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DEDICATED TO THE HEALTH OF ALL CHILDREN™

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ACADEMIC AND SUBSPECIALTY ADVOCACY

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AAP Advocacy on Academic and Subspecialist Issues

The American Academy of Pediatrics is actively engaged in federal advocacy for the needs of academic and subspecialist pediatricians and the children their work benefits. 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 Public 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.

Heath Care Reform Implementation

The Academy is working with Congress and the Administration to ensure that the implementation of the Affordable Care Act (ACA) benefits children and helps pediatricians serve their patients better. The AAP has commented on numerous proposed regulations to implement the law, weighing in on issues including appropriate pediatric benefits and Medicaid payment for pediatric subspecialists. The Academy is advocating to preserve funding for ACA provisions that will improve access to care for children.

Essential Health Benefits

On December 16, the Department of Health and Human Services (HHS) released pre-regulatory guidance (a "Bulletin") on the highly anticipated Essential Health Benefits (EHB) package, which is the minimum package of benefits that all insurance packages listed in Exchanges, in the individual market, and in the small group market must cover beginning Jan. 1, 2014. In its News Release announcing the guidance, HHS declared that the Bulletin is meant to give states more flexibility in implementing health reform. However, by statute, HHS is charged with determining which services and benefits must be provided within the 10 categories of the essential health benefits package. Insurers and advocacy groups have been awaiting an HHS rule on the package which would have spelled out what services must be covered—and, by implication, what a minimum acceptable plan would cost. But instead of a prescriptive package, HHS set forth in the Bulletin that it is designing a program where states may choose an existing health plan and use it as a template for its future competitors. Under the guidance, states would determine their own essential health benefits by selecting from the following options to create a "benchmark":

- one of the state's three largest small-group plans;
- one of the state's three largest health plans for state employees;
- one of the three largest health plans offered under the Federal Employees Health Benefits Plan (FEHBP); or
- the largest HMO operating in the state's commercial market.

All other insurers in the individual and small group markets would then be required to provide benefits of equal or greater value to the benchmark. The Bulletin states that plans would be able to modify coverage within the specific benefit categories, provided they do not reduce the overall coverage value of the plan. If a state does not want to select benefits, the default would be the benefits available through the largest small business plan in the state.

HHS is accepting comments on the proposal until Jan. 31, and the Academy will submit comments largely based on its November 15 comment letter to Secretary Sebelius, which advocated for the EHB to mirror the benefits and services covered under Medicaid's Early Periodic Screening Diagnosis & Treatment (EPSDT) benefit.

On October 18, HHS held a private meeting with health care provider groups to seek their input on EHB. Dr. Patience White, MD, FAAP provided testimony on behalf of the AAP highlighting the Academy's position that pediatric benefits in EHB should be similar to those in Medicaid rather than those in the typical small employer plan. HHS held similar meetings with consumer advocates, employers, and insurers the same week. During the month of November, HHS held regional listening sessions throughout the country in an effort to receive broad public input. Nine Fellows of the AAP provided testimony at 7 of these regional listening sessions.

The Courts

On November 14, the Supreme Court announced its decision to review the constitutionality of the individual mandate and several other provisions of the Affordable Care Act. Oral arguments will be heard this coming March, with a decision expected in June. Four lawsuits challenging the law were presented to the justices, but the court will focus on the multistate lawsuit filed by 26 states and the National Federation of Independent Business in Florida—*State of Florida v. U.S. Dep't of Health & Human Services*—in

which the plaintiffs argued that the individual mandate provision exceeds Congress' power to regulate interstate commerce and that the provision requiring states to expand Medicaid to all adults with incomes up to 133% of the federal poverty level is also unconstitutional. The 11th Circuit Court of Appeals on August 15th ruled the individual mandate provision unconstitutional but left the Medicaid expansion intact. The U.S. Department of Justice asked the Supreme Court on September 28 to review the 11th Circuit Court's decision. The high court will devote five-and-a-half hours to the case over three days. On March 26th, the justices will hear one hour of arguments on whether courts have the authority under the Anti-Injunction Act to rule on the individual mandate before 2014 (the Anti-Injunction Act prevents courts from halting taxes before they take effect). The individual mandate provision takes effect in that year and U.S. residents could face penalties for failing to obtain health insurance. The Obama administration has said the mandate is a tax, not a fine, but has requested that the Court rule as early as possible regarding the applicability of the Anti-Injunction Act issue. On March 27, the justices will hear arguments on the constitutionality of the individual mandate for two hours.

