

Permanent Doc Fix Unlikely to Emerge from Supercommittee

Despite the hopes and urgings of physician groups, it is not expected that any deficit reduction proposal developed by the Joint Select Deficit Reduction Committee (dubbed the “supercommittee”) will include a repeal of the current Medicare physician payment system and a permanent fix. Speakers at a September 12 panel discussion on the outlook for the supercommittee’s work, sponsored by the Alliance for Health Reform, called it unlikely that a long-term overhaul of the Medicare physician payment system will be recommended. Instead, they predicted a recommendation for another short-term fix of perhaps two years, similar to those adopted by Congress in the past.

One of the speakers, Center on Budget and Policy Priorities president Bob Greenstein, said the high cost of adopting a permanent fix, which could exceed \$300 billion over 10 years, will prevent the supercommittee from recommending a permanent change to the reimbursement system. Another speaker, Project Hope Senior Fellow and former head of the Medicare and Medicaid programs Gail Wilensky said she was “not hopeful” the panel would adopt any sweeping changes to the health care system, including Medicare’s physician payment system.

The bipartisan and bicameral 12-member supercommittee was created by the *Budget Control Act of 2011* and charged with producing a plan to reduce federal deficits by at least \$1.2 trillion over 10 years. The supercommittee’s deadlines are: issue a report on the plan, with legislative language, by November 23; and send the plan to the floor of the House and Senate for passage before December 23. Failure to produce a plan will trigger automatic, across-the-board spending cuts known as sequestration.

With respect to the possibility of sequestration, some of the panelists’ comments reflected calculations that the automatic cuts might be a better alternative than any larger and more-devastating cuts that the supercommittee might propose, since under the sequestration process reductions to Medicare payments and plans would be capped at 2%. Other panelists maintained that it would be shortsighted for the supercommittee to allow a 2% reimbursement cut to become law rather than recommend entitlement reforms because the cuts are likely to exacerbate problems in Medicare and merely postpone fundamental reforms of the system.

One of the speakers on the panel, CIGNA vice president of public policy G. William Hoagland, suggested that, if a first year of cuts were to take place under sequestration, “the results will be so unpalatable” there will be some kind of agreement forced between the parties. He noted similarities between today and 1986 when a sequester with an impact on defense took place and President Ronald Reagan “was forced into a corner” to accept a tax increase.

For various reasons, some speakers expressed optimism that the supercommittee could produce a deal. Dean Rosen, a partner at Mehlman Vogel Castagnetti, Inc., said a collapse in public confidence in Congress may spur lawmakers to take action. He also cited the possible defense budget reduction as goading lawmakers to act. As a final point, Rosen said lawmakers do not like to cede control, and the cuts that would be implemented if the supercommittee fails to act would take place over 10 years without their input. (Cont’d page 3)

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House Holds Hearing on Drug Shortages

According to testimony given at a hearing held by the House Energy and Commerce Committee's Health Subcommittee on September 23, early warnings from drug companies about looming shortages of pharmaceuticals along with better manufacturing practices would help address the growing problem of drug shortages. The problem is quickly becoming a national health care crisis, as shortages of cancer, anti-infection, and anesthesia drugs occur without warning when patients are in desperate need of the medications.

Subcommittee Chair Joe Pitts (R-PA) opened the hearing noting that the number of drug shortages reported to the Food and Drug Administration (FDA) increased from 61 in 2005 to 178 in 2010. He added, "So far this year, FDA has continued to see an increasing number of shortages, especially those involving older sterile injectable drugs." In addition to cancer and anesthesia drugs, the products include "drugs needed for emergency medicine, and electrolytes needed for patients on IV feeding," he said. A staff memo Pitts released at the hearing said that more than 240 drugs in 2010 were either in short supply or completely unavailable.

Administration witnesses included Howard Koh, assistant secretary for health at the Department of Health and Human Services (HHS), and Sandra Kweder of the FDA. Koh said that the number of drug shortages has been rising steadily over the past five years and added, "This trend has continued into 2011 with an even greater number of shortages." Both Koh and Kweder suggested some remedies for the problem, but neither voiced confidence that it would be solved anytime soon because of the complex reasons for the shortages. One reason they cited is that consolidation of the pharmaceutical industry has left fewer suppliers of the drugs subject to shortages, which in turn results in fewer plants being forced to make more of the drugs. With plants so busy filling orders for so many different types of drugs, they are not taking time to do needed maintenance;

this leads to breakdowns in manufacturing, which ultimately cause supply problems.

Other reasons included: changes in inventory and distribution practices (e.g., "just in time" methods whereby hospitals save on inventory costs by ordering only small quantities of drugs, leaving providers less able to deal with shortages when they occur); shortages of underlying raw materials; and unanticipated demand.

One major reason cited in the hearing is that manufacturers are losing interest in producing drugs that are off-patent and sold as generics at prices that leave little room for profits. This brought up a question of whether government policy is in some way interfering with the forces of supply and demand. Representative Tim Murphy (R-PA) asked, "In our push to make products more affordable, are we tripping over ourselves?" In essence, his question was: Are prices being cut so much that manufacturers don't want to make the drugs? In response, Koh said, "Those are precisely the issues that we are wrestling with," and "Further economic analysis is intensely underway right now."

"These shortages cause delays in treatment and surgery, compel physicians to make changes in care plans and force patients to receive substitute therapies that add expense to patient care."

— House Staff Memo

The administration officials also mentioned a disturbing aspect of the issue — development of a "gray market" in which some suppliers have been able to come up with quantities of drugs in shortage and sell them to hospitals at exorbitant prices. Some of those drugs are counterfeit and in other cases, their quality is suspect.

