RxCrossroads Specialty Solutions
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LEGISLATIVE NEWSLETTER
SEPTEMBER 2017

RXCROSSROADS SPECIALTY SOLUTIONS
REIMBURSEMENT & COVERAGE POLICY UPDATES

RxCrossroads Specialty Solutions provides legislative updates related to reimbursement and coverage news that closely impacts the pharmaceutical and biotech marketplaces. We monitor the payer landscape to proactively inform programs and services designed for clients.

HEALTH REFORM NEWS

Congress Pivots to Targeted ACA Reform Effort

Following highly-partisan efforts to repeal and replace the Affordable Care Act (ACA), culminating in narrow defeat of the Senate Republican's "skinny ACA repeal bill" in late July, key legislators are now trying to craft a narrow health reform package, aimed primarily at stabilizing the current individual insurance markets. Senate Health, Education, Labor, and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) and Ranking Member Patty Murray (D-WA) are leading the discussions on possible legislation, with multiple committee hearings expected to be held this month. Several governors and state insurance commissioners are among those to testify at these Senate HELP Committee hearings.

In another development, leaders from the 12 state-based health exchanges recently recommended that Congress take several specific actions to stabilize state exchanges. These steps include funding the ACA's cost sharing reduction program, providing more state flexibility, establishing a permanent federally-funded reinsurance program, enforcing the individual mandate, among other priorities. While the state exchanges overall have had fewer problems than the federally-facilitated marketplace, their long-term stability is a significant concern.

It remains to be seen whether a legislative compromise can be reached in Congress, yet persistent problems in the marketplace will keep pressure on for action by policymakers. Also of significance, the Senate's current procedure authority ("budget reconciliation instructions") for health reform will expire on September 30, whereby only 51 votes for Senate passage are required. After that time, 60 votes will be needed to overcome a possible Senate filibuster on health reform, unless a new budget resolution establishes reconciliation procedures that could be used for health reform.

Health Pocket Releases Analysis of 2017 Drug Cost-Sharing Trends

A new analysis by Health Pocket on prescription drug out-of-pocket costs in 2017 under ACA plans found that the biggest annual average increase occurred for Silver plan beneficiaries taking specialty drugs. Silver Plans are the most popular, among the four different ACA plan metal types. Specifically, the analysis found a 16% increase in specialty drug cost-sharing from 2016 to 2017, which produces a $226 to $1,763 in additional monthly out-of-pocket costs among the top five specialty drugs. Platinum plans were the only ones whereby specialty drug cost sharing lowered between 2016 and 2017 (by 11%). However, only 1% of exchange marketplace consumers are enrolled in Platinum plans in 2017.

CAPITOL HILL NEWS

Congress Approves Legislation Reauthorizing Drug User Fee Programs

Congress recently passed and President Trump signed into law legislation (H.R. 2430) reauthorizing the Food and Drug Administration (FDA) user fee amendments (UFAs), thus allowing the agency to continue to collect fees from drug manufacturers of prescription brand drugs, generic drugs, biosimilars, and medical devices through Fiscal Year 2022. Congress also included numerous bipartisan provisions in the UFAs bill intended to help spur competition in the marketplace, including:

- Creating a priority review system for generic drug applications when there are not more than three approved drug products already on the market, and there are no patents or market exclusivity. Under the legislation, the FDA would review the applications within eight months of the date of submission.
- Expediting the review of drugs that are designated as competitive generics. Any generics that are expedited would receive 180 days of exclusivity upon approval, but this would be forfeited if the drug is not marketed within 75 days.
- Directing manufacturers to notify the FDA about withdrawals or drugs not available for sale after approval.

The user fee package included a host of priority issues for rare disease advocates, including provisions that make updates to the Pediatric Research Equity Act (PREA) in order to increase the number of children participating in oncology trials; improve the device inspection process; enhance communication during drug development; and include patient perspectives into the drug development process.

"Right to Try" Bill Advances in the Senate

An amended version of "Right to Try" legislation, sponsored by Senator Ron Johnson (R-WI), recently passed the Senate by unanimous consent. "Right to Try" bills, which have been pushed at both the federal and state level, would forbid the Food and Drug Administration (FDA) from taking action to restrict experimental drugs from being produced, manufactured, distributed, prescribed, or dispensed and would allow prescribers and manufacturers to grant terminally ill patients access to the experimental drugs so long as the drugs have completed Phase I clinical trials. Supporters of the bill in the House are working towards swift consideration.

