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# AAMC Legislative and Regulatory Update



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September 2009

**AAMC Legislative and Regulatory Update  
September 2009  
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## Introduction

As Congress returns to Washington following a month-long recess full of contentious town hall meetings with constituents, it faces a daunting agenda. For academic medicine, the two most pressing concerns are health care reform and the FY 2010 spending bills.

After weeks of negotiations among the Democratic ranks, four of the five congressional committees of jurisdiction have approved their respective health care reform proposals, while hopes for a bipartisan agreement continue in the Senate Finance Committee. But lingering concerns over cost, the impact of the proposals on urban and rural communities, the viability of a new public option for health insurance coverage, and looming procedural questions – including the threat of reconciliation – remain to be resolved.

In the House, the Ways and Means Committee and the Education and Labor Committee each approved their own versions of the America's Affordable Health Choices Act (H.R. 3200) on July 17. The Energy and Commerce Committee, however, deliberated dozens of amendments and ultimately approved its version of the bill on July 31, just before the House adjourned for August recess. To reach the committee vote, Energy and Commerce Chair Henry Waxman (D-Calif.) made concessions to several committee members representing rural, conservative "Blue Dog," and liberal factions of the Democratic Party, and pledged to address some 60 additional outstanding Democratic and Republican amendments before the legislation reaches the House floor. Though all three committee-approved bills build upon the original "tri-committee" bill introduced July 14 (and the preceding "discussion draft"), the House leadership and the House Rules Committee now must reconcile the differences in the bills and craft a package that will appeal to a majority of House Members upon floor consideration, presumably in September.

Meanwhile, the Senate Health, Education, Labor, and Pensions (HELP) Committee spent a month considering nearly 500 amendments to its draft bill, the Affordable Health Choices Act, before approving it on July 15 along party lines. While the HELP bill authorizes numerous quality, prevention, and workforce programs, decisions about the Medicare and Medicaid programs – as well as mechanisms to finance the costs of health care reform – will be driven by the Senate Finance Committee, and six members in particular: Chair Max Baucus (D-Mont.), Ranking Member Charles Grassley (R-Iowa), and Sens. Kent Conrad (D-N.D.), Jeff Bingaman (D-N.M.), Mike Enzi (R-Wyo.), and Olympia Snowe (R-Maine). For months, the "gang of six" has engaged in closed-door, consensus-driven negotiations, the product of which will likely determine the make-up of the bill considered by the full Senate. As this document went to print, details of the Senate Finance Committee's proposal were beginning to emerge, and the President was preparing to address a joint session of Congress.

The AAMC commented on the House Tri-Committee's discussion draft of H.R. 3200 ([www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf](http://www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf)), as well as the Senate HELP Committee's draft bill ([www.aamc.org/advocacy/library/workforce/corres/2009/061509.pdf](http://www.aamc.org/advocacy/library/workforce/corres/2009/061509.pdf)) shortly after they were released. The AAMC also submitted comments on the three "options" papers released by the Senate Finance Committee, and has delivered several letters to House and Senate leaders in recent months. These materials are available on the AAMC Web site at: [www.aamc.org/advocacy/library/start.htm](http://www.aamc.org/advocacy/library/start.htm).

On the appropriations front, Democratic leaders have acknowledged they will fall short of their goal of completing all 12 annual spending bills by the October 1 start of the federal fiscal year. Although the House passed all 12 bills prior to the August recess, only four bills have made it through the Senate floor, and none has gone to conference. Senate Majority Leader Harry Reid (D-Nev.) hopes to finish seven or eight spending bills by September 30, while House Majority Leader Steny Hoyer (D-Md.) has said the House will probably have to pass a continuing resolution by the end of the month to keep the federal government running past October 1.

One of the bills awaiting Senate consideration is the Labor-HHS-Education bill (H.R. 3293), which the House passed on July 24 and the Senate Appropriations Committee approved on July 30. This bill traditionally is one that invokes considerable attention on the Senate floor, and this year promises more of the same, as the Republicans have vowed to offer a litany of amendments.

What follows is a summary, as of September 8, of the major legislative and regulatory actions of importance to academic medicine. Listed at the end of each item is the last name of the AAMC staff person responsible for monitoring that issue. If you wish to receive additional information on a specific issue, you are encouraged to visit the AAMC Government Affairs and Advocacy Web site at: [www.aamc.org/advocacy/start.htm](http://www.aamc.org/advocacy/start.htm) or contact these individuals directly.

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## **American Recovery and Reinvestment Act**

On February 17, President Obama signed the “American Recovery and Reinvestment Act” (ARRA, P.L. 111-5). The House approved the conference agreement [House Rpt. 111-016; [http://thomas.loc.gov/cgi-bin/cpquery/R?cp111:FLD010:@1\(hr016\)](http://thomas.loc.gov/cgi-bin/cpquery/R?cp111:FLD010:@1(hr016))] on the \$787 billion economic recovery package on February 13 by a 246-183 vote, with no Republicans supporting the measure. The Senate approved the bill later the same day by a 60-38 vote, with Republican Senators Susan Collins (Maine), Olympia Snowe (Maine), and Arlen Specter (Pa.) voting in favor of the package.

AAMC President and CEO Darrell G. Kirch, M.D., praised the measure, stating, “The federal funding included for research, medical education, and patient care will help ensure that the nation's medical schools and teaching hospitals will continue to be regional economic engines. At the same time, this new support will strengthen the missions of these institutions to advance medicine, educate the next generation of doctors, and care for their local communities.” Dr. Kirch’s February 13 statement is available at: [www.aamc.org/newsroom/pressrel/2009/090213.htm](http://www.aamc.org/newsroom/pressrel/2009/090213.htm)

The conference agreement includes \$311 billion in discretionary funding, including \$166.7 million to the Department of Health and Human Services. Information on how the HHS funds are being allocated is available at: [www.hhs.gov/recovery/](http://www.hhs.gov/recovery/). The following programs are of interest to academic medicine. *[Moore]*

**National Institutes of Health:** The conference agreement provides \$10.4 billion for NIH. Of this amount, \$8.2 billion is appropriated to the Office of the Director, with \$7.4 billion designated for transfer to the Institutes, Centers, and Common Fund in the same proportion as the FY 2009 appropriation. The conference agreement provides \$1.3 billion for the National Center for Research Resources (NCRR), with \$1 billion for “competitive awards for the construction and renovation of extramural research facilities” and \$300 million for “shared instrumentation and other capital equipment.” The conference agreement also provides \$500 million for the Buildings and Facilities account to be used for construction and renovation of NIH intramural buildings. NIH has posted a number of documents relating to the ARRA funding at: [www.nih.gov/recovery/index.htm](http://www.nih.gov/recovery/index.htm).

The AAMC, through the Ad Hoc Group for Medical Research, is sponsoring a series of Congressional briefings on how NIH is investing ARRA funds to help stimulate the economy and advance medical research. The first briefing featured a presentation by Anthony Fauci, M.D., Director, National Institute of Allergy and Infectious Diseases, on June 1, followed by a second briefing on July 10 with Thomas R. Insel, M.D., Director, National Institute of Mental Health. Slide sets and video Web casts of the briefings are available on the Ad Hoc Group Web site at: [www.aamc.org/research/adhocgp/news.htm](http://www.aamc.org/research/adhocgp/news.htm). *[Moore, Rasouli]*

**Health Professions:** The conference agreement provides \$500 million to the Health Resources and Services Administration (HRSA) for health professions workforce development through scholarships, loan repayment, and grants to training programs for equipment. An accompanying explanatory statement allocates \$300 million of this

funding for the National Health Service Corps (NHSC), with \$75 million to remain available through Sept. 30, 2011, for “extending service contracts and the recapture and reallocation of funds in the event that a participant fails to fulfill his or her term of service.” The conference agreement also designates 20 percent of NHSC funds for field operations.

On June 2, the NHSC announced that it would begin accepting applications for loan repayment using ARRA funds. The NHSC will now accept loan repayment applications continuously until ARRA funds are expended or September 30, 2010, whichever comes first. For the first time, clinicians do not need to be employed in an approved site in a Health Professional Shortage Area when applying, but must be available to begin work within 30 days of being notified that their application has been accepted. NHSC anticipates most applications will be processed within eight weeks of the submission of a complete application. More information is available at: <http://nhsc.hrsa.gov/loanrepayment/>. [Shick]

On July 28, Secretary of Health and Human Services Kathleen Sebelius and HRSA Administrator Mary Wakefield, Ph.D., R.N., announced details of how \$200 million appropriated through ARRA for HRSA’s health professions training programs will be allocated. According to the announcement, funds will be directed as follows:

- \$47.6 million for the Title VII Primary Care Medicine and Dentistry program;
- \$80.2 million for scholarships, loans, and loan repayment awards, including \$40 million in Title VII Scholarships for Disadvantaged Students, \$1.2 million for the Title VII Faculty Loan Repayment program, and \$39 million for nurses and nurse faculty;
- \$10.5 million for Title VII public health workforce training programs, including preventive medicine residencies;
- \$10.2 million to increase health professions diversity, including \$4 million for the Title VII Centers of Excellence, \$3 million for the Title VII Health Careers Opportunity Program, and \$3.2 million for nursing workforce diversity programs under Title VIII;
- \$50 million in grants to health professions training programs to purchase equipment; and
- \$1.5 million to assist state professional licensing boards in reducing barriers to telemedicine.

The announcement notes that awards will be made “over the next several months,” with funding opportunities for some programs announced over a timeframe that allows applicants “adequate time to prepare materials.” HRSA also has indicated that it will offer new competition for the primary care and preventive medicine/dental public health programs, telemedicine state licensure grants, and grants for equipment. However, the remainder of funding opportunities – including funds for scholarships and loan repayment, diversity programs, and all nursing programs – will be used to award the backlog of approved but unfunded 2009 and qualified 2008 applications. HHS announced the first round of nursing awards on August 12.

HHS estimates that the funds will support training 8,000 students and health professionals by the end of FY 2010. Additional details are available on the HRSA Web site at: <http://bhpr.hrsa.gov/recovery/> [*Rasouli*]

**Health Information Technology Incentives:** The ARRA provides an estimated \$22 billion in funding for programs and incentive payments to promote the adoption of health information technology (HIT). This funding includes incentive payments for hospitals, physicians, and other “eligible professionals” under the Medicare and Medicaid programs as well as matching grants, such as demonstration projects to develop curricula integrating certified electronic health records (EHRs) in the clinical education of health professionals.

The two committees established by the ARRA to advise the Office of the National Coordinator for Health Information Technology (ONC) have held monthly public meetings since May. The HIT Policy Committee and the HIT Standards Committee have been developing recommendations to the ONC and the Centers for Medicare and Medicaid Services (CMS) regarding issues such as how providers can demonstrate “meaningful use” of EHRs to be eligible for federal Recovery Act funding and how EHRs will be certified. The committees also will make recommendations for other issues related to the nation’s HIT infrastructure.

The HIT Policy Committee adopted a recommended definition of “meaningful use” in the form of a “meaningful use matrix.” As required by ARRA, the definition sets a threshold definition for 2011 and becomes progressively more stringent in later years. The HIT Policy Committee also adopted recommendations on the certification process and on general principles regarding information exchange. The HIT Standards Committee also adopted various recommendations developed by its workgroups and will continue to identify performance standards for the seven “meaningful use” measures for which no standards currently exist.

CMS and the ONC are expected to take into account the advice of these two committees in developing regulations to be released later this year. CMS intends to publish a proposed rule with 60 day comment period regarding the Medicare and Medicaid HIT incentives in late December, including a proposed definition of “meaningful use.” The ONC will publish an interim final rule with comment period regarding standards, certification, and implementation specifications by December 31. CMS has indicated that it will release a final rule on the Medicare and Medicaid HIT incentives by “late spring.”

The AAMC comment letters on the proposed definitions of “meaningful use” are available on the AAMC’s HIT Web page at:  
<http://aamc.org/members/gir/hit/start.htm>.

The agendas and all materials from each of the HIT Policy and Standards Committee meetings are located on the committees’ Web sites at:  
[http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&parentname=CommunityPage&parentid=5&mode=2&in\\_hi\\_userid=10741&cached=true](http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&parentname=CommunityPage&parentid=5&mode=2&in_hi_userid=10741&cached=true)

and

[http://healthit.hhs.gov/portal/server.pt?open=512&objID=1271&parentname=CommunityPage&parentid=8&mode=2&in\\_hi\\_userid=10741&cached=true](http://healthit.hhs.gov/portal/server.pt?open=512&objID=1271&parentname=CommunityPage&parentid=8&mode=2&in_hi_userid=10741&cached=true).

The Department of Health and Human Services (HHS) has announced the release of funding for several grants supported by ARRA. On August 20 HHS announced the release of \$1.2 billion in funding to health information technology (HIT) extension centers and to states. This announcement followed Secretary of Health and Human Services Kathleen Sebelius' August 18 delegation of authority to National Coordinator for Health Information Technology David Blumenthal, M.D., M.P.P., to administer a majority of the HIT-related grant and loan programs funded through ARRA.

Other agencies recently have issued requests for proposals for additional HIT funding supported by ARRA. The Social Security Administration opened a solicitation that will allocate \$24 million to accelerate disability claims processing by automating the exchange of health records through the Nationwide Health Information Network. Additionally, the Department of Labor recently announced the release of \$125 million for health care workforce training, specifically soliciting applications that focus on health information technology career training.

Application information regarding the extension center (Funding Opportunity No. EP-HIT-09-003) and state grants programs (Funding Opportunity No. EP-HIT-09-001) is available at: [www.grants.gov](http://www.grants.gov).

The Social Security Administration's solicitation is available at: [www.fbo.gov/index?s=opportunity&mode=form&id=df343db1bf298ef9336bb8da0e723863&tab=core&cck=1&au=&ck](http://www.fbo.gov/index?s=opportunity&mode=form&id=df343db1bf298ef9336bb8da0e723863&tab=core&cck=1&au=&ck).

The Department of Labor's grant announcement is available at: <http://edocket.access.gpo.gov/2009/pdf/E9-17416.pdf>. [*Legislative: Mitchell, Rasouli; Regulatory: Baer, Mihalich-Levin*]

**Health Information Privacy:** In addition to HIT Incentives, the ARRA includes several new health information privacy requirements. After considering public comments in response to April 2009 guidance, the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) on August 19 issued a "Breach Notification" interim final rule with request for comments. As directed by the ARRA, the rule requires health care providers and other entities covered by the Health Insurance Portability and Accountability Act (HIPAA) to notify affected individuals following a breach of unsecured protected health information (PHI). Breaches affecting more than 500 individuals must be reported promptly to affected individuals, the HHS Secretary, and the media. In smaller cases, HHS can be notified on an annual basis. The Federal Trade Commission (FTC) has issued companion breach notification regulations that apply to vendors of personal health records and certain others not covered by HIPAA.

HHS decided not to include the limited data set as a method for rendering data as protected health information. However, in cases of impermissible use or disclosure of a

limited data set, a covered entity or business associate must perform a risk assessment to determine whether the risk of identifying a particular individual poses any significant risk of harm. If there is no significant risk of harm to the individual, then no breach has occurred and no notification is required.

