The US Oncology Network
Health Policy Report

Wednesday, May 16, 2012

SGR Replacement Legislation Introduced in House; Key Committees Request Input on Potential Long-Term Payment Solutions

On May 9, Representatives Allyson Schwartz (D-PA) and Joe Heck (R-NV) introduced the Medicare Physician Payment Innovation Act, the first bipartisan legislation to permanently replace Medicare's sustainable growth rate (SGR) formula and also avoid the looming 30 percent cut to physicians set to take effect under the SGR on January 1, 2013.

The proposal from Reps. Schwarz and Heck would replace the SGR with new payment model options to be developed by the Centers for Medicare and Medicaid Services (CMS), which are to aim toward giving physicians greater stability and flexibility in payment based on specialty, region or type of practice.

The legislation would leave in place 2012 Medicare payment levels through 2013. After 2013, it would provide annual positive payment updates of 0.5 percent for specialty physician services over the next four years and a 2.5 percent increase in primary care physician payments during the same timeframe.

The plan would direct CMS to produce by October 2016 no fewer than four alternatives to the traditional fee-for-service (FFS) system for physicians who are unable to participate in existing delivery and payment reform models. The legislation would not force physicians into the new delivery models. However, doctors who continue using the FFS system would receive decreasing payments for services of up to 5 percent beginning in 2019 through 2022.

Payment offsets for the legislation would be created through budgetary war savings derived from future overseas troop withdrawals.

The American Medical Association (AMA) has said in a statement that the legislation is "an important step in the right direction," but that it has concerns about the bill's provisions that might limit options for physicians who are unable to participate in new delivery models. The AMA has said it is willing to work with Reps. Schwartz and Heck to address this issue.

While it remains to be seen how serious the lame duck Congress will be in implementing a permanent fix, it signals a renewed focus among lawmakers recently on how to permanently address the current flawed SGR formula.

In a letter at the end of April, GOP members of the House Ways and Means Committee asked approximately 70 medical societies to provide insights on alternatives to fee-for-service payment models, such as shared savings programs and bundled payment models, designed to encourage better care. The letter's questions to the groups were categorized into three areas:

1) Rewarding quality and efficiency (use of quality measures and utilization of tools such as electronic health records);

2) Alternative payment models (experiences with alternative payment approaches such as shared savings and bundled payment models); and

3) Patient involvement and regulatory relief (advice about how to encourage Medicare beneficiaries to seek appropriate care and whether any regulatory hurdles stand in the way of helping patients).

On May 10, the Senate Finance Committee focused on how to create a permanent SGR fix at a roundtable discussion featuring former Centers for Medicare and Medicaid Services (CMS) administrators Gail Wilensky, Bruce Vladek, Tom Scully and Mark McClellan. At the forum, anticipated to be the first of several to be held by the Committee on the topic, the former administrators agreed that an SGR replacement should give physicians the ability to act independently of hospitals and should be structured in a way so as to positively impact the rest of Medicare spending. The administrators also said that Congress should act in the short-term this year to avoid the 30 percent cuts while working on a permanent SGR replacement in the long-term.

Additional recommendations from the former CMS chiefs included:

- An effective long-term strategy would be to move toward a bundled payment system. In this scenario, Congress and CMS should start with payments for chronic conditions and expensive, high-volume services. ***(Continued on page 2)***

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- A bundling approach can be achieved already and doesn't require being executed as a pilot. Instead, bundled payments could be offered as options within the current payment system so that Medicare can systematically move toward a bundle.

- Medicare should establish a separate payment system for urban and rural providers in light of their uniquely different circumstances.

- Congress should ask physicians whether a new proposed system will improve patient care and whether they can prove it.

Thus far, Congress has not been able to identify a permanent replacement for the SGR, which creates major reimbursement cuts each year that lawmakers typically act to avert with short-term legislative fixes.

House Energy and Commerce Committee Approves FDA User Fee Legislation

Following the cancelation of its previously scheduled April 26 markup, on May 10 the House Energy and Commerce Committee voted unanimously in support of legislation (HR 5651) to reauthorize user fees for prescription drugs and medical devices as well as establish new fee programs for generic drugs and biosimilars for five years.

In April, the Senate Health, Education, Labor and Pensions (HELP) Committee passed a very similar bill that is expected to go to the floor for vote soon. House Energy and Commerce Committee Chairman Fred Upton (R-MI) has said this bill will advance to the House floor by the end of May, with the goal of working with the Senate to send a bill to President Obama for signing into law by July 4.

Current user fees for prescription drugs and medical devices are set to expire September 30. FDA representatives have said postponing authorization after September 30 could lead to the laying off of about 2,000 staff members.

Although the House and Senate bills closely resemble each other, there are a number of key differences between the two user fee proposals. For example, the Senate legislation would provide an extra five years of protection against generic competition to makers of antibiotics that treat a "serious or life-threatening" condition, while the House version of the bill would offer the incentives to any drug that treats a host of infections, not just the most serious.

Both pieces of legislation would require drug manufacturers to report potential drug shortages to the FDA at least six months in advance or as soon as possible. The House bill would mandate that FDA maintain a public, updated list of all drugs in shortage. The Senate bill would require a record-keeping of drug shortages, but would not require FDA to make the information public. The Senate bill would also call for a task force to help prevent drug shortages. On the house side, the Government Accountability Office (GAO) would conduct a study to look at economic factors contributing to drug shortages.

Potential floor amendments and the House-Senate negotiations to reconcile the two bills could delay final action. Thus far, however, the user fee process has been bipartisan and cooperative as the House and Senate forge ahead on the must-pass legislation, which also has strong support from industry and the FDA.

