AMERICAN PEDIATRIC SOCIETY

ASSOCIATION OF MEDICAL SCHOOL PEDIATRIC DEPARTMENT CHAIRS

SOCIETY FOR PEDIATRIC RESEARCH

Public Policy Council

Chair
Myron Genel, M.D.
Yale University School of Medicine
Child Health Research Center
Department of Pediatrics
464 Congress Avenue, P.O. Box 208081
New Haven, C.T. 06520-808
(203) 785-6019
(203) 737-5972 fax
myron.genel@yale.edu

Washington Staff
Mark Del Monte, J.D.
mdelmonte@aap.org

James Baumberger
jbaumberger@aap.org

601 Thirteenth Street, N.W.
Suite 400 North
Washington, D.C. 20005
(800) 336-5475
(202) 347-8600
(202) 393-6137 fax

American Pediatric Society

Stephen Berman, M.D.
University of Colorado

Richard L. Bucciarelli, M.D.
University of Florida

Association of Medical School Pediatric Department Chairs

Bonita Stanton, M.D.
Wayne State University

David Clark, M.D.
Albany Medical College, NY

Society for Pediatric Research

Leona Cuttler, M.D.
Case Western Reserve University

Thomas P. Green, M.D.
Northwestern University

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*

TABLE OF CONTENTS

BUDGET AND APPROPRIATIONS

FY 2011 Appropriations

Although the 2011 Federal Fiscal Year began on October 1, 2010, Congress has yet to complete the annual appropriations process. With the entire House of Representatives and one-third of the Senate up for re-election this November, legislators feel growing pressure from constituents to lower federal spending and address the deficit. Combined with a difficult political environment for incumbents, this year is proving to be especially challenging for federal appropriations.

Traditionally by this time of year, both chambers of Congress have advanced a large majority of the twelve annual appropriations bills through the full committee process, and many have even received final Congressional approval. To date, the full Senate Appropriations Committee has approved its Fiscal Year 2011 (FY11) Labor-HHS-Education spending bill. The House version has only received subcommittee approval thus far. Of particular note, the current topline allocation in the Senate bill is $6.8 billion less than that in the House, and the Senate version does not fully address significant funding shortfalls in the federal Pell Grant and Low Income Home Energy Assistance (LIHEA) programs.

FY 2011 Labor-HHS-Education and Related Agencies Appropriations *Discretionary program levels in billions of dollars*				
FY 2010 Comparable	FY 2011 Request	FY 2011 House Subcommittee Mark	FY 2011 Senate Committee Mark	Sessions/McCaskill amendment impact
163.7	177.9	176.4	169.6	163.7

Before each bill can be finalized and specific program lines agreed upon, significant negotiations are required to work out discrepancies between both chambers' topline numbers. An effort by Sen. Jeff Sessions (R-AL) and Sen. Claire McCaskill (D-MO) to force further cuts in non-security discretionary spending in FY11 could further complicate matters, pushing the Senate Labor-HHS-Education topline to $13 billion lower than the House.

A new element in the federal appropriations process this year stems from the Affordable Care Act, which passed in March 2010. The law includes many reforms that benefit children and pediatricians, but they still lack the funding needed to be implemented. Many Affordable Care Act programs which do have funding, like the $10 billion Prevention and Public Health Fund, are also being targeted to pay for other spending priorities rather than being implemented as the law intended. And finally, the significant increase to public health program and research spending previously passed under the American Recovery and Reinvestment Act (also known as the federal stimulus package) is set to expire at the end of 2010, increasing the already steep competition for federal resources.

Congress passed a Continuing Resolution (CR) to keep the government funded past the start of the new fiscal year, October 1, 2010. With a CR, operations will continue at FY10 levels. Bowing to Republican

pressure, the passed CR was "clean," meaning extra funding for priority programs or special projects was not included.

The current CR runs until December 3, 2010, when Congress is expected back in town for a lame duck session. At that time, a more detailed CR can be negotiated to fund operations through the end of the calendar year or into the next when an omnibus appropriations package can be authored and negotiated. There is even a small chance that FY11 may be permanently funded by a long-term CR, dependant upon the results of the midterm elections.

In addition to timing challenges, two recent steps taken by the White House to address the national deficit will impact federal health care spending for Fiscal Year 2011 and beyond. First, earlier this year the Administration created a National Commission on Fiscal Responsibility and Reform, which will address both mandatory and discretionary spending priorities in its recommendations to the President and Congress, including many children's health and education programs. Second, the Office of Management and Budget issued a directive to all federal agencies (non-security spending only) to reduce their budget requests by 5 percent for Fiscal Years 2012 and 2013.