HHS also updated its guidance to specify encryption and destruction as technologies and methodologies that render protected health information unusable, unreadable, or indecipherable to unauthorized individuals. Entities subject to the HHS and FTC regulations that secure health information as specified by the guidance through encryption or destruction are relieved from notification requirements in the event of a breach of such information. HHS interim final regulations are effective starting September 23, with public comment period until October 23. HHS will not impose sanctions for failure to provide notifications for breaches discovered before February 22, 2010.

The April 2009 Draft HHS Guidance, FR Doc. E9-9512, RFI is available at: [www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/federalregisterbreachrfi.pdf](http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/federalregisterbreachrfi.pdf)

ARRA, P.L. 111-5 is available at: [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111\\_cong\\_public\\_laws&docid=f:publ005.111.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_public_laws&docid=f:publ005.111.pdf)

AAMC May 21 comment letter is available at: [www.aamc.org/advocacy/library/teachhosp/corres/2009/052109.pdf](http://www.aamc.org/advocacy/library/teachhosp/corres/2009/052109.pdf)

The HHS Health Information Breach Notification Regulation is available at: [www.federalregister.gov/OFRUpload/OFRData/2009-20169\\_PI.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-20169_PI.pdf)

According to an ARRA implementation plan for the Office of the National Coordinator for Health Information Technology, the office will issue most ARRA-required regulations regarding the HIPAA Privacy Rule by February 18, 2010. The plan is available at: [www.hhs.gov/recovery/reports/plans/onc\\_hit.pdf](http://www.hhs.gov/recovery/reports/plans/onc_hit.pdf). [Tartakovsky, Baer]

**Comparative Effectiveness Research:** On August 6, the Agency for Healthcare Research and Quality (AHRQ) announced an “Intent to Publish Grant and Contract Solicitations for Comparative Effectiveness Research (CER) Projects with Funds from the American Recovery and Reinvestment Act (ARRA).” ARRA provided \$300 million directly to AHRQ for comparative effectiveness research projects. According to the announcement, funding initially will focus on 14 priority conditions previously established by the Secretary of Health and Human Services. AHRQ anticipates that funding opportunities will be posted beginning in fall 2009, with funding beginning in spring 2010.

Announcements will provide \$100 million for a new “Clinical and Health Outcomes Initiative in Comparative Effectiveness” (CHOICE), which will support a series of prospective studies in routine clinical practice as well as new study designs focused on “under-represented populations.” A total of \$48 million of ARRA funds will be available

to establish or enhance national patient registries that allow longitudinal research focused on under-represented populations. The notice also describes that AHRQ will provide:

- \$9.5 million to establish infrastructure;
- \$10 million to establish a “Citizen’s Forum” of public stakeholders;
- Funds to enhance existing contracts for evidence synthesis (\$50 million), evidence generation (\$24 million), translation and dissemination (\$5 million);
- \$3 million for salary and benefits related to ARRA awards; and,
- \$1 million in other grants.

The notice is available at: <http://grants.nih.gov/grants/guide/notice-files/NOT-HS-09-009.html>. The list of 14 priority conditions is available at: <http://effectivehealthcare.ahrq.gov/aboutUs.cfm?abouttype=program#Conditions>.

**Table 1**  
**Discretionary Programs of Interest to AAMC**

<b>Program</b>	<b>FY 2009 Omnibus</b>	<b>President’s Budget</b>	<b>FY 2010 House</b>	<b>% change 09-10</b>	<b>FY 2010 Senate Com.</b>	<b>% change 09-10</b>
<b>NIH</b>	\$30.317 B	\$30.759 B	\$31.259 B	3.1%	\$30.759 B	1.5%
<b>Title VII</b>	\$222 M	\$265 M	\$266 M	20.1%	\$243 M	9.8%
<b>Title VIII</b>	\$171 M	\$263 M	\$263 M	54 %	\$217 M	26.7%
<b>AHRQ</b>	\$372 M	\$372 M	\$372 M	0%	\$372 M	0%
<b>Children’s GME</b>	\$310 M	\$310 M	\$320 M	3.2%	\$315 M	1.6%
<b>NHSC</b>	\$135 M	\$169 M	\$142 M	5.1%	\$142 M	5.1%
<b>CDC</b>	\$6.67 B	\$6.699 B	\$6.737 B	1.0%	\$6.828 B	2.4%
<b>VA Medical Care</b>	\$40.4 B	\$44.5 B	\$44.5 B	10%	\$44.7 B	10.5%
<b>VA Research</b>	\$510 M	\$580 M	\$580 M	13.7%	\$580 M	13.7%
<b>NSF</b>	\$6.490 B	\$7.045 B	\$6.937 B	6.9%	\$6.917 B	6.6%

**FY 2010 Labor-HHS-Education Appropriations Bill**

On July 30, the Senate Appropriations Committee approved (29 – 1) its version of the FY 2010 Labor-HHS-Education Appropriations bill (H.R. 3293, S. Rpt. 111-66), two days after the corresponding subcommittee approved the spending bill by voice vote. In a July 28 statement, Subcommittee Chair Tom Harkin (D-Iowa) referenced the \$10.4 billion for the National Institutes of Health (NIH) and other funding provided in the American Recovery and Reinvestment Act (ARRA, P.L. 111-5) as “a major factor in shaping this bill” and stated the committee’s bill “instead emphasizes several other important programs” that did not receive substantial ARRA funding. The committee report accompanying the bill states, “The Committee understands that fiscal year 2011 will be an even more difficult year, because several programs that were well-funded in ARRA will face the prospect of falling off a cliff. The Committee expects to restore a special emphasis on its traditional priority programs next year to help ease the transition to a post-ARRA budget.”

The House of Representatives July 24 approved (264-153) its FY 2010 House Labor-HHS-Education Appropriations bill (H.R. 3293, H.Rpt.111-220), one week after the full Appropriations Committee voted to pass the package. The committee considered a series of amendments on July 17 before approving the spending bill by voice vote. *[Moore]*

House Report 111-220 is available at:

[http://thomas.loc.gov/cgi-bin/cpquery/R?cp111:FLD010:@1\(hr220\)](http://thomas.loc.gov/cgi-bin/cpquery/R?cp111:FLD010:@1(hr220))

Senate Report 111-66 is available at:

[http://thomas.loc.gov/cgi-bin/cpquery/R?cp111:FLD010:@1\(sr066\)](http://thomas.loc.gov/cgi-bin/cpquery/R?cp111:FLD010:@1(sr066))

**National Institutes of Health (NIH):** The Senate Committee bill includes the President's request of \$30.8 billion for the NIH, a \$442 million increase over the FY 2009 level. This total includes \$300 million to be transferred from NIH to the Global Fund to Fight HIV/AIDS, Malaria, and Tuberculosis.

The House-approved version of the bill provides \$31.3 billion for NIH, a \$942 million increase over FY 2009, and \$500 million above the President's request and the Senate Committee bill. This funding level includes the \$300 million transfer from NIH to the Global Fund and a \$500 million transfer to NIH from the Project BioShield Special Reserve fund under the Department of Homeland Security.

Both the House and Senate Committee bills reject the Administration's proposal to earmark increases for cancer and autism research. The House Committee report accompanying the bill notes "The Committee believes it is more appropriate to allocate funding in a way that permits scientific peer review to decide the most promising research to support." The Senate Committee report agrees, stating, "the President's plan would set a dangerous precedent. The Committee has long subscribed to the view that funding levels for individual diseases should be determined without political interference."

During floor consideration of the bill, the House approved by voice vote an amendment offered by Rep. Darrell Issa (R-Calif.) to prohibit NIH from funding three peer-reviewed grants supported by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse (NIDA) to study alcohol and substance use and increased HIV risks among vulnerable populations in Thailand, China, and Russia and develop interventions to reduce AIDS transmission. No such provision is in the Senate Committee's bill.

The Senate bill includes \$549 million for the Common Fund, the same amount as the President's request, and \$8 million (1.5 percent) above the FY 2009 level. The House bill provides \$534 million, a \$7 million cut.

Both the House and Senate bills reject the Administration's proposal to limit salaries of researchers through an NIH grant to not more than the rate of Executive Level II (\$177,000 in 2009) and continue language from previous years setting the limit at Executive Level I (\$196,700 in 2009).

With regard to extramural conflicts of interest, the House Committee report notes, “The Committee is encouraged that NIH has issued an advance notice of proposed rulemaking as a first step in responding to the Committee's directive in fiscal year 2009 to develop a conflict of interest policy for extramural grantees, both institution administrators and scientists. The Committee understands that the comment period on the advance notice has just ended. It urges NIH to rapidly review the comments received and take the next steps to develop a robust extramural conflict of interest policy. It is clear from reports of continued abuses that NIH policy must be strengthened to deal with the increasing complexity of public-private interactions in biomedical research.”

The Senate Committee bill includes legislative language (section 219) requiring the Secretary of HHS by May 1, 2010, to “amend regulations at 42 CFR Part 50 Subpart F for the purpose of strengthening Federal and institutional oversight and identifying enhancements, including requirements for financial disclosure to institutions, governing financial conflicts of interest among extramural investigators receiving grant support from the National Institutes of Health.” The Appropriations Committee also requests HHS, within 30 days of enactment of the bill, to provide to the Committees on Appropriations of the House of Representatives and the Senate a schedule for meeting that deadline.

The House and Senate committee reports both address the use of Class B dealers. Citing the committee-requested National Academy of Sciences (NAS) report on random source dogs and cats, the House report notes “The Committee would like to eliminate the use of Class B dealer animals in NIH research, but also wants to be certain that sufficient supplies of non-Class B dealer random source animals exist,” while the Senate committee report states “The Committee therefore expects the NIH to phase out, as quickly as possible, the use of any of its funds for the purchase of, or research on, dogs or cats obtained from those USDA-licensed Class B dealers who acquire dogs or cats from third parties ... and resell them. Specifically, the NIH should not award any new grants or contracts that involve such animals and should immediately begin supporting alternative sources of random source animals from non-Class B dealers.”

Both the House and the Senate committees urge NIH to pursue the NAS's recommendations to issue Requests for Proposals to provide or develop specific animal models and/or to support private research animal colonies. The committees also direct NIH to submit by April 1, 2010, an action plan, including a timeline to prohibit use of Class B dealer animals. The Senate committee report adds that NIH should “address these concerns with a degree of urgency that has been sorely lacking in the 2 years” since the NAS study was requested. *[Moore, Rasouli]*

**Health Professions:** The House-approved bill provides \$266.3 million for the Title VII health professions training programs, a \$44.6 million (20.1 percent) increase over FY 2009. Within this total, the bill provides the President's recommended increases for the Centers of Excellence, Health Careers Opportunity Program, Scholarships for Disadvantaged Students, Primary Care Medicine and Dentistry programs, and Geriatric Training programs. The bill also provides a \$1.6 million (4.9 percent) increase over both FY 2009 and the President's request for the Area Health Education Center (AHEC) program.

The Senate committee bill provides \$243.4 million for Title VII, a \$21.7 million (9.8 percent) increase over FY 2009, but \$21.3 million less than the President's request, and \$22.9 million less than the House bill. The Senate committee bill includes the President's proposed increases for the Title VII Centers of Excellence and Health Careers Opportunity Program, and also increases funding for the Primary Care Medicine and Dentistry program and the Public Health and Preventive Medicine program. In addition, the Senate committee bill provides \$5.7 million for Title VII Health Professions Workforce Information and Analysis; the program has received no funding since FY 2005, when it was funded at \$716,000.

For the Title VIII Nursing Education programs, the House bill provides the President's recommended \$263.4 million, a \$92.3 million or 54 percent boost, including increases to the Title VIII Nursing Loan Repayment and Nursing Faculty Loan programs. The Senate committee bill provides \$216.7 million, a \$45.7 million (26.7 percent) increase over FY 2009, but \$46.7 million less than both the President's request and the House bill.

*[Rasouli]*

**National Health Service Corps:** Both the House-approved and the Senate committee bills provide \$142 million for NHSC. The funding level represents a \$7 million (5.2 percent) increase over FY 2009, but is \$27 million less than the President proposed.

*[Shick]*

**National Research Service Awards (NRSA):** Like the President's budget, the House and Senate committee bills preserve for FY 2010 the NIH's authority to transfer 1 percent of its budget for National Research Service Awards (NRSA) to the Health Resources and Services Administration (HRSA) and the Agency for Healthcare Research and Quality (AHRQ). The language inadvertently had been deleted from NIH authorizing legislation in 2006, but has been restored in the enacted appropriations bills since then. *[Rasouli]*

**Children's Hospitals Graduate Medical Education:** The House-approved bill provides \$320 million for the Children's Hospitals GME program, a \$10 million (3.2 percent) increase over both FY 2009 and the President's request. The Senate committee bill provides \$315 million for the program, a \$5 million (1.6 percent) boost over FY 2009 and the President's request. *[Rasouli]*

**Agency for Healthcare Research and Quality:** Both the House-approved and the Senate committee bill provide \$372.1 million for AHRQ, as provided in FY 2009 and the President's budget request. The House-approved bill provides \$12.5 million for "Patient-Centered Health Research," funded at \$50 million in FY 2009 under the heading "Clinical Effectiveness Research." According to the House report, the \$37.5 million (75 percent) cut is included due to the \$1.1 billion invested for such research through the American Recovery and Reinvestment Act. The House-approved bill also increases funding over FY 2009 for prevention and care management, patient safety, and healthcare-associated infections (HAI) activities. The Senate committee bill preserves AHRQ funding for comparative effectiveness research at the FY 2009 level of \$50 million.

Both the House and Senate committee reports express concern over dwindling support for investigator-initiated research. The House bill pledges “additional funding” for such research “to advance discovery and the free marketplace of ideas.” Despite praise for AHRQ’s activities on comparative effectiveness, patient safety, and HAIs, the Senate committee report notes “AHRQ’s investigator-initiated research activity has languished.” Citing the timeliness and potential for research on health disparities, access, health care financing and organization, and other issues, the Senate committee report urges AHRQ to prioritize investigator-initiated research, providing \$23.6 million “to develop a more balanced research agenda.” *[Rasouli]*

**Centers for Disease Control and Prevention:** For the CDC, the House-approved bill exceeds the President’s request by \$38 million and provides \$6.737 billion in program level funding, a \$67 million (1 percent) increase over FY 2009. The Senate committee bill provides \$6.828 billion in program level funding, a \$158.9 million (2.4 percent) increase over FY 2009, and \$130 million more than the President’s request. *[Rasouli]*

**Bioterrorism and Emergency Preparedness:** Both the House-approved and Senate committee bills more than double funding within the Public Health and Social Services Emergency Fund (PHSSEF) for the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR). The bulk of the increase is achieved by fulfilling the President’s request to transfer the Project BioShield Special Reserve Fund to ASPR from the Department of Homeland Security.

