THE CRD ASSOCIATES'

HEALTH POLICY REPORT

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The Headlines:

- **A December Dash on Appropriations?**
- **Experts Dispute Claims of Doctor Shortage**
- **HHS and NIH Enhance Clinical Trial Results Transparency**
- **Last Chance for SGR Repeal?**

December Dash on Appropriations?

Congress returned to work December 1 only to face year-end drama that seems to have caught Washington by surprise. Republican leaders, namely House Speaker John Boehner and incoming Senate Majority Leader Mitch McConnell, planned to use the lame-duck session of Congress to clear out pending legislative issues. That, they thought, would give the party the ability advance a proactive agenda in 2015. But not all the rank-and-file agree—particularly when it comes to completing work on the 12 spending bills necessary to keep the government operating.

For the past several weeks, House and Senate appropriations staff have been toiling away on a fiscal 2015 omnibus spending bill that would fund federal departments agencies, a measure that they hope to clear before the current continuing resolution (CR) expires on December 11.

However, some conservatives have other ideas. Instead of sending the president an omnibus spending bill, they would prefer to replace the CR with one that would last for some or all of the nearly 10 months remaining in the fiscal year.

House Appropriations Chairman Harold Rogers (R-KY) has plunged ahead with writing an omnibus, suggesting Speaker Boehner agrees with this approach. But Boehner last week said that a decision on an approach to appropriations will have to await intraparty discussions. The mainstream GOP view in favor of an omnibus is that getting the fiscal 2015 spending bills done before 2015 will clear the decks for the new Republican majority in both chambers to start fresh with fiscal 2016 measures early next year. But some conservatives argue that spending bills should be written not by a lame-duck Congress but by newly sworn-in Republicans next year. Others think that a CR for the entire remainder of fiscal 2015 will have the same effect as passing an omnibus, allowing a Republican-controlled Congress to start fresh with fiscal 2016 bills.

The issue was further complicated when the president announced plans to take executive action implementing immigration reform.

At press time, support seemed to be coalescing around a plan to pass a combination of a CR and an omnibus spending bill. This would involve passing an omnibus through the rest of the fiscal year, but selecting out and passing separately those funding programs related to illegal immigration, which would be dealt with in a short-term CR lasting through the first quarter of 2015

Essentially, the plan would punt the immigration fight to early next year and separate it from the must-pass spending legislation.

It is unclear which path Congress will take, but appropriators on both sides of the aisle continue to insist that a full-fledged omnibus remains a possibility, with aides from both parties saying that negotiations are continuing and that progress is being made, even as the time grows short.

Experts Dispute Claims of Doctor Shortage

Many medical groups, like the Association of American Medical Colleges, contend that there is a physician shortage, and that the shortage will grow to 130,000 in the next 10 to 12 years. But as Kaiser Health News recently reported, health care economists are less convinced.

"Concerns that the nation faces a looming physician shortage, particularly in primary care specialties, are common," wrote an expert panel of the Institute of Medicine (IOM) in a report on the financing of graduate medical education in July. "The committee did not find credible evidence to support such claims."

Gail Wilensky, a health economist and co-chair of the IOM panel, says previous predictions of impending shortages "haven't even been directionally correct sometimes. Which is we thought we were going into a surplus and we ended up in a shortage, or vice versa."

In addition to a numerical shortage, there's also a mismatch between what kind of doctors the nation is producing and the kind of doctors it needs, says Andrew Bazemore, a family physician with the Robert Graham Center, an independent project of the American Academy of Family Physicians.

"We do a lot of our training in the northeastern part of our country, and it's not surprising that the largest ratio of physicians and other providers, in general, also appear in those areas," says Bazemore. "We have shown again and again that where you train matters an awful lot to where you practice." That ends up resulting in an oversupply in urban centers in the Northeast and an undersupply elsewhere.

Even aside from geography, there are other questions, he says, such as "do the providers reflect the populations they serve? And that means by their race and ethnicity, by their age, by their gender?"

While few dispute the idea that there will be a growing need for primary care in the coming years, it is not at all clear whether all those primary care services have to be provided by doctors.

"There are a lot of services that can be provided by a lot of people other than primary care doctors," says Wilensky. That includes physician assistants, nurse practitioners, and even pharmacists and social workers.

"How many physicians we 'need' depends entirely on how the delivery system is organized," Wilensky says.

Currently, physicians who are specialists earn considerably more than those who practice primary care, which many experts say is a huge deterrent to doctors becoming generalists.

At the same time, "team-based care" is considered by many to be not only more cost-effective, but also a way to lower the number of doctors the nation needs to train.

"All of the efforts to the future...are to mold and morph our medical system into one that is less 'single-combat warriors' practicing medicine here and there, and physicians and others practicing in efficient systems," says Fitzhugh Mullan, a professor of medicine and health policy at George Washington University.