CHILD NUTRITION REAUTHORIZATION

The National School Lunch Program (NSLP), the School Breakfast Program (SBP), the Summer Food Service Program (SFSP), the Child and Adult Care Food Program (CACFP), the Special Milk Program (SMP), the Fresh Fruit and Vegetable Snack Program (FFVP) and the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) are all due for their regular five-year reauthorization. In March, the Senate Agriculture Committee unanimously passed the Healthy, Hunger Free Kids Act out of committee. The bill was passed unanimously by the full Senate in August. In July, the House Education and Labor Committee introduced H.R. 5504, the Improving Nutrition for America's Children Act. H.R. 5504 was passed out of the Education and Labor Committee with bipartisan support on July 15. The House is expected to vote on this bill when Congress reconvenes for the lame duck session in November; previously, controversy over the funding offsets prevented House consideration of the legislation.

Both the House and Senate bills reauthorize the child nutrition programs and focus on expanding program access to reduce child hunger, improving nutritional quality to promote health and reduce childhood obesity, and simplifying program management and improving program integrity. Both bills include a number of pediatric recommendations, including:

- Allow the Secretary of Agriculture to establish national nutritional standards based on the Dietary Guidelines for Americans for all foods sold in schools;
- Increase meal reimbursement by six cents per meal to help implement the new nutrition standards;
- Establish direct certification for children in families receiving SNAP (food stamp) benefits and a pilot direct certification program for Medicaid beneficiaries in select areas in the U.S.;
- Create categorical eligibility for all children in foster care;

- Create a universal meal service option for schools in high-poverty areas to offer free meals to all students without collecting individual paper applications;
- Expand access to the After School Meal Program and the Summer Food Service Program;
- Strengthen breastfeeding promotion in the WIC program by providing mandatory funding to recognize exemplary breastfeeding practices at WIC clinics; and
- Implement electronic benefit transfer (EBT) for WIC.

DRUGS AND DEVICES

Pediatric Devices Law Implementation and Reauthorization

For several years, the pediatric advocates have engaged in intensive efforts to ensure that children have access to devices that are sized appropriately and accommodate their growing bodies and unique physiology. The American Academy of Pediatrics, supported by the Public Policy Council, worked with Congress to formulate and pass the Pediatric Medical Devices Safety and Improvement Act of 2007 (included in the Food and Drug Administration Amendments Act of 2007, or FDAAA). Since its passage, activity on pediatric medical and surgical device issues has grown significantly. The FDA has become increasingly sensitive to pediatric device issues and the FDA's Center for Devices and Radiological Health (CDRH) has committed itself to implementing the law and working to improve devices for children.

Pediatric leadership recently met with the director of the FDA Center for Devices and Radiological Health (CDRH), Jeffrey Shuren, MD, JD, to foster further dialogue on pediatric devices and discuss the implementation of the devices bill. FDA reported that it is progressing in its implementation of the pediatric devices law. The center recently issued regulations on the reporting of pediatric data in device applications, an important step forward in helping the agency meaningfully track device applications that implicate children. The agency also reported that the first humanitarian use device (HUD) was approved under the new pediatric humanitarian device exemption (HDE) rules modified by the law.

The Public Policy Council submitted comments 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. In the comment letter, the PPC stressed the difficulties in developing devices for children and the particular vulnerabilities of the population.

DEVICES LAW REAUTHORIZATION

Certain provisions of the Pediatric Medical Devices Safety and Improvement Act of 2007 will expire on September 30, 2012 when the original five-year authorization timeline of the law comes to a close. This expiration is aligned with the sunset Prescription Drug User Fee Act and the Medical Device User Fee Act (PDUFA and MDUFA), both of which must be reauthorized every five years in order to avoid significant budget shortfalls and layoffs at FDA. Two pediatric drugs bills, the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) also expire on this same timeline. This will allow the BPCA, PREA and pediatric devices bill reauthorizations to ride along with the PDUFA/MDUFA renewal as a coordinated package of initiatives for children. The pediatric devices bill reauthorization will allow an

opportunity to reflect on the successes of the legislation and contemplate potential changes to continue to improve the state of pediatric medical and surgical devices.

IMPLEMENTATION OF PEDIATRIC DEVICES LAW TRACKING PROVISIONS

On April 1, 2010, FDA published regulations to implement Section 302 of pediatric devices law. Sec. 302 relates to the reporting of pediatric information in new medical and surgical device applications. Specifically, the provision requires device applicants to include "readily available" information on "any pediatric subpopulations that suffer from the disease or condition that the device is indented to treat, diagnose, or cure, and the number of affected pediatric patients." This will help FDA meaningfully track device approvals relevant to children and report this information to the public.

