

Tuesday, December 20, 2011

House and Senate Continue to Disagree on Doc Fix Legislation

Over the last week there has been a flurry of activity on H.R. 3630, the Middle Class Tax Relief and Job Creation Act of 2011, that includes the fix to the 27.4% cut to Medicare physician payment scheduled to take place January 1, 2012.

Tuesday of last week, the House of Representatives passed a bill that would pay for a two-year Medicare physician payment patch, with a 1% update. The Senate amended that bill this past Saturday to provide a two-month Medicare physician payment patch through February 2012, with a 0% update. While \$3.2 billion in cuts to Medicare Part B drugs were originally discussed as a possible offset for the cost of this temporary fix, they were not included in final passage of the bill (see details below). This Senate legislation also included a two-month extension for payroll tax deduction, unemployment benefits, additional Medicare extenders, the Temporary Assistance for Needy Families program, as well as language on the Keystone XL pipeline.

Today, the House of Representatives voted to reject the Senate amended version of H.R. 3630 and voted to request a formal conference to resolve the differences between the two chambers. House Republicans renewed their commitment for at least a one-year extension to the many expiring provisions in H.R. 3630. It is unclear how the House and Senate plan to proceed, but some agreement will need to be reached before the end of the year if the 27.4% cut to Medicare physician reimbursement is to be averted.

Additionally, yesterday the Centers for Medicare and Medicaid Services (CMS) released a notification to instruct its Medicare claims administration contractors to hold all claims containing 2012 services paid under the Medicare Physician Fee Schedule for the first 10 business days of January due to Congress' failure to reach an agreement. If the cuts do go into effect it is likely the Congress will return sometime during the month of January and enact a retroactive fix as they have in years past.

[Click here](#) for a summary of the health provision in the Senate bill.

[Click here](#) to read the Senate bill text.

Coalition Continues to Voice Opposition to ASP Cuts

Working with a vocal coalition of community-based cancer providers, manufacturers, distributors, and patient groups, The US Oncology Network has thus far successfully convinced Congress to remove from consideration the \$3.2 billion proposed payment cuts to cancer care drug reimbursement. These Average Sales Price (ASP) cuts, originally considered by the Joint Select Committee on Deficit Reduction as a potential offset within federal debt reduction efforts, had resurfaced over the past few weeks as the Congress has worked to fix the 27.4% Medicare physician reimbursement cuts scheduled to take effect on January 1, 2012.

On December 14, *Inside Health Policy* ran an article (see page 4) about coalition members' joint [letter](#) to the leadership of both chambers of Congress arguing that such a move would take this reimbursement well beyond a sustainable level. Additionally, as part of the coalition's campaign, Ted Okon, executive director of Community Oncology Alliance (COA), penned an editorial entitled "Cutting Cancer Patients' Care is Not the Right Fix" (see page 4) that ran in *The Hill's* Congress Blog on December 15.

This media coverage was in conjunction with the coalition's inside the beltway [advertisements](#) highlighting the harm that cuts to cancer-fighting drugs would bring to cancer care in the community. This coalition will continue to work to convince Congress that these ASP cuts combined with the already scheduled 2% across the board [cuts](#) to all physician Medicare reimbursement would be devastating to the provision of community-based cancer care.

New Essential Health Benefits Bulletin Allows States to Set Minimum Essential Health Benefits

On December 16, the Department of Health and Human Services (HHS) released a 15-page informational [bulletin](#) on essential health benefits (EHB), which calls for states to use existing health plans as benchmarks for benefits that must be offered in individual and small group insurance plans inside or outside the new health insurance exchanges to begin in 2014 under the Affordable Care Act (ACA). (*Continued on page 2*)

Tuesday, December 20, 2011

New Essential Health Benefits Bulletin Allows States to Set Minimum Essential Health Benefits (cont'd)

The Centers for Medicare and Medicaid Services (CMS) issued the bulletin as guidance, noting that it will pursue formal rulemaking on the EHBs that plans must cover under the ACA. The benefits coverage requirement will apply to plans that went into effect after the ACA was enacted in March 2010, as well as plans modeled on Medicaid benchmarks and Basic Health Plans that states can opt to create.