Finally, on March 28, the justices will hear 90 minutes of debate on the issue of severability, or whether striking down the individual mandate means invalidating the entire law, and will also hear arguments regarding the constitutionality of the Medicaid expansion.

Advocacy organizations are expected to spend millions of dollars over the next few months trying to influence the Supreme Court's decision. Lobbyists' efforts are expected to include ideological appeals, arguments about the law's popularity among U.S. residents, and campaigns that certain justices (Kagan and Thomas) recuse themselves from the case because of conflict of interest. The AAP signed on to an amicus brief drafted by the Center for American Progress on the individual mandate issue and plans to sign on to another amicus brief, drafted by the National Health Law Program, on the Medicaid expansion issue. Both briefs have evolved from other efforts to which the Academy lent its name in lower courts. The Obama administration and other groups filed briefs on the individual mandate issue with the Supreme Court on January 6, the first filing deadline.

Congress

Several Democrats and Republicans say they expect the GOP to renew efforts to repeal the federal health reform law in 2012. According to *The Hill*, Republicans plan to focus on the most controversial provisions of the reform law—the Independent Payment Advisory Board (IPAB) and the Community Living Assistance Services and Supports Act (CLASS Act)—while the Supreme Court considers the constitutionality of the law and the 2012 elections approach. House and Senate GOP lawmakers have introduced legislation (HR 452, S 668) to dismantle IPAB, whose 15 health experts will be tasked with making recommendations to Congress to reduce Medicare spending growth if certain targets in growth are not met. Meanwhile, leading Democrats acknowledge that the debate on the law will continue through 2012, and they are optimistic about their chances. Senator Tom Harkin (D-IA) said, "This won't be settled until after the next election."

Budget and Appropriations

Congress is currently operating in a divisive and polarizing fiscal environment. The Budget Control Act passed in August attempted to deal with deficit reduction by creating a 12-member Joint Select Committee on Deficit Reduction (JSC) tasked with creating a proposal with at least $1.2 trillion in savings over ten years. Unfortunately, the JSC was unsuccessful, setting up impending cuts to discretionary programs starting in January 2013. Before the end of 2011, President Obama signed an omnibus appropriations package for Fiscal Year 2012 that made cuts to discretionary programs, but was not as detrimental to health programs as was originally predicted. The AAP is undertaking dedicated lobbying efforts to urge both chambers of Congress to protect vital child health programs as they begin work on the FY 2013 budget.

FY 2012 Appropriations

On December 23, 2011 President Obama signed an omnibus appropriations package (H.R. 2055) that contained the nine remaining Fiscal Year (FY) 2012 spending bills, including the Labor-Health and Human Services-Education bill. The bipartisan spending package was negotiated over the past several months by members of the House and Senate Appropriations Committees and was embodied in a conference agreement on the FY 2012 Military Construction-Veterans Affairs bill. In mid-November, the President signed into law the other three appropriations measures (Agriculture, Commerce-Justice-Science, and Transportation-Housing and Urban Development) that make up the customary twelve annual appropriations bills.

The final omnibus spending measure provides a total of **$156.3 billion in regular discretionary funding for Labor, Health and Human Services, and Education programs, which is $1.1 billion below FY 2011 levels**. Also included in the appropriations package was a 0.189 percent across-the-board cut that will impact most health spending accounts. This cut is **not** reflected in the funding levels detailed below.

