

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.

TOP NEWS

House Passes Bill Making Major Changes to the Affordable Care Act



On May 4, after months of intense efforts and negotiations, the U.S. House of Representatives narrowly passed legislation by a 217-213 vote making comprehensive changes to the 2010 health care reform law, called the Affordable Care Act (ACA). Twenty Republicans opposed the bill and no Democrats supported it. Passing this legislation seeks to deliver on Republican's long-standing promise to repeal ACA, and also address rapidly-rising costs of ACA coverage, and insurers' growing reluctance to continue to offer ACA plans.

Major provisions in the House-approved bill include the following:

- Repeals most of the taxes and tax increases imposed by the ACA, including the pharmaceutical tax and the medical device tax;
- Makes fundamental changes to Medicaid by changing it from an open-ended entitlement program to a program providing either block grants or per capita payments to states;
- Removes the individual and employer mandate penalties;
- Increases age rating ratios from 1 to 3 to 1 to 5 in the individual and small group market and allows states to go higher by waiver;
- Permits states to seek a waiver from the ACA's essential health benefit requirements and from other coverage rules and requirements;
- Imposes a penalty on individuals who do not maintain continuous coverage;
- Includes \$138 billion in funding for states in providing coverage and assistance with out-of-pocket expenses for higher-cost consumers;
- Ends the ACA's means-tested subsidies as of 2020, and substitutes them with age-adjusted fixed-dollar tax credits.

The House-passed bill did not receive an updated analysis on its impact on the federal budget and on insurance coverage before the vote, though an estimate of an earlier version of it found that the changes would result in 14 million fewer people having coverage by 2018, rising to 24 million fewer covered individuals by 2026.

The Senate will next take up ACA reform, and major changes to the House-passed bill are considered likely. Republicans hold (only) a two-vote margin in the Senate, meaning crafting compromise and addressing virtually all Senate Republicans' issues and concerns will be necessary for its passage. In the meantime, the U.S. Department of Health and Human Services (HHS) is reportedly working on substantive changes to the ACA that can also be achieved via the federal regulatory process.

DRUG PRICING NEWS

Federal and State Policymakers Keep Drug Pricing in the Spotlight

Federal and state policymakers continue to announce proposals and advance bills aimed at lowering the costs of prescription drugs. Five examples of recent developments are as follows:

- A comprehensive drug pricing bill was introduced by House and the Senate Democrats titled “The Improving Access to Affordable Prescription Drugs Act.” Among its provisions, the bill would allow drug re-importation from Canada; enable HHS to negotiate Medicare Part D drug prices; require drug manufacturers to publicly report a wide range of financial information; end drug manufacturer “pay for delay” agreements; close the Medicare Part D coverage gap in 2018; disallow tax deductions for direct-to-consumer drug advertising, among other provisions. This legislation was introduced as a comprehensive bill and is not likely to advance as such, yet the sponsors may try to move certain provisions as part of other legislative actions in Congress.
- Two bills have been introduced to make reforms to the FDA’s Risk Evaluation and Mitigation Strategy (REMS) program. The first bill, called the Fair Access for Safe and Timely Generics Act (FAST Generics Act), is intended to provide more legal and other tools to allow generic and biosimilar manufacturers to obtain access to drugs and biologics, in order to develop and test new generic products. The other bill, the Creating and Restoring Equal Access to Equivalent Samples (CREATES Act), would allow generic manufacturers to seek injunctive relief if they cannot obtain a sample, and authorizes a judge to award damages to discourage further delays. The bill would also give FDA more discretion to approve alternative safety protocols instead of requiring generic manufacturers to enter into existing protocols.
- A key committee in the California Senate [approved legislation](#) (SB 17) that would require drug manufacturers to provide notice to purchasers prior to any significant increase in prices, and would require explanations about those increases. The bill would also require health plans to report the percentage of premiums spent on drugs and on their drug purchasing trends.
- The Maryland Legislature approved a first-in-the-nation generic drug pricing bill ([HB 631](#)) that would authorize the Attorney General to bring court action against drug manufacturers that significantly raise prices of generic and off-patent drugs. The legislation also authorizes the state Attorney General to require detailed cost information when a 30-day supply of a drug costs \$80 or more and the price of that drug has increased by more than 50% over the last year. The legislation will become law without the governor’s signature.



LEGISLATIVE NEWS

Congress Takes Steps to Reauthorize the FDA’s Prescription Drug User Fee Programs

Congressional leaders recently released a bipartisan [draft](#) of legislation to reauthorize user fees collected from manufacturers of brand and generic prescription drugs, as well as medical devices and biosimilars. The five-year drug user fee reauthorization proposal aims to improve the efficiency and predictability of the FDA’s review process.

The four user fee programs are set to expire in September, and therefore this issue represents “must pass” legislation in the coming months for Congress. The draft proposal reflects negotiations that took place between the FDA and industry and key stakeholders groups for the past few years.

Additional provisions of note in the draft user fee reauthorization proposal include: a new review model for biosimilars; a new approval pathway for complex generics; a priority review voucher program for first generics; a REMS study; and five-year reauthorization of the authority of FDA to issue grants for orphan drug development.

The user fee reauthorization legislation is being carefully watched since it may serve as a legislative vehicle for possible consideration of a host of other policy proposals related to prescription drugs.

The committees recently asked for additional stakeholder comments on the discussion draft, and will continue to advance it via committee hearings in the next few weeks, with possible floor action over the summer.