According to HHS Secretary Kathleen Sebelius, the bulletin outlines how the agency plans to move forward in defining an EHB package, and will ensure that families and small businesses buying their own coverage will have access to plans offering affordable and comprehensive benefits. The EHB proposal will also provide states with flexibility as they establish their state-based exchanges, she said.

The bulletin would apply to 2014 and 2015, allowing HHS to assess the EHB standards process for 2016 and beyond. The agency would also periodically review and update EHBs based on coverage affordability or other market changes. Under the ACA, an EHB package must cover services in at least 10 categories, such as emergency services, hospital and physician services, preventive care and prescription drugs. The benefits covered in the health plan selected by a state would constitute its EHB. States would be able to update their benchmark EHB package to keep up with innovations in care and coverage, and in states where the federal government runs the insurance exchange, the states would still choose the benchmark plan used to define EHBs.

The four benchmark plan options for states outlined by HHS are:

- 1) One of the three largest small group plans in the state;
- 2) One of the three largest state employee health plans;
- 3) One of the three largest federal employee health plan options; or
- 4) The largest HMO plan offered in the state's commercial market

If a state does not select a plan to establish the EHB, HHS would then use the largest small group plan in the state based on enrollment as the default plan.

No timing was indicated for the EHB regulations to be issued; however, HHS requested public comments on the informational bulletin by January 31.

Click [here](#) to read the bulletin.

CMS Releases Proposed Physician "Sunshine" Rule

On December 14, the Centers for Medicare and Medicaid Services (CMS) released a [proposed regulation](#) designed to create more transparency about financial relationships between physicians and pharmaceutical and device manufacturers or other private interests.

The proposed rule would implement a portion of the Affordable Care Act (ACA) known as the Physician Payments Sunshine Act. It would mandate that applicable manufacturers of drugs, devices, biological or medical supplies covered by Medicare, Medicaid or the Children's Health Insurance Program report annually to the Secretary of Health and Human Services (HHS) payments or transfers of other items of value to physicians and teaching hospitals. These types of payments would fall under categories such as consulting fees, food and beverages and research payments.

According to CMS, the proposed rule provides special consideration to research payments in recognition of the essential need for collaboration between physicians and teaching hospitals and manufacturers in developing new products. While manufacturers would still be required to report payment the year it was made, the proposed rule would allow CMS to delay the publication of certain research payments for four years after the payment date or until FDA approval of the product, whichever is sooner.

It would also require group purchasing organizations and manufacturers to report to CMS if they are owned fully or in part by physicians, or if physicians have invested in them. The regulation would give physician owners and investors 45 days to review and correct such information related to them. *(Continued on page 3)*

Tuesday, December 20, 2011

CMS Releases Proposed Physician “Sunshine” Rule (*cont’d*)

Violators of the reporting requirements will be subject to civil monetary penalties of up to \$150,000 annually for failure to report, and up to \$1 million for knowingly failing to report.

The proposal is published in the December 19 Federal Register. Comments on the proposed rule will be accepted through February 17.

[Click here](#) to read the proposed rule.

Senate HELP Committee Holds Drug Shortages Hearing

On December 15, the Senate Health, Education, Labor and Pensions (HELP) Committee held a [hearing](#), “Prescription Drug Shortages: Examining a Public Health Concern and Potential Solutions,” on the nation’s shortages of cancer, anti-infection and anesthesia drugs.

Witnesses included Senator Amy Klobuchar (D-MN); Sherry Glied, Ph.D., Assistant Secretary for Planning and Evaluation, Department of Health and Human Services (HHS); Sandra Kweder, M.D., Deputy Director, Office of New Drugs, Food and Drug Administration (FDA); Marcia Crosse, Ph.D., Director, Health Care, Government Accountability Office (GAO); Murray Aitken, Senior Vice President, Health Care Insight, IMS; Ralph Neas, J.D., Chief Executive Officer, Generic Pharmaceutical Association; and John Maris, M.D., Chief, Division of Oncology, Children’s Hospital of Philadelphia.