The U.S. Department of Health and Human Services (HHS)

is allocated a total of $69.7 billion, a decrease of nearly $700 million from FY 2011. Funding levels for specific agencies within HHS are as follows:

- **Administration for Children and Families (ACF):** $29.2 billion, a decrease of $855 million from FY 2011 levels.
- **Centers for Disease Control and Prevention (CDC):** $6.1 billion, an increase of $38 million from FY 2011 levels.
- **Centers for Medicare and Medicaid Services (CMS):** $3.9 billion for CMS Program Management, an increase of $241 million from FY 2011 levels.
- **Health Resources and Services Administration (HRSA):** $6.5 billion, a decrease of $41 million from FY 2011 levels.
- **National Institutes of Health (NIH):** $30.7 billion, an increase of $299 million from FY 2011 levels.
- **Substance Abuse and Mental Health Administration (SAMHSA):** $3.5 billion, a decrease of $27 million from FY 2011 levels.

The following programs important to AAP experienced funding cuts:

- **Title V Maternal and Child Health Block Grant:** $646 million, a decrease of $10 million from FY 2011 levels.
- **Title X (Family Planning):** $297 million, a decrease of $2 million from FY 2011 levels. Earlier this year, the House proposed completely eliminating funding for this program.
- **CDC's Childhood Lead Poisoning Prevention Program:** $2 million, a decrease of $27 million from FY 2011 levels.
- **Title VII Health Professions:** $233 million, a decrease of $19 million from FY 2011 levels.

Despite these cuts, several programs of importance to children and families will see funding increases or have their budgets remain nearly identical to FY 2011 levels:

- **Head Start:** $8 billion, an increase of $424 million from FY 2011 levels.
- **National Institute of Child Health and Human Development:** $1.3 billion, an increase of 6 million from FY 2011 levels.
- **Emergency Medical Services for Children:** $21 million, identical to FY 2011 levels.
- **Children's Hospital Graduate Medical Education:** $268 million, identical to FY 2011 levels.
- **Prevention and Public Health Fund:** $1 billion, identical to FY 2011 levels.

This final appropriations package will fund the federal government through the remainder of the fiscal year, which concludes on September 30, 2012.

In addition, this appropriations package included several concerning policy provisions on reproductive health, syringe exchange and gun control. One specific provision impacts the work of the Federal Trade Commission and other agencies focused on foods marketed to children. The provision would require the Interagency Working Group on Food Marketing to Children (led by the Federal Trade Commission) to follow President Obama's executive order of January 18 before it can issue final recommendations. This requires federal departments and agencies to assess costs and benefits of regulatory actions. AAP has been supportive of the guidelines and will continue to work with the FTC to argue for strong final recommendations.

FY 2013 Appropriations

The Director of the Office of Management and Budget (OMB) issued guidance on August 17 to federal agencies and directors on their budget submissions for the 2013 fiscal year, which commences on October 1, 2012. Unless previously instructed, OMB has given parameters that overall agency requests for 2013 should be at least 5 percent below the 2011 enacted discretionary appropriation level. OMB is in the process of compiling federal agency budgetary requests and drafting the President's budget for its February release.

Budget Control Act and Joint Select Committee on Deficit Reduction

On August 2, Congress passed the Budget Control Act of 2011 (Public Law 112-365), narrowly avoiding default by raising the national $14.3 trillion debt ceiling through 2012. The law authorized the following:

- Cutting $900 billion over ten years. These cuts will be determined by congressional appropriations committees. Although they will not impact Medicaid or the Children's Health Insurance Program (CHIP), these initial cuts could apply to funding for programs important to children.
- Forming a joint congressional committee, which was to recommend more than $1.2 trillion in further deficit reduction by November 23, 2011 or trigger automatic cuts.
- Requiring congressional votes on a proposal for a balanced-budget constitutional amendment.

The twelve members of the bipartisan Joint Select Committee on Deficit Reduction, also known as the "Super Committee," were Senators Patty Murray (D-WA; co-chair), Max Baucus (D-MT), John Kerry (D-MA), Jon Kyl (R-AZ), Pat Toomey (R-PA), Rob Portman (R-OH) and Representatives Jeb Hensarling (R-TX; co-chair), Dave

Camp (R-MI), Fred Upton (R-MI), James Clyburn (D-SC), Xavier Becerra (D-CA), and Chris Van Hollen (D-MD).

