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### **Johnson Pay-for-Performance Bill Eliminates Flawed Payment Formula**

On July 28, Congress introduced legislation that seeks to implement Pay-for-Performance (P4P) standards while repealing the SGR. House Ways and Means Health Subcommittee Chair Nancy Johnson (R-CT) introduced the “Medicare Value-Based Purchasing for Physician's Services Act of 2005” (H.R. 3617), which sunsets the flawed Sustainable Growth Rate (SGR) formula that will result in payment cuts for providers and also implements P4P standards in the Medicare program. According to the bill, beginning in 2007, those physicians who voluntarily participate in the program will receive an annual update equal to the Medicare Economic Index (MEI) when reporting quality measures.

The MEI is designed to estimate the increase in the total cost for the average physician to operate a medical practice. Participating providers who do not report measures would receive an update of MEI minus one percentage point. Beginning in 2009, physicians who meet quality measures or demonstrate progress towards meeting them would receive a full MEI update, while providers that fail to do so will receive an update of MEI minus one percentage point. The legislation also establishes that medical societies would be directly involved in creating measures, which would be submitted to quality organizations. The organizations, such as the National Quality Forum, would act as a clearinghouse – compiling the information and submitting recommendations to CMS.

In exchange for the implementation of P4P, H.R. 3617 would repeal the SGR formula, replacing the current methodology with a more stable payment formula based on the Medicare Economic Index (MEI). The SGR formula compares physician expenditures and other services with the gross domestic product (GDP), which measures overall growth of the economy, to arrive at annual spending targets and physician payment rates. This flawed formula will result in an approximate 4.3 percent reduction in physician Medicare reimbursement, beginning January 1, 2006, and a cumulative decrease of approximately 26 percent through 2011. In contrast, MEI estimates the increase in total cost for the average physician to operate a medical practice, taking into account changes in the cost of such expenditures as wages, fringe benefits, office expenses, and professional liability insurance. This legislation is considered the main legislative vehicle for achieving action on these important issues.

The Johnson bill is being supported by the majority of the major medical specialty groups. However, The Endocrine Society has not yet taken a formal position on it.

### **House Holds Hearings on NIH Reauthorization**

The House Energy and Commerce Committee released its first draft of legislation to reauthorize and restructure NIH at a July 19 hearing. As originally drafted, the legislation would change how money is appropriated and distributed within NIH. In lieu of 27 separate institutes that are separately appropriated, Congress would appropriate funds to only four line items. Consequently, NIH would be restructured into two new divisions: 15 “mission specific institutes” and nine “science enabling institutes,” each of which would receive a congressional appropriation. In addition, the Office of the Director and another division dedicated to research that cuts across institutes would also received funding. The proposal would grant the Director broad authority on the distribution of funds within NIH and would allow the agency head to allocate appropriations into what the agency believes are the most pertinent areas of research.

The legislation is still in the very early stages of development and indications are that it will need to be refined to address numerous concerns from both the research community and patient advocacy groups. Many in both camps are concerned with the unprecedented level of fiscal autonomy given to the Director under the legislation. The Endocrine Society continues to be in close contact with congressional authorizers and research leadership groups, such as the Federation of American Societies for Experimental Biology (FASEB), to ensure that the voice of the researcher is protected during the reauthorization process.

### **Society Helps Create FASEB Clinical Research Subcommittee**

The first conference call of the newly established Clinical Research Subcommittee of the Federation of American Societies for Experimental Biology’s (FASEB) Science Policy Committee was held on July 19. The Endocrine Society’s Janet Hall, M.D. is the chair of the Subcommittee. Dr. Hall and members of the Research Affairs Committee, as well as the Society’s FASEB Board representatives, Peggy Shupnik, Ph.D., and Wylie Vale, Ph.D., were the driving forces behind the creation of the Subcommittee within FASEB. During the initial call Subcommittee members were tasked with outlining the goals of the Subcommittee and the process for attaining those goals.

The immediate goals of the Subcommittee include collection of data on training and career paths for clinical investigators to analyze apparent trends monitoring legislation and events related to the creation of clinical trial registry and monitoring NIH initiatives relevant to clinical research with specific reference to Roadmap initiatives. The Subcommittee is also working on development of a presentation on clinical research that would include information to help lay audiences understand what clinical research is and what happens during a clinical trial.

### **Patient Safety Measure Signed into Law**

On July 29, President Bush signed into law legislation designed to improve patient safety by encouraging health care providers to share information about medical mistakes through a voluntary system. The “Patient Safety and Quality Improvement Act” (S. 544) encourages providers to submit data on medical errors to certified patient safety organizations, but stipulates that the data cannot be used against providers in malpractice lawsuits. Once the data are collected, patient safety organizations will create a national database of patient safety

information. These organizations will also work to develop voluntary national standards to promote the exchange of health care information to prevent future errors from occurring.

