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Physician Payment Fix in S-CHIP Nixed, Appropriations Bills in Trouble

Earlier this summer, both the U.S. House of Representatives and Senate passed legislation reauthorizing the State Children's Health Insurance Program (S-CHIP). Also contained in the House-passed version of the legislation was a provision that would have increased physician payments in 2008 and 2009 by 0.5 percent and ultimately changed the way that Medicare physician payments are calculated. Currently, physician payments are calculated using a complex method called the sustainable growth rate (SGR). The SGR has been a controversial process for some time, as it uses the Gross Domestic Product (GDP) in combination with other formulae to determine physician payments.

The version of the legislation passed by the Senate did not include provisions to alter the physician payment formula, and when Congress returned from its August recess, members of both legislative chambers were tasked with ironing out the differences between the two pieces of legislation. Though it has not yet come up for a vote in Congress, the compromise that members have initially agreed upon strips all language from the bill related to altering the Medicare physician payment formula and providing a payment increase in 2008 and 2009. Both chambers have expressed their desire to fix the physician payment formula, but will not do so in the S-CHIP legislation. Instead, the Senate has expressed its plan to eliminate the physician payment cut in end-of-the-year legislation.

Also in doubt is the passage of the 12 individual appropriations bills which provide funding to government agencies. Prior to adjourning for the August recess, the House passed all 12 spending measures. However, the Senate has passed only four of the spending bills to date and has yet to schedule the remaining eight bills for floor consideration. None of the four appropriations bills that have been passed individually by both chambers has gone through conference committee and been passed by the full Congress. Biomedical research is funded through four independent appropriations bills and of those, only one has been passed by both the Senate and House—the Military Construction, Veterans Affairs, and Related Agencies Appropriations Bill, which funds the VA Medical and Prosthetics Research Division. The remaining three bills have not been scheduled for consideration by the full Senate. The funding levels passed by the Senate Appropriations Committee and the full House are included in the chart below. Increases over FY 2007 funding levels are included in parentheses.

	Senate Appropriations Committee	House
National Institutes of Health*	\$29.9 billion (+\$1 billion)	\$29.65 billion (+\$750 million)
Dept of Energy Office of Science	\$4.49 billion (+\$698 million)	\$4.51 billion (+\$717 million)
National Science Foundation	\$6.55 billion (+\$636 million)	\$6.51 billion (+\$592 million)
VA Medical and Prosthetics Research Division	\$500 million (+\$86 million) (passed by the full Senate)	\$480 million (+\$66 million)
* House bill requires that NIH transfer \$201 million of its increase to the Global AIDS fund, and Senate requires that NIH transfer \$300 million of its increase to the Global AIDS fund.		

The current funding for FY 2007 runs out at the end of September, requiring the passage of a short-term continuing resolution in order to maintain government operations while the Senate and House determine the process for addressing the remaining appropriations bills. The CR, which will likely extend funding through mid-November, will fund government agencies at FY 2007 levels for the duration of the CR. It is likely that Congress will pass an omnibus spending bill for FY 2008, which will include funding levels for all or a majority of government agencies. However, the President has threatened to veto any appropriations bill, including an omnibus spending package, which exceeds the level of discretionary funding in his FY 2008 budget. Current congressional authorizations exceed his budget by \$23B.

Society staff will continue to monitor the progress of both the physician payment fix and the appropriations process, and will provide opportunities for Society members to contact their members of Congress at key points during the process. Society staff will also be meeting with key Senate and House offices to share the concerns of the endocrinology community.

Congress Mandates Expansion of Clinical Trials Registry

Last week, the U.S. House of Representatives and Senate both passed the FDA Amendments Act of 2007 (H.R. 3580), which contains language expanding requirements for reporting clinical trials and their results in clinical trials registry databases. The bill reauthorizes the U.S. Food and Drug Administration (FDA), the current authority of which expires at the end of this month. The President is expected to sign the bill into law by September 30.

Earlier this year, the House and Senate had passed independent bills reauthorizing the FDA, each of which expanded requirements for reporting to clinical trials registries. The bills differed somewhat in the stringency of the reporting requirements and the mechanisms by which reporting would take place. Congress was under time pressure to pass compromise legislation quickly, and so they bypassed the typical conference process of reconciling the two bills and instead negotiated an altogether new House bill (H.R. 3580). Though the process was atypical, the outcome was not. The new bill contains clinical trials registry language that is a compromise between the two original bills.