The AAP sent several letters to the JSC supporting many important issues including protecting entitlement programs like Medicaid/CHIP, Graduate Medical Education (GME), the Supplemental Security Income disability program, the Affordable Care Act, and other programs important to child health.

Just days before the November 23 deadline, the Joint Select Committee on Deficit Reduction announced that they would be unable to come up with a bipartisan agreement to reach $1.2 trillion in deficit reduction. Despite working for three months on a package of combined budget cuts and revenue raisers, the JSC was unable to coalesce around a compromise piece of legislation.

The BCA was written so that if the JSC could not present to Congress a piece of legislation that would trim the deficit by at least $1.2 trillion over 10 years, a set of automatic cuts to defense and domestic spending ($600 billion each, known as sequestration) would go into effect beginning in January 2013. This mechanism was meant to serve as an incentive for the JSC to work towards a bipartisan agreement. It is possible that Congress could still come up with $1.2 trillion in savings between now and the beginning of 2013 in order to avoid sequestration. President Obama has vowed to veto any legislation passed by Congress that would extend the January 2013 deadline or eliminate the automatic cuts. The Congressional Budget Office estimates that these cuts will be somewhere between 6-10%.

Pediatric Research

National Institutes of Health (NIH)

FY 2012 Appropriations

On December 23, President Obama signed a "megabus" appropriations package that contained the nine remaining Fiscal Year (FY) 2012 spending bills, including the Labor-Health and Human Services-Education (LHHS) bill.

Within the LHHS bill the **NIH** received *$30.632 billion*, the **NICHD** *$1.31 billion* and the **National Children's Study** (NCS) *$191 million* (this includes the 0.189 percent recission applied to most Labor-HHS-Education programs). For the NIH overall, that is a very small decrease from FY11 levels and is essentially flat-funding for the NCS and NICHD. The bill did not include a previous transfer of $300 in NIH funding million to the Global Fund for HIV (this money was transferred to the State and Foreign Operations Appropriations bill).

Funding Prospects for FY 2013

At the beginning of December, Alan Guttmacher, MD, Director of the Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD) at the National Institutes of Health (NIH) provided the American Academy of Pediatrics Committee on Pediatric Research with an update on the prospects for the FY13 budget. According to Dr. Guttmacher, the outlook for 2013 is very much dependent on the outcomes of the 2012 elections and the state of the economy. The economy is the biggest driver for determining the level of funding. The current administration has high regard for the value and importance of the work done at the NIH, so the NIH has relative security as a result, however much could change depending on the results of this fall's elections. Dr. Guttmacher stressed that the current fights surrounding budget cutting at the NIH are not just a 1-2 year temporary problem but more likely a 10-year trend.

National Center for Advancing Translational Science (NCATS)

The National Institutes of Health (NIH) has announced the establishment of a new center to advance translational research. The National Center for Advancing Translational Sciences (NCATS) was authorized and funded as part of the Fiscal Year 2012 appropriations bill and will strive to reengineer the process of developing drugs, diagnostics, and devices. While it currently takes more than 15 years to move from molecular discovery to new therapy, NCATS will "take bold action to transform the translational research enterprise" and work to create new inventive methods and technologies that will enhance the development, testing, and implementation of diagnostics and therapeutics across a wide range of human conditions and diseases.

The National Center for Research Resources (NCRR) has been eliminated and its functions, including the Clinical Translation Science Awards (CTSAs), will be rolled into NCATS as part of the reorganization. The NCATS will have a budget of $575 million and while the search for the head of the new center continues, Acting Director Thomas R. Insel, MD, and Acting Deputy Director Kathy Hudson, PhD, will be at the helm. Dr. Insel is the director of the National Institutes of Mental Health and Dr. Hudson is the deputy director for science, outreach, and policy at the National Institutes of Health.

For more information, check out the new NCATS website.

