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REIMBURSEMENT & COVERAGE POLICY UPDATES

Omnicare Specialty Care Group (SCG) 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.

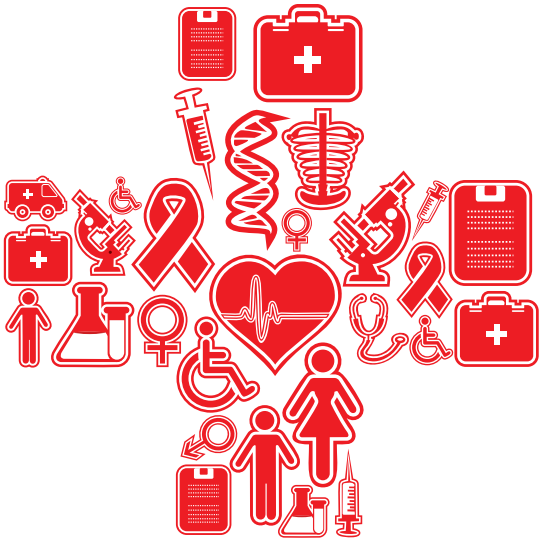
AFFORDABLE CARE ACT NEWS

ACA Enrollment Reaches 17.6 Million

The U.S. Department of Health and Human Services (HHS) recently announced that a total of 17.6 million people have gained coverage under the Affordable Care Act (ACA). This total includes 15.3 million people who gained coverage through the individual marketplace or through Medicaid, as well as the 2.3 million young adults who obtained coverage via their parent's plan until they turn 26 years old. HHS also made available an Issue Brief with data on various characteristics of those with ACA coverage and also the remaining uninsured (e.g., ethnicity, gender, residence in Medicaid expansion or non-expansion state).

CMS Posts Proposed Benchmark Plan for Each State for 2017

The Center for Medicare and Medicaid Services (CMS) recently posted states' proposed selections for their essential health benefits (EHB) benchmark plans for 2017. ACA requires non-grandfathered health plans in the individual and small group markets to cover prescription drugs, and also services in nine other EHB benefit categories. In plan years 2014 through 2016, the EHB benchmark plan is a plan that was sold in 2012, yet for plan year 2017 and beyond, the EHB benchmark plan is a plan that was sold in 2014. For 2017, two documents are provided by CMS for each proposed EHB benchmark plan per state, which are: (1) a summary of the plan's coverage of certain benefits that appear on the Plans & Benefits Template, including a list of covered prescription drug categories and classes; and (2) supporting plan documents that provide detail regarding all plan coverage, limits, and exclusions. CMS accepted comments on the 2017 proposed benchmark plans until September 30.



NEWS FROM CAPITOL HILL

Legislation to Reduce Barriers to Clinical Trials Becomes Law

Legislation titled the Ensuring Access to Clinical Trials Act of 2015 (S. 139) passed both the House and the Senate, and has been signed into law. The bill will make permanent a law that allows people living with rare diseases to participate in clinical trials without counting up to $2,000 of the compensation they receive as income when calculating eligibility for Supplemental Security Income and

Medicaid. The National Institute for Rare Disorders (NORD), the Muscular Dystrophy Association (MDA), the Cystic Fibrosis Foundation, the Biotechnology Industry Organization (BIO), were among the 75 organizations that actively supported the legislation.

New Orphan Drug Bill Clarifies FDA Authority on Usable Data

Several key Senators recently introduced The Advancing Targeted Therapies for Rare Diseases Act of 2015, which aims to help advance development of drugs for Duchenne Muscular Dystrophy, Cystic Fibrosis, certain cancers, and other rare genetic diseases. Specifically, the legislation would affirm the FDA's authority to consider research and data that supports previously-approved targeted treatments, as part of evaluating therapies for patients with the same disease, but different mutations. Thus, the bill would allow companies to expand the scope of their current testing on these rare and serious or life-threatening diseases.

Childhood Cancer Care Bill