \$498 million for the Title VII and Title VIII Health Professions Programs, a 26.7% increase of \$105 million over the FY 2009 omnibus, but \$30 million below the President's request. This includes \$254 million for Title VII and \$244 million for Title VIII.

Titles VII and VIII will receive an increase in funding through the economic stimulus package to be used in the next two years of \$200 million. According to the conference agreement the funds are “allocated for all the disciplines trained through the primary care medicine and dentistry program, the public health and preventive medicine program, the scholarship and loan repayment programs authorized in Title VII (Health Professions) and Title VIII (Nurse Training) of the PHS Act, and grants to training programs for equipment. Funds may also be used to foster cross-State licensing agreements for healthcare specialists.” An additional \$300 million is also provided for the National Health Service Corps.

Pediatric Work Force in Health Care Reform

As a part of the overall health care reform effort, the PPC along with the American Academy of Pediatrics was aggressively engaged in advancing pediatric primary care and subspecialty workforce issues in the debate to care for newly-insured patients. The health reform law recognizes this need, and includes many important provisions to strengthen the pediatric workforce.

The Health Reform Law Will:

- Reauthorize Title VII and VIII programs at an increased funding level of \$450.1 million (+ sums as necessary), which is to take effect during FY 2010. The new authorization language clarifies that the training program provide financial assistance in the form of traineeships and fellowships to physicians who are participants in any such programs and who plan to teach or conduct research in a family medicine, general internal medicine, or general pediatrics training program. It corrects some concerns among administration officials who have tried to eliminate or decrease the pediatric research portion of the grant program.
- Create a loan repayment program for pediatric subspecialists and providers of

mental and behavioral health services for children and adolescents. The provision allocates a combined \$50 million per year for loan repayment to individuals who commit to pursuing full-time employment in pediatric medical subspecialties, pediatric surgical specialties, or child and adolescent mental and behavioral health care fields. Participants in this new program would be eligible for up to \$35,000 per year in loan repayment funds for three years.

- Increase workforce supply and support training of health professionals through scholarships and loans. The law supports primary care training and capacity-building and also provides state grants to providers in medically underserved areas. Provisions include training and recruiting providers to serve in rural areas, establishing a public health workforce loan repayment program, and also providing medical residents with training in preventive medicine and public health.
- Amend the current law for federally supported student loan funding by easing criteria for schools and students to qualify for loans, lower interest rates, shorten payback periods and ease the non-compliance provision.
- Establish a National Health Care Workforce Commission to make recommendations and disseminate information on workforce priorities, goals and policies, including education and training, workforce supply and demand, and retention practices.
- Reform the Graduate Medical Education (GME) program to increase the supply, education and training of doctors, nurses and other health care workers, especially in pediatric, geriatric and primary care fields. The health reform law increases the number of GME training positions by redistributing currently unused slots, with

priorities given to primary care and general surgery and to states with the lowest resident physician-to-population ratios. It also increases flexibility in laws and regulations that govern GME funding to promote training in outpatient settings and ensure the availability of residency programs in rural and underserved areas.

- Establish Teaching Health Centers, which are community-based, ambulatory patient care centers. These include federally qualified health centers and other federally funded health centers that are eligible for Medicare payments for the expenses associated with operating primary care residency programs.
- Mandate the development of national and regional centers for health workforce analysis to collect and report data related to Title VII. The centers will collaborate with state and local agencies to collect labor and workforce statistical information and provide analysis and reports on Title VII programs to the National Health Care Workforce Commission.

PEDIATRIC THERAPEUTICS

BPCA/PREA Implementation and Reauthorization

Legislative and regulatory efforts to increase information on drugs used in children have now yielded over 350 drug labels with revised pediatric information. The Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA), reauthorized by the Food and Drug Administration Amendments Act (FDAAA) of 2007 (H.R. 3580, PL 110-85), have continued to successfully generate valuable pediatric data. Since the reauthorization of the laws, FDA has improved internal coordination in the pediatric studies program and has also increased its transparency.

The Pediatric Review Committee (PeRC), an internal FDA committee mandated by PL 110-85 and tasked with providing oversight and

coordination between BPCA and PREA, has been in operation for over two years. PeRC is under the authority of the Center for Drug Evaluation and Research (CDER). The PeRC meets weekly and reviews pediatric plans, deferrals, waivers, and assessments.

The PeRC recently released a retrospective review of PREA assessments, as required by FDAAA. The review is included at the end of this report. The report, mandated by FDAAA, looked at a representative sample of PREA assessments from 2004 to 2007 to determine the quality and consistency of the assessments, as well as the appropriateness of any waivers or deferrals granted. The review found generally high quality scientific data in PREA assessments, although noted several specific scientific problems, particularly in the earlier years of the study. While deferrals were found to be mostly appropriate, almost one-third of waivers were applied inappropriately during the study period. It is important to note that the study reviewed assessments completed before the creation of the PeRC. Since its creation, the PeRC has helped FDA achieve higher quality and more consistent assessments across the 17 review divisions within CDER, some of which have few or no pediatricians.