National Children's Study (NCS)

Enrollment for the vanguard phase of the NCS is coming to an end and the main arm of the study is approaching its launch. The NCS will hold its first Advisory Committee meeting of 2012 on January 24 in Bethesda, MD at the National Institutes of Health.

The FY12 "megabus" funds the NCS at $193.5 million. This includes the 0.189 percent recission of most Labor-Health and Human Services programs and is an increase over

FY11 levels. When Dr. Guttmacher addressed COPR, he relayed that while funding for the NCS is not a sure thing, because like every other federally funded program it cannot be guaranteed, he is confident that the program's future funding is relatively safe and secure.

Federal Funding for Stem Cell Research

The D.C. Court of Appeals has set April 23, 2012 for oral arguments for the plaintiff's appeal in the case of Sherley vs. Sebelius. Dr. James Sherley and Dr. Theresa Deisher, the two researchers who had lost their challenge to government funded embryonic stem cell research, had filed an appeal in September with the D.C. Circuit Court of Appeals to overturn U.S. District Court Judge Royce Lamberth's July dismissal of their initial law suit. The Circuit court is likely to be unsympathetic because they already ruled against the plaintiffs when they rejected the preliminary injunction in April that had been issued by the District court.

Pediatric Research Consortia Establishment Act

The Pediatric Research Establishment Consortia Act (H.R.1080), a bill to amend Title IV of the Public Health Service Act to establish the National Pediatric Research Consortia, was introduced in the House of Representatives by Representative Diane DeGette (D-Colo.). This bipartisan legislation would create a national system of pediatric research, treatments and cures for childhood diseases. There is currently no Senate companion bill.

H.R. 1080 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. Passage of this bill appears unlikely given the current fiscal environment.

AAP Submits Comments to HHS on Human Research Protections Proposal

In October, the AAP submitted comments to HHS in response to the agency's human research protections advanced notice of proposed rulemaking, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators." The HHS-stated goal of the proposed rule is to simultaneously enhance protections for research subjects while improving effectiveness of the federal oversight system, with an extra focus on higher-risk studies. Despite the expansion in volume, location, complexity and types of research, there has been no change made to these rules since 1991.

The AAP's comments emphasized the need to think about children and other vulnerable populations at every step if HHS decides to go forward with a revision to research guidelines for human subjects. The AAP's comments were formally endorsed by the American Pediatric Society, the American Society of Pediatric Hematology/Oncology, the American Society of Plastic Surgeons, the Association of Medical School Pediatric Department Chairs, and the Society for Pediatric Research.

Pediatric Workforce/Graduate Medical Education

GME Financing for Children's Hospitals (CHGME)

At the beginning of December, the AAP resent a letter to all 100 Senators to take up and pass S. 958, legislation reauthorizing the Children's Hospitals Graduate Medical Education (CHGME) program. CHGME is a critically important program that provides funding for pediatric training at 55 freestanding children's hospitals across 30 states. S. 958 would extend the program through 2016 and authorize funding at $330 million per year.

S. 958 continues to be held up in the Senate due to an amendment that Sen. Sheldon Whitehouse (D-R.I.) wants to bring to the floor for a full vote. Sen. Whitehouse's amendment is an expansion of the bill's definition of children's hospitals covered under the program to include certain psychiatric hospitals. According to Sen. Whitehouse, this amendment would cover an additional 24 residents at 3 facilities in Rhode Island and the Bronx, and would cost no additional money. It would however, decrease the GME payment to existing program participants by approximately $23,000 per facility. The House has already passed their companion version of the bill (H.R. 1852), so should an amendment process begin in the Senate, progress on the bill could be stalled.

Senators Ask IOM to Conduct Review of Nation's GME Programs

At the end of December, seven senators, Democrats Jeff Bingaman and Tom Udall of New Mexico and Mark Udall and Michael Bennet of Colorado, and Republicans Jon Kyl of Arizona, Charles E. Grassley of Iowa and Michael D. Crapo of Idaho, sent a letter to the Institute of Medicine (IOM) requesting a review of the governance and financing of the graduate medical education (GME) system. "We believe our GME system is under increasing stress and the projections for our health care workforce are of significant concern," the letter said. "There is growing concern that the United States is failing to adequately match medical training with our medical needs on a national level."