Some of the new requirements include expansion of the types of trials that must be registered to include clinical trials (other than preliminary studies) of all drugs, devices, and biologics; reporting of results on efficacy for registered trials; and reporting of additional results for approved and unapproved drugs and devices. Implementation of the new requirements is at the discretion of the Secretary of Health and Human Services and is not clearly outlined at this time.

The Endocrine Society recognizes that the new mandate presents at very least potential confusion for its clinical researchers and at worst potentially burdensome reporting requirements. The Society will work both independently and with other concerned organizations to mitigate any burden to the extent possible and to inform members of specific new requirements arising from the legislation.

The full text of the legislation can be read here: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_bills&docid=f:h3580eh.txt.pdf.

Society to Host DXA Webcast for Providers

The Endocrine Society, in cooperation with the National Osteoporosis Foundation, American Association of Clinical Endocrinologists, International Society for Clinical Densitometry, and American Society of Bone and Mineral Research, will host an interactive webcast on October 9, 2007. The webcast will be of interest to physicians who provide DXA scans in their offices and will:

- provide participants with information on the current and anticipated cuts to DXA payments (which will be reduced from \$140 in 2006 to \$35 in 2010),
- highlight the work of the DXA coalition in addressing the cuts, and
- provide information on how physicians can become involved in the efforts of the DXA coalition.

Speakers will include Ethel Siris, MD, President of the National Osteoporosis Foundation, Andrew Laster, MD, Vice President of International Society for Clinical Densitometry, Marjorie Luckey, MD, and Roberta Biegel, Senior Director of Public Policy & Government Relations for the National Osteoporosis Foundation.

The webcast will be held from 12:00–1:30 p.m. Eastern (9:00–10:30 a.m. Pacific) on October 9th, with time allotted for questions from participants. To register for the call, please visit the URL listed below.

<http://www.medconference.net/DXA>

We encourage all physicians who provide DXA services in their office to participate in the call and join the DXA Coalition in fighting these cuts. Your help is needed in demonstrating the detrimental effect these cuts will have on patient access to a vital diagnostic tool.

CSR Reports Ongoing Changes to Peer Review

In the latest issue of *peer review notes*, the Center for Scientific Review (CSR) describes some of the recent and ongoing changes that have resulted from critical examination of the peer-review process for grant applications. Some changes include the abolition of application

deadlines for chartered reviewers, full implementation of shorter review cycles for new-investigator R01 submissions, and pilot projects for shorter R01 applications. Two other articles in this issue report on the CSR Open House workshops and the activities of two working groups on peer review that report to the NIH director. The Endocrine Society has been actively engaged in both processes as the voice for endocrine science and research endocrinologists.

One idea that has emerged from the Open Houses and peer review working groups is the concept of a two-tiered review process for grant applications, similar to the system used by editorial boards in reviewing submissions for journal articles. This idea is being pursued by CSR and a separate story in *peer review notes* describes the next steps for the initiative.

To read the September 2007 issue of CSR *peer review notes*, click here:
<http://cms.csr.nih.gov/NR/rdonlyres/8E310A92-FA88-400C-8D3F-8553810A2A5C/14230/PRNSept2007FINALWeb3.pdf>.

For questions regarding articles listed in *Endocrine Insider* or information on advocacy and policy activities within The Endocrine Society, contact the Government & Public Affairs department:

Janet B. Kreizman, Senior Director
301-941-0252
Jkreizman@endo-society.org

Charles E. Blue, Director, Media Relations
301-941-0240
Cblue@endo-society.org

Stephanie Kutler, Assoc. Director
301-941-0254
Skutler@endo-society.org

Loretta L. Doan, PhD, Manager, Science Policy
301-941-0258
Ldoan@endo-society.org

Lisa Marlow, Manager
240-482-1392
Lmarlow@endo-society.org

Holly Whelan, Manager, Health Policy
301-951-2613
Hwhelan@endo-society.org

Aaron Lohr, Manager, Media Relations
240-482-1380
Alohrr@endo-society.org

Stacey Trunnell, Administrative Assistant
240-482-1389
Strunnell@endo-society.org