Based on the review, the PeRC recommended that pediatric plans be more detailed and be discussed earlier in the drug development process and that approval letters be more specific in detailing pediatric postmarketing requirements. FDA is currently drafting guidance for industry on complying with PREA and will include these recommendations in the guidance.

As required by FDAAA, FDA has begun posting written requests for which a positive determination was made on or after September 27, 2007. So far, FDA has posted written requests for 33 drugs. They can be found at http://www.fda.gov/cder/pediatric/bpca_determination.htm. To date, 351 drugs have been relabeled as a result of BPCA, PREA, and the pediatric rule

(PREA's predecessor)
<http://www.fda.gov/oc/opt/pediatriclabeling.html>.

GAO BPCA/PREA Study

BPCA and PREA will expire and need to be reauthorized in the fall of 2012. The Government Accountability Office (GAO) is currently engaged in a review of the programs and has met with pediatric experts to gather information. GAO will submit a report with recommendations for the programs before they expire. FDA is in the beginning stages of contracting with the Institute of Medicine (IOM) to conduct a review of written requests under BPCA and the use of extrapolation, as required by FDAAA.

GAO brought a group of neonatologists together to discuss barriers to studying drugs in the neonatal population. The participants on the call included Bob Ward, MD, John van den Anker, MD, Jack Aranda, MD, Robin Steinhorn, MD, David Burchfield, MD, and Michele Walsh, MD.

Pediatric Medical Devices Bill Implementation

For several years, there have been intensive pediatric efforts to ensure that children have access to devices that are sized appropriately and accommodate their growing bodies and unique physiology.

Congress passed the Pediatric Medical Devices Safety and Improvement Act in 2007 (included in the Food and Drug Administration Amendments Act of 2007, or FDAAA). The bill was designed to increase the tracking of pediatric device approvals by FDA, coordinate the federal response to pediatric device needs, and strengthen postmarket surveillance of devices used in children. It gave FDA the authority to require prospective surveillance periods longer than 36 months if necessary to assess the safety and effectiveness of devices used in growing children.

It also eliminated the profit restriction on pediatric-specific devices approved under the Humanitarian

Device Exemption (HDE) and authorized grants to non-profit consortia to facilitate the development, production, approval, and distribution of pediatric medical devices. Congress recognized the importance of the pediatric device consortia and appropriated \$2 million for the program in Fiscal Year 2009 and \$3 million in Fiscal Year 2010. The Office of Orphan Products Development (OOPD) successfully provided grants to establish four consortia.

Since the adoption of the legislation, two significant meetings have been held to advance pediatric device activities at the federal level. The first meeting in July, 2008, was convened for the purpose of soliciting feedback on draft pediatric device development plans prepared by FDA, NIH, and AHRQ in response to a requirement in the legislation that HHS report to Congress on expanding research and other federal efforts related to pediatric device development.

The second meeting, held last October, was convened on FDA's own initiative and gathered pediatric experts in six specialty areas— musculoskeletal disease, cardiovascular disease, abdominal and GI diseases, neurologic disorders, renal diseases, and audiological disorders—to discuss the unique device needs of children, challenges in developing pediatric devices, and best practices for conducting pediatric clinical device trials.

Pediatric advocates have recently met with FDA to foster further dialogue, and the Center for Devices and Radiological Health (CDRH) is currently considering requests to increase the amount of pediatric expertise within the Center and to speed compliance with the device law's provisions and timelines. In April 2010, FDA released a regulation requiring new device applicants to submit information on the number of children affected by the condition a device is intended to treat. This will help FDA track pediatric-relevant device applications and approvals.

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PPC submitted comments, along with other pediatric societies, to CDRH in response to a request for suggestions on how the agency should shift regulatory expectations in the face of new scientific evidence and novel technologies. The comment letter stressed the difficulties in developing devices for children and the particular vulnerabilities of the population.

Generic Biologics in Health Reform

The health reform bill recently signed into law created a regulatory pathway for the approval of generic, or follow-on biologics (FOBs) and applied

existing pediatric drug testing laws to FOBs. The new pathway offers extensive innovator market exclusivity (12 years) and requires extensive generic clinical trials. The new law applies the Best Pharmaceuticals for Children Act (BPCA) to biologics, offering innovator companies an additional six months of market exclusivity for completing FDA-requested clinical trials in children. It also applies the Pediatric Research Equity Act (PREA) to follow-on products so that companies will be required to submit pediatric assessments of their products if they would be used in children.

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