HHS and NIH Enhance Clinical Trials Results Transparency

The U.S. Department of Health and Human Services has issued a Notice of Proposed Rulemaking (NPRM) that proposes regulations to implement reporting requirements for clinical trials that are subject to Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). The proposed rule clarifies requirements to clinical researchers for registering clinical trials and submitting summary trial results information to ClinicalTrials.gov, a publicly accessible database operated by the National Library of Medicine, part of the National Institutes of Health. A major proposed change from current requirements is the expansion of the scope of clinical trials required to submit summary results to include trials of unapproved, unlicensed, and uncleared products.

"Medical advances would not be possible without participants in clinical trials," said NIH Director Francis S. Collins, M.D., Ph.D. "We owe it to every participant and the public at large to support the maximal use of this knowledge for the greatest benefit to human health. This important commitment from researchers to research participants must always be upheld."

ClinicalTrials.gov currently contains registration information for more than 178,000 clinical trials and summary results for more than 15,000. These numbers include trials that are not subject to FDAAA. Among the primary benefits of registering and reporting results of clinical trials, including both positive and negative findings, is that it helps researchers prevent unnecessary duplication of trials, particularly when trial results indicate that a product under study may be unsafe or ineffective, and it establishes trust with clinical trial participants that

the information from their participation is being put to maximum use to further knowledge about their condition.

Developed by NIH in close coordination with the FDA, the proposed rule details procedures for meeting the requirements established by FDAAA to improve public access to clinical trial information. FDAAA and the proposed rule apply to certain interventional studies of drugs, biological products, and devices that are regulated by the FDA, but, generally, not to phase 1 trials of drugs and biological products and small feasibility studies of devices. The proposed rule specifies how data collected and analyzed in a clinical trial would be required to be submitted to ClinicalTrials.gov. It would not affect requirements for the design or conduct of clinical trials or for the data that must be collected during clinical trials.

"This proposed rule would close an important gap, making additional information about clinical studies of investigational drugs, medical devices and biological products available to the public," said FDA Commissioner Margaret A. Hamburg, M.D. "It would help eliminate unnecessary duplicative trials, advance biomedical innovation, and provide the public with a much richer understanding about the clinical trials for these products."

Notable changes from current requirements and practice that are outlined in the proposed rule include:

-- A streamlined approach for determining which trials are subject to the proposed regulations and who is responsible for submitting required information.

-- Expansion of the set of trials subject to summary results reporting to include trials of unapproved products.

-- Additional data elements that must be provided at the time of registration (not later than 21 days after enrolling the first participant) and results submission (generally not later than 12 months after completion).

-- Clarified procedures for delaying results submission when studying an unapproved, unlicensed, or uncleared product or a new use of a previously approved, licensed, or cleared product and for requesting extensions to the results submission deadline for good cause.

-- More rapid updating of several data elements to help ensure that users of ClinicalTrials.gov have access to accurate, up-to-date information about important aspects of a clinical trial.

-- Procedures for timely corrections to any errors discovered by the responsible party or by the Agency as it processes submissions prior to posting.

Read a summary of the proposed changes: <http://www.nih.gov/news/health/nov2014/od-19_summary.htm).

Last Chance for SGR Repeal?

As the lame duck session winds down, so do the chances for permanent repeal of the flawed sustainable growth rate (SGR) formula. Both the House and the Senate introduced the *SGR Repeal and Medicare Provider Payment Modernization Act* (HR 4015/S 2000) earlier this year, but legislators failed to reach an agreement on how to offset the $180 billion cost of the bill and instead passed the 17th short term SGR patch. If Congress adjourns at the end of the year without repealing the SGR, this first bipartisan, bicameral agreement on repeal will expire with it.

However, there is bipartisan support to address this issue now rather than in the next Congress. Some Republicans are calling for this bill to be passed without an offset or with partial offsets. Senator Orrin Hatch (R-UT), the expected chair of the Senate Finance Committee next year, has appeared open to passing the bill without an offset. Members of the GOP Doctors Caucus, including Representatives Phil Roe (R-TN) and Joe Heck (NV) have publicly said they would support the bill without an offset.

Without action, the new 114th Congress will have to introduce repeal legislation that may or may not mirror the *SGR Repeal and Medicare Modernization Act*, which the physician community has broadly endorsed. The current Ways & Means Committee Chairman David Camp (R-MI) who played a large role in developing this legislation will be retiring at the end of the year, and the new committee chairman may wish to put his own mark on the legislation. Also,

Republican control of both houses of Congress will influence what policy is developed and how the policy will be offset.

Timing will also be a factor. The current patch expires at the end of March. While that is currently 4 months away, it does not leave much time for the new Congress to act once they are sworn in this January. It takes time at the start of each Congress for committees to get organized. The committees of jurisdiction may not have much time to address the policy issues and may choose to pass another short-term fix instead.

Everyone agrees on the need to repeal the SGR and replace it with a stable payment system that values quality over volume. However, the cost continues to be an obstacle and will remain one in the next Congress.

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