The House-approved bill provides \$1.644 billion for ASPR, an \$856.7 million (109 percent) increase over FY 2009, but \$510 million less than the President’s budget. Unlike the President’s request, the House bill transfers \$500 million from the BioShield Reserve Fund to the NIH’s National Institute of Allergy and Infectious Diseases. Also within the ASPR total, the bill adopts the President’s request to transfer \$305 million from the BioShield Special Reserve Fund to fund advanced research and development, a \$30 million (10.9 percent) boost over funding provided in FY 2009. The House ASPR total also includes \$420 million for Hospital Preparedness grants, a \$32.4 million (8.4 percent) increase over the FY 2009 total for the program.

The Senate committee bill provides \$2.140 billion for ASPR, a \$1.352 billion (171 percent) increase over FY 2009. Like the House-approved bill, the Senate committee ASPR total also includes the President’s recommendation of \$305 million for advanced research and development and his proposed \$32.4 million increase for Hospital Preparedness grants. *[Rasouli]*

**National Institute of Disability and Rehabilitations Research:** Both the House and the Senate committee bills match the President’s request of \$110.7 million for NIDRR. The funding level represents a \$3 million (2.8 percent) increase over FY 2009. *[Shick]*

### **FY 2010 National Science Foundation Funding**

On June 18, the House approved, 259-157, the FY 2010 Commerce-Justice-Science Appropriations bill (H.R. 2847, H.Rpt. 111-149), which includes funding levels for NSF. The House-approved bill provides \$6.937 billion for NSF, a \$447 million (6.9 percent)

increase over FY 2009, but \$108 million less than the President's budget. For research and related activities, the House-approved bill includes \$5.642 billion (\$459 million or 8.9 percent more than FY 2009) compared to \$5.733 billion in the President's request.

Meanwhile, the Senate Appropriations Committee unanimously approved its version of H.R. 2847 (S.Rpt. 111-034) on June 25, providing \$6.917 billion for the NSF. The total represents a \$427 million (6.6 percent) increase over FY 2009, but falls \$128 million short of the President's budget. The Senate committee provides \$5.618 billion for research and related activities at NSF, a \$435 million (8.4 percent) increase over FY 2009. The funding level is \$115 million lower than the President's budget. *[Rasouli]*

### **FY 2010 Food and Drug Administration Funding**

The House approved its FY 2010 FDA spending bill (H.R. 2997, H. Rept. 111-181) on July 9, and the Senate approved its version (S. 1406, S. Rept. 111-39) nearly a month later on August 4. Like the President's request, the bills provide \$2.35 billion for the FDA, a \$299 million (14.6 percent) increase over funding appropriated in FY 2009. The FDA budget is supplemented by drug and device user fees, yielding an expected total of \$3.04 billion for FDA in FY 2010. *[Rasouli]*

### **FY 2010 Veterans Affairs (VA) Medical Care and Research Funding**

On July 10, 2009, the House passed (415-3) the FY 2010 Military Construction and Veterans Affairs appropriations bill, which also includes advanced funding for VA medical care in FY 2011. The House bill includes \$44.5 billion for FY 2010 VA medical care, a \$4.1 billion (10 percent) increase over FY 2009; and \$48.2 billion for FY 2011 VA medical care, a \$3.7 billion (8 percent) increase over FY 2010. VA research receives the President's request of \$580 million, a \$70 million (13.7 percent) increase over FY 2009. The House FY 2010 appropriations bill does not include funding for research or information technology.

The House report language directs the VA Under Secretary for Health to provide a report to the House and Senate Appropriations committees on the recommendations of the VA Blue Ribbon Panel on VA-Medical School Affiliations. The Blue Ribbon Panel, chaired by former AAMC President Jordan Cohen, M.D., was created in 2006 to advise the VA "on issues related to comprehensive philosophical framework to enhance VA's partnerships with medical schools and affiliated institutions.

The Senate Appropriations Committee approved its version of the spending bill (S. 1407) on July 7. The Senate committee bill includes \$44.65 billion for VA medical care, a \$4.25 billion (10.5 percent) increase over FY 2009. The Senate committee bill provides \$580 million for VA research, matching the President's request and the House-approved bill. Additionally, the Senate committee bill provides FY 2011 advanced funding for VA medical care at \$48.19 billion, a \$3.54 billion (7.9 percent) increase over FY 2010, but does not include advanced funding for VA research. *[Shick]*

## Health Care Reform

The Senate Health, Education, Labor, and Pensions (HELP) Committee's draft health care reform legislation and the House "Tri-Committee" bill (H.R. 3200) approved by the committees on Ways and Means, Energy and Commerce, and Education and Labor, include numerous provisions of interest to academic medicine.

Meanwhile, the Senate Finance Committee continues its bipartisan negotiations, likely based on three "options" papers released earlier this year, as well as an AAMC-supported agreement with members of the hospital community and the White House. Under the agreement, hospitals will "contribute" \$155 billion to coverage expansion efforts through payment reductions and delivery improvements over the next 10 years.

An overview of the House Tri-Committee and Senate HELP bills is provided below; additional details about specific provisions are available in the AAMC comments provided to the Senate HELP Committee ([www.aamc.org/advocacy/library/workforce/corres/2009/061509.pdf](http://www.aamc.org/advocacy/library/workforce/corres/2009/061509.pdf)) and the House Tri-Committee ([www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf](http://www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf)). Please also see sections on Medicare Direct GME and IME Payments (pg. 16), Medicare Physician Payments (pg. 25), Medicaid (pg. 30), and Title VII Reauthorization (pg. 33), for a more detailed analysis of relevant provisions.

**House Tri-Committee:** Building on a "discussion draft" released June 19, the chairs of the House committees on Ways and Means, Energy and Commerce, and Education and Labor, jointly introduced the "Tri-Committee" America's Affordable Health Choices Act (H.R. 3200) on July 14. On July 17, the Ways and Means Committee (23-18) and the Education and Labor Committee (26-22) approved amended versions of the bill. The Energy and Commerce Committee approved (31-28) its own version on July 31, after considering and approving numerous amendments. The three versions of the bill will need to be reconciled before going to the House floor. As introduced, the Tri-Committee bill:

- Includes a redistribution of unused graduate medical education (GME) training slots, the preservation of Medicare-funded GME training slots when teaching hospitals close, and the elimination of regulatory barriers to placing residents in non-hospital settings for portions of their training;
- Includes Medicare physician payment reform that fully eliminates the scheduled 21 percent cut and implements in CY 2011 newly rebased target growth rates for two distinct service categories: evaluation and management (E&M) and Medicare preventative services; and all other services;
- Reduces Medicare disproportionate share hospital (DSH) payments beginning in FY 2017, if, between FYs 2012 and 2014, the number of uninsured individuals drops by over 8 percent;
- Reduces Medicaid DSH payments by \$10 billion beginning in FY 2017, using a new methodology to implement the cuts;
- Directs the Secretary of HHS to revise the geographic adjustment factors used by the Medicare physician and inpatient hospital payment systems;

- Includes an initiative to reduce “potentially preventable” hospital readmissions, starting in FY 2011;
- Extends the Physician Quality Reporting Initiative (PQRI) through 2012, along with the creation of incentive payments for counties with low rates of Medicare per capita spending on physician services;
- Establishes that GME costs would qualify for federal Medicaid “matching” payments and establishes greater accountability for “how such payments are being used;”
- Limits the creation and expansion of physician-owned hospitals;
- Allows practitioners to practice part-time in the National Health Service Corps (NHSC);
- Creates a new program providing scholarship and loan repayment for physicians providing “primary health services” and other health professionals that agree to serve in shortage areas designated by the Secretary of HHS;
- Reauthorizes some of the Title VII health professions and Title VIII nursing education programs (see Title VII Reauthorization on pg. 33), and creates a new program under Title VII awarding grants to eligible “teaching health centers” (such as community health centers) that participate in the demonstration project under section 1502(d) of the bill; and,
- Incrementally increases funding deposited in a new Public Health Investment Fund, authorizing appropriators to use the Fund to supplement appropriations for designated programs, including the NHSC, Title VII, and other health programs.

Additionally, both the Ways and Means and Energy and Commerce committees adopted language that requires an Institute of Medicine (IOM) study of geographic variations in per capita health care spending (see page 19). The study would review spending among Medicare and privately insured individuals. The IOM would be required to submit a report to Congress within three years of enactment. The report must include recommendations “for addressing variation in per capita spending by promoting high-value care.” The provision states that the IOM shall “specifically address” whether (and how) Medicare payments for physicians and hospitals “should be further modified to incentivize high-value care.”

The Energy and Commerce Committee also adopted several amendments of interest, including provisions to:

- Direct the HHS Secretary to study the amended and new public health and workforce development programs under Division C of the bill and to terminate any existing program found to be duplicative;
- Authorize the HHS Secretary to award grants to establish new or assist existing “verified” trauma centers to “further core missions,” with preference for centers that have at least one GME fellowship in trauma or trauma-related specialties “for which demand is exceeding supply;”
- Establish within the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR) an Emergency Care Coordination Center to promote and fund research in emergency medicine and trauma care and to promote preparedness;
- Establish a demonstration program under ASPR providing matching grants to applicants that design, implement, and evaluate coordinated emergency medical

systems that allow tracking of hospital resources and include region-wide systems;

- “Encourage” the NIH Director through the Pain Consortium to continue and expand basic and clinical research on pain causes and treatments;
- Limit the use of comparative effectiveness research in coverage determinations;
- Implement a new process for establishing “appropriate” Medicaid reimbursement levels; and
- Require “best practice” guidelines to reflect recommendations from physician societies.

**Senate HELP Committee:** The HELP Committee approved its draft Affordable Health Choices Act on July 15, with a party-line 13-10 vote. The bill organizes health care reform provisions under the committee’s jurisdiction into titles on coverage, quality, prevention, workforce, fraud and abuse, and biologics. Of particular interest to medical schools and teaching hospitals, the bill (as released):

- Establishes a program for publicly reporting readmission rates;
- Authorizes grant funding for the development of community health teams to support the medical home model;
- Creates a demonstration program through grant funding to develop and implement patient safety and quality improvement curriculum into health professionals’ clinical education;
- Requires the Secretary of Health and Human Services (HHS) to publish a notice of proposed rulemaking to establish in consultation with relevant stakeholders a methodology for designating medically underserved populations and health professions shortage areas;
- Directs the Secretary to establish a Center for Health Outcomes Research and Evaluation to conduct and support research that compares the “outcomes, effectiveness, and appropriateness” of health care services;
- Incrementally increases the authorization for the National Health Service Corps (NHSC) to \$1.15 billion in FY 2015, and establishes a formula to increase authorizations in future years;
- Establishes a primary care extension program offering grants through states to assist primary care providers in educating health care professionals on preventive medicine, health promotion, chronic disease management, mental health, and other areas;
- Promotes efforts to prevent, detect, and address health care fraud and abuse;
- Establishes a National Health Care Workforce Commission to collect, review, and report information on projected health workforce needs and capacity;
- Reauthorizes some of the Title VII health professions and Title VIII nursing education programs (see Title VII Reauthorization on pg. 33);
- Establishes and deposits funding into a “Prevention and Public Health Investment Fund” to increase funding for designated public health and wellness programs; and,
- Amends and expands the trauma and emergency medical care programs under Title XII of the Public Health Service Act, including grants for regionalized emergency care and response systems; grants to assist trauma centers in defraying

substantial “uncompensated care costs,” furthering the core missions of trauma centers, and providing emergency relief; and grants to eligible entities in underserved areas to establish new trauma services.

The committee debated nearly 500 amendments over the course of one month before approving the bill. Much of the discussion focused on concerns about the legislation’s projected cost, as well as concerns about comparative effectiveness research and the bill’s proposed Center for Health Outcomes Research and Evaluation. Though text of the considered amendments has not yet been made publicly available, the committee discussed and adopted several amendments of interest, including provisions to:

- Clarify the definition of “medical home” and direct health teams to use medical home models based on evidence-informed medicine;
- Require the HHS Secretary to consider unique characteristics of rural and low-volume hospitals when developing criteria to reduce readmissions;
- Modify proposed programs to expand eligibility for additional health professionals, populations, or geographic areas;
- Reinstate the “20/220 pathway” of the Economic Hardship Deferment;
- Direct the Institute of Medicine to make recommendations on reducing unnecessary hospital readmissions; and
- Address legal and regulatory barriers that prevent hospitals, group practices, and other entities from providing hardware, software, and technology support to other providers in the community. *[Mitchell, Rasouli]*

### **Healthcare Innovation Zones (HIZs)**

On July 8, Representative Allyson Schwartz (D-Pa.) introduced the AAMC-supported “Healthcare Innovation Zone (HIZ) Program Act of 2009” (H.R. 3134), which establishes a program to support health care delivery innovations that promote provider integration and align incentives to improve health and reduce costs. The HIZs would comprise integrated health care delivery networks that include a teaching hospital, medical school, and a full spectrum of inpatient, outpatient, post-acute and preventative care for Medicare beneficiaries and privately insured individuals. Under the HIZ program, the secretary will award between 10 and 25 planning grants of between \$250,000 and \$1 million to entities for the purpose of designing an HIZ model. The secretary will then test an unspecified number of planning grant proposals under a three-year HIZ demonstration project. The demonstration project will waive/exempt participants from certain legal and regulatory barriers preventing integration and alignment.

In a July 10 press release, AAMC President and CEO Darrell G. Kirch, M.D., thanked Representative Schwartz for introducing the legislation “which will enable providers to truly reform delivery systems and improve the health of communities.” He added that “our nation faces a complex health care crisis of access, quality, and cost and there is an urgent need to design and test large scale, innovative models to transform the way we deliver and pay for care.”

The AAMC press release is available at:  
[www.aamc.org/newsroom/pressrel/2009/090710.htm](http://www.aamc.org/newsroom/pressrel/2009/090710.htm). *[Lyles, Fisher, Grover]*

## **Medicare Direct Graduate Medical Education and Indirect Medical Education Payments**

**Restoration of Capital IME Payments:** Released July 31, Medicare's FY 2010 Inpatient PPS Final Rule Fully restored Medicare's indirect medical education (IME) adjustment to capital payment rates for teaching hospitals. Although these payments were scheduled by CMS to be eliminated entirely beginning October 1, 2009, CMS states that in response to public comments and based on an updated analysis of hospital capital margins, the agency decided that teaching hospitals will continue to receive the full capital IME adjustment. The AAMC is extremely pleased that CMS considered the margin data that the AAMC and many of its members provided to the agency and that CMS exercised its authority to restore the capital IME adjustment. This issue generated more comment letters than any other proposal in the proposed rule. *[Legislative: Mitchell, Crytzer; Regulatory: Fisher, Mihalich-Levin]*

**MedPAC Recommendations on Indirect Medical Education (IME) Payments:** In its March 1 Report, the Medicare Payment Advisory Commission (MedPAC) recommended a reduction in the Medicare hospital operating indirect medical education (IME) add-on payment from 5.5 percent to 4.5 percent in 2010, with the savings going to fund a quality incentive payment program. The commission also made this recommendation in 2007 and 2008. The recommendation would represent an 18 percent cut in operating IME payments to teaching hospitals, about \$1 billion annually. Congress must act upon MedPAC's recommendation before the cut can be implemented.

