

Public Policy Council
Washington Update
January 6, 2012

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President Signs Fiscal Year 2012 Appropriations Bill

On December 23, President Obama signed a “megabus” appropriations package that contains the nine remaining Fiscal Year (FY) 2012 spending bills, including the Labor-Health and Human Services-Education bill. The bipartisan spending package was negotiated in December by members of the House and Senate Appropriations Committees and is embodied in a conference agreement on the FY 2012 Military Construction-Veterans Affairs bill (H.R. 2055). The \$724 billion bill includes \$156.3 billion in discretionary spending, \$1.2 billion less than in fiscal 2011 and \$24.6 billion less than President Obama requested. About three-quarters of the funding — \$568 billion — is mandatory spending for Medicare, Medicaid and programs related to the ACA. However, it managed to continue funding for several Democratic-backed programs that Republicans tried to eliminate.

Also passed on December 23 was a bipartisan temporary two-month extension of the payroll tax cut extension, unemployment benefits and the SGR fix. When lawmakers return to Washington later this month they will have to work on a long-term compromise to avoid the expiration of all three programs.

A few highlights from the chart below: 1) All numbers reflect a 0.189 percent recission (decrease) applied to most Labor-HHS-Education programs, 2) **NIH** - \$30.632 billion; **NICHD** - \$1.32 billion; **National Children’s Study** - \$193.5 million. For the NIH overall that is a very small decrease from FY11 levels, however it reflects a minor increase for the National Children’s Study and NICHD. The bill did not include a previous transfer of \$300 million to the Global Fund for HIV (this money was transferred to the State and Foreign Operations Appropriations bill). As a result, there is an effective increase in program level NIH funding. 3) the executive salary cap has been lowered to Executive Level II. That level is applicable for all Health and Human Services (HHS) salaries, and 4) **Maternal Child Health Block Grant** - \$645.1 million; **Title VII/VIII** - \$465.1 million. These numbers reflect an \$11 million and \$50 million (respective) decrease from FY11 levels however, compared to the draft LHHS appropriations bill put out by the House of Representatives, these numbers are much more palatable.

Fiscal Year 2012 Labor, Health and Human Services Funding Bill Highlights						
Program	FY2011 Final	FY2012 House LHHS Draft	FY2012 Senate LHHS	FY2012 Omnibus*	Compared to FY2011 Final	Percent Change
Title V Maternal and Child Health Block Grant	\$656.3 million	\$654.5 million	\$606.3 million	\$645.1 million	-\$11.2 million	-1.7%
Title VII/VIII Health Professions	\$514.9 million	\$194.4 million	\$497.9 million	\$465.1 million	-\$49.8 million	-9.7%
Training in Primary Care Medicine	\$39 million	\$0	\$39 million	\$38.9 million	\$74,000	-0.2%
National Institutes of Health (NIH)	\$30.688 billion	\$31.748 billion	\$30.498 billion	\$30.632 billion	-\$56 million	-0.18%
National Center for Advancing Translational Science (NCATS)	N/A	\$0	\$582.3 million	\$576.4 million (\$10 million for Cures Acceleration Network)	N/A	N/A
Executive Salaries	Executive Level I \$199,700	Executive Level III \$165,300	Executive Level I \$199,700	Executive Level II \$179,700	Executive Level I \$199,700	N/A
National Institute for Child Health and Human Development (NICHD)	\$1.317 billion	\$1.352 billion	\$1.303 billion	\$1.32 billion	+\$4 million	+0.3%
National Children's Study (NCS)	\$191 million	\$193.9 million	\$189.2 million	\$193.5 million	+\$2.5 million	+1.3%
Emergency Medical Services for Children (EMSC)	\$21.4 million	\$0	\$21.4 million	\$21.35 million	-\$50,000	-0.189%
Title X Family Planning	\$299.4 million	\$0	\$299.4 million	\$296.8 million	-\$2.6 million	-0.8%
Teen Pregnancy Prevention	\$104.8 million	\$20 million	\$104.8 million	\$104.6 million	-\$200,000	-0.189%
Centers for Disease Control (CDC)	\$5.649 billion	\$5.59 billion	\$5.766 billion	\$5.657 billion	+\$8 million	+0.14%
Children's Hospital Graduate Medical Education (CHGME)	\$268 million	\$268 million	\$268 million	\$267.5 million	-\$500,000	-0.189%

* The FY 2012 figures in this table reflect a 0.189 percent recession applied to most Labor-HHS-Education programs

NICHD Director Provides Budget Update to AAP Committee on Pediatric Research

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 following issues:

Fiscal Year 2013 Funding:

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 next 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 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. Dr. Guttmacher 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 funding is safe and secure.