Witnesses supported the idea of giving the FDA more authority to correct these shortages, with the GAO urging lawmakers to require drug manufacturers to report supply disruptions and grant FDA the authority to fine those not complying with this reporting requirement.

Several committee members focused on increasing FDA authority as well as investigating the gray market, including the idea of banning the secondary sale of a drug at a price higher than the original purchase, which they argued would eliminate the incentive for raising the prices for drugs in shortage.

The HELP Committee hearing followed recent hearings held by House Oversight and Government Reform subcommittee on health care and the Senate Finance Committee, which featured insights on the issue from medical and pharmaceutical experts, representatives from community cancer care and policy analysts.

HHS Announces 32 Pioneer ACOs

On December 19, the Department of Health and Human Services (HHS) named 32 health care providers to participate in Medicare’s Pioneer accountable care organization (ACO) model, which will be overseen by the Centers for Medicare and Medicaid Services (CMS) Innovation Center. This network of doctors and hospitals will be taking the lead in testing several payment structures that aim to improve quality of care and cut costs.

Part of the Affordable Care Act (ACA), ACOs aim to refocus health care payments on quality, coordinated care, as opposed to the quantity of services provided. If ACOs create savings for the Medicare program, the savings will be split between the providers and Medicare. The Pioneer ACO participants, however, will be eligible for a larger percentage of the savings. According to HHS, the initiative could save up to \$1.1 billion over five years.

The 32 pioneer participants were selected for their “significant experience” in providing coordinated, patient-centered care, according to HHS, with many of them already operating in arrangements much like ACOs.

The first performance period will begin January 1, 2012.

For a full list of participating organizations, click [here](#).

Tuesday, December 20, 2011



Senate Dems Urged To Reject Cancer Care Pay Cuts As SGR Offset

Posted: December 14, 2011

Senate Democrats working to craft their own version of a physician payment patch are facing pressure from a wide-ranging group of stakeholders to reject any proposals that would pay for the patch by cutting back Medicare payments for the cancer care delivery system. Such cuts were not included in the “doc fix” measure that passed the House Tuesday (Dec. 13), but were considered during the super committee deficit reduction discussions and the stakeholders fear they could emerge as an offset for physician payment reforms.

Lowering reimbursements for Medicare Part B drugs, which has been broached by several deficit reduction groups, could compromise patients' access to care and exert more pressure on the nation's “already severely strained” cancer care delivery system, the group says in a Dec. 7 letter to congressional leaders on both sides of Capitol. The letter was signed by 20 stakeholders, including cancer doctors, patients groups and the biologics industry.

A proposal that was broached by the deficit reduction group led by Vice President Joe Biden, and also laid out in a deficit-cutting options document generated by House Ways and Means Democrats, would lower reimbursements for Part B drugs from averages sales price plus six percent down to ASP plus three percent. The shift would save \$3 billion over 10 years, according to the Congressional Budget Office.

The cancer care stakeholders note that, in contrast to the pay cut option which they say could be devastating to community practices and their patients, a bipartisan group of more than 50 members of Congress have co-sponsored legislation that would go the opposite direction and boost cancer drug payments. That bill would exclude the customary prompt pay discount from drug manufactures to wholesalers when calculating the average sales price. The legislation is sponsored by Rep. Ed Whitfield (R-KY) and Gene Green (D-TX) in the House (H.R. 905), where it has 46 cosponsors, and by Sens. Pat Roberts (R-KS) and Debbie Stabenow (D-MI) in the Senate, where it (S. 733) is also supported by Sens. Kay Hagan (D-NC) and Robert Casey (D-PA).

The groups point out that many community-based oncology practices have closed and others are already threatened, and when patients must travel for care the result can be duplicative and unnecessary services that cost patients financially as well as emotionally.

The stakeholders further note that a recent Milliman study indicated that care provided in community-based settings was 14.2 percent lower than that provided in other settings.