On June 15, 2010, eleven advocacy groups, including the PPC groups and AAP, submitted comments to FDA in support of the regulation which was issued as a direct final rule. In the view of the groups, being three years after the enactment of the law, it was long past time for FDA to move ahead with the implementation of the tracking provisions. The comments argued that the submission requirement is necessary and would pose no significant burden to device applicants. Comments opposing the rule were submitted by the Advanced Medical Technology Association (AdvaMed).

FDA withdrew the direct final rule on July 20, 2010 in response to the adverse comments received by AdvaMed. The PPC, the AAP, and other groups reiterated their position on the regulation in a July 23, 2010 comment letter to FDA on unmet public health needs in medical devices. The regulation is now pending as a proposed rule, which will take significantly longer to implement than would have the direct final rule.

PEDIATRIC DEVICE CONSORTIA

Congress recognized the importance of the pediatric device consortia authorized in FDAAA 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) at FDA successfully completed the first series of consortia grants last September. According to OOPD, "those who received funding scored best in their unique abilities to serve as a national platform to advance the development of pediatric medical devices while supporting device projects whose outcomes could have a significant impact on the practice of pediatric medicine."

A $1 million grant was awarded to James Geiger, MD and the University of Michigan Pediatric Device Consortium (M-PED). Awards of $500,000 each were granted to Pedro DelNido, MD's Pediatric Cardiovascular Device Consortium and Michael Harrison, MD's University of California, San Francisco Pediatric Device Consortium. The additional $1 million for the second year of the program allowed it to continue funding existing grantees and to add an additional grantee at $500,000, Pablo Garcia and Sanjeev Dutta, MD's MISTRAL (Multidisciplinary Initiative for Surgical Technology Research—Advanced Laboratory) pediatric medical device consortium. Early congressional drafts of Fiscal Year 2011 appropriations bills indicate continued funding at $3 million. Pediatric advocates will continue to work for full funding of the program at $6 million/year.

CHIEF PEDIATRIC MEDICAL OFFICER

Earlier this year, the Center for Devices and Radiological Health (CDRH) indicated its desire to hire an internal pediatric champion and circulated a job description for a Chief Pediatric Medical Officer. The Chief Pediatric Medical Officer will report directly to the CDRH Director and will be tasked with coordinating and integrating pediatrics across the center. In August 2010, Susan Cummins, MD, FAAP assumed the role of Chief Pediatric Medical Officer.

UNMET PUBLIC HEALTH NEEDS IN MEDICAL AND SURGICAL DEVICES

CDRH is also seeking comment on unmet public health needs in medical device development. The agency published an official request for comment in the Federal Register on May 26, 2010 and held a public meeting on the topic on June 24, 2010.

The comments are meant to inform a new body established by CDRH, the Council on Medical Device Innovation. The council is composed of participants from various federal agencies, including the National Institutes of Health, the Centers for Disease Control and Prevention, the Centers for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, among others. The purpose of the council is to "identify the most important unmet public health needs, the barriers to innovative medical device development or redesign that could address those needs, and actions the Federal Government can take to reduce those barriers while assuring the safety, effectiveness, and quality of medical devices marketed in the United States."

The PPC several other advocacy groups submitted a comment letter to FDA outlining the significant device gaps for children and recommending areas of focus necessary to make improvement. It stresses the importance of quickly implementing the Pediatric Medical Device Safety and Improvement Act and reiterates the comments from June 15, 2010 that supported an FDA regulation to implement the provision of the law that requires new device applicants to submit "readily available" information relevant to pediatrics.

BPCA/PREA Implementation and Reauthorization

Legislative and regulatory efforts to increase information on drugs used in children have now yielded over 397 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 almost three 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 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 35 drugs. They can be found at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/UCM049997. To date, 397 drugs have been relabeled as a result of BPCA, PREA, and the pediatric rule (PREA's predecessor) http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PediatricTherapeuticsResearch/UCM163159.pdf.

GAO AND IOM STUDIES

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. The office also brought together a group of neonatologists together to discuss barriers to studying drugs in the neonatal population.