As for solutions, they both said earlier warnings that manufacturers expect shortages would help. A bipartisan bill — H.R. 2445 — introduced by Representative Diana DeGette (D-CO) addresses that issue. The measure requires companies to alert the FDA when they expect shortfalls. Kweder pointed out that, when FDA does hear about a potential shortage, it is able to work with the company to solve the problem or with other manufacturers to increase their supplies **(Cont'd page 3)**

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of the drug. Koh added that, through this FDA drug shortages program, the agency prevented 99 drug shortages in 2011.

Witnesses representing industry included Jonathan Kafer of Teva Pharmaceuticals and Mike Alkire of Premier Healthcare Alliance. Kafer said that drug shortages are a complex and multi-stakeholder issue, and that all involved must work together to resolve the issue. He called for greater communication among all the stakeholders (active ingredient suppliers, generic and brand manufacturers, wholesalers and distributors, health care providers, and government agencies), along with expedited FDA review of new manufacturing facilities and active ingredient suppliers when a drug shortage occurs. In addition, Kafer said FDA should collaborate with the Drug Enforcement Administration (DEA) to establish a process that would streamline DEA's quotas of active drug ingredients in response to drug shortages of controlled substances. Currently, DEA limits the amount of active ingredients manufacturers may purchase for controlled substances.

Alkire's suggestions for dealing with drug shortages included:

- ▶ shorten the approval process for medically necessary generic drugs that appear to be in shortage;
- ▶ encourage staff of FDA's drug shortage program to engage members of the health care community in discussions to prioritize which drugs are critically necessary for treatment that may be at risk for shortage due to insufficient manufacturing capacity;
- ▶ enable more flexibility in regulations that apply to quotas for registered manufacturers of controlled substances;
- ▶ create a fast-track approval of new active pharmaceutical ingredient suppliers for medically necessary drugs in shortage;
- ▶ work with manufacturers to slow the trend of acquiring the bulk of raw materials used in pharmaceuticals outside the United States;
- ▶ require manufacturers to notify FDA of planned discontinuation or interruption in the manufacture of drugs as soon as practicable; and
- ▶ create a stakeholder committee to advise FDA on market conditions.

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Whatever happens regarding Medicare's physician payment system, the consensus seems to be that, with vigorous disagreement likely between the Democratic and Republican members of the supercommittee, there will be no sweeping health care reforms emerging. The meetings of the supercommittee are now underway; the first one was held on September 13. Meanwhile, Medicare's Sustainable Growth Rate (SGR) formula, if unchanged, calls for a 29.5% cut in physician payment rates in January 2012.

From the States . . .

Physicians Oppose Washington's Plan to Limit ED Visits of Medicaid Patients

A new plan, developed by the **Washington** legislature and signed by Governor Chris Gregoire (D) as part of the 2011-2013 state budget, limits Medicaid patients to three "non-emergency" visits to the ED each year. Over objections of physician and hospital task force representatives, the state adopted a list of conditions generated solely by the state Medicaid office classified as "non-emergent" and, as a consequence, is taking away coverage for more than 700 diagnoses that have serious medical conditions, including chest pain, abdominal pain, miscarriage, and breathing problems. According to physicians and the hospital association within the state, the plan will put the most vulnerable members of society – including children – at risk of serious harm.

The plan undermines the "prudent layperson standard" under both federal and state law, which requires health plans to cover visits to EDs based on an average person's belief that he or she may be suffering a medical emergency due to the symptoms he or she is experiencing, not a final diagnosis. Designed to protect patients who experience the symptoms of a medical emergency but who, after a medical examination and testing by a trained professional, are diagnosed with acute care or a non-emergent medical condition, the prudent layperson standard addressed the problem of retrospective denials of emergency care by health plans. Further, it protected patients from having to self-diagnose their medical conditions out of fear of receiving a bill when they sought care for symptoms that are often emergent and life-threatening. The federal standard also required Medicaid managed care plans not to set limitations on the number of emergency visits that Medicaid managed care plans cover.

Washington's new policy means that the state's Medicaid fee-for-service clients will not receive critical prudent layperson protections that are required for patients of all Medicaid-managed care plans across the

country, all private health plans as mandated by the *Patient Protection and Affordable Care Act*, and all federal military and civilian employees mandated by a Presidential Executive Order. And, unlike all other citizens in the state, Medicaid fee-for-service clients who suffer chest pains, or any one of more than 700 conditions, cannot know if their care will be covered and will thus be discouraged by the state from seeking care that could be needed to save their lives.

As an example, the **Washington** State Medical Association president Doug Myers stated, "Severe chest pain can be a symptom of a heart attack or an esophagus problem that is not an emergency, but the patient cannot self-diagnose." He went on to say, "Limiting Medicaid patients to three emergency department visits poses a significant threat to patient safety, leaving many to avoid or delay seeking needed emergency care in fear it will be deemed a 'non-emergency' and they will exceed the allowable limit. The end result of this kind of policy will be the need for prolonged and more intensive care, which not only harms the patients, but increases costs for everyone."

Myers also stated, "We are not blind to the budgetary challenges facing our state." He added, "We expected to work closely with state officials to come up with a list of truly non-emergent conditions. But we are not willing to sacrifice patient safety and many of these cuts pose a dangerous and significant threat to the safety of our patients."

In summing up the situation, Nathan Schlicher, a practicing emergency physician and healthcare attorney in Tacoma, said, "There is a real possibility of expensive litigation against the state for implementing a plan that on its face contradicts federal and state law. It is our duty to protect our patients, while caring for them in the emergency department and now we may have to do so in the courtroom. The state has gone beyond the legislative language in creating this list and it our responsibility to protect our patients."