Additionally, the stakeholders stress there continue to be concerns about drug shortages for oncology treatments and worry that reimbursement changes could further destabilize the market. Sen. Orrin Hatch (R-UT) is considering drafting legislation that would increase Medicare drug reimbursements for certain drugs in short supply. -- Amy Lotven (alotven@iwpnews.com)

THE HILL'S
Congress Blog
Where lawmakers come to blog

Cutting cancer patients' care is not the right fix

By Ted Okon, Community Oncology Alliance - 12/15/11

As the House and Senate are again scrambling to prevent a major reimbursement cut to doctors under Medicare's beleaguered physician payment formula, we in the cancer community understand the urgent need to keep physician practices solvent and able to continue accepting Medicare patients. However – no matter how high the threat of physician cuts climbs – Congress must not look to cancer care as a funding source for the latest physician payment patch.

Cancer care in the U.S. has entered a state of crisis. In communities nationwide, an alarming number of patient-preferred local clinics – which provide state-of-the-art cancer care to more than 80 percent of America's cancer patients – are shutting down. There have been 199 reported closures over the last three years due to inadequate reimbursement, according to the Community Oncology Alliance's latest estimate, and hundreds more are struggling to stay open.

(Continued on page 5)



Tuesday, December 20, 2011

Cutting cancer patients' care is not the right fix (*cont'd*)

When community cancer clinics close and patients move to hospitals for their care, many of which are farther away, this impacts both the patient and taxpayers. For example, a recent Milliman study found total Medicare spending on chemotherapy patients to be significantly lower in the physician's office, amounting to an extra \$623 million saved per year. And when patients must travel farther for treatment, this leads to added transportation costs and more time spent away from home and loved ones.

Although community cancer centers continue to provide efficient care delivery, the latest technologies and best practices, they are grappling with a flawed reimbursement method for drugs and services that is threatening their survival. This average sales price (ASP) based payment mechanism for life-saving cancer drugs has led to substantial reductions in Medicare payments, and reimbursement that often does not even cover clinics' overhead, staff time and services required for administering complex, time-intensive chemotherapy regimens.

Insufficient reimbursement for cancer drugs under ASP is also contributing to the dangerous drug shortage impacting cancer care.

Without the financial incentive to produce widely relied upon generic injectable cancer drugs, manufacturers are discontinuing production and sources for these medications are consolidating – which means that when one facility has a manufacturing glitch, the effects are far-reaching. As leading oncologists recently testified before lawmakers, these shortages are resulting in rationing of drugs and severe price gouging. “Right now it feels like practicing medicine in a third world country,” one oncologist said of her daily medical practice.

This undermining of cancer care during a time where we should be stepping up our investment in saving and prolonging lives has unintentionally resulted from right-minded but untested policy changes that have shifted the way cancer care is delivered. But instead of now working to thoughtfully reform and bolster the nation's cancer care foundation, some policy proposals have recently emerged that could cripple cancer care delivery. This includes lowering Medicare Part B payments for cancer-fighting drugs under ASP – which would be too much for community clinics to bear, since they rely on fair payments on these medications to account for staff time with patients and other vital care services.

In contrast, almost 50 bipartisan Congressional leaders have co-sponsored progressive, forward-looking legislation, HR 905 (Whitfield/Green) and S 733 (Stabenow/Roberts), to correct the current ASP payment calculation and strengthen the viability of community practices by ensuring more appropriate payment under Medicare Part B. This is a substantial step in the right direction, and I urge more lawmakers to join this bipartisan effort to improve cancer patients' access to care in the community.

Let's not wait until cancer care, like physician payment, is at the edge of the cliff. We should look ahead, modify and improve the current reimbursement structure and create appropriate incentives for manufacturers to continue bringing life-saving cancer drugs to market. And in doing so, we should not adversely impact oncologists and the community based clinics that are dramatically improving the survival rates of today's patients battling cancer.

We have made tremendous progress in the war declared on cancer Congress declared 40 years ago – and in the haste of another physician payment quick fix on Capitol Hill, let's not lose that all-important war now by taking our eye off patients' access to local clinics, state-of-the-art-care and therapies that are saving their lives.

Ted Okon is the Executive Director for the Community Oncology Alliance