According to the Association of American Medical Colleges (AAMC), western states (where all seven senators come from) have fewer physicians and fewer students enrolled in GME programs compared with states in the Northeast. As a result, the letter requests that the independent review pay particular attention to the inequities in funding across states based on their needs and capacity. The letter also requests an analysis of accreditation, reimbursement policy and the care of the underserved, and sets a deadline for IOM recommendations by the third quarter of 2012.

Pediatric Subspecialty Workforce Loan Repayment Program

In November, a coalition of specialty and pediatric subspecialty groups met with officials from the Bureau of Clinician Recruitment and Service at the Health Resources and Services Administration (HRSA). The coalition advocated for the pediatric subspecialty loan repayment program (Section 5203 of the Affordable Care Act) to be included in President Obama's FY 2013 budget. This meeting is just one in a series of Administration and Hill appointments that the AAP has participated in on these important issues.

Section 5203 was authorized by the Affordable Care Act, but has yet to be funded. The program, which expires on Sept. 30, 2014, would incentivize training and practice in pediatric medical subspecialties in underserved areas across the United States. The program offers up to $35,000 in loan forgiveness for each year of service for a maximum of three years. The FY 2011 Labor-HHS-Education Appropriations bill failed to fund the Section 5203 initiative.

In July, the AAP joined with 25 other pediatric and specialty groups in sending a letter to House and Senate appropriators in support of funding for Section 5203. The letter requested $5 million for the program, which would be administered by the Health Resources and Services Administration, to be included in the FY 2012 appropriations package.

Title VII Training Grant Appropriations

The AAP and its advocacy partners continue to advocate for strong federal support for the Title VII grant program. 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.

In the final FY 2012 spending package Title VII received $233 million, a 7.6 percent cut below FY 2011 levels. The President's FY 2012 budget had requested $449.45 million for Title VII, which was roughly a 65 percent increase over FY 2011 enacted levels.

The AAP, in conjunction with the Health Professions and Nursing Education Coalition (HPNEC), has sent numerous letters to Congress asking lawmakers to continue prioritizing funding for the health care workforce through essential programs such as Title VII. Most recently, in November the AAP joined HPNEC in sending a letter to Congressional appropriators advocating for strong federal support for Title VII and Title VIII programs in the FY 2012 Labor-HHS-Education bill.

Drugs and Devices

Drug Shortages

In response to an increasing number of drug shortages in recent years that have threatened to impact access to important medicines, on October 31, President Obama signed an executive order on drug shortages. The order directed the FDA to take steps that will help to prevent and reduce current and future disruptions in the supply of lifesaving medicines; to use all appropriate administrative tools to require drug manufacturers to provide adequate advance notice of manufacturing discontinuances that could lead to shortages of drugs that are life-supporting or life-sustaining, or that prevent debilitating disease; to take steps to expand its current efforts to expedite its regulatory reviews, including reviews of new drug suppliers, manufacturing sites, and manufacturing changes, whenever it determines that expedited review would help to avoid or mitigate existing or potential drug shortages; and to communicate to the Department of Justice any findings that shortage have led market participants to stockpile the affected drugs or sell them at exorbitant prices. The President also endorsed the pending drug shortages legislation, the Preserving Access to Life-Saving Medications Act.

In conjunction with the executive order, two reports were released: one by the FDA and one by HHS providing an economic analysis of the causes of drug shortages. In response to the President's action, the AAP issued a press release applauding the move as a first step toward improving the situation for children and their health care providers, yet calling on more that can and should be done.

Sen. Amy Klobuchar (D-MN) introduced the Preserving Access to Life-Saving Medications Act (S. 296) on February

7, 2011. The shortages, which have included propofol, erythromycin ophthalmic ointment, oncology drugs, and parenteral nutrition products, have primarily occurred among generic sterile injectables with only one or two manufacturers.