**Graduate Medical Education (GME) in Health Care Reform:** The three House Committees (Energy and Commerce, Ways and Means, and Education and Labor) responsible for health care reform legislation completed work on amended versions of the "America's Affordable Health Choices Act of 2009" (H.R. 3200) before the August Congressional recess. Differences in the three bills will need to be reconciled before they are combined and introduced on the House floor. All three versions include language that nationally redistributes unused GME training slots among qualified teaching hospitals to expand or establish primary care training programs. Preference for receiving such slots will be given to hospitals that currently exceed their Medicare "cap," place greater emphasis upon training in a health profession shortage area, and have low resident-to population ratios. Additionally, the bills preserve and redistribute GME slots when teaching hospitals close. They also remove regulatory barriers to placing residents in non-hospital settings for a part of their training.

Before the mark-ups, the Chairs of the three committees released a discussion draft of H.R. 3200. The AAMC July 3 commented on the draft, strongly urging the Chairmen to include in their health reform legislation the GME language included in the AAMC-supported bills introduced by Reps. Joseph Crowley (D-N.Y.) and Allyson Schwartz (D-Pa.) (H.R. 2251 and H.R. 2350) (described below). Additionally, the AAMC comments applauded provisions in the draft language that addressed current regulatory barriers to placing residents in non-hospital locations for portions of their training. The AAMC comment letter is available at:

**[www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf](http://www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf)**

As the House and Senate drafted their respective health care reform bills, members of the AAMC Council of Deans (COD) and Council of Teaching Hospitals (COTH) sent a July 2 letter to members of the House committees on Energy and Commerce, Ways and Means, and Education and Labor; the Senate committees on Finance and Health, Education, Labor, and Pensions (HELP); congressional leadership; and the Obama Administration. The letter stated, “Our medical schools are increasing enrollment but the number of physicians-in many specialties will not meet the needs of our communities unless teaching hospitals are able to expand graduate medical education (GME) training.” The letter, signed by 157 CEOs and deans, continue “Creating more residency training slots supported, in part, by Medicare is essential to increase the physician supply.” The letter is available at: [www.aamc.org/advocacy/library/gme/corres/2009/070209.pdf](http://www.aamc.org/advocacy/library/gme/corres/2009/070209.pdf).

At press time the Senate Finance Committee had not yet introduced its health care reform package. The Finance Committee package is expected to include proposals from a series of three options papers released earlier in the year. In response to the three options papers, the AAMC submitted a series of comment letters on May 16, 20, and 28. In the May 28 letter, the AAMC acknowledged that “controlling rising health care costs is one of our nation's greatest challenges,” and stated its commitment “to helping the Senate Finance Committee tackle that challenge.” However, the AAMC strongly opposed any reduction in Medicare GME support. The AAMC comments noted the unique education, research, and patient care missions of major teaching hospitals, which typically work in close collaboration with medical school faculty. Additionally, the AAMC urged Congress to lift the current cap on Medicare-supported residency slots. The AAMC also recommended the committee include the language of the Nelson/Crowley bill in the health care reform legislation, particularly because “the bill makes a more comprehensive and significant investment in physician training by adding 15 percent more Medicare-funded GME positions. ” The AAMC’s May 28 letter is available at: [www.aamc.org/advocacy/library/teachhosp/corres/2009/052809.pdf](http://www.aamc.org/advocacy/library/teachhosp/corres/2009/052809.pdf).

The AAMC’s May 16 and 20 comment letters are posted at (respectively): [www.aamc.org/advocacy/library/teachhosp/corres/2009/051609.pdf](http://www.aamc.org/advocacy/library/teachhosp/corres/2009/051609.pdf) and [www.aamc.org/advocacy/library/teachhosp/corres/2009/052009.pdf](http://www.aamc.org/advocacy/library/teachhosp/corres/2009/052009.pdf).

The Finance Committee’s April 28, May 11, and May 18 policy options papers are available at: <http://finance.senate.gov/sitepages/Policy%20option%20report.html>.

**Legislation to Increase Training Slots:** On May 5, Senators Bill Nelson (D-Fla.), Charles Schumer (D-N.Y.), and Majority Leader Harry Reid (D-Nev.) and Representatives Joseph Crowley (D-N.Y.), Kendrick Meek (D-Fla.), and Kathy Castor (D-Fla.) introduced the AAMC-supported “Resident Physician Shortage Reduction Act of 2009” (S.973/H.R. 2251), which increases the number of Medicare-supported graduate medical education (GME) training positions by 15 percent (approximately 15,000 slots). Two-thirds of these slots will be given to hospitals that apply for slots for new or expanded residency programs, with preference given to hospitals that apply for primary care or general surgery slots. The remaining one-third of slots will be allocated proportionately to hospitals operating over their caps.

The bill also would permit Medicare IME reimbursement for educational activities that occur in the hospitals as well as Medicare DGME reimbursement for educational activities that occur in clinical nonhospital settings such as physician offices. Additionally, the legislation preserves residency slots from closed hospitals and redistributes them among nearby teaching hospitals.

AAMC President and CEO Darrell Kirch, M.D., sent letters to the bill sponsors on May 5, stating, “The AAMC strongly supports your efforts and leadership to expand residency positions through this legislation.” The letter also pledges the AAMC’s “continued support” in light of the bill’s role in “enhancing the nation’s ability to meet future physician workforce needs.” The letter is available at:

**[www.aamc.org/advocacy/library/workforce/corres/2009/050509.pdf](http://www.aamc.org/advocacy/library/workforce/corres/2009/050509.pdf)**.

As of August 28, S. 973 had 7 cosponsors and H.R. 2251 had 38 cosponsors.

AAMC-supported legislation introduced May 20 by Representative Allyson Schwartz (D-Pa.), the “Preserving Patient Access to Primary Care Act of 2009” (H.R. 2350), includes the AAMC- supported provisions contained in S. 973/H.R. 2251. As of August 28, H.R. 2350 had 126 cosponsors. [*Crytzer, Marquez, Mitchell*]

### **Medicare Disproportionate Share Hospital (DSH) Payments**

The House health care reform bills include language that reduces Medicare disproportionate share hospitals (DSH) payments beginning in FY 2017, if, between 2012 and 2014, the number of uninsured individuals drops by over 8 percent. The Secretary could then increase DSH payments to certain hospitals based on their level of uncompensated care; the hospital increases could not exceed half of the initial reduction.

At press time, the Senate Finance Committee had yet to introduce their health care reform package. However, on July 8, the White House, Senate Finance Committee Chair Max Baucus (D-Mont.), the American Hospital Association (AHA), the Catholic Health Association (CHA), and the Federation of American Hospitals (FAH) announced an AAMC-supported agreement to help offset the cost of expanding health coverage to 95 percent of all Americans. Under the agreement, the hospital community will contribute \$155 billion in support of coverage expansions, including up to \$50 billion in combined Medicare and Medicaid DSH payment reductions. The cuts would not be implemented until 2015 and only if there was significant growth in coverage.

In a July 8 statement, AAMC President and CEO Darrell G. Kirch, M.D., praised the agreement stating, “The AAMC strongly supports the agreement announced today and believes it moves our nation closer to achieving meaningful health care reform.” The letter continued, “We greatly appreciate the thoughtful approach this agreement takes to guarantee that the safety net remains intact during the transition to a better system.” The AAMC press release is available at:

**[www.aamc.org/newsroom/pressrel/2009/090708.htm](http://www.aamc.org/newsroom/pressrel/2009/090708.htm)**. [*Crytzer, Marquez, Mitchell*]

## **Geographic Variations in Medicare Spending**

The House health care reform bills contain AAMC-supported language that requires an Institute of Medicine (IOM) study of geographic variations in per capita health care spending among Medicare and privately insured individuals. The IOM must make recommendations for addressing such variations by promoting high-value physician and hospital services (including payment incentives). The Secretary is directed to revise the geographic adjustment factors used by the Medicare physician and inpatient hospital payments systems to assume payment “accuracy”. However, such adjustments may not reduce any payments rates.

In response to the aforementioned language, AAMC President and CEO Darrell G. Kirch, M.D., sent July 21 a letter to Speaker of the House Nancy Pelosi (D-Calif.) urging support for House health care reform language that allows law-makers an opportunity to “better understand” the reasons that drive geographic variations in spending. The letter specifically supports the sections that which requires the IOM to examine the reasons for variations in spending on medical care and continue to “hold harmless” providers in areas with higher geographic payment adjustments “until all of the contributing factors are better understood.” The letter states, “We look forward to working with the IOM to expand the knowledge base from which Congress and providers can make better decisions about our nation’s investment in health and health care.” The AAMC letter is available at: [www.aamc.org/advocacy/library/teachhosp/corres/2009/072109.pdf](http://www.aamc.org/advocacy/library/teachhosp/corres/2009/072109.pdf).  
*[Mitchell, Marquez]*

## **Independent Medicare Advisory Council (IMAC)**

There are ongoing discussions among the House, Senate, and Obama Administration about establishing an “Independent Medicare Advisory Council” (IMAC) as part of health care reform. Expected to be located within the executive branch, the IMAC would have broad authority to implement major Medicare policy changes with limited input from Congress, beneficiaries, or providers. A letter signed by 75 bi-partisan House members was sent July 31 to Speaker Nancy Pelosi (D-Calif.) voicing “strong opposition” to the inclusion of an IMAC in any health care reform legislation. According to the letter, the IMAC would eliminate the current advisory role of MedPAC, place authority within the executive branch, and severely limit Congressional oversight of the Medicare program. It would also limit state and community input into the Medicare program, potentially ignoring significant differences and health care needs among states and communities. The letter, circulated by Representative Richard Neal (D-Mass.), states, “We urge you to reject the inclusion of these proposals or any like proposal in H.R. 3200 or any other legislation.” The letter is available at: [www.aamc.org/advocacy/library/teachhosp/073109nealimaclettertopelosi.pdf](http://www.aamc.org/advocacy/library/teachhosp/073109nealimaclettertopelosi.pdf).  
*[Crytzer, Marquez, Mitchell]*

## **FY 2010 Medicare Inpatient PPS Final Rule**

On July 31, 2009, the Centers for Medicare and Medicaid Services (CMS) released the fiscal year (FY) 2010 Medicare hospital inpatient prospective payment system (IPPS) final rule. Finalized policies take effect for discharges on or after October 1, 2009.

**Restoration of Capital IME Payments:** The final rule restores the capital indirect medical education (IME) adjustment to capital payment rates for teaching hospitals, effective for FY 2010. Although these payments were scheduled by CMS to be eliminated entirely beginning October 1, 2009, CMS states that in response to public comments and based on an updated analysis of hospital capital margins, the agency decided that teaching hospitals will continue to receive the full capital IME adjustment in FY 2010. The AAMC is extremely pleased that CMS considered the margin data that the AAMC and many of its members provided to the agency and that CMS exercised its authority to restore the capital IME adjustment. This issue generated more comment letters than any other proposal in the proposed rule.

**Market Basket Update with No Corresponding Documentation and Coding Reduction:** The final rule implements a 2.1 percent market basket update to the IPPS standardized amount, with CMS declining to implement the proposed corresponding 1.9 percentage point “documentation and coding” offset. CMS had proposed this offset to remove the effect of increases in aggregate payments caused by changes in hospital documentation and coding practices under the MS-DRG system that do not reflect increases in severity. CMS states that the agency will wait until it has all the FY 2009 data before considering whether to phase in future adjustments beginning in 2011. The 2.1 percent update for inflation is lower than in prior years, which CMS states reflects the slowing rate of inflation.

**Effect of the Final Rule on Teaching Hospitals:** With all changes, CMS estimates that teaching hospitals with 100 or more residents will see average *operating* per case payment increases of 1.7 percent from the current year, compared to operating increases of 1.6 percent for other teaching and nonteaching hospitals. With all other changes, CMS estimates that teaching hospitals with 100 or more residents will see average *capital* per case payment increases of 2.1 percent, compared to capital increases of 1.9 percent and 1.8 percent for other teaching and nonteaching hospitals, respectively.

**Decrease in Labor-Related Share:** In the final rule, CMS decreased the labor-related share from 69.7 percent to 68.8 percent for hospitals with wage indices greater than 1.0. (The labor-related share for hospitals with wage indices less than or equal to 1.0 will remain at 62 percent, as required by the Medicare Modernization Act.) CMS explained that the decline is in part a result of more recent survey data that, for the first time, account for professional services obtained outside a hospital’s local labor market. Previously, all professional fee expenses were considered to vary with the local labor market and were included in the labor-related share. CMS also attributed the decline to consolidation of administrative functions in home offices that are not in the same local labor market as individual hospitals. This final decrease is, however, 1.7 percent less than the decrease from 69.7 percent to 67.1 percent the agency initially published in the proposed rule, a change CMS attributed to a revised methodology for allocating home office costs.

**Increase in Outlier Payment Threshold:** The FY 2010 finalized cost threshold is 15.4 percent higher than the level in FY 2009. Under the final rule, the fixed-loss cost threshold for FFY 2010 will be equal to a case’s MS-DRG payment plus any IME and

DSH payments, and any additional payments for new technologies, plus \$23,140. This amount of \$23,140 is up from \$20,045 in FY 2009 but is lower than the proposed rule's level of \$24,240.

**Changes Affecting DGME and IME Payments:** The final rule contains several provisions affecting DGME and IME payments. Most importantly, CMS finalized the proposed rule's "clarified" definition of "new medical residency training program" (at 42 C.F.R. § 413.79(1)) when a new teaching hospital is attempting to establish its resident cap. The regulations define "new medical residency training program" as one "that receives initial accreditation by the appropriate accrediting body or begins training residents on or after January 1, 1995." Following this definition, many hospitals relied solely on accreditation of a new program by the appropriate accrediting body for purposes of determining whether the program's residents could be included in the resident cap.

CMS now states that the agency will look beyond accreditation to factors that include but are not limited to: (1) whether the program director is new; (2) whether the teaching staff is new; (3) whether there are new residents; (4) the relationship between hospitals (for example, common ownership or a shared medical school or teaching relationship); (5) the degree to which the hospital with the original program continues to operate its own program in the same specialty; (6) whether the program has been relocated from a hospital that closed; (7) if the program was relocated from a closed hospital, whether the program was part of the closed hospital's FTE cap determination; and (8) whether the program is part of any existing hospital's FTE cap determination. Factors listed here as (6) through (8) (CMS does not number the factors) were new in the final rule.

Additionally, CMS finalized the agency's proposals to increase flexibility in submission deadlines for new hospitals joining Medicare GME affiliated groups and to exclude all observation beds from the available bed count used to determine the intern and resident-to-bed (IRB) ratio for IME payment purposes.