House Passes Budget Reconciliation Bill

On May 10, the House passed GOP-supported legislation to replace the Budget Control Act (BCA) mandated sequestration cuts of $1.2 trillion over 10 years with specified cuts to healthcare spending. The House reconciliation bill is a companion bill to the Republican-led budget the House adopted in March, and passed the House with a vote of 218 to 199 along party lines. Senate Democrats have pledged opposition to the bill, however, and President Obama has promised veto action against it.

The GOP legislation would repeal the initial $98 billion in automatic, across-the-board cuts to discretionary spending scheduled to take place on January 2, to be replaced with a combination of discretionary and mandatory reductions through a reconciliation process. ***(Continued on page 3)***

House Passes Budget Reconciliation Bill *(cont'd)*

The bill would defund certain provisions within the Affordable Care Act (ACA), such as the Prevention and Public Health Fund and additional grants to states for health insurance exchanges; enact Medicaid changes and create stricter eligibility reviews for Medicaid enrolees; and limit damages on medical malpractice awards in order to meet the savings targets established by the BCA.

Although the bill in its current form will not pass in the Senate, House Republicans hope for it to entice Democrats into negotiations for replacing the BCA sequester. The Congressional Budget Office (CBO) has estimated that the House-passed bill would net $237.8 billion in deficit reduction over a decade if it were to become law. Groups speaking out in opposition to the bill include the American Hospital Association and the American Public Health Association, among others.

If Congress is unable to pass legislation to block the sequestration cuts, according to a report released this month by Research America, the National Institutes of Health (NIH) would lose $2.39 billion, the Centers for Disease Control and Prevention (CDC) would lose $445 million, the Food and Drug Administration (FDA) would lose $191 million, and the Agency for Healthcare Research and Quality (AHRQ) would lose $29 million from their fiscal 2013 budgets.

Comments Submitted on Meaningful Use Stage 2 Proposed Rule

Public comments on the Stage 2 Meaningful Use proposed rule for the electronic health records (EHR) Medicare and Medicaid incentive payment programs were due on May 7. In a joint letter to the Centers for Medicare and Medicaid Services (CMS), the American Medical Association (AMA) and nearly 100 state and medical specialty societies requested that the agency lower certain hurdles from the proposed Stage 2 meaningful use requirements.

Specifically, the groups asked that any new proposed Stage 2 measures be introduced first as optional elements that physicians may select from rather than mandatory core measures.

The letter also asked CMS to align the program's rewards and penalties for noncompliance with those of the rules and penalties for CMS' physician quality reporting and e-prescribing programs.

Whereas Stage 1 of Meaningful Use encouraged providers to buy EHR systems and begin using them to record patient information and some data on clinical performance measures, Stage 2 is designed to spur providers to report data on more performance measures. Some provider and hospital groups and lawmakers have said that the Stage 2 objectives may be too ambitious for some smaller or individual practice physicians to meet.

In addition to the AMA-led letter, the American Hospital Association (AHA) raised technical and security concerns about allowing patients greater access to their own health information, and the Federation of American Hospitals (FAH) asked that CMS ensure that certified EHRs be able to routinely produce the quality reports required to meet the agency's meaningful use requirements. "Taken as a whole the proposed requirements for meeting stage two raise the bar too high and are not feasible for the majority of hospitals to achieve," the AHA said in an April 30 letter to CMS.

McKesson Corporation also sent a letter commenting on the proposed rule, recommending the following to CMS:

- Provide a minimum of 18 months for the implementation of Stage 2 and allow a 90-day reporting period for the first year of Stage 2;
- Provide a roadmap and time frame for Meaningful Use Stage 3 as soon as possible;
- Focus on further development of the current infrastructure required for clinical quality measures, tested measure specifications, closer alignment with workflow and the feasibility of implementation within an EHR;
- Include only those new objectives which have established standards and align with clinical practice;
- Require only those patient engagement objectives which are within the providers' control and support optimal workflows to optimize patient care; and
- Establish standards for and guidance on health information exchange.

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Comments Submitted on Meaningful Use Stage 2 Proposed Rule *(cont'd)*

On May 7, CMS' Acting Administrator acknowledged stakeholders' concerns about the Meaningful Use program, but indicated that these objections will not delay publication of a final rule. The Stage 2 rules are scheduled to take effect October 1, 2013 for hospitals and January 1, 2014 for physicians and other eligible professionals.

Click here to read the AMA comment letter.

Click here to read the McKesson comments.

CMS to Delay Release of Sunshine Payments Rule

No Data Collection Until 2013

The Centers for Medicare & Medicaid Services (CMS) announced it will delay implementing the Physician Payments Sunshine Act and will not begin collecting data until 2013. This despite a letter recently sent to CMS by the authors of the sunshine law, Sens. Herb Kohl (D-Wis.) and Chuck Grassley (R-Iowa), who urged CMS to issue a final rule by June so that data collection could begin this year. The agency said it is delaying collecting data from drug and medical device manufacturers in order to provide time for organizations to prepare for data submission and to sufficiently address the important input received during the rulemaking process.

The Sunshine Act specifies that almost all payments or services provided directly or indirectly to physicians directly by drug or device companies must be reported to the Centers for Medicare and Medicaid Services (CMS). These payments will be recorded and maintained in a publicly searchable database by CMS, with data to be made available 90 days after the final rule is issued.

CMS received more than 300 comments on the proposal from a wide range of stakeholders, including comments from McKesson Corporation, the Healthcare Distribution Management Association (HDMA), drug and medical device manufacturers, physician specialty societies and coalitions of continuing education groups.

The comments from McKesson and drug and medical device manufacturers urged CMS to extend the implementation period to allow an adequate timeframe for organizations to develop reporting systems.

Click here to read the McKesson comments.