

Tuesday, November 22, 2011

Deficit-Lowering Deal Escapes Select Committee

On November 21, the Joint Select Committee on Deficit Reduction (Select Committee) announced that it was unable to reach an agreement on a deficit-lowering deal. A statement issued by committee co-chairmen Rep. Jeb Hensarling (R-TX) and Sen. Patty Murray (D-WA) read:

“After months of hard work and intense deliberations, we have come to the conclusion today that it will not be possible to make any bipartisan agreement available to the public before the committee’s deadline.

“Despite our inability to bridge the committee’s significant differences, we end this process united in our belief that the nation’s fiscal crisis must be addressed and that we cannot leave it for the next generation to solve. We remain hopeful that Congress can build on this committee’s work and can find a way to tackle this issue in a way that works for the American people and our economy.”

The statement came as little surprise on Monday, with final staff discussions over the weekend reportedly focused primarily on how the committee would announce that it was unable to meet its mandate of identifying at least \$1.2 trillion in savings over the next decade by Thanksgiving.

While senior staffers made a last round of checks on Sunday to determine whether a final agreement was possible, committee members took to political news programs to place blame on the group’s inability to reach a compromise – with Republicans calling out Democrats’ unwillingness to cut entitlement programs and Democrats citing GOP refusals to consider significant tax increases on the wealthy.

Although the Select Committee’s official deadline is Wednesday, November 23, according to committee rules the panel needed to produce legislation before midnight on Monday.

With the committee’s failure to reach an agreement, the Budget Control Act will now call for \$1.2 trillion in automatic spending cuts at the beginning of 2013 – a process known as sequestration – which will include a maximum 2 percent cut in all Medicare spending on providers, Medicare Advantage plans and Part D drug plans with no eligibility, premium or out of pocket changes to Medicare beneficiaries.

This timing gives Congress a little more than a year to act to prevent these widespread cuts from occurring. Health policy experts are predicting that although health care programs avoided significant cuts from the Select Committee, they will be a major target in future debt-reduction talks.

Upon Congress’ return from the Thanksgiving holiday, members will have a number of other pressing issues to tackle prior to renewed debt reduction negotiations. The chambers will have only about five weeks to pass several expiring measures – including an SGR fix, unemployment benefits and tax extenders – by year’s end.

End of Year SGR Fix Needed to Avoid 27.4 Percent Payment Cut in January

When Congress reconvenes after Thanksgiving recess, an SGR fix is considered one of the few key bills that it “must pass” by the end of the year. With the Select Committee’s failure to include a fix as part of a deficit reduction plan, it must instead be achieved through a legislative vehicle.

This month, Representative Allyson Schwartz (D-PA) unveiled a plan to permanently repeal and reform the SGR, which calls for freezing physician pay at the 2011 rate for one year before providing primary care physicians with a 2.5 percent pay increase and specialty physicians with a 0.5 percent increase from 2013 to 2016 while the Centers for Medicare and Medicaid Services’ (CMS) Center for Medicare and Medicaid Innovation (CMMI), created under health care reform, tests new payment models.

The bill would mandate that the CMMI issue by October 2015 at least four delivery system and payment models from which physicians could choose to participate moving forward. Payments would be frozen at the 2016 level for one year, allowing practices to move into their chosen new payment system by 2017. If practices were to choose not to transition from Medicare fee-for-service (FFS) payment, their reimbursement would then decrease by -2 percent in 2018, -3 percent in 2019, -14 percent in 2020 and -5 percent in 2021, then stabilizing at the - 5 percent rate.

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End of Year SGR Fix Needed to Avoid 27.4 Percent Payment Cut in January (cont'd)

Rep. Schwartz's plan was released with support from several physician groups including the American College of Physicians, the American Osteopathic Association and the American Academy of Family Physicians, among others. The American Medical Association, however, said in a statement, "While we applaud Rep. Schwartz's general framework, we cannot support the proposal's outline for future updates and penalties given the workflow changes and investments we expect will be required from physicians."

A major obstacle to Rep. Schwartz's plan passing in the Congress is that it does not include a way to pay for permanently repealing the SGR. Due to the high cost of permanently repealing the SGR, estimated to cost more than \$300 billion, a one to two year legislative fix is considered more likely.

Among other plans under discussion, Rep. Michael Burgess (R-TX) has said he is developing legislation that would patch the SGR for one or two years, potentially with offsets from the Affordable Care Act. No matter the bill ultimately developed, without some sort of Congressional action the SGR is set to deliver a 27.4 percent payment cut to physicians on January 1, 2012.

U.S. Supreme Court to Rule on Health Reform Law

On November 14, the U.S. Supreme Court announced that it would hear the lawsuit against the Affordable Care Act (ACA) filed by 26 states and the National Federation of Independent Business. Specifically, the high court will rule on whether the law's individual coverage mandate is constitutional under the interstate commerce clause, and if not, what other provisions of the legislation need to be struck along with it.

States participating in the lawsuit challenging the ACA are Alabama, Alaska, Arizona, Colorado, Florida, Georgia, Idaho, Indiana, Iowa, Kansas, Louisiana, Maine, Michigan, Mississippi, Nebraska, Nevada, North Dakota, Ohio, Pennsylvania, South Carolina, South Dakota, Texas, Utah, Washington, Wisconsin and Wyoming.