Currently, drug manufacturers are only required to report discontinuances of products to FDA if they are the sole producer of a life-saving, medically necessary product. S. 296 would expand that requirement to include non-sole source manufacturers. The bill would require reporting of information on any type of adjustment or interruption that is likely to result in a change of production. Planned disruptions would have to be reported 6 months in advance, other disruptions would need to be reported as soon as possible, and civil monetary penalties could be collected for failing to report. The FDA would be required to identify drugs vulnerable to shortage and create "continuity of operations" plans to addressing those potential disruptions. If a shortage results from an FDA enforcement action, the agency would be required to perform expedited re-inspections of facilities to speed the manufacturing process back online.

The bill was introduced as an early marker of a potential legislation solution, but there are on-going discussions with stakeholders on the correct package of provisions needed to accurately address this problem. In June, a similar, but not identical, bill was introduced in the House by Representatives Diana DeGette (D-CO) and Tom Rooney (R-FL).

The AAP was invited to serve on a panel at FDA's Center for Drug Evaluation and Research Drug Shortage Workshop on Monday, September 26. Dr. DeWayne Pursley, Chair of AAP's Section on Perinatal Pediatrics, spoke on behalf of the AAP. In preparation for the FDA workshop and likely congressional action on this issue in the coming months, Daniel Frattarelli, MD, FAAP, the Chair of the Committee on Drugs, convened a conference call with the Chairs of relevant AAP Committees and Sections to hear their specific experiences with drug shortages and their recommendations for policy solutions. Participants discussed different examples of recent drug shortages which seem to disproportionately affect intravenous medications. Comments focused on prevention of shortages through the development of critical medications list and stockpiling, improving communication with providers and pharmacists, addressing distribution challenges, and allowing temporary, emergency supply from foreign countries during a shortage.

The December 2011 AAP News featured a cover story on the issue of drug shortages where several FAAPs provided expert recommendations. Pediatricians are encouraged to report drug shortages directly to the FDA. Information on how to report a shortage can be found at FDA's drug shortages website: http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm. AAP staff continue to monitor legislative and administrative action related to drug shortages to ensure the needs of pediatricians are being met. Additionally, AAP is working with other organizations on shortages of ADHD medications.

Pediatric Devices Law Implementation and Reauthorization

For several years, the Academy has engaged in intensive efforts to ensure that children have access to devices that are sized appropriately and accommodate their growing bodies and unique physiology.

AAP 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.

GAO Report

In late 2011, the Government Accountable Office (GAO) released a report on pediatric medical devices required by the 2007 law. The report raised serious concerns about the FDA's ability to track pediatric uses of devices being evaluated by the agency. However, the report contained valuable information showing the early success of the humanitarian device exemption (HDE) pediatric profit allowance that was passed in the 2007 bill. The report showed that since the passage of the bill, pediatric HDE designations have increased five-fold.

The report surveyed pediatricians and children's hospitals on payment for the Medtronic Melody heart device, an HDE device approved under the new pediatric profit allowance. The survey results raised serious concerns about payment for this device by both private insurers, Medicaid, and the Children's Health Insurance Program. Finally, the GAO found that in the first two years, the pediatric medical device consortia consulted on 107 devices.

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.

Two pieces of the law must be reauthorized: (1) the profit allowance for pediatric humanitarian use devices, and (2) the pediatric medical device consortia program. The AAP also wishes to make sure that tracking provisions in the 2007 law are finally implemented.

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 each of the succeeding years. Pediatric advocates will continue to work for full funding of the program at $6 million/year. The recent GAO report found that 107 products have been consulted on by the consortia to date.

Humanitarian Device Reform Act of 2011

On October 14, 2011, a bill called the *Humanitarian Device Reform Act of 2011* (H.R. 3211) was introduced in the House of Representatives by Rep. Charles Bass (R-NH). Similar legislation was introduced in the Senate on November 15, 2011 by Sen. Al Franken (D-MN), the *Patient Access to Medical Innovation Act* (S.1865). This legislation would undermine the pediatric medical device development incentive established in 2007. Initial data show that the pediatric incentive has been successful. While many assume that since it has worked for children it should be expanded to adults as well, the specifics of the proposal would cause serious unintended consequences for the pediatric program.