Drug Pricing Remains on Legislators' Agendas

BETTER JOBS, BETTER WAGES, BETTER FUTURE
A BETTER DEAL
#ABETTERDEAL

Several announcements in recent weeks demonstrate that drug pricing remains a major focus in Congress. For example, Senator HELP Committee Chairman Lamar Alexander (R-TN) announced that two hearings will be held this Fall on drug pricing. These hearings will likely occur only after the Senate finishes up its work on ACA reform. In another development, Congressional Democrats unveiled a package of proposals aimed at lowering drug prices, as part of its "Better Deal" economic agenda. These proposals include: setting up an independent regulator to monitor prescription drug pricing, allowing HHS to negotiate drug prices in Medicare Part D, and requiring drug manufacturers to provide HHS with justification for any significant price hikes.

State legislative activity on drug pricing also has continued in recent months, with transparency proposals and caps on drug price increases among the issues in focus. The National Academy for State Health Policy (NASHP) recently published a paper analyzing state drug pricing legislative trends, which found that more than 30 states have drug price transparency bills. The NASHP research profiled activities in Vermont, Nevada, Maryland, California, New York, and Pennsylvania, among other states.

CENTER FOR MEDICARE AND MEDICAID SERVICES (CMS) NEWS

CMS Looking Closely at Value-Based Pricing Models for Prescription Drugs

In a recent news release, CMS indicated that the agency is continuing to explore the development of innovative payment arrangements, such as outcome-based pricing for medications in relation to clinical outcomes. CMS indicates that it will be issuing further guidance to explain how pharmaceutical manufacturers can engage in innovative payment arrangements.

CMS Announces Part D Premiums for 2018

CMS recently announced the average basic premium for a Medicare Part D prescription drug plan in 2018 is projected to slightly decline, to an estimated $33.50 per month. This represents a decrease of approximately $1.20 below the actual average premium of $34.70 in 2017. The projection for the average premium for 2018 is based on bids submitted by drug plans for basic drug coverage for the 2018 benefit year. CMS points to the relatively stable Medicare Part D premiums as a clear indicator of the success of the structure of the Part D program.

CMS Releases Proposed Medicare Physician Fee Schedule Payment Rule for 2018

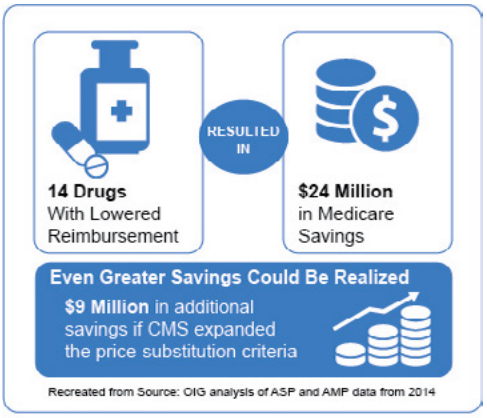
CMS released its proposed rule for payment rates and related provisions for the Medicare Physician Fee Schedule for 2018. Among the provisions of note, CMS solicits comments on the effects of its payment policy for biosimilars that went into effect in 2016. Under current policy, the average sales prices for all national drug codes (biosimilars products) are included in the same billing and payment code. CMS seeks research and perspectives on the impact of that policy.

OTHER REGULATORY NEWS

HHS OIG Releases Two Reports on Part B Drug Pricing

A new report from the U.S. Health and Human Services Department (HHS) Office of the Inspector General (OIG) estimates that charging drug manufacturers rebates if drug prices exceed inflation would have saved Medicare Part B up to $1.8 billion in 2015 for 64 "high expenditure" drugs. Rep. Sander Levin (D-MI) had requested this OIG report, and issued a statement urging action to require these rebates. In the report, OIG identifies several administrative hurdles to a Medicare Part B rebate program.

In another new OIG report on Medicare Part B drug payments, the OIG analyzed the effects of current CMS price substitution policy. Currently, if an average sales price (ASP) exceeds the average manufacturer price by 5% in the 2 previous quarters or 3 of the previous 4 quarters, HHS substitutes the ASP-based payment amount with a lower calculated rate. OIG found that CMS lowered Part B reimbursement for 14 drugs on the basis of this data analysis in 2014, saving $24 million that year. OIG notes that an additional $9 million would have been saved if the price-substitution criteria on exceeding the 5% threshold was limited to a single quarter. OIG recommends that CMS expand the price substation policy, yet CMS did not concur with this recommendation, though the agency indicates that it may consider policy changes in the future.



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