Tuesday, January 11, 2022

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FULL STORIES

Network Physician Urges Ohio Lawmakers to Protect Patients from Insurer "White Bagging" Tactics

Writing in the Ohio Capital Journal, Dr. D. Randolph Drosick, a practicing oncologist and President of Oncology Hematology Care, Inc. in Cincinnati, discusses the potential harms posed by so-called "white bagging" policies and advocates for legislation that would prevent insurers from imposing these policies on patients and practices throughout the state. Under a "white bagging" arrangement, all of a patient's infused medications must be ordered and shipped from a specialty pharmacy affiliated with the patient's insurance company rather than be provided directly by the medical practice.

"While waste and delays with oral chemotherapy treatment is worrisome, our level of concern skyrockets at the thought of the harm caused by inappropriately dosed or delayed infusion drugs mixed off site," Dr. Drosick writes. "Any error in preparation can cause delays and without the ability to take advantage of an on-site prescription drug inventory to tweak doses in real time, these delays can derail a patient's whole treatment plan."

Ohio House Bill 451, sponsored by state Reps. Scott Oelslager and Gayle Manning, would prevent insurers from imposing mandatory white bagging policies on practices in the state.

Dr. Drosick's advocacy is part of a growing movement of physician specialists around the country who are speaking out against white bagging polices that threaten to delay care, compromise patient safety, and increase drug waste.

To read Dr. Drosick's op-ed, CLICK HERE.

To read Ohio House Bill 451, CLICK HERE.

Negotiations on Build Back Better Act Stall in the New Year

Shortly before lawmakers left Washington for the Christmas holiday, Senator Joe Manchin (D-WV) – already a skeptic of his party's expansive social policy agenda – formally announced his opposition to the Build Back Better Act, ensuring that the bill will not have sufficient support to pass the chamber in its current form. Citing concerns over the bill's impact on inflation, Senator Manchin's comments came as a surprise to those who believed the Senator and the White House were close to a deal.

While talks with Senate leadership and the White House are expected to resume at some point in the new year, Senate Majority Whip Dick Durbin (D-IL) confirmed on January 5 that negotiations over all aspects of the bill are currently "on hold."

Despite this setback, it is possible Democratic leadership may attempt to move forward with a pared back social spending bill containing the provisions that are most amenable to Senator Manchin and other Democrats skeptical of the initial package. Lawmakers may also consider a standalone drug pricing bill, though it would need to garner the support of at least 10 Republican Senators in order to pass with a filibuster-proof majority.

For his part, Senator Manchin has stated that he strongly supports the drug pricing provisions in Build Back Better Act – and would prefer that they be stronger – though others in his party have been more critical of the bill's approach.

To view a summary of the most recent version of the Senate Finance Committee's bill, CLICK HERE.

CMS Proposes Action on DIR Fees

On January 6, 2022, the Centers for Medicare & Medicaid Services (CMS) released the Medicare Advantage and Part D Proposed Rule for CY 2023, which included a policy proposal to require Part D plans apply all price concessions they receive from network pharmacies at the point of sale. Under current practice, pharmacy price concessions, known as direct and indirect remuneration (DIR), are assessed after the point of sale. Specifically, the proposed rule would redefine the "negotiated price" as "the lowest amount a pharmacy could receive as its reimbursement for a covered Part D drug under its contract with the Part D plan sponsor." According to CMS, this policy is aimed at reducing beneficiary out-of-pocket costs and improving price transparency and market competition in the Part D program. If finalized, the policy would go into effect on January 1, 2023.

This proposal from CMS follows a letter CMS Administrator Chiquita Brooks-LaSure sent to Senate Finance Chairman Ron Wyden (D-OR) on December 14 indicating the agency was planning to develop a rule addressing price concessions and DIR. Administrator Brooks-LaSure was responding to a letter Senator Wyden sent in October urging the agency to review pharmacy closures nationwide with a focus on how DIR fees are driving these closures.

Separately, Senator Wyden sent a letter to the Federal Trade Commission (FTC) asking it to investigate whether "exploitive" practices by pharmacy benefit managers (PBMs) are causing local pharmacies to close their doors or consolidate with larger chains. The letter came after 37 Bi-Mart pharmacies, mostly located in non-urban parts of Oregon, announced they would be closing. Sen. Wyden asked the FTC to explore if PBM practices are making the pharmacy market less competitive. According to the letter, over 1,200 independently-owned rural pharmacies shut down between 2003 and 2018, potentially pointing to a nationwide trend.

States are also continuing to increase oversight over PBMs. On December 31, New York State Governor Kathy Hochul (D) signed legislation into law that would require PBMs to become licensed and conform to state standards starting on January 1, 2023. The law will create regulations with minimum standards for PBMs to help address conflicts of interest, deceptive and anti-competitive practices, unfair claims practices, and consumer protections.