The incentive was passed as part of the *Pediatric Medical Device Safety and Improvement Act of 2007*, which was championed by the Academy and supported by medical device companies and several other advocacy groups. The 2007 bill created this pediatric incentive by modifying the humanitarian device exemption (HDE) program at the Food and Drug Administration (FDA). It lifted the profit restriction for HUDs labeled for use in a pediatric population. We already have data that lifting the profit restriction has been successful for children and for adults.

The number of pediatric HUD designations increased five-fold in the four years after the passage of the law—from 4 between 2004 and 2007 to 21 between 2008 and 2011. (A HUD designation is the first step to getting an approved HDE device.) While it takes several years for a HUD designation to result in a HDE approved for marketing, we have already seen the approval of three devices under the new profit allowance. A third device has been recommended for approval by an FDA advisory committee.

Under the proposed House and Senate legislation, device manufacturers would no longer need to submit an application for a pediatric indication since they could make a profit by submitting an application only for the adult indication.

The AAP sent a letter to Rep. Bass and Sen. Franken outlining the Academy's concerns with the legislation and asking them to work with the Academy as the legislative process continues. A similar letter has also been sent to the FDA.

Physician Payment

Medicare Physician Payment

Sustainable Growth Rate Formula

On December 23, President Obama signed a two-month delay to the scheduled 27% cut to the Medicare payment rate under the Sustainable Growth Rate formula as part of an agreement to extend the payroll tax cut and unemployment compensation for two months. The Senate had passed the bill by an 89-10 vote on December 17 while the House agreed to a similar measure on December 23. Congress has until the end of February to pass another SGR "fix."

As part of the two-month proposal, both the House and Senate are appointing conferees to discuss a longer-term extension of the SGR formula, payroll tax cut, and unemployment benefits. One of the conferees, Representative Allyson Schwartz (D-PA) had sent the debt/deficit "Super Committee" a detailed proposal on November 16 to fix the SGR formula. Her proposal seeks flat payments for physicians in 2012 and an annual increase of 0.5% for specialists from 2013 through 2016. General practitioners would receive a 2.5% annual increase. And in 2018, gradual cuts would be enacted in reimbursement for physicians participating in fee-for-service systems that pay by procedure.

Medicaid Physician Payment

Payment for CPT Code 96110

The Centers for Medicare and Medicaid Services (CMS) reinstated payment for CPT Code 96110 on December 28. This victory is in large part thanks to Academy members' efforts in submitting comments in response to the initial CMS decision to stop paying for services billed under CPT code 96110, a code that values essential developmental, behavioral and psychosocial screenings. In a Bulletin

released on December 28, Cindy Mann, the Director of Medicaid and CHIP at CMS wrote:

"We want to be clear that Medicaid and other private payers will be able to continue to use code 96110 even though it is a statutorily non-covered service under Medicare. In addition, many State Medicaid programs rely upon Medicare-published relative value units, including those associated with code 96110. At the request of Medicaid and concerned stakeholders, Medicare will provide the relative value units for this code."

CMS has now posted the revised relative value units (RVUs) on its website. The payment rate for 96110 will be based on 0.28 total Relative Value Units (0.27 practice expense and 0.01 malpractice). For additional information on this coding change and what it means for pediatric practices, please visit FederalAdvocacy.aap.org, and stay tuned for the February issue of AAP News, which will provide additional details on CMS' decision.

Supreme Court Review of Medicaid Access Case

The Supreme Court on October 3 heard oral arguments in a case (*Douglas v. Independent Living Centers of Southern California*) that may determine whether Medicaid beneficiaries and providers have the right to sue their state after payment cuts, which plaintiffs frequently argue violate the equal access provision of the Medicaid statute. The equal access provision requires that Medicaid rates must be "sufficient to enlist enough providers" so beneficiaries can access care to the same extent as the privately insured population in a particular area. The case is also significant because the outcome could impact the health reform law's expansion of Medicaid in 2014. The court has yet to rule on the case.

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

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