FDA has successfully completed a contract with the Institute of Medicine (IOM) to conduct a review of BPCA and PREA, as required by FDAAA. The IOM is currently seeking pediatric experts to help with the review. The report will:

1. Review and assess a representative sample of written requests issued by the Secretary and studies conducted under BPCA since 1997, and labeling changes made as a result of such studies;

2. Review and assess a representative sample of studies conducted since 1997 under PREA or precursor regulations, and labeling changes made as a result of such studies;

3. Using a representative sample of written requests issued by the Secretary and studies conducted under BPCA since 1997 and studies conducted since 1997 under PREA or precursor regulations, review and assess (a) the use of extrapolation for pediatric subpopulations; (b) the use of alternative endpoints for pediatric populations; (c) neonatal assessment tools; and (d) ethical issues in pediatric clinical trials;

4. Using a representative sample of studies conducted since 1997 under PREA or precursor regulations, review and assess the number and type of pediatric adverse events;

5. Review and assess the number and importance of biological products for children that are being tested as a result of the amendments made by the Biologics Price Competition and Innovation Act of 2009* and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

6. Review and assess the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and

7. Offer recommendations for ensuring pediatric testing of biological products, including consideration of any incentives, such as those provided under section 505A of the Federal Food, Drug, and Cosmetic Act or section 351(m) of the Public Health Service Act.

Rare Diseases Testimony and Legislation

On July 21, 2010, Dan Frattarelli, MD, delivered PPC-endorsed testimony before the Senate Committee on Health, Education, Labor and Pensions on the issue of treatments for pediatric rare diseases. Dr. Frattarelli discussed how children with rare diseases share similar “small market” drug and device barriers as children in general. He praised the success of BPCA and PREA in increasing the information available on drugs to treat rare diseases in children. He also discussed the importance of the new pediatric device law. Dr. Frattarelli stated that new tools are necessary to collect and interpret disparate data on treatments for rare diseases for the benefit of all children. He also advocated for new investments into the training of pediatric clinical pharmacologists in order to ensure that the workforce necessary to study drugs in children is adequate.

Senators Sam Brownback (R-KS) and Sherrod Brown (D-OH) have introduced legislation to incentivize the development of rare pediatric diseases. The bill, S. 3697, is called the Creating Hope Act of 2010. Current law, championed by Sen. Brownback, provides an FDA priority review voucher as an incentive for anyone who successfully secures FDA approval for a drug to treat a tropical disease. The voucher, which is sellable and transferable, can be exchanged for the expedited FDA review of another new drug application. It is estimated that a voucher could be worth in the range of several hundred million dollars in an open market. The Creating Hope Act expands this program to pediatric rare diseases.

HEALTH REFORM

The Affordable Care Act

On March 23, 2010, President Obama signed into law *The Patient Protection and Affordable Care Act* (Public Law 111-148). On March 30th, the President signed into law *The Health Care and Education Reconciliation Act* (Public Law 111-152). Together, these laws make up the health reform package, known collectively as the Affordable Care Act, and contain a number of strong provisions that impact children and the pediatricians who care for them. Implementation of the Affordable Care Act has been underway since passage in March, but many of the children's health provisions went into effect on September 23rd, the date that marks six months to the day the Patient Protection and Affordable Care Act became law. The September 23rd provisions include:

- Ban on pre-existing condition exclusions for children up to age 19.
- Five billion dollars to fund affordable health coverage for uninsured individuals with pre-existing conditions through the Pre-existing Condition Insurance Plan (PCIP) program, also known as the temporary high-risk pools.
- Extension of dependent coverage under parents' plans for young adults up to the age of 26.
- Requirement that *Bright Futures* preventive services for children be covered with no cost-sharing (deductibles, co-pays or other forms of coinsurance)
- Barring of private insurance plans from rescinding coverage, except in the case of fraud or intentional misrepresentation.
- Barring of private insurance plans from imposing lifetime dollar limits on coverage for "essential health benefits."
- Restriction and gradual phasing out of annual limits on coverage.
- Choice of participating pediatricians as a child's primary care provider.
- Requirement that out-of-network emergency services be covered at the same cost as in-network emergency services.
- Requirement for plans to establish internal appeals and external review processes for patient appeals on denials of coverage.

The AAP and the PPC have been working closely with Congress and the Administrative agencies in charge of implementation to ensure that the Affordable Care Act is implemented to provide the best possible outcomes for children and the pediatricians who care for them.

Shortly after the Affordable Care Act became law, several insurance companies threatened to stop offering new child-only health policies, citing concerns that families would enroll their children only when they fell ill and subsequently drop the coverage, leading to adverse selection. In response to these concerns, on July 27th, the Obama Administration issued guidance stating that insurers in the individual market could restrict enrollment of children, whether in family or individual coverage, to specific open enrollment periods, if allowed under state law. The number and length of open enrollment periods

would be left up to insurers, unless a state requires continuous open enrollment or requires an open enrollment period of a particular length or frequency. In discussions with the Administration, the pediatric representatives expressed deep concern with this barrier to access for families whose children fall ill outside of the open enrollment period.