The Court has indicated it will hear five and a half hours of oral arguments, beginning in February or March 2012.

It will consider the following issues related to the ACA:

1. The constitutionality of the individual mandate, which requires all individuals to obtain health insurance by 2014 or face a financial penalty;
2. The severability of the mandate from the rest of the ACA;
3. The constitutionality of the law's mandatory Medicaid expansion; and
4. Whether or not the Supreme Court has jurisdiction over the individual mandate in light of the Anti-Injunction Act.

This last issue could lead to a delay in the court's ruling until after 2014. If the court considers the penalty for those who do not buy insurance to be a "tax," the court challenge against the tax cannot be held until the tax is collected under the terms of the Anti-Injunction Act.

The U.S. Supreme Court's announcement was anticipated after split appellate court decisions on the law's individual mandate. The court is expected to rule on the case by June 2012.

FDA Revokes Approval of Avastin Breast Cancer Indication

On November 18, the Food and Drug Administration (FDA) announced that it is revoking approval of Avastin's breast cancer indication after concluding that the drug has not been shown to be safe and effective for that use.

Avastin is currently prescribed to about 17,500 women with breast cancer annually and works by effectively blocking blood flow to tumors. The FDA's decision applies to Avastin's use in combination with the cancer drug paclitaxel for patients with the form of metastatic breast cancer known as HER2 negative who have not been treated with chemotherapy.

Cited risks include severe high blood pressure; bleeding and hemorrhaging; heart attack or heart failure; and the development of perforations in different parts of the body such as the nose, stomach, and intestines. With this decision, Avastin's breast cancer indication must now be removed from its product labeling. *(Continued on page*

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FDA Revokes Approval of Avastin Breast Cancer Indication (*cont'd*)

The revocation of Avastin's breast cancer indication follows this summer's FDA Oncology Drug Advisory Committee's (ODAC) 12 to 1 vote in favor of doing so. The Committee's decision was based on new research indicating that the benefits of the drug – which costs approximately \$8,000 a month or up to \$100,000 per year – do not outweigh the risks for breast cancer patients. Though supported by some cancer care experts, patient advocates and others, ODAC's decision was criticized by some patient advocates and lawmakers who characterized the move as a first step toward the rationing of medicine and denying patients access to preferred treatments.

Following the FDA's decision to rescind Avastin's breast cancer approval, physicians will still be able to write prescriptions for it for breast cancer as an off-label use. However, insurers – including Medicare and Medicaid – could stop paying for the treatment for use in breast cancer following this decision.

CMS has said it will continue to reimburse for Avastin following the withdrawal of its approval as a breast cancer drug and has no immediate plans to change coverage policies, but it has also said that it will continue to “monitor the issue and evaluate coverage options as a result of action by the FDA.”

It is unclear whether CMS will be willing to undergo a National Coverage Decision (NCD) determination for Avastin taking into account the amount of time and resources required, as well as anticipated push back from some politicians who have raised questions about whether ODAC factored cost-effectiveness into its review.

Genentech, which makes Avastin, said in a statement that “despite today's action, we will start a new Phase III study of Avastin in combination with paclitaxel in previously untreated metastatic breast cancer and will evaluate a potential biomarker that may help identify which people might derive a more substantial benefit from Avastin.”

The FDA has said that additional research on Avastin could support effectiveness in certain subgroups of breast cancer patients, and that it would consider approval for those subgroups in those cases.

[Click here](#) to read the FDA's press release announcing the decision.

Poll Reveals Physicians' Overwhelming Support of Palliative Care

A poll released on November 15 by the *National Journal* and The Regence Foundation indicated that 96 percent of surveyed physicians agreed that taking measures to improve the quality of life for seriously ill patients is more important than extending life for as long as possible.

Many doctors revealed it can be difficult to talk to patients about palliative care options, however. For example, according to the poll, one in four physicians said they feel that if they bring up palliative care options, they worry it could be perceived as if they have given up on the patient. Forty-two percent of physicians also said they believe encouraging palliative care could interfere with efforts to extend lives – although a panel discussion following the release of the survey results pointed out that the two goals do not need to be mutually exclusive.

The poll showed a significant “generation gap” in physicians' training on palliative care. Seventy-three percent of physicians age 39 or younger reported “a great deal” or “some” exposure to palliative care during medical school compared to 36 percent of those age 40-49, 23 percent of those age 50-59, and only 6 percent of those age 60 or older.

At a *National Journal* event following the release of the survey data, oncologist and bioethicist Ezekiel Emanuel noted that palliative care has made significant strides in the past 20 years but called upon the medical community to push for further integration of palliative care into physician education programs.

Emanuel stressed that one of the greatest obstacles to fully implementing palliative care is preparing physicians for how to bring up end-of-life care options to patients. Other physician concerns are that health insurance companies and Medicare do not fully reimburse for consultations, there is a shortage of palliative care physicians and patients are not able to afford the cost of care.

Emanuel concluded that in the future, Medicare and private insurance companies will need to make program and policy choices to better support palliative care decisions as 93 percent of Americans polled believe end-of-life decisions should be a top priority for the U.S. health care system.