### **House Passes Malpractice Reform...Again**

The House of Representatives has again passed legislation seeking to curb increasing medical malpractice costs. On July 28, the House passed H.R. 5 The Help Efficient, Accessible, Low-cost, Timely Healthcare (HEALTH) Act, which establishes new provisions for regulating lawsuits for health care liability claims. The new provisions include: limiting noneconomic damages to \$250,000 in malpractice lawsuits; making each party in a malpractice lawsuit liable only for the amount of damages directly proportional to such party's percentage of responsibility; allowing courts to restrict the payment of attorney contingency fees; and limiting the liability of manufacturers, distributors, suppliers, and providers of medical products that comply with Food and Drug Administration standards.

During contentious debate in the House, Republicans claimed the bill would cut health care costs and increase patient access to care, while Democrats countered that the measure would prevent patients from being compensated for medical malpractice and would do little to contain health care costs. The measure now moves to the Senate where it is unlikely to pass. Senate Judiciary Committee Chairman Arlen Specter (R-PA) has said the legislation is essentially stalled in the Senate due to opposition from Senate Democrats; similar measures in the past several years have experienced the same fate.

### **VA Research Funding Levels Approved by Senate**

On July 21, the Senate Appropriations Committee approved the Military Construction and Veterans Affairs Appropriations Bill for Fiscal Year (FY) 2006. The legislation appropriates funds for the Department of Veterans Affairs (VA) and includes nearly \$2 billion in emergency supplemental funding in an attempt to address the previous year's shortfalls.

The bill adds nearly \$5 billion to last year's VA funding level and provides more than \$70.7 billion to fund the VA. This amount includes \$23.3 billion for medical services, \$2.8 billion for medical administration, \$3.2 billion for medical facilities, and \$412 million for medical and prosthetic research.

On May 26, the House of Representatives approved its version of the FY 2006 Military Quality of Life and Veterans Affairs Appropriations bill. The House version provides \$393 million for the VA research program, a cut of 2.3 percent from FY 2005. This is the same level proposed in the President's FY 2006 budget proposal and the FY 2006 budget resolution. Senate and House negotiators will now meet to work out the differences between the two versions of the appropriations legislation.

### **Zerhouni Push to Establish a "Home" for Clinical & Translational Scientists**

National Institutes of Health (NIH) Director Elias Zerhouni, MD recently challenged the medical research community to establish intellectual "homes" in which to train clinical and translational scientists.

Zerhouni encouraged NIH and the medical research community to do "something bold" to reenergize and revamp the training of future clinical scientists. For the past 20 years, NIH

has contributed millions in trying to solve the research training problem. They established loan repayment programs, “K” awards, mentor programs, and programs to increase the number of research instructors for the purpose of creating a home for clinical and translational scientists. After additional research and feedback, NIH discovered that one problem was the training environment. Directors in departments of medicine spent 80 percent of their time in recruitment and performing other administrative duties. Their focuses were diverted away from translation of clinical sciences. The faculty size of academic departments has also increased dramatically. Years ago, an average department would consist of 25 faculty members; today an average department size is 300. “Once, the department was an environment where you could think and mentor,” said Zerhouni.

In order to rectify this problem, NIH has requested applications for either full grants or planning grants. The goal is to create a full, degree-granting academic home with a permanent faculty to train the best thinkers for the discipline of clinical and translational science.

During a stakeholders meeting in May, NIH said that they would redeploy funds for new training programs aimed at validating clinical research. In appropriations language accompanying its Fiscal Year (FY) 2006 funding bill for the Department of Health & Human Services (HHS), NIH approved of the new direction in training. “The decision to help institutions create the academic home and integrated resources will aide research institutions in advancing the new discipline, create a cadre of translational and clinical investigators and transform discoveries into clinical practice,” reads the Appropriations Committee language.

The House of Representatives appropriators expressed interest in learning how NIH will integrate existing grants into more efficient awards and how the new program will transform clinical and translational sciences. The House’s FY 2006 spending proposal for NIH would fund all programs in the agency’s Roadmap for Medical Research at the request level of \$333 million. Of the \$333 million, \$83 million has been appropriated for the Office of the Director and another \$250 million has been contributed by NIH Institutes and Centers. According to agency budget documents, NIH is set to spend \$119.6 million in FY 2006 on reengineering initiatives. Zerhouni has stated that NIH has spent about \$8 billion of its total budget on support of clinical research in past years.

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