**Changes Affecting DSH Payments:** CMS finalized several proposed changes that affect Medicare disproportionate share hospital (DSH) payments, including how the Medicare and Medicaid fractions that make up the disproportionate patient percentage are calculated. Specifically, CMS finalized the agency's proposal to include labor and delivery (L&D) bed days in the Medicare DSH calculation, even when a patient does not occupy a routine bed prior to occupying an ancillary L&D bed. CMS also adopted the agency's proposal to exclude all observation beds and patient days from the DSH calculation and to allow hospitals additional options regarding the methodology used to report days in the numerator of the DPP Medicaid fraction.

**Quality:** In the quality area, there were no proposed additions or deletions to the list of conditions included in the hospital acquired conditions (HAC) program. In the interim, CMS will be conducting an evaluation of the impact of the HAC program in conjunction with AHRQ and CDC.

The final rule outlines changes to the measures required for reporting under the Reporting of Hospital Quality Data for Annual Hospital Payment Update (RHQDAPU) program.

CMS adopted the four additional measures the agency proposed for FY 2011: two surgical infection prevention measures and two structural measures focused on participation in stroke and nursing care registries.

The final rule also reiterates CMS's plans to build the infrastructure and develop the measure standards necessary to report quality measures through electronic health records (EHR). CMS currently is working with the Office of the National Coordinator for Health Information Technology (ONC) to identify and harmonize standards for submission of emergency department, stroke, and venous thromboembolism measures through EHR submission.

**Other Areas of Interest:** The final rule also contains provisions that affect long-term care hospitals, critical access hospitals, new technology payments, EMTALA waivers, satellite facilities, and the wage index.

To access the display copy of the final rule, go to:

[www.federalregister.gov/OFRUpload/OFRData/2009-18663\\_PI.pdf](http://www.federalregister.gov/OFRUpload/OFRData/2009-18663_PI.pdf).

The AAMC has prepared a Summary & Analysis document highlighting areas of interest to the academic medical community, located at:

[www.aamc.org/advocacy/teachhosp/inptpps/histreg/start.htm](http://www.aamc.org/advocacy/teachhosp/inptpps/histreg/start.htm). [*Faerberg, Fisher, Mayes, Mihalich-Levin*]

### **CY 2010 Hospital Outpatient Prospective Payment System**

On July 20, the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* a proposed rule that contains changes to the outpatient prospective payment system (OPPS) as well as proposed payment rates for Ambulatory Surgical Centers (ASCs). If finalized, CMS will implement the changes to both the OPPS and the ASC payment system January 1, 2010. The AAMC submitted comments on the proposed rule, which were due August 31.

CMS proposes to raise the base OPPS payment rate by the full market basket increase of 2.1 percent.

A key issue in the proposed rule relates to changes in the requirements for "direct supervision" of hospital outpatient therapeutic services furnished in a hospital and in on-campus provider-based departments (PBDs) of a hospital. The new definition requires that the physician be present on the same campus, in the hospital, or the on-campus PBD, and immediately available to furnish assistance and direction through the performance of the procedure. In the 2009 final OPPS rule, CMS clarified that "direct supervision" means that the physician must be "on the premises of the location" where the service is provided. Prior to the 2009 final rule, many hospitals had understood that CMS required general supervision of outpatient therapeutic services furnished "incident to" a physician's service in the hospital and the on-campus PBDs. Despite the confusion about the level of supervision, CMS states in the proposed rule that "we have not instructed contractors to delay initiation of enforcement actions or to discontinue pursuing pending enforcement actions regarding the physician supervision of hospital outpatient services."

In the rule, CMS also proposes a new methodology for calculating the payment rate for separately payable drugs and biologicals. If finalized, under the new methodology, hospitals will receive the same payment rate as they are receiving in 2009 – the average sales price (ASP) plus 4 percent. If CMS had not made this proposal and instead used the current methodology, separately payable drugs would be reimbursed at ASP minus 2 percent. Recognizing that the current methodology underestimates the acquisition and overhead costs of separately payable drugs and biologicals while it overestimates the costs of packaged drugs and biologicals, the new methodology would redistribute some of the overhead cost of packaged drugs and biologicals to separately payable drugs and biologicals. In its comment letter, the AAMC urged CMS to pay for separately payable drugs and biologicals at a rate equal to ASP plus 6 percent, the same rate as the physician office setting payment rate, until the agency can further improve the methodology for determining the cost of these products.

The proposed rule does not add any additional measures to the hospital outpatient quality reporting program. Thus, the reporting requirements for the calendar year 2011 would remain the same. The proposed rule also does not expand the Hospital Acquired Condition (HAC) program to the hospital outpatient setting. While CMS is still committed to addressing HACs in the hospital outpatient setting, the agency realizes there are significant operational as well as structural challenges to implementing such a program at this time.

To access the rule, the AAMC's comment letter, and summary and analysis document go to: [www.aamc.org/advocacy/teachhosp/outptpps/start.htm](http://www.aamc.org/advocacy/teachhosp/outptpps/start.htm) [Mayes]

### **Quality Regulations**

In the inpatient PPS (IPPS) final rule (see page 19), CMS finalized the decision not to make any additions or deletions to the current list of conditions included in the hospital acquired conditions (HAC) program for this year. In the interim, CMS will be conducting an evaluation of the impact of the HAC program in conjunction with AHRQ and CDC.

The IPPS final rule outlines changes to the measures required for reporting under the Reporting of Hospital Quality Data for Annual Hospital Payment Update (RHQDAPU) program. CMS adopted the four additional measures the agency proposed for FY 2011: two surgical infection prevention measures and two structural measures focused on participation in stroke and nursing care registries.

The IPPS final rule also reiterates CMS's plans to build the infrastructure and develop the measure standards necessary to report quality measures through electronic health records (EHR). CMS currently is working with the Office of the National Coordinator for Health Information Technology (ONC) to identify and harmonize standards for submission of emergency department, stroke, and venous thromboembolism measures through EHR submission.

The Outpatient PPS (OPPS) proposed rule does not add any additional measures to the hospital outpatient quality reporting program. Thus, the reporting requirements for the calendar year 2011 would remain the same.

The OPPS proposed rule also does not expand the Hospital Acquired Condition (HAC) program to the hospital outpatient setting. CMS proposed to utilize the results of the impact study for the inpatient HAC program to inform future decisions for the outpatient setting. [Faerberg]

### **Inpatient Rehabilitation Facility Final Rule**

On August 7, the Centers for Medicare and Medicaid Services (CMS) published in the *Federal Register* its Medicare inpatient rehabilitation facility (IRF) final rule for federal fiscal year (FY) 2010. The final rule modifies the methodology for calculating the teaching adjustment factor. It also applies a 2.5 percent increase factor to IRF payment rates. The changes will be effective October 1, 2009.

The teaching adjustment is based on a regression analysis as well as the IRF's ratio of resident-to-average daily census (RADC). CMS finalized its proposal to change the methodology to reflect three years of data, rather than one year of data to avoid year-to-year fluctuations. The AAMC supported the proposed methodology in its June 29 comment letter.

The final rule is available at: <http://edocket.access.gpo.gov/2009/pdf/E9-18616.pdf>

To access the AAMC comment letter go to:

[www.aamc.org/advocacy/teachhosp/rehab/fy2010\\_rehab\\_rule\\_comment\\_letter.pdf](http://www.aamc.org/advocacy/teachhosp/rehab/fy2010_rehab_rule_comment_letter.pdf)  
[Mayes]

### **Inpatient Psychiatric Facility Payment System**

On May 1, the Centers for Medicare and Medicaid Services (CMS) issued a notice in the *Federal Register* updating the prospective payment rates for Medicare inpatient psychiatric facilities (IPFs) starting July 1, 2009, when the 2010 rate year begins. IPF PPS payment rates are updated by 2.1 percent. This increase is based on a market basket that reflects the cost structures of inpatient rehabilitation facilities, inpatient psychiatric facilities, and long-term care facilities.

Of interest to the academic medicine community was CMS's request for comments on whether it should implement a temporary resident cap increase policy in the full time equivalent (FTE) resident cap when the IPF increases the number of FTE residents it trains due to acceptance of relocated residents. Currently an IPF is subject to a cap on the number of residents that it can count for purposes of calculating the teaching adjustment. The cap is based on the number of residents that trained in the IPF during the "base year," that is, the hospital's most recent cost report for the period ending before November 15, 2004. The cap is not increased when the IPF accepts and completes the training of residents relocated from an IPF that closes or an IPF or acute care hospital that remains open, but closes its psychiatric residency program. In its comment letter, the AAMC

urged CMS to permit a temporary increase in the resident cap when the IPF increases the number of residents it trains due to acceptance of relocated residents. At this time no decision has been released on this issue.

The AAMC comment letter is available at:

[www.aamc.org/advocacy/teachhosp/psych/ry2010psych\\_rule\\_comment\\_letter.pdf](http://www.aamc.org/advocacy/teachhosp/psych/ry2010psych_rule_comment_letter.pdf)

The IPF notice is available at: <http://edocket.access.gpo.gov/2009/pdf/E9-9962.pdf>  
[Mayes]

### **Medicare Physician Payments**

**Legislative:** The AAMC continues to work with the American Medical Association (AMA) and other physician groups to advocate for the repeal of the problematic sustainable growth rate (SGR) currently used to calculate Medicare physician payments. Without Congressional action, physicians face a 21 percent cut in Medicare payments effective January 1, 2010.

**Health Care Reform** – The three House Committees (Energy and Commerce, Ways and Means, and Education and Labor) with jurisdiction over health care reform legislation, completed marking up amended versions of “America’s Affordable Health Choices Act of 2009” (H.R. 3200) before the August Congressional recess. Differences in the three bills will need to be reconciled before they are combined and introduced on the House floor. All three versions include language to avert the 21 percent cut in Medicare physician payments. Specifically, the House bills establish a one-year inflationary payment update in CY 2010 (based on the Medicare Economic Index), and implement in CY 2011 newly rebased target growth rates for two distinct “service categories”: evaluation and management (E&M)/Medicare preventative services; and all other services. The annual target growth rates for the first and second service categories are set at 2 percent and 1 percent, respectively. The Congressional Budget Office (CBO) estimates the fix would cost \$228.5 billion over the 2010-2019 period. The AAMC submitted July 3 comments while the committees drafted the SGR proposal. The letter asks Congress to repeal the sustainable growth rate (SGR) formula used to calculate Medicare physician payments. The letter is available at:  
[www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf](http://www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf).

In conjunction with the reform language, the House July 22 approved legislation (H.R. 2920) that excludes the cost of repealing Medicare’s SGR formula from “pay-go” requirements. In this context, the House would not have to find offsets for the cost of their physician fix legislation. The status of this legislation in the Senate is uncertain (see page 44).

At press time the Senate Finance Committee had not yet introduced its health care reform package. The Finance committee package is expected to include proposals from a series of three options papers released earlier in the year. In response to the three options papers, the AAMC submitted a series of comments which included strong support for repealing the SGR and implementing a new update methodology that links physician updates to an inflationary index (e.g., the Medicare Economic Index). The Finance

Committee option papers included one proposal to establish a 1 percent update in Calendar Years (CYs) 2010 and 2011 and a 0 percent update in CY 2012. Another option would have the same schedule of updates for 2010 & 2011, but in CY 2012, it would revert to the SGR methodology, with an update “floor” of negative 3 percent. Beginning in 2014, the fee schedule update for localities with two-year average fee-for-service growth rates at or greater than 110 percent of the national average would have a negative 6 percent floor. In its letter, the AAMC warned that such an option did not provide a “long-term, stable, predictable, sustainable solution.” The AAMC comment letter is available at:

**[www.aamc.org/advocacy/library/teachosp/corres/2009/051609.pdf](http://www.aamc.org/advocacy/library/teachosp/corres/2009/051609.pdf). [Crytzer, Marquez, Mitchell]**

**Regulatory:** On July 19 the Centers for Medicare and Medicaid Services (CMS) published the proposed revisions for the Medicare 2010 Physician Fee Schedule (74 Fed Reg 33520). CMS estimates the update for physician services will decrease by 21.5 percent from calendar year 2009. Although the update formula has produced negative updates since 2002, Congress has often approved legislation that prevented the cuts from being implemented. It is expected that Congressional action also will prevent the 2010 cuts. The projected cuts are the result of an update methodology that is based on the sustainable growth rate (SGR), a formula that calculates targets for physician spending. CMS cannot modify the formula, but the agency is proposing to use its administrative authority to remove physician administered drugs from the update calculation. This will not affect the 2010 rates, but will reduce the number of years physicians are projected to receive a negative update, thereby reducing the cost of an SGR repeal, should Congress choose to enact one.

The rule also makes several proposals to modify relative value units (RVUs), which are the base units for physician payments. These include replacing consultation codes with visit codes, using new practice expense data, increasing the utilization rates for expensive equipment, and updating malpractice expense data.

CMS estimates the RVU changes, without taking into account the negative update, will increase payments to primary care by 6 percent to 8 percent. Specialties receiving the highest positive updates include: optometry (12 percent), physical and occupational therapy (10 percent), family practice (8 percent), geriatrics (8 percent), physical medicine (7 percent), general practice (6 percent), internal medicine (6 percent), anesthesiology (6 percent), and interventional pain management (6 percent). Specialties that are estimated to receive at least a 10 percent decrease include: cardiology, interventional radiology, nuclear medicine, radiation oncology, radiology, audiologist, IDTFs, and portable x-ray suppliers. An UHC-AAMC Faculty Practice Solution Center forecasting model confirms shifts in specialty payments, but predicts an overall 2.4 percent increase in the professional fees of faculty practices.

The rule also proposes implementation of a MIPPA provision that requires the establishment of a “special payment rule for teaching anesthesiologists.” For services furnished on or after January 1, 2010, the provision allows payment under the regular fee schedule for the teaching anesthesiologist’s involvement in the training of residents in

either a single case or in two concurrent cases. This is similar to the way in which teaching surgeons are paid.

The rule includes proposed changes to the Physician Quality Reporting Initiative (PQRI) and the Electronic Prescribing Incentive Program, such as including a group reporting option and allowing data submission from electronic health records. The PQRI group reporting option is based on the Physician Group Practice (PGP) demonstration. CMS proposes that to participate group practices must have at least 200 eligible professionals within a single tax identification number (TIN) and must agree to public reporting of performance data. *[Patton, Baer]*

### **Physician Quality Initiatives**

**Physician Quality Reporting Initiative (PQRI):** The Centers for Medicare and Medicaid Services (CMS) has stated that results for the 2008 Physician Quality Reporting Initiative (PQRI), the voluntary pay-for-reporting program that provides incentives to physicians and other eligible professionals to submit data on quality measures, will be available in October 2009. The results were delayed in part because CMS re-ran 2007 results to correct some technical issues.

CMS included several proposals for the 2010 PQRI in the proposed physician fee schedule rule (see Medicare Physician Payments). Eligible professionals and groups that satisfactorily submit data will receive an incentive payment of 2 percent of their total Medicare Part B allowed charges that were paid under the physician fee schedule during the 2010 reporting period.