Translational Research Center Established at the NIH

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 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 remain 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 NCATS new [website](#).

Americans Opposed to Cutting Funding for Medical Research, Teaching Hospitals

In December, the Association of American Medical Colleges (AAMC) released a [survey](#) which found that most Americans (self-identified Democrats, Republicans and Independents) are opposed to cutting federal funding for medical research and teaching hospitals, which provide training for new doctors, care for sicker patients and special medical services. The telephone survey contacted 800 registered voters and was conducted from Nov. 16-20. The survey found that more than six in 10 voters (62 percent) oppose significantly cutting federal funding for medical research, and that nearly eight in 10 voters (77 percent) oppose significantly cutting funding to teaching hospitals.

PPC and AAP Urge Senate to Pass CHGME Reauthorization Bill

At the beginning of December, the four PPC member organizations joined with the American Academy of Pediatrics (AAP) in resending a letter to all 100 Senators to take up and pass S. 958, legislation reauthorizing the Children's Hospitals Graduate Medical Education (CHGME) program before the end of this year. 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.

CHGME 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.

"Sunshine" Rule Released by CMS

On December 14, the Centers for Medicare and Medicaid Services [released](#) a [proposed rule](#) that would require drug and device manufacturers to disclose payments and gifts they give to physicians beginning sometime this year. This is required under the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act (ACA) in an effort to increase transparency in the financial relationships between industry and prescribers. Under the "Sunshine" rule, funding from drug companies that goes to research institutions will be attributed to the principal investigators. According to CMS, the research payments will be listed separately and will not be included when computing how much each physician received from industry. Companies are to designate research payments as either direct (payments provided to a physician or teaching hospital) or indirect (to institutions).

D.C. Court of Appeals Sets Date for Oral Arguments for Stem Cell Research Funding Case

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.

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. Many people, from both professional and public vantage points, believe that the GME system needs to be revamped in order to more effectively train physicians who focus on information technology, integrated care and other approaches needed for changes in the health care delivery system. 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.

NICHD Extends Deadline for Associate Director for Extramural Research Search

The search for the new Associate Director for Extramural Research at the Eunice Kennedy Shriver National Institute for Child Health and Human Development (NICHD) at the National Institutes of Health (NIH) has been extended to **March 1, 2012**. See the job posting on the NICHD [website](#).

Senate Finance Hearing on Drug Shortages

The Senate Finance Committee, chaired by Senator Max Baucus (D-MT) held a [hearing](#) at the beginning of December entitled, "Drug Shortages: Why They Happen and What They Mean." Witnesses and senators discussed potential solutions to the dramatic increase in drug shortages, including changing the federal reimbursement model for drugs and devices, amending FDA reporting requirements, or creating a national stockpile of drugs.

Later that week, the Senate Health, Education, Labor and Pensions (HELP) Committee held a similar [hearing](#). Witnesses from both the public and private sector discussed public health concerns and their potential solutions. Mike Enzi, Ranking Member of the HELP Committee (R-Wyo.), said that he believes

the FDA should expedite review of applications for drugs in shortage. Congress has become increasingly interested in the topic of drug shortages and President Obama signed an executive order on the subject in October. The order directed the FDA to take steps to prevent shortages of lifesaving medicines.

Upcoming Meetings

The **NIH National Children's Study (NCS) Advisory Committee** will hold its first meeting of 2012 on January 24 in Bethesda, MD. Follow this link to the National Children's Study [website](#) for further information regarding the committee meeting.

On Thursday January 26, the **National Institute of Child Health and Human Development (NICHD) Council** will hold a meeting at its headquarters in Bethesda, Maryland. On the [agenda](#) will be an update from the Director, a discussion regarding the upcoming reorganization of the NICHD, an update on the National Children's Study, a report of the Subcommittee on Planning and Policy and other Council business.