



Friday, February 22, 2019

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Internal Documents Show CMS Preparing Radiation Therapy Bundle

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New Bills Aim to Address Drug Prices, PBM Transparency

Last week, members of Congress introduced several bills to address prescription drug costs and increase transparency among pharmacy benefit managers (PBMs). [Read below.](#)

House Ways & Means Committee Holds Hearing on Drug Pricing

On February 12, the House Ways & Means Committee held a hearing entitled "The Cost of Rising Prescription Drug Prices." [Read below.](#)

Hospital Groups ask Court to Require CMS Recalculate 340B Payment Rates

A group of hospital systems suing the Centers for Medicare & Medicaid Services (CMS) over cuts the agency made to the 340B program last year petition the court to require CMS to recalculate payments to make up for those cuts. [Read below.](#)

CMS Issues National Coverage Decision for CAR-T Cell Therapies

Last week, the Centers for Medicare & Medicaid Services (CMS) issued a proposed national coverage decision for CAR-T cell therapies provided patients receive treatment in a CMS-approved registry or clinical study and are monitored for two years after treatment. [Read below.](#)

Network Physicians Meet with Lawmakers to Stress Part B Reform Concerns

Last week, Chief Medical Officer (CMO) Marcus Neubauer, M.D. and P&T Committee Chair Leslie Busby, M.D. visited Capitol Hill to advocate against specific provisions included in the Administration's proposed International Pricing Index (IPI) model, primarily the insertion of third-party vendors in the procurement and administration of Part B drugs. While in Washington, Drs. Neubauer and Busby met with the offices of Senator Michael Bennet (D-CO) and Senator Cory Gardner (R-CO), as well as key health policy staff for Senate Majority Leader Mitch McConnell (R-KY), Speaker Nancy Pelosi (D-CA), Senate Finance Committee, House Ways and Means Committee, and House Energy and Commerce Committee.

On February 12, *The Hill* published an op-ed about the impact of drug pricing reforms by Dr. Busby. The article argues the IPI model would disrupt the seamless care millions of cancer patients experience today by inserting third-party vendors into the procurement and distribution of certain Medicare drugs.

The third-party vendor system in the proposal is similar to the failed Competitive Acquisition Program (CAP) launched by the Centers for Medicare & Medicaid Services (CMS) in 2006. Though the goal of the CAP was to generate cost savings for beneficiaries by encouraging competition between vendors, the program was scrapped two years later after the experiment was plagued by low physician enrollment and officials struggled to convince more than one vendor to sign up for the program.

Dr. Busby urges policymakers not to go down that path again because any scheme inserting a new, unaffiliated vendor into the supply chain will increase the complexity and costs of drug management systems for oncology practices and delay patient care.

To read Dr. Busby's op-ed in *The Hill*, [CLICK HERE](#).

Internal Documents Show CMS Preparing Radiation Therapy Bundle

An internal document inadvertently posted online revealed new details regarding the Centers for Medicare & Medicaid Services' (CMS) anticipated bundled payment model for radiation oncology services. The document comes in the form of an internal transmittal to Medicare Administrative Contractors.

Though the agency claims the document is for planning purposes only, it contains important details on how the agency could potentially move forward.

The proposed bundled payments would include 17 kinds of cancer in the model and consist of 90-day episodes. Both freestanding centers and hospital outpatient departments would be

expected to participate. Following a 90-day episode, the document notes participants would be able to bill radiation therapy services as fee-for-service for the same beneficiary for 28 days before a new episode could be triggered.

Last November, HHS Secretary Azar hinted at a forthcoming mandatory alternative payment model for radiation oncology during a speech about value-based care transformation. However, no further updates have been provided regarding timing of an announcement.

To view the document, [CLICK HERE](#).

New Bills Aim to Address Drug Prices, PBM Transparency

Last week, members of Congress introduced several bills to address prescription drug costs and increase transparency among pharmacy benefit managers (PBMs).

The Prescription Drug Price Transparency Act (H.R. 1035), introduced by Congressman Doug Collins (R-GA), aims to increase transparency and accountability from PBMs by:

- ensuring Maximum Allowable Cost (MAC) pricing lists are updated every seven days for Medicare Part D, Medicare Advantage Part-D, and FEHBP;
- preserving pharmacy access for patients by protecting their ability to choose a pharmacy;
- requiring PBMs disclose sources used in MAC price determinations; and
- providing greater oversight to prevent waste, fraud, and abuse of taxpayer funds in Medicare Part D, Medicare Advantage Part-D, and FEHBP.