For individual eligible professionals, CMS is expanding the current reporting mechanisms (claims and registries) to include electronic health records. CMS is also proposing to simplify measures group reporting and is proposing to add a minimum patient sample size in order for eligible professionals to receive the incentive.

As required by Medicare Improvements for Patients and Providers Act (MIPPA), CMS is offering a new group reporting option for PQRI. To participate, groups must have at least 200 eligible professionals within a single tax number and agree to have performance data publicly reported. The groups would report on 26 measures for a sample of patients.

*[Patton]*

**E-prescribing:** MIPPA legislation created a separate reporting program for the adoption of electronic prescribing technology. In 2010, professionals can earn a 2 percent incentive payment on Medicare total allowed charges. The e-prescribing incentive is separate from and in addition to the PQRI incentive. Penalties for not using e-prescribing start in 2012. (Note: Professionals that receive the HIT incentive payments for meaningful use of electronic health records are not eligible to receive the e-prescribing incentive. The HIT incentive payments are first available in 2011.)

CMS proposes to simplify 2010 data submission, by expanding the reporting mechanisms and by only requiring professionals to report when e-prescribing occurs. *[Patton]*

**Value Based Purchasing and Resource Use Reporting:** In the proposed physician fee schedule rule (see Medicare Physician Payments), the Centers for Medicare and Medicaid Services (CMS) summarized the results of the first phase of resource use report (RUR) pilot. In phase II, CMS proposes to include a new disease group (diabetes), and to merge the cost and quality report measurement. CMS also will evaluate measurement at the group-level as well as at the individual professional level.

MIPPA requires CMS to present a Physician Value Based Purchasing Plan (PVBP) to Congress by May 2010. CMS considers resource use reporting and quality reporting the building blocks of a Physician Value-Based Purchasing plan. *[Patton]*

### **ICD-10 Final Rule**

On January 16, 2009, the Department of Health and Human Services (HHS) published a final rule that would replace the current ICD-9 codes set used to report health care diagnoses and procedures on health care transaction claims with a new version, known as ICD-10. The implementation of the new coding system would begin on October 1, 2013.

According to the final rule, the primary reason for moving to ICD-10 is that the ICD-9 system is running out of new codes, which are needed to accommodate advances in medicine and medical technology; ICD-9 has 17,000 codes compared to 155,000 codes in the ICD-10 system. CMS also states that the ICD-10 code set would better support value-based purchasing and quality initiatives. However, because the costs and time needed to learn the new codes and update transaction software has been a great concern to providers, particularly physicians, the AAMC and others had submitted comments to CMS urging the agency to delay the implementation of the new coding system. In response to those comments, the final rule extended the compliance deadline for the implementation of the new coding system from the proposed October 1, 2011, deadline.

In a related final rule, also published on January 16, CMS also extended the compliance date for the implementation of updated versions of the standards for certain electronic health care transactions for health plans, health care clearinghouses and certain providers from the proposed April 1, 2010, deadline to January 1, 2012. This rule is related to the ICD-10 final rule because the updated version (version 5010) of the X12 transaction standards is needed to accommodate the use of greatly expanded ICD-10 code sets.

The final rule is available at: <http://edocket.access.gpo.gov/2009/pdf/E9-743.pdf>  
*[Fisher, Mayes]*

In recognition of the new implementation deadline, CMS requested feedback from providers on whether updates to ICD-10 and/or ICD-9 codes should be frozen prior to final implementation of ICD-10, and if so, when the freeze should be instituted. Public comments will be discussed at a September 16, 2009, meeting of the CMS ICD-9 Coordination and Maintenance Committee. To assist in the conversion of coding data, CMS and the CDC unveiled General Equivalence Mappings (GEMs), bi-directional mappings designed to assist in converting policies, edits, and trend data from ICD-9 to ICD-10. *[Dardani]*

## Resident Duty Hours

The AAMC provided testimony at a duty hours congress sponsored by the ACGME June 11-12, 2009. As in its April 21, 2009, letter to ACGME commenting on the recommendations of the December 2008 IOM report, “Resident Duty Hours: Enhancing Sleep, Supervision, and Safety”, the testimony stated that, with very little solid evidence linking resident schedules to patient care outcomes, resident duty hours and schedules ultimately are not the central issue. Focusing on schedules will not address—and may distract academic medicine from—the larger issues of detection and management of fatigue, quality of resident supervision, appropriateness of resident workloads, and effectiveness of information transfer among residents and other members of the patient care team. If these larger issues are addressed, the need to regulate resident duty schedules can and should lessen or disappear.

Noting both the cost of change and the complexity of the environment-- pull one thread in this complex care delivery environment and there can be multiple unintended consequences-- the Association urged caution. It endorsed maintaining the current 80-hour per week standard, but recommended that moonlighting hours be included in the 80-hour limit.

An ACGME task force chaired by Dr. Susan Day of Pacific Medical Center, the ACGME chair, and Dr. E. Stephen Amis of Albert Einstein College of Medicine/Montefiore Department of Radiology, chair of the Council of Review Committee Chairs, is considering potential changes in duty hours for consideration by the ACGME board. The AAMC testimony is available at:  
[www.aamc.org/members/gra/acgme\\_testimony.pdf](http://www.aamc.org/members/gra/acgme_testimony.pdf). [Yoder]

## Medicare Payment Advisory Commission (MedPAC)

**Medical Education Chapter in June Report:** In June 2009, MedPAC released its annual Report to the Congress: *Improving Incentives in the Medicare Program*. The first chapter in the report is dedicated to medical education issues. The chapter, entitled: *Medical Education in the United States: Supporting long-term delivery system reforms*, discusses how well medical schools and residency programs are preparing future physicians to be leaders in shaping and implementing needed changes in the health care delivery system. The commission first began work on this issue in October 2008. AAMC staff met with MedPAC staff in January 2009 to discuss the project.

The chapter reviews the multifaceted process of becoming a physician, including the role of the organizations involved in accreditation and certification; the costs and benefits for hospitals and physicians involved in teaching and supervising residents; internal medicine residency programs’ curricula as they relate to delivery reforms; and the financial disincentives and regulatory issues that discourage residency rotations in nonhospital settings.

The commission outlines some of the areas that it will explore in the future such as structuring medical education subsidies to provide incentives for delivery system reforms and to generate a balance of health care professionals that includes the right share of

generalists and subspecialists. Expanding contributions to medical education from other health care payers will be another option the commission is planning to analyze.

**Data Book:** In June, MedPAC released its 2009 Data Book, which contains tables and figures accompanied by brief discussions on a broad range of Medicare topics. The Data Book includes financial margin information for hospitals, including teaching hospitals. MedPAC's analyses of Medicare data show that, between 2006 – 2007, total margins have improved for all hospitals regardless of teaching status. Major teaching hospitals saw a 0.6 percentage points increase in the aggregate total margin, from 4.8 percent to 5.4 percent, compared to a 0.7 percentage points increase for both other teaching and nonteaching hospitals. The aggregate total margin for major teaching hospitals remains below the aggregate total margin for other types of hospitals.

In 2007, Medicare inpatient margins were 7.4 percent for major teaching hospitals, -4.9 percent for other teaching hospitals and -8.9 percent for nonteaching hospitals. Medicare overall margins in 2007 were 1.1 for major teaching hospitals, -6.4 percent for other teaching hospitals and -9.3 percent for nonteaching hospitals. This year's Data Book did not include historic Medicare inpatient or overall margin data by teaching status.

The June Report and Data Book are available on MedPAC's website at: [www.medpac.gov/](http://www.medpac.gov/) [*Fisher, Mayes*]

## Medicaid

**Disproportionate Share Hospital (DSH) Payments:** The three House Committees (Energy and Commerce, Ways and Means, and Education and Labor) with jurisdiction over health care reform legislation, completed marking up amended versions of "America's Affordable Health Choices Act of 2009" (H.R. 3200) before the August Congressional recess. Differences in the three bills will need to be reconciled before they are combined and introduced on the House floor. All three versions include language that reduces Medicaid DSH payments by \$10 billion over the next ten years, starting in FY 2017 (\$1.5 billion in FY 2017, \$2.5 billion in FY 2018, and \$6 billion in FY 2019). They also the HHS Secretary to issue recommendations regarding "the distribution of Medicaid DSH among the states."

At press time the Senate Finance Committee had not yet introduced their health care reform package. The Finance committee package is expected to contain language based on a July 8 joint health care reform agreement negotiated by the White House, Senate Finance Committee Chairman Max Baucus (D-Mont.), the American Hospital Association (AHA), the Catholic Health Association (CHA), and the Federation of American Hospitals (FAH). The agreement would phase in policies to expand coverage by 95 percent of all Americans. To help achieve this goal, the hospital community will contribute \$155 billion over 10 years in the form of reduced Medicare hospital payments and reductions in Medicare and Medicaid disproportionate share hospital (DSH) payments. The DSH reductions will begin in 2015, and be linked to coverage expansions. Under the agreement, approximately 60 percent of total DSH payments would be preserved over 10 years.

In a July 8 statement, AAMC President and CEO Darrell G. Kirch, M.D., praised the agreement stating, “We greatly appreciate the thoughtful approach this agreement takes to guarantee that the safety net remains intact during the transition to a better [health care delivery] system.”

The AAMC press release is available at:  
[www.aamc.org/newsroom/pressrel/2009/090708.htm](http://www.aamc.org/newsroom/pressrel/2009/090708.htm).

**Medicaid Support for Graduate Medical Education:** The AAMC, in collaboration with AHA, NAPH, and NACH, continues to track closely whether the new Administration will take any action related to the May 23, 2007, Medicaid proposed rule eliminating federal matching payments for GME costs [72 Fed. Reg. 28930]. According to CMS estimates, the proposed rule would eliminate \$1.7 billion in federal Medicaid funding. In a December 2008 meeting with President Obama’s transition team, the AAMC reiterated strong concerns that the proposed rules arbitrarily reversed long-standing Medicaid policy and endangered efforts by teaching hospitals to address current and future physician shortages for all Americans—not just Medicaid beneficiaries.

AAMC materials submitted to Obama transition team are available at:  
[www.aamc.org/advocacy/obamatransition.pdf](http://www.aamc.org/advocacy/obamatransition.pdf). [*Regulatory: Fisher; Legislative: Mitchell, Crytzer*]

**Medicaid Outpatient Services Definition Rescinded:** On June 30, 2009, CMS rescinded the agency’s December 28, 2007, final Medicaid rule entitled “Clarification of Outpatient Hospital Facility (Including Hospital Outpatient Clinic) Services Definition.” The rule would have limited Medicaid reimbursement for hospital outpatient services to those services reimbursed by the Medicare program. The AAMC supported this rescission in a June 1, 2009, comment letter to the agency.

The rescission notice is available at: <http://edocket.access.gpo.gov/2009/pdf/E9-15345.pdf> and the AAMC’s comment letter is available at:  
[www.aamc.org/advocacy/library/teachhosp/corres/2009/060109.pdf](http://www.aamc.org/advocacy/library/teachhosp/corres/2009/060109.pdf).

### **Medical Liability Reform**

As a member of the Health Coalition on Liability and Access (HCLA), the AAMC continues to support passage of comprehensive medical liability reform legislation that includes:

- unrestricted awards for economic damages;
- a \$250,000 cap on non-economic damages (“pain and suffering”);
- capping punitive damages at the greater of \$250,000 or twice economic damages;
- limits on attorneys’ contingency fees;
- “joint and several liability” reforms;
- no double recovery of damages; and
- payment of certain awards over time. [*Mitchell*]

## **Human Embryonic Stem Cell Research**

On March 9, 2009, President Barack Obama issued an Executive Order lifting restrictions on the federal funding of human embryonic stem cell research. The Order directed the National Institutes of Health to issue guidelines to permit such funding. President Obama's action is the first significant change in federal stem cell policy since August 9, 2001, when President George W. Bush announced a policy that federal funds could only be used to support research using human embryonic stem cells lines that were derived before that date. Between 2001 and 2009, the NIH Human Embryonic Stem Cell Registry listed 21 human embryonic stem cell lines that meet the eligibility criteria.

The National Institutes of Health issued guidelines to permit expanded funding of human embryonic stem cell research on July 6, 2009. Draft Guidelines were issued on April 17, 2009, and open for public comments, of which more 49,000 were received.

The NIH Guidelines limit federal funding to lines derived from embryos created by IVF for reproductive purposes and that are in excess of clinical need. Stem cell lines derived from somatic cell nuclear transfer, parthenogenesis, or via the IVF process if the embryo was created for research purposes are not eligible for federal funding. In addition, NIH will not fund research using otherwise eligible stem cell lines if the cells are introduced into non-human primate blastocysts or if the cells may have contributed to the germ line. For stem cell lines already in existence when the Guidelines were issued, a Working Group of the Advisory Committee to the Director, will advise NIH on whether the “core ethical principles and procedures used in the process for obtaining informed consent for the donation of the embryo were such that the cell line should be eligible for NIH funding.” NIH will also use the Working Group to assess foreign derived stem cell lines, created both before and after the effective date of the Guidelines. Lines deemed eligible will be listed on the NIH Registry and not need additional review.

In the 111th Congress, several stem cell-related bills have been introduced. Most notable are H.R.872 (DeGette) and S. 487 (Harkin), which are identical to the legislation passed by Congress in the 110th Congress to lift the Bush limitations, but which was vetoed. Congressional action has not been scheduled.

The AAMC is a founding member of the Coalition for the Advancement of Medical Research (CAMR). The Coalition is comprised of universities, scientific societies, patients' organizations, and other entities that are devoted to ensuring that federal funding will be available for stem cell research. Working alone and in conjunction with CAMR, AAMC has actively supported broader federal funding policies regarding stem cell research. AAMC commended President Bush for his Executive Order and is generally pleased with the final NIH Guidelines. *[Moore, Mazzaschi]*

### **Implementation of the Mandatory NIH Public Access Policy**

The FY 2008 appropriations bill for NIH (P.L. 110-161, Division G) contained a provision (section 218) mandating that all NIH funded investigators “submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be

made publicly available no later than 12 months after the official date of publication.” PubMed Central is an archive of full-text biomedical journal articles maintained by the NLM. Congress made the provision permanent in the FY 2009 appropriations bill for NIH (P.L. 111-8, Division F, Section 217).

Beginning on April 7, 2008, all articles arising from NIH funds must be submitted to PubMed Central upon acceptance for publication. As of May 25, 2008, NIH applications, proposals, and progress reports were required to include the PubMed Central reference number when citing an article that falls under the policy and is authored or co-authored by a covered researcher. The responsibility for managing copyright issues has been left to investigators and their institutions. An increasing number of publishers are now posting articles routinely on PubMed Central. However, some major publishers are not cooperating with NIH.

On February 3, 2009, House Judiciary Committee Chairman John Conyers (D-Mich.) introduced “the Fair Copyright in Research Works Act” (H.R. 801) to overturn the NIH’s Public Access Policy. The legislation, which was first introduced in the 110<sup>th</sup> Congress, also would prevent other federal research funding agencies from adopting similar public access policies. The bill, which currently has six co-sponsors, was referred to the House Judiciary Subcommittee on Courts and Competition Policy on March 16. [*Mazzaschi*]

### **Title VII Reauthorization**

The health care reform bills approved by the Senate Health, Education, Labor, and Pensions (HELP) Committee and the House “Tri-Committee” include provisions to reauthorize Title VII health professions programs.