To read the CMS factsheet on the proposed rule, CLICK HERE.

To read the proposed rule in its entirety, CLICK HERE.

To read the National Community Pharmacists Association's statement on the proposed rule, CLICK HERE.

To read CMS Administrator Brooks-LaSure's letter to Sen. Wyden, CLICK HERE.

To read Sen. Wyden's letter to FTC Chair Lina Khan, CLICK HERE.

To read the text of the New York law that would require PBMs to become licensed, CLICK HERE.

CMS Officially Rescinds 'Most-Favored Nation' Drug Payment Model

On December 27, the Centers for Medicare & Medicaid Services (CMS) issued a final rule to formally rescind the Center for Medicare & Medicaid Innovation's (CMMI) Most Favored Nation (MFN) Model for Medicare Part B drugs. Originally proposed in November 2020, the MFN Model was proposed to be a mandatory, seven-year demonstration project under which Medicare would have limited payment for Medicare Part B drugs and biologics to the lowest price drug manufacturers receive for the same drugs in 22 similar countries.

Based on CMS' announcement, the agency made the decision to rescind the MFN Model due to the following factors:

- Imposition of a nationwide injunction requiring CMS to complete notice and comment rulemaking procedures before implementing such a model
- Procedural issues with the November 2020 interim final rule identified by multiple courts
- Concerns expressed by stakeholders – of all the comments CMS received in response to the proposed rule, only one commenter supported completely rescinding the model.

CMS has indicated that it will continue to take stakeholder feedback into account as the agency considers future policies to support value-based payments for Part B drugs and lower costs to beneficiaries and the Medicare program.

Since the MFN model was proposed, The Network and its coalition partners have warned that it would disrupt patient access to cancer care, fail to reduce patient costs, and stifle healthcare innovation.

To read the final rule rescinding the MFN Model, CLICK HERE.

For more background on the MFN Model, CLICK HERE.

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On December 9, House Ways & Means Health Subcommittee Chair Lloyd Doggett (D-TX), Health Subcommittee Ranking Member Devin Nunes (R-CA) and Health Subcommittee members Mike Thompson (D-CA), Mike Kelly (R-PA), and David Schweikert (R-AZ), introduced the Telehealth Extension Act. The bipartisan legislation includes a number of policies to support the continued delivery of telehealth services that have been more widely adopted during the COVID-19 public health emergency.

Specifically, the Telehealth Extension Act would:

- Permanently lift geographic and site-based restrictions so Medicare beneficiaries can use telehealth regardless of their zip code or site of care.
- Support the adoption of telehealth in underserved communities by ensuring Federally Qualified Health Centers, Rural Health Clinics, Indian Health Service facilities, and Native Hawaiian Health Care Systems can furnish telehealth services.
- Provide a two-year temporary extension of COVID-19 emergency telehealth waivers.
- Promote program integrity with reasonable guardrails for a small subset of telehealth services that have been targets of fraud without limiting access to care.
- Require an in-person appointment within 6 months prior to ordering durable medical equipment (DME) or major clinical laboratory tests.

- Authorizes CMS to audit outlier physicians ordering DME and lab tests at high rates and recover fraudulent payments.
- Improve disaster preparedness by providing broad authority for CMS to authorize telehealth flexibilities during future emergencies.
- Allow for further study of the utilization and impact of telehealth in different care settings.

The bill is supported by a variety of stakeholders including the American Nurses Association and the National Rural Health Association.

To view the lawmakers' statement, CLICK HERE.

Biden Administration Appeals 340B Ruling on Contract Pharmacies

On December 29, the Department of Justice appealed a federal judge's ruling that pharmaceutical companies have the authority to restrict sales of 340B-discounted drugs to contract pharmacies. The move came just one day after the U.S. Department of Health and Human Services (HHS) said it would appeal the case, as well as several related cases that address whether the Health Resources and Services Administration (HRSA) has the power to fine drugmakers that restrict sales of 340B products to covered entities' contract pharmacies.

The appeals were filed a week after more than 850 hospitals across the United States urged the federal government to appeal the court's decision. In a letter to HHS Secretary Xavier Becerra, the hospitals urged further enforcement of regulations and laws to ensure that access to 340B savings is protected and preserved.

AbbVie became the latest pharmaceutical to restrict its discounts under the 340B program on the same day the federal government appealed the ruling. Including AbbVie, 10 other drug manufacturers have restricted 340B discounts to date. In its letter to safety net hospitals, AbbVie said it will begin withholding discounts on February 1 if the hospitals do not turn over patient claims data for contract pharmacies.

To read the notices of appeal, CLICK HERE and HERE.

To read hospitals' letter to HHS Secretary Xavier Becerra, CLICK HERE.