Unfortunately, the insurers that threatened to stop offering new child-only policies beginning September 23rd, did so. On September 24th, Secretary Sebelius sent a letter to the President and CEO of America's Health Insurance Plans (AHIP) noting the Administration's disappointment and providing additional guidance. The letter outlined actions that insurers could take in order to continue offering child-only plans while addressing their concerns regarding adverse selection. These actions include:

- adjusting rates for health status, as permitted by state law,
- permitting child-only rates to be different from rates for dependent children, consistent with state law,
- imposing a surcharge for dropping coverage and subsequently reapplying, if permitted by state law,
- instituting rules to prevent dumping by employers, to the extent permitted by state law,
- closing the block of business for current child-only policies, if permitted by state law, and
- selling child-only policies that are self-sustaining and separate from closed child-only books of business, if permitted by state law.

Some states, like Maine, Massachusetts, Nevada, New Jersey, New York, and Vermont, have "guaranteed issue" requirements, which means that health plans must allow individuals to enroll regardless of health status, age, gender, and other factors (such as pre-existing conditions). Other states have responded to plans leaving the child-only market by enacting legislation. California enacted legislation that requires individual-market issuers that offer family coverage to also offer child-only policies. In New Hampshire, insurers offering coverage in the individual market must offer child-only policies and cannot deny coverage based on a pre-existing condition to a child who applies for such a policy. In addition, a number of states, including California, Colorado, Ohio, Oregon, and Washington, have established uniform open enrollment periods, and others, such as Minnesota, have considered doing so. These actions help create a level playing field by preventing families from signing up for coverage for children only when their costs are high. This helps ensure that no insurer will receive a disproportionate share of children with pre-existing conditions, since all insurers must accept children during the same period.

Advocacy groups have discussed alternative solutions for getting children with pre-existing conditions access to coverage, including through the Pre-Existing Condition Insurance Plan Program (PCIP). There are concerns about the shortcomings of the PCIP regulation released on July 30 in relation to children with pre-existing conditions. Namely, the PCIP rule:

- did not make clear whether or not pediatric services were included,
- did not include child-only plans as an option in the PCIP,

- requires a 6-month waiting period with no waiver for children who may have had insurance but were not covered for their pre-existing conditions,
- did not set standardized open enrollment periods, and
- does not include a longer enrollment period in the initial year.

On October 6th, the HHS Office of Consumer Information and Insurance Oversight's Office of Insurance Programs issued guidance on newborn coverage in the PCIP. Namely, the guidance stated that PCIPs can - on a temporary basis - cover newborns of mothers that are enrolled in the PCIP and that any child, regardless of whether a parent is enrolled in a PCIP, could qualify for the PCIP program by satisfying the eligibility requirements of the specific State where their child resides.

Another option under discussion has been the decision by twelve states to offer unsubsidized buy-ins to the Children's Health Insurance Program (CHIP). Oregon both has required a consistent annual open enrollment period through an emergency regulation and is marketing its CHIP buy-in program to ensure that families have private and public options for insuring their children. No federal approval is required for this type of buy-in, and the Centers for Medicare and Medicaid Services has offered to work with states interested in adopting this option.

On October 13th, Secretary Sebelius in a public letter to the National Association of Insurance Commissioners, outlined efforts by the Department of Health and Human Services, working with states, to ensure insurance companies keep their promise to "make pre-existing conditions exclusions a thing of the past" for children. The letter highlights that the Affordable Care Act makes it illegal for insurance companies to deny coverage to children with pre-existing conditions and referenced the report released on October 12th by the House Energy and Commerce Committee finding that more than 651,000 people were denied coverage because of a pre-existing medical condition between 2007 and 2009.

In the letter, Secretary Sebelius also states that the PCIP program includes coverage of pediatric benefits, prescription drugs, and inpatient, outpatient, and mental health services. Coverage is provided at standard premium rates charged in the commercial individual market, with no pre-existing condition exclusions. PCIPs normally require an applicant to produce a denial letter from an insurer to be eligible for PCIP coverage. However, uninsured children with pre-existing conditions can qualify if they have a letter from their doctor or are charged a high rate, depending on the state program's rules. The Administration is also working to ensure that PCIPs in all states offer coverage for children at a premium based on the standard rate for children, which should greatly improve affordability.