Congressman Collins also introduced the Phair Pricing Act (H.R. 1034), which seeks to lower the cost of prescription medication for patients in the Medicare Part D program by:

- requiring all price concessions between a pharmacy and PBM be included at the point of sale to decrease patient's costs;
- realigning market incentives to ensure patients have access to and receive the best possible care;
- directing the Secretary of Health and Human Services to establish a working group of stakeholders to create quality measures based on a pharmacy's practice; and
- ensuring PBMs disclose all fees, price concessions, and programs to CMS.

Separately, Senate Finance Committee Ranking Member Ron Wyden (D-OR) introduced the Creating Transparency to Have Drug Rebates Unlocked (C-THRU) Act which aims to improve transparency and ensure people in Medicare receive a fair share of rebate savings. It would require PBMs to publicly disclose the aggregate amount of rebates they receive from pharmaceutical companies, and what proportion of those rebates go to Medicare beneficiaries. After two years of public reporting, the legislation would then require a minimum percentage of rebates and discount to be passed from a PBM to a health plan, which will lower premiums or other cost-sharing amounts paid by patients. The bill would require cost-sharing for Part D

enrollees to be based off the negotiated price of the drug as agreed to by the drug manufacturer and PBM so that Part D enrollees fully benefit from discounts and rebates provided by drug manufactures.

To read a summary of the Prescription Drug Price Transparency Act and the Phair Pricing Act, [CLICK HERE](#). The full text of the bills can be found [HERE](#) and [HERE](#).

To read a summary of the C-THUR Act, [CLICK HERE](#). The full text of the bill can be found [HERE](#).

House Ways & Means Committee Holds Hearing on Drug Pricing

On February 12, the House Ways & Means Committee held a hearing entitled “The Cost of Rising Prescription Drug Prices.” Prior to the hearing, Committee Chair Richard Neal (D-MA) and Ranking Member Kevin Brady (R-TX) issued a joint statement acknowledging “the time is now to take meaningful action to lower the cost of prescription drugs” and pledging to work “together to end this cycle while preserving access to life-saving innovations.”

Witnesses included:

- Mark E. Miller PhD, Executive Vice President of Health Care, Arnold Ventures
- Rachel Sachs, Associate Professor of Law, Washington University
- Alan Ruether, Legislative Consultant, UAW Retiree Medical Benefits Trust
- Odunola Ojewumi, patient
- Joseph R. Antos PhD, Wilson H. Taylor Scholar In Health Care and Retirement Policy, American Enterprise Institute

To read the joint statement by Representatives Neal and Brady, [CLICK HERE](#).

To read the testimonies of all the witnesses, [CLICK HERE](#).

Hospital Groups Ask Court to Require CMS Recalculate 340B Payment Rates

A group of hospital systems suing the Centers for Medicare & Medicaid Services (CMS) over cuts the agency made to the 340B program last year petitioned the court to require CMS to recalculate payments to make up for those cuts.

CMS cut reimbursement for Part B drugs under the 340B program by 30 percent, or \$1.6 billion, beginning in January. The groups, led by the American Hospital Association, the Association of American Medical Colleges, and America’s Essential Hospitals filed a lawsuit alleging the cuts would disproportionately harm hospitals serving low income patients. In December, the U.S.

District Court for the District of Columbia ruled CMS had overstepped its authority in making the cuts and announced it will make an additional ruling on the issue of remedies.

Both sides were ordered to submit briefs following the ruling. In its brief to the court, the hospital groups urged the court to order CMS to recalculate the payments due to 340B hospitals last year so that they receive the same average sales price plus 6 percent rate they received in 2017, plus interest.

However, the government countered that doing so would require all hospital outpatient payments be recalculated in order to keep the pay system budget neutral and instead urged the court to allow CMS to develop its own fix. Additionally, the court declined to impose injunctive relief regarding the 2019 payment rates; therefore, the payment policy finalized under the 2019 OPPS rule remains in place.

The hospitals' court brief can be view [HERE](#) and CMS' brief [HERE](#).

To read more on the case, [CLICK HERE](#).

CMS Issues National Coverage Decision for CAR-T Cell Therapies

Last week, the Centers for Medicare & Medicaid Services (CMS) issued a proposed national coverage decision for CAR-T cell therapies provided patients receive treatment in a CMS-approved registry or clinical study and are monitored for two years after treatment. The proposed rule would apply to all FDA-approved CAR-T therapies prescribed by a treating oncologist and provided in either a hospital inpatient or outpatient setting. The agency announced this move will help shape future decisions about the types of treatments Medicare will cover.

Previously, coverage for CAR-T was left up to local Medicare Administrative Contractors.

The proposed decision memo is open for public comments until March 17, 2019.

To view the proposed CAR-T National Coverage decision, [CLICK HERE](#).