Many of the provisions in the draft HELP Committee bill correspond directly with recommendations of the AAMC’s Title VII Reauthorization Committee ([www.aamc.org/advocacy/library/laborhhs/t7reauth.pdf](http://www.aamc.org/advocacy/library/laborhhs/t7reauth.pdf)). As released, the bill:

- Updates the Title VII student loan programs, including the Primary Care Loan;
- Establishes a National Center for Health Care Workforce Analysis to coordinate with State and Regional Centers for Health Workforce Analysis, and authorizes grants to establish and maintain a longitudinal database of Title VII outcomes measures;
- Authorizes funding and activities for the Title VII primary care medicine programs distinctly from the Title VII primary care dentistry programs;
- Allows Title VII primary care medicine grantees to train physicians teaching in community-based settings, develop joint degree programs in interdisciplinary training in public health and other areas, and develop demonstration programs providing training in new competencies as recommended by the HRSA Advisory Committee on Training in Primary Care Medicine and Dentistry;
- Prioritizes Title VII primary care applicants that, among other priorities, establish formal relationships and submit joint applications with community health centers, Area Health Education Centers (AHEC), rural health clinics, or clinics in underserved areas;

- Reauthorizes at higher funding levels the Title VII diversity programs, including the Centers of Excellence, Health Careers Opportunity Program, Scholarships for Disadvantaged Students, and Faculty Loan Repayment;
- Expands the Title VII geriatric education training program to develop CME-satisfying fellowships on geriatrics, chronic care management, and long-term care for health professions faculty and to offer family caregiver training or to incorporate mental health best practices in training courses;
- Reauthorizes AHECs with a “Point of Service Maintenance and Enhancement Award” to maintain and improve existing AHECs, requires that each AHEC program include at least one area health education center that is not a school of medicine or the parent institution, and includes a “Sense of Congress” that each state should have an AHEC program;
- Establishes a new pediatric specialty loan repayment program and a new public health workforce loan repayment program with obligated service requirements;
- Directs the HHS Secretary to support the development, evaluation, and dissemination of model health professions curricula for cultural competency, prevention, and public health proficiency, and aptitude for working with individuals with disabilities;
- Establishes a grant program to support distance learning, continuing education, collaborative conferences, and electronic and telelearning activities, with priority for primary care.

A more detailed analysis of the HELP Committee’s Title VII provisions, including AAMC’s comments, is available online at:

**[www.aamc.org/advocacy/library/corres/2009/061509.pdf](http://www.aamc.org/advocacy/library/corres/2009/061509.pdf)**.

The House Tri-Committee bill (H.R. 3200), drafted by the committees on Ways and Means, Energy and Commerce, and Education and Labor, includes provisions similar to the HELP draft bill. Like the HELP draft, the Tri-Committee bill as introduced:

- Updates the Title VII Primary Care Loan program;
- Establishes a National Center for Health Workforce Analysis;
- Reauthorizes the Title VII diversity programs;
- Authorizes funding and activities for the Title VII primary care medicine programs distinctly from the Title VII primary care dentistry programs; and,
- Allows Title VII primary care medicine grantees to use funds to train physicians teaching in community-based settings.

Additionally, the joint House bill adds eligibility for geriatric medicine to the Title VII primary care medicine programs, but does not address the Title VII geriatric education training programs. New Title VII programs in the House bill include a grant program promoting training in interdisciplinary and team-based care, as well as a grant program to address health disparities by promoting interdisciplinary cultural and linguistic competency. However, the Tri-Committee bill does not reauthorize the AHEC program.

The House committees establish under Title VII a new HRSA Advisory Committee on Health Workforce Evaluation and Assessment. Similar to the Senate HELP Committee’s proposed National Health Care Workforce Commission (established independently of

Title VII in the HELP bill), the advisory committee is tasked with collecting, reviewing, and reporting information on projected health workforce needs.

The House bill also makes designated Title VII programs eligible to receive supplemental funding through the new "Public Health Investment Fund." The bill deposits \$4.6 billion in FY 2010 (with levels increasing thereafter) into the Fund and authorizes appropriators to increase funding over FY 2008 levels for selected Title VII, Title VIII, and several other health programs. The Senate HELP bill includes a similar mechanism, but does not make Title VII programs eligible for supplemental appropriations through the fund.

The manager's amendment approved by the Energy and Commerce Committee creates a new program under Title VII awarding grants to eligible "teaching health centers" to support developing new primary care residency training programs. Eligibility for the grants is reserved for community health centers and other entities that participate in a "teaching health center" demonstration project under section 1502(d) of the Tri-Committee bill. The committee also approved an amendment directing the HHS Secretary to review the bill's amended and new public health and workforce development programs. The Secretary then is required to terminate any existing program that is determined duplicative of a program addressed in the bill.

AAMC's comments on the Tri-Committee's original discussion draft of H.R. 3200 include additional details on the bill's Title VII provisions. The comments are available on the AAMC Web site at:

[www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf](http://www.aamc.org/advocacy/library/gme/corres/2009/070309.pdf). [Rasouli]

### **Physician Immigration**

On March 20, President Obama signed into law legislation (P.L. 111-9) to extend through September 30, 2009, the Conrad State 30 program. The legislation was introduced February 23 by Representative Zoe Lofgren (D-Calif.).

Currently, the Conrad State 30 program allows physicians on J-1 visas to waive the J-1 requirement to return to their home country for two years if they agree to serve for three years in a U.S. underserved area. Each state is allowed 30 such waivers.

On March 18, Senator Kent Conrad (D-N.D.) introduced a bill (S. 628) to authorize the Conrad State 30 permanently with additional reforms. The bill is similar to legislation he sponsored in the 110th Congress (S. 2672). S. 628 would:

- Permanently authorize the Conrad State 30 program;
- Allow physicians on H-1B visas to enter the program;
- Exempt physicians who participate in the program from green card caps; and
- Provide a mechanism by which the per state caps can increase beyond 30 waivers.

S. 628 also would prohibit H-1B visa physicians from serving in "flex-slots," positions located outside underserved areas. Additionally, it would reset H-1B visa physicians' visa expiration to six years from the time they enter the Conrad State 30 program. [Shick]

## **Physician Workforce Enhancement**

On March 4, the House Energy and Commerce Committee favorably reported to the House the “Physician Workforce Enhancement Act of 2009” (H.R. 914).

H.R. 914 was introduced on February 9, by Representatives Michael Burgess (R-Texas), a physician, and Gene Green (D-Texas) and currently has 42 cosponsors. The legislation creates a loan program for establishing residency training programs in rural areas. H.R. 914 would provide eligible public and non-profit hospitals with up to \$1 million in interest free loans to establish residency training programs in family medicine, internal medicine, emergency medicine, obstetrics/gynecology, general surgery, preventive medicine, pediatrics or behavioral/mental health.

Under H.R. 914, hospitals must commence repayment within 18 months of receiving the loan, complete repayment within 24 months, and use the funds "only for costs directly attributable" to the training program. Recipients terminating the residency programs before full repayment of the loans would face financial penalties. The bill authorizes the loan program under Title VII of the Public Health Service Act at an appropriated amount of \$25 million for the period of fiscal years 2010 through 2020. [*Mitchell, Crytzer*]

## **Higher Education Act Negotiated Rulemaking**

In June and August of 2009, the Department of Education published a series of Notices of Proposed Rulemaking following the completed Negotiated Rulemaking sessions for the “Higher Education Opportunity Act” (HEOA, P.L. 110-315). Comments on the proposed regulations were due by September 8, 2009. Negotiators were divided into the following subject area “teams:”

- Team I-Loans-Lender/General Loan Issues;
- Team II-Loans-School-based Loan Issues;
- Team III-Accreditation;
- Team IV-Discretionary Grants; and
- Team V-General and Non-Loan Programmatic Issues.

Three of the five teams reached a consensus on the proposed regulations considered during the three rounds of negotiated rulemaking sessions February through May. When such negotiating sessions end with consensus among the parties on a package of regulatory changes, the department is bound to propose them as agreed by the committee. Negotiating Teams IV and V failed to reach a consensus.

Carrie Steere-Salazar represented the AAMC and graduate/professional schools on Team I. Ms. Steere-Salazar is director of Student Financial Services at the University of California, San Francisco, School of Medicine and chair of the AAMC Committee on Student Financial Assistance (COSFA).

On May 26, the department published a *Federal Register* notice announcing its intention to establish new negotiated rulemaking committees in the fall of 2009. The notice also

announced three public meetings starting June 15 where interested parties may suggest issues that should be considered for action by the negotiating committees. The department will also be conducting forums after each of the three hearings to discuss: how changes to the department's financial aid communications and processes (including the Free Application for Federal Student Aid (FAFSA) could improve college planning, preparation and access; and how best to leverage federal postsecondary programs to foster student educational persistence and degree attainment. *[Shick]*

### **False Claims Act Amendments**

On May 20, President Obama signed the "Fraud Enforcement and Recovery Act" (FERA, P.L. 111-21). The law primarily addresses mortgage fraud, but also amends the federal False Claims Act (FCA). The final measure includes amendments that Congress considered under broader FCA reform bills such as the "False Claims Act Correction Act of 2009" (H.R. 1788) and "False Claims Act Clarification Act of 2009" (S. 458). The House and Senate Judiciary Committees reportedly have agreed that P.L. 111-21 will complete action on FCA legislation in this Congress.

Of particular importance to medical schools and teaching hospitals, the final measure includes an amendment offered by Senator Jon Kyl (R-Ariz.) to help clarify that the legislation only imposes liability under FCA for knowing and improper "retention" of an overpayment, as opposed to mere "receipt" of an overpayment such as through federal grants, contracts, or Medicare payments. The AAMC April 21 joined 16 organizations in a coalition letter that supported adoption of the Kyl amendment. The letter is available at: [www.aamc.org/advocacy/library/research/corres/2009/042109senate.pdf](http://www.aamc.org/advocacy/library/research/corres/2009/042109senate.pdf)

Another amendment expands FCA anti-retaliation protections to a "contractor, or agent," in addition to an employee, without requiring the prohibited retaliatory acts to be taken by an "employer." Under the amendment, liability could potentially extend to many different types of relationships that do not involve an employment contract. However, the same provision also would limit liability to discrimination "in the terms and conditions of employment" as a result of action taken by the employee to stop further FCA violations.

P.L. 111-21 makes certain liability provisions retroactively effective June 7, 2008, to address a number of court rulings that proponents claim stray from the original intent of 1986 FCA amendments. The constitutionality of this provision has been called into question and could delay enforcement of the bill with years of litigation.

P.L. 111-21 does not include language considered in FCA reform bills last year that would have calculated the liability at three times the total "amount of money or property paid or approved because of the act of that person." Instead, P.L. 111-21 retains the existing FCA language to calculate monetary liability at three times the amount "of damages which the Government sustains because of the act of that person."

A number of FCA amendments considered by the House and Senate in the broader FCA reform bills were left out of the final bill:

- P.L. 111-21 does not include language that addressed “contingent” obligations, which could have resulted in FCA suits to enforce a fine before the duty to pay that fine had been formally established.
- P.L. 111-21 maintains an institution’s ability to move to dismiss suits brought by individuals acting without the government if the institution can show that action is based on information that has been publicly disclosed. The final measure rejects earlier proposals that would have prevented such motions and required the Department of Justice (DOJ) to move to dismiss the action.
- While earlier legislation proposed a lengthy 10-year statute of limitations for FCA suits, P.L. 111-21 continues the current tiered system with multiple limits less than 6 years.
- P.L. 111-21 upholds Rule 9(b) of the Federal Rules of Civil Procedure, which requires that all persons asserting fraud actions in Federal court must plead the elements of fraud with particularity. The final measure rejects earlier proposals that would have exempted FCA relators, holding whistleblowers to a lower standard than every other Federal litigant, and to an even lower standard than that applicable to the DOJ in FCA cases.

In his opening remarks at the House Judiciary Committee consideration of H.R. 1788 on April 28, Ranking Member Lamar Smith (R-Texas) noted the past success of the FCA and its ongoing importance for oversight of the Recovery Act spending, but questioned whether the proposed reforms were needed. He specifically mentioned the opposition of the AAMC, the Association of American Universities, and the American Hospital Association. Rep. Dan Maffei (D-N.Y.) outlined the funding process of grants from the National Institutes of Health and university controls to prevent fraud, as well as the process that hospitals use to reconcile Medicare overpayment. Rep. Maffei also submitted the coalition letter for the record. (see below)

The House Judiciary Committee approved (20-6) H.R. 1788 on April 28 before the full House consideration of FERA on May 6. While H.R. 1788 was a broader FCA reform bill, P.L. 111-21 is expected to complete action on FCA amendments this Congress. The AAMC April 21 joined 16 organizations in letters to the House Judiciary committee noting concerns with H.R. 1788. The coalition letter states that the current statute is working appropriately and that new legislation is unwarranted. The letter is available at: [www.aamc.org/advocacy/library/research/corres/2009/042109.pdf](http://www.aamc.org/advocacy/library/research/corres/2009/042109.pdf). [Moore, Shick]

### **Patent Reform**

On March 3, Senate Judiciary Chair Patrick Leahy (D-Vt.) and Senator Orrin Hatch (R-Utah), a senior member of the committee, introduced the “Patent Reform Act of 2009” (S. 515). Representatives Conyers and Smith introduced companion legislation (H.R. 1260) the same day.

Following extensive negotiations and further compromises in the Senate Judiciary Committee, particularly on provisions affecting the award of damages on patent infringement, S. 515 was reported on April 2, by a 15-4 vote. A coalition of higher education associations including the AAMC, the Association of American Universities,

the American Council on Education, the Council on Governmental Relations, the Association of Public and Land-Grant Universities, and the Association of University Technology Managers sent a letter to the Senate leadership encouraging them to bring the bill before the full Senate for a vote, which has not yet happened. The coalition letter is available at:

[www.aamc.org/advocacy/library/research/corres/2009/050709.pdf](http://www.aamc.org/advocacy/library/research/corres/2009/050709.pdf)

Meanwhile, the House Judiciary Committee on April 30 held a hearing on the H.R. 1260. Both House Judiciary Chair John Conyers (D-Mich.) and Ranking Member Lamar Smith (R-Texas) indicated that they have no intention of accepting the Senate language as it stands, particularly on the provisions relating to apportionment of damages.