Additionally, prior to the enactment of the Affordable Care Act, 34 states had established high-risk pools for all residents with pre-existing conditions whom private insurers declined to insure. These pools are an additional option in those states for children with pre-existing conditions, and some states, including Mississippi, are planning to open their pools to all uninsured children. Finally, every state has coverage available to children without regard to pre-existing conditions through their Medicaid and CHIP programs; in most states, these programs are available to families with incomes below $44,000 (twice the poverty level).

Prevention and Public Health Fund Support

The Affordable Care Act established the Prevention and Public Health Fund, a dedicated funding stream for a variety of public health and community-based prevention activities. The fund will provide the necessary support and infrastructure to promote overall health throughout the country. It may be used to support a number public health issues, including health promotion and disease prevention, access to vaccines, capacity to respond to infectious disease outbreaks, tobacco control and cessation programs, and obesity prevention, among others. The fund will also be used to support the training of current and future public health professionals.

In August, Sen. Mike Johanns (R-NE) identified this fund as a way to offset his amendment to an unrelated bill, the Small Business Jobs and Tax Credit Act, H.R. 5297. Members of the public health community sent a letter to the Senate expressing strong opposition to the use of the Prevention and Public Health Fund as an offset for Sen. Johann's amendment, which would eliminate all funding for the Prevention and Public Health Fund until Fiscal Year 2018. The amendment was subsequently defeated in the Senate.

Coverage of Preventive Services Interim Final Rules Letter

In September, the PPC and other groups submitted comments to the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury regarding the Interim Final Rules for Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services under Section 2713 of the Patient Protection and Affordable Care Act (ACA). The groups expressed strong support for the Interim Final Rules, which state clearly that all private health plans must cover, without cost-sharing, all services described in Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents, 3rd edition. In addition to overall support for the Interim Final Rules, the PPC urged the Departments to give special consideration to several important issues, including:

- Implications of inadequate payment or inappropriate bundling for access to preventive health services;
- The minimal impact of pediatric preventive care coverage on insurance premiums;
- Timely adoption of updates to *Bright Futures*;
- Application of Section 2713 to the Medicaid program;
- Access to preventive care services under grandfathered plans;
- Implications of cost-sharing for conditions identified through preventive care;
- Enforcement and compliance issues;
- Support for the delivery of preventive care in the medical home; and
- Incorporation of *Bright Futures* guidelines into electronic medical records.

PEDIATRIC RESEARCH

Federal Funding for Stem Cell Research

On September 28, 2010, a U.S. Court of Appeals issued a permanent stay requested by the Obama administration to reinstate funding for embryonic stem cell research that was halted on August 23, 2010

by a district court judge. As a result of the district court judge's original order, the National Institutes of Health (NIH) announced that it would suspended any new grants for such research and that it would not renew any current projects.

A law restricting the destruction of embryos for research purposes has been on the books for some time, but the judge's ruling was surprising because Congress has always regarded the stem cell research policies of both the Bush and Obama administrations as consistent with this existing law.

The Court of Appeals, which issued the stay on the injunction, plans to hear the Obama administration's appeal of the district court ruling. Meanwhile, Congress is considering clarifying the existing law to explicitly authorize the Department of Health and Human Services to conduct embryonic stem cell research.

National Children's Study (NCS) Appropriations

President Obama's FY2011 budget proposed $194.4 million for the National Children's Study, up from $193.8 million. The Senate appropriations committee provided the same amount in its FY2011 bill. While the Senate had previously expressed concern about the cost of the program, this year it praised the management of the study and the direction in which it was headed.

The public health community collectively supported $194.4 million in funding for the last fiscal year, 2010. 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 FY2010. Although the House approved $194.4 million, the Senate did not specify a funding amount for FY2010. The final omnibus appropriations bill for FY2010 provided the National Children's Study $193.8 million.

Pediatric Research Consortia Establishment Act

The Pediatric Research Consortia Establishment Act, a bill to amend Title IV of the Public Health Service Act to establish the National Pediatric Research Consortia, passed in the House of Representatives by voice vote on October 1, 2010. The House version of the bill (H.R. 758) was sponsored Rep. Dianna DeGette (D-CO). The bill now goes on to the Senate where the prospects of action in the lame duck session seem remote. The Senate version (S. 353) is sponsored by Senators Sherrod Brown (D-OH) and Kit Bond (R-MO.). The pediatric societies provided their collective support to this important legislative effort in the 110th Congress and will continue to do so.

The Pediatric Research Consortia Establishment Act authorizes up to 20 National Pediatric Research Consortiums at institutions throughout the country. The consortiums 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.