Key Senators Prompt GAO to Initiate Review of the Orphan Drug Program

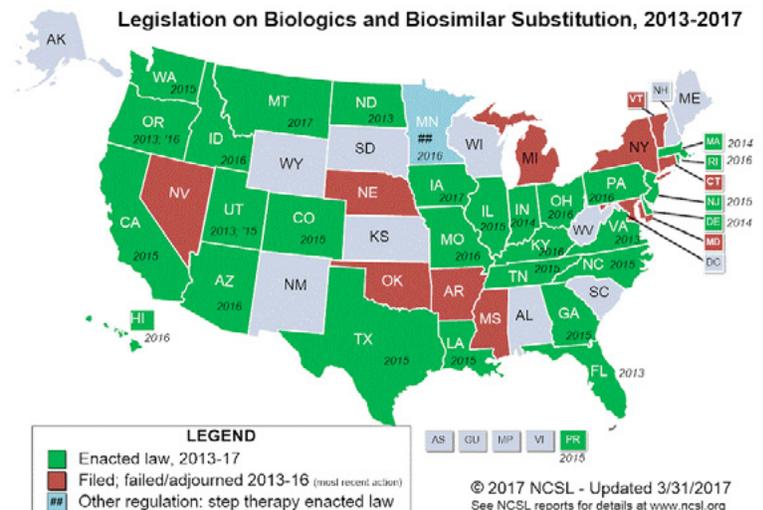
The Government Accountability Office (GAO) plans to do an extensive review of the FDA's Orphan Drug Program, following a formal request from Sens. Orrin Hatch (R-UT), Chuck Grassley (R-IA) and Tom Cotton (R-AR) that urges the GAO to do so. The Orphan Drug Act, signed into law in 1983, created incentives for drug manufacturers to develop drugs for rare diseases. Under the program, a manufacturer receives seven years of exclusive rights to the marketplace for a treatment for an orphan disease, and can also seek a new seven-year exclusivity period on the drug if approved to treat another disease. The GAO is expected to begin this comprehensive review of the program by early 2018.

NCSL Provides Updated Overview of State Biosimilar Laws

The National Conference of State Legislatures (NCSL) recently updated its [overview of state biosimilar laws](#). The NCSL overview notes that at least 37 states have considered legislation establishing state standards for substitution of a biosimilar prescription product to replace an original biologic product.

The NCSL document also identifies the following eight typical features of these state laws:

- **FDA Approval:** A biosimilar under consideration for substitution must first be approved as “interchangeable” by the FDA.
- **Prescriber Decides:** The prescriber would be able to prevent substitution by stating “dispense as written” or “brand medically necessary.”
- **“Notification” vs “Communication:”** In bills enacted in 2013-2014, the language usually required that the prescriber “must be notified” of any allowable substitution made at a pharmacy. In 2015 bills the language commonly has been adjusted to say “communicate with,” allowing a notation in an electronic medical record (EMR), PBM records or pharmacy record accessible by the prescriber.
- **Patient Notification:** At least 12 states require that the patient be notified that a substitute or switch has been made, with some states requiring patient consent.
- **Records:** The pharmacist and the physician must retain records of substituted biologic medications.
- **Immunity:** Some state legislation provides immunity for pharmacists who make a substitution in compliance with biologics state law.
- **Web Lists:** The state must maintain a public or web-based list of permissible interchangeable products.
- **Pricing:** Some state laws require the pharmacist to explain the price of the biologic and the interchangeable biosimilar. Also, Colorado, Georgia, Illinois, North Carolina and Texas require that any authorized or allowable substitution must have the lowest cost.



OTHER REGULATORY NEWS

MedPAC Unanimously Approves Medicare Part B Reform Recommendations



During its April meetings, the Medicare Payment Advisory Commission (MedPAC) voted on a [package of draft recommendations](#) to change reimbursement policies for Medicare Part B drugs. MedPAC is an advisory body that makes non-binding recommendations. The Part B proposals will be formally included in their June Report to Congress.

As part of near-term proposed changes, MedPAC calls for the following modifications to the Average Sales Price (ASP) system changes in 2018:

- Require all manufacturers of Medicare Part B products to submit ASP data, with penalties for failure to do so;
- Lower wholesale acquisition cost (WAC)-based payments to WAC +3%;
- Require manufacturer rebates when the ASP for their product exceeded an inflation benchmark, and tie the beneficiary cost-sharing and the ASCP-add-on to the inflation-adjusted ASP;
- Require the HHS Secretary to use a common billing code to pay for a reference biologic and its biosimilars.

For longer-term reforms, MedPAC approved a proposal calling for a voluntary Drug Value Program (DVP) by 2022, which would include the following:

- Medicare contracts with private vendors to negotiate Part B prices;
- Providers buy all DVP products at venter-negotiated prices;
- Medicare pays providers the DVP-negotiated price and pays vendors an administrative fee, with possible shared savings;
- Beneficiaries would pay lower cost-sharing;
- Medicare payments under the DVP cannot exceed 100% of ASP;
- DVP vendors use a formulary and other tools.

MedPAC also calls for reducing the ASP add-on in 2022, when implementing the DVP program.

The package of Part B reforms would save Medicare an estimated \$250-\$750 million the first year, and \$1-\$5 billion over 5 years, according to MedPAC staff.

CMS Releases Final Call Letter for 2018

In early April, CMS published the [Final Call Letter](#) for 2018 that makes payment and policy updates for Medicare Advantage and Part D programs for the upcoming contract year. Two provisions of note in the Final Call letter include: 1) a requirement that drug tiering exemptions must be approved to the lowest tier that contains a drug used to treat the same condition; and 2) plan sponsors with a specialty tier must include only those Part D drugs with negotiated prices exceeding \$670 per month in CY 2017.

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