A key feature of both the House and Senate bills would change U.S. Patent and Trademark Office (PTO)'s procedures from giving priority to the "first to invent" to granting "priority" for a patent to the first inventor to file an application. Current PTO rules often result in lengthy and expensive "interference proceedings" to determine which of two applicants developed the invention first, regardless of when the patent applications were filed. A "first inventor to file" system would be both less expensive to this country and more in harmony with practices in other nations. The AAMC and the academic coalition have worked to ensure that patent reform proposals provide a grace period by which inventors can publish pertinent discoveries while not disadvantaging themselves in a first-to-file system. [*Ehringhaus, Heinig, Shick*]

### **Gene Patent Policy**

On May 15, the AAMC responded to a request from the Department of Health and Human Services Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) regarding a draft report, "Public Consultation Draft Report on Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests." The committee report lists a range of "policy options" to ensure access to reliable genetic diagnostic tests. The draft includes, among these options, a proposal to re-examine federal agencies' authority and use of "march-in rights" under the 1980 Bayh-Dole Act as a means to rescind licensing arrangements presumed by the federal government to be overly restrictive of access to a genetic test. The legislative history of Bayh-Dole indicates that such provisions were intended to be used exceptionally, if at all. The university community has generally opposed efforts to reinterpret or reassert these march-in provisions in ways that would weaken licensees' settled expectations to use university technology and that would be contrary to the spirit of the Act.

In its comment letter, the AAMC supported efforts consistent with standing NIH guidelines and the academic community's "Nine Points" document to encourage reliance on non-exclusive licensing for gene-based diagnostic tests. A central concern is that exclusive licensing and monopoly practices could restrict availability of testing services or impair refinement of tests (for lack of competitive checks), although case studies conducted on behalf of SACGHS did not indicate major differences in availability or quality of patented tests compared to non-patented tests. The AAMC also supported creation of databases or information on licensing practices. The Association does not at this time consider revision or reinterpretation to Bayh-Dole to be warranted given the

case studies and other findings of the discussion draft. The AAMC comment letter is available at:

[www.aamc.org/advocacy/library/research/corres/2009/050309.pdf](http://www.aamc.org/advocacy/library/research/corres/2009/050309.pdf) [Ehringhaus, Heinig, Shick]

### **Dual Use Research and Biosecurity Issues**

On August 13, President Obama extended the authority of the U.S. Department of Commerce to administer the nation's export control system, which is intended to prevent export of sensitive technologies that could directly or inadvertently undermine U.S. national security. Many technologies or components of technical systems used in academic research, including biomedical research, have been subject to export controls in the past, and universities have closely monitored and participated in policy discussions on export controls.

The President also directed the White House National Economic Council and the National Security Council to launch a broad, interagency review of the overall U.S. export control system. The White House stated that "the aim of the review is to consider reforms to the system to enhance the national security, foreign policy, and economic security interests of the United States...", noting that the export control system, largely developed during the Cold War, should be adapted to the contemporary security environment of the United States.

Under the previous Administration, an expert advisory committee led by Norman Augustine, retired Chairman and CEO of Lockheed Martin Corporation reviewed a subset of the export control system relating to "deemed exports" or transfer of sensitive technologies within U.S. borders to individuals from other countries. The Deemed Export Advisory Committee called for a far more streamlined system focused more selectively on protecting key technologies and loosening restrictions on others. The recommendations were generally supported by the academic community, which hosts large populations of international students and other scholars. The extent to which the Obama Administration's new review will build upon or incorporate the earlier recommendations, or develops alternative policies remains to be seen.

Several other policy initiatives begun in the previous administration relating to biosecurity and dual-use research remain to be concluded or decided upon under President Obama. Last year, the Federal Government charged the Department of Health and Human Services' National Science Advisory Board on Biosecurity (NSABB) to review options for a "personnel reliability" program that could affect all individuals and institutions conducting research with biological select agents. On May 20, the NSABB issued a draft report recommending enhancements to extant security requirements for personnel working with select agents that have been significantly strengthened since 2001, but the NSABB found it unnecessary to implement a national personnel reliability program at this time. Previously, NSABB developed an "oversight framework" to guide researchers and federally funded institutions in overseeing and monitoring dual-use research, including "dual-use research of concern" (DURC) that focuses on particular areas of investigation most pertinent to security concerns. The Bush Administration did not make a final decision to approve or implement the framework, and it remains to be

seen if the Obama Administration will act on the current version or return the framework for further revision or consideration.

Finally, Senator Joe Lieberman (I-Conn), Chair of the Homeland Security and Governmental Affairs Committee, has been working on legislation that follows up on recommendations of the Congressionally-mandated Commission on the Prevention of WMD Proliferation and Terrorism released last year, and which included a major focus on biosecurity. Senators Lieberman and Susan Collins (R-Maine), the ranking member of the committee, introduced the “WMD Prevention and Preparedness Act of 2009” (S. 1649) on September 8. [*Ehringhaus, Heinig*]

### **Biosimilars Legislation**

On July 31, during consideration of the House tri-committee health care reform proposal the House Energy and Commerce Committee approved (47 – 11) an amendment offered by Representatives Anna Eshoo (D-Calif.) and Joe Barton (R-Texas) that incorporated the principles of the Pathways to Biosimilars Act (H.R. 1548). The Eshoo/Barton amendment applies to biologics and applications to license a biological product as a biosimilar. The legislation allows for 12 years of data exclusivity for a reference product. There is also a two-year period of marketing exclusivity for the first licensed biosimilar for a reference product. Exclusivity periods could be extended by two years with the approval of a significant new disease indication, and for six months for conducting pediatric studies.

A similar amendment was passed (16-7) by the Senate Health, Education, Labor and Pensions (HELP) Committee on July 13 during consideration of its health care reform proposal. The amendment was introduced by Senators Orrin Hatch (R-Utah), Mike Enzi (R-Wyo.), and Kay Hagan (D-N.C.).

The amendments are in contrast to the “Promoting Innovation and Access to Life-Saving Medicine Act,” which was introduced as H.R. 1427 on March 11 by Energy and Commerce Chair Henry Waxman (D-Calif), and Representatives Frank Pallone (D-N.J.), Nathan Deal (R-Ga.) and Jo Ann Emerson (R-Mo.), and as S. 726 on March 26 by Senators Chuck Schumer (D-N.Y.), Susan Collins (R-Maine), Sherrod Brown (D-Ohio), Mel Martinez (R-Fla.), Debbie Stabenow (D-Mich.) and David Vitter (R-La.).

H.R. 1427/S. 726 grants makers of an original brand name biologic drug a five-year period of exclusivity in marketing, and a three year exclusivity period for a modification to an already FDA-approved drug. The legislation would allow for the first company to prove to the FDA that their generic is interchangeable with the brand name to be given six months of exclusive marketing before other generic versions are allowed. Exclusivity periods for brand name biologics can be extended up to one year if it is proved that the drug can be used for a new disease indication, or if the applicant conducts pediatric studies. [*Moore*]

## **Great Ape Protection Act**

On March 5, Representatives Adolphus Towns (D-N.Y.), David Reichert (R-Wash.), Jim Langevin (D-R.I.), and Roscoe Bartlett (R-Md.), introduced the “Great Ape Protection Act” (GAPA, H.R. 1326), a bill to ban “invasive” research on chimpanzees, bonobos, gorillas, orangutans, or gibbons. Similar to legislation introduced in the previous Congress, the bill prohibits any research that “may cause death, bodily injury, pain, distress, fear, injury, or trauma to a great ape,” including drug testing, restraining, tranquilizing, anesthetizing, isolation, social deprivation, and other activities.

Additionally, the measure bans “related activities,” such as breeding or transporting great apes for research purposes, and the use of Federal funds for such research within or outside the United States. Civil penalties are accrued at not more than \$10,000 a day for each violation. GAPA also directs the Secretary of Health and Human Services to provide for the permanent retirement of great apes under control of the Federal government for research. The bill, which had 62 cosponsors as of August 27, has been referred to the House Committee on Energy and Commerce. [*Rasouli*]

## **Pandemic Preparedness**

On June 24, the President signed a supplemental spending bill (P.L. 111-32) that includes \$1.85 billion in funds for pandemic flu preparedness activities at the Department of Health and Human Services (HHS), as well as funds for military operations abroad and international economic and security assistance. The pandemic preparedness funds include:

- \$1.3 billion to continue to address the current H1N1 outbreak, prepare for increased severity of the virus or future outbreaks, and to support other activities, including development and purchase of vaccines and countermeasures. The HHS Secretary, in consultation with the Director of the Office of Management and Budget (OMB), may transfer funding within HHS or to other Federal agencies;
- At least \$200 million for preparedness and response activities at the Centers for Disease Control and Prevention; and
- At least \$350 million for upgrading state and local preparedness and response capacity.

Additionally, the supplemental includes \$5.8 billion as a “contingent emergency appropriation” to support Federal, State, and local public health and emergency response agencies if necessary. To activate the funding, the President must provide written notice to Congress that the emergency influenza funds are required and must designate specific amounts for obligation. The funds may be transferred within HHS and to other Federal agencies by the HHS Secretary in consultation with the OMB Director. [*Rasouli*]

## **Expanded Access to Investigational Drugs**

The Food and Drug Administration (FDA) August 12 and 13 published two final rules to clarify the options in gaining access to investigational drugs and biologics for seriously ill patients who are not eligible to participate in clinical trials. The “expanded access rule” describes individual and group access options, specifies safeguards to protect patients,

and preserves the role of clinical trials in developing safety and effectiveness data on drugs available under expanded access. In the “charging rule,” the FDA clarifies charging authorization process and specifies cost recovery options for the drug manufacturers. The rules will go into effect October 13.

The “Expanded Access to Investigational Drugs for Treatment Use” final rule amends existing regulations to expand and clarify circumstances under which seriously ill patients are allowed to access the investigational drug. It explains the procedures and standards for the treating physicians and the patients who want access to investigational drugs that showed promise in the early phases of a clinical trial. The rule specifies that expanded access should be considered only when approved therapies are not available or options are exhausted and potential benefits justify potential risks. Such access must not interfere with investigational drug development. A drug’s safety and effectiveness for marketing approval should be demonstrated in clinical trials.

The “Charging for Investigational Drugs Under an Investigational New Drug Application” final rule amends the existing charging rule to explain when a drug manufacturer can charge a patient for an investigational drug in a clinical trial or expanded access program. Written authorization to charge must be obtained from FDA by the sponsor. The rule describes direct and indirect costs recovery conditions and options.

Expanded Access to Investigational Drugs for Treatment Use Rule is available at: <http://edocket.access.gpo.gov/2009/pdf/E9-19005.pdf>.

Investigational Drugs Under an Investigational New Drug Application Rule is available at: <http://edocket.access.gpo.gov/2009/pdf/E9-19004.pdf>. [Tartakovsky]

### **Physician Payments Sunshine Act**

On January 22, 2009, Senators Chuck Grassley (R-Iowa) and Herb Kohl (D-Wis.) reintroduced the "Physician Payments Sunshine Act" (S. 301), which requires drug and medical device manufacturers to disclose all their payments and other transfers of value to “covered recipients” – which the bill defines as physicians, physician medical practices, or physician group practices – if the total annual payments per recipient exceeds \$100. The legislation requires drug, device, or medical supply manufacturers that receive payments through Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP) to disclose to the Department of Health and Human Services (HHS), on an annual basis, anything of value given to covered recipients, such as payments, gifts, honoraria, or travel. This would include funding provided for continuing medical education and research grants.

The bill requires companies to report the name and business address of the covered recipient, the specialty and Medicare billing number if the recipient is a physician, the value and the date of the payment or other transfer of value, and its form (e.g., cash, in-kind services, stocks or stock options). The bill also requires a description of the nature of the payment or transfer of value among various categories specified in the bill, such as consulting fees, honoraria, gifts, entertainment, travel, education, and research.

Companies that knowingly fail to report are subject to penalties up to \$1 million, a change from the \$100,000 maximum penalty in the previous bill.

In addition, manufacturers, group purchasing organizations, and distributors subject to this legislation must also report on an annual basis any ownership or investment interest held by physicians and their immediate families.

Reporting of payments or other transfers of value related to product development agreements for services in connection with the development of new drugs, devices, biologicals, or medical supplies may be delayed until the earlier of the date of FDA approval or two calendar years after the payment or transfer is made.

The bill also requires HHS to establish no later than November 1, 2009, procedures for companies to submit information and procedures for HHS to make the submitted information available to the public via a searchable online registry. The registry must be available to the public by September 20, 2011. Reporting by companies would be mandatory beginning March 31, 2011.

S. 301 preempts state laws that require reporting the same information mandated in the bill but does not preclude state laws that require additional information from companies not specifically covered by federal law.

S. 301, which currently has 11 co-sponsors, has been referred to the Senate Finance Committee.

Representative Baron Hill (D-Ind.) introduced similar legislation (H.R. 3138) in the House on July 9. The principle differences with the Senate bill are that H.R. 3138 lowers the annual limit for reporting to \$25 and delays the reporting of payments related to product development agreements up to four years.

The House Tri-committee health care bill (H.R. 3200) also includes physician payment sunshine provisions similar to S. 301/H.R. 3138. The tri-committee bill expands the definition of “covered recipient” to include, among others, hospitals, medical schools, sponsors of continuing medical education programs, patient advocacy or disease specific groups, and biomedical researchers. The tri-committee bill also requires, beginning no later than March 31, 2011, that each hospital or other health care entity that bills under Medicare part A or part B report annually on the ownership shares of each physician and immediate family members who, directly or indirectly, owns an interest in the entity.

The AAMC has endorsed the Senate Physician Payments Sunshine Act in both the 110th and 111<sup>th</sup> Congresses. *[Moore]*

### **PAYGO Legislation**

On July 22, the House passed (265-166) legislation requiring the cost of new mandatory spending programs or tax cuts be offset elsewhere in the budget. The Statutory Pay-As-You-Go Act of 2009 (H.R. 2920) would require the Office of Management and Budget (OMB) to determine at the end of each session of Congress whether the overall cost of

new non-emergency mandatory spending increases or tax cuts enacted in that session has been offset by other tax increases or spending cuts. If the new initiatives have not been paid for, the President would be required to make an across-the-board cut or "sequestration" of entitlement spending. H.R. 2920 mandates OMB to assess the cost of the new policies over 10 years.

When the Democrats assumed control of Congress in 2007, they instituted procedural pay-as-you-go or "Pay-go" rules that often have been waived. President Obama June 9 called on Congress to place the rules in statute.

H.R. 2920 would exempt the costs of extending four existing policies: preempting the annual cuts to Medicare physician reimbursement, limiting the alternative minimum tax, and extending the 2001 and 2003 tax cuts. In a July 22 floor statement in support of passage, House Majority Leader Steny Hoyer (D-Md.) acknowledged the "exemptions as a crucial concession to political reality.... It is clear that there is bipartisan support in Congress for extending those current policies without offsetting savings."

On August 6 Senators Claire McCaskill (D-Mo.) and Michael Bennet (D-Colo.) introduced "pay-as-you-go" (PAYGO) legislation that would require offsets for extending existing programs. The prospects for the legislation in the Senate are uncertain. Budget Committee Chair Kent Conrad (D-N.D.) does not support exempting the four policies, and has said that he would like to see PAYGO legislation included in a larger debt and deficit-reduction proposal. *[Moore]*



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