NIH Appropriations

The president's FY 2011 budget requested $32 billion for the National Institutes of Health (NIH), an increase of $1 billion over the previous fiscal year. Both the Senate and the House have equaled this request in their committee and subcommittee, respectively, bill drafts. The National Institute of Child Health and Human Development are slated for a $40 million increase, to $1.369 billion. Currently, however, the NIH is funded until December under the continuing resolution, which is continuing last year's $31 billion appropriation.

Agency for Healthcare Research and Quality (AHRQ) Appropriations

The President's FY2011 budget proposes $611 million in funding for AHRQ, an increase of $214 million over the current FY2010 level. The FY2010 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

Pediatric Workforce and Health Care Reform

PRIMARY CARE WORKFORCE

On September 27, 2010, the Department of Health and Human Services (HHS) announced $253 million in new investments authorized under the Affordable Care Act (ACA) to increase the number of health care providers and strengthen the primary care workforce. This is the first allocation from the $500 million Prevention and Public Health fund for FY 2010 created by the Affordable Care Act. Half of this fund— approximately $250 million—will be used to boost the supply of primary care providers by providing new resources for:

- **Creating additional primary care residency slots**: $167.3 million for training more than 500 new primary care physicians by 2015;
- **Supporting physician assistant training in primary care:** $30.1 million for supporting the development of more than 600 new physician assistants;
- **Encouraging students to pursue full-time nursing careers:** $31 million for encouraging over 600 nursing students to attend school full-time so that they have better odds of completing their education;
- **Establishing new nurse practitioner-led clinics:** $14.8 million for the operation of 10 nurse-managed health clinics which assist in the training of nurse practitioners;

- **Encouraging states to plan for and address health professional workforce needs:** $5.6 million for states to plan and implement innovative strategies to expand their primary care workforce by 10 to 25 percent over ten years to meet increased demand for primary care services.
- **Supporting states in training personal and home care aides**: $4.2 million for training more than 5,100 qualified personal and home care health aids by 2013.

More information on the Prevention and Public Health Fund workforce grants, including list of grant awards by state are available at http://www.hhs.gov/news/press/2010pres/09b/state_charts.html

PEDIATRIC SUBSPECIALTY WORKFORCE

Section 5203, "Health Care Workforce Loan Repayment Programs," of the Affordable Care Act authorized loan repayment programs for pediatric subspecialists and pediatric surgical specialists to help improve children's access to timely pediatric specialist care.

This provision, authorized by P.L. 111-148 and P.L. 111-192 but not yet appropriated, would incentivize training and practice in pediatric medical subspecialties in underserved areas across the United States by establishing and implementing a loan repayment program of up to $35,000 for each year of service for a maximum of three years. The program is authorized at $30 million for each of FY 2010 through FY 2014 for loan repayments for pediatric medical specialists and pediatric surgical specialists and $20 million for each of FY 2010 through FY 2013 for loan repayments for child and adolescent mental and behavioral health professionals.

To date, the FY 2011 Senate Labor-HHS-Education Appropriations bill has passed through committee but fails to fund the Section 5203 initiative. The House Appropriations bill has only passed subcommittee and top line numbers are all that are publicly available at this time; however, staff has confirmed that the Section 5203 provision is not addressed in the FY 11 House Labor-HHS-Education Appropriations bill either.

The PPC signed a letter to the Chairmen and Ranking Members of the Senate and House Labor, Health and Human Services, and Education Subcommittees on Appropriations urging them to fully fund the Section 5203 in FY 2011. This letter was also distributed to all members on the Appropriations Committee in both chambers. Senator Sherrod Brown, a newly appointed member of the Appropriations Committee and champion of Section 5203 in the Affordable Care Act, has indicated that this issue is his highlight priority in the FY 11 Labor-HHS-Education bill among all authorized, but not yet appropriated, programs in health reform.

General Pediatrics Training Grants Appropriations

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 so requires ongoing and concerted support from the PPC.

As Title VII appropriations are being discussed in Congress, pediatric groups have emphasized that pediatricians are important primary care providers and support for pediatric training grants is essential to address the nation's changing health care needs. Although Title VII is designed to bolster the primary care workforce, funding is not necessarily divided evenly among all players. Representatives for pediatrics have called attention to specific aspects of the appropriations bill impacting the pediatric workforce, including opposition to section 747 that carved-out funding specifically for family medicine programs. Since then, the Senate passed their appropriations bill excluded the family physician carve-out, however, we await the House's final decision as they have yet to make their version public.

On July 27, the full Senate Appropriations Committee approved its FY 2011 Labor-HHS-Education bill, including $356 million for the Title VII health professions programs, a $96.5 million (40.3 percent) increase over FY 2010 levels. The Senate spending measure included substantial increases for the faculty loan repayment, allied health, workforce information and analysis, and public health and preventive medicine programs. The primary care medicine and primary care dentistry programs, which, as a result of the Affordable Care Act are now funded as separate lines, both received substantial increases over the comparable amounts for the programs in FY 2010.

The Title VIII nursing education programs received $292 million in the FY 2011 Senate-approved bill, a $48.4 million (19.8 percent) increase over FY 2010. The Title VIII faculty loan program, advanced education nursing, and nurse education, practice and retention programs each received increases, while the remainder of the Title VIII programs were flat funded.

On July 15, the House Labor-HHS-Education Appropriations Subcommittee passed its FY 2011 spending measure, which included $356 million for the Title VII health professions programs and $292 million for nursing education. At this time, it is unclear how the funding will be allocated between existing programs and newly-authorized programs under the Affordable Care Act.

The president's FY 2011 budget requests $260 million for the Title VII health professions programs, a $5.9 million (2.3 percent) increase over FY 2010 enacted levels. The increase is designated solely for the Title VII health workforce information and analysis program, which is proposed at $8.8 million, a nearly $6 million (210 percent) increase over FY 2010. The program received approximately $2.8 million in FY 2010 after several years of receiving no funding. For all other Title VII programs, the president is requesting no increase. For the Title VIII nursing education programs, the president's budget requests $244 million in FY 2011, with none of the programs proposed for increases over FY 2010.

The Health Professions and Nursing Education Coalition (HPNEC) has called for $600 million in FY 2011 for Titles VII and VIII (nursing) to effectively meet the growing demand for pediatric and adolescent health services.

Separate from the federal appropriations process, $250 million dollars in FY 2010 Affordable Care Act Prevention and Public Health Fund money was allocated from the Administration to strengthen the primary care workforce. The new investments will be used specifically for: creating additional primary care residency slots, supporting physician assistant training in primary care, encouraging students to pursue full-time nursing careers, establishing new nurse practitioner-led clinics, and assisting States in addressing health professional workforce needs. This funding compliments existing FY 2010 Title VII and Title VIII appropriations.

GME Financing for Children's Hospitals (CHGME)

President Obama's FY2011 budget outline proposes $318 million in funding for CHGME. The PPC and the AAP continue their collaboration with the National Association of Children's Hospitals (NACH) to urge the House and Senate Appropriations Committees to include funding for the CHGME at the authorized level of $330 million in FY2011. The House and Senate both passed the FY2010 Consolidated Appropriations Act which approved $317 million for CHGME.

PHYSICIAN PAYMENT

Medicaid FMAP Extension

On August 10, 2010, President Obama signed the Education, Jobs, and Medicaid Assistance Act (PL 111-226) into law, extending a smaller version of the enhanced Federal Medical Assistant Percentage (FMAP) included in the 2009 *American Recovery and Reinvestment Act* to states through June of 2011. Earlier that same day, the House reconvened from its August recess to pass the Act (H.R. 1586), which the Senate had passed on August 5, 2010. Without the extension, the enhanced Medicaid match rate was set to expire on December 31, 2010.

The FMAP extension was dropped from the House's job creation bill (HR 2847) and the Senate's long term extenders package (HR 4213) in May. On August 2, Senators Murray, Harkin, Reid, and Schumer introduced an amendment (S.A. 4575) to H.R. 1586 (the Aviation Safety and Investment Act of 2010), which included State Medicaid support as well as education funding. Under the new law's $16.1 billion FMAP extension, states will receive expanded match rates through June of 2011, including 6.2 % through the end of 2010, 3.2% starting January 2011 until April 2011, and 1.2% starting in April 2011 through June 2011, with an additional increase based on unemployment rates. Offsets include a return to pre-Recovery Act food stamp funding levels effective March 2014.

CMS issued an informational bulletin on this law on August 18, 2010: (http://www.cms.gov/apps/docs/08-18-10-cmcs-informational-bulletin-FMAP-Extension-Guidance.pdf).

Medicaid Physician Payment

Section 1202 of the Affordable Care Act provides federal financing to improve Medicaid payment to physicians with a primary specialty designation of internal medicine, family medicine, or

pediatrics. Under the law, states must pay for many primary care services at Medicare payment rates in 2013 and 2014. States will receive 100% federal matching funds (FMAP) for the difference in payment above the state's rates that were in place on July 1, 2009. On April 30, 2010, the PPC signed a letter to Secretary Sebelius arguing that the payment reform under Section 1202 should be considered to include pediatric subspecialists as well as primary care pediatricians. Pediatric subspecialists bill many of the evaluation and management codes slotted for rate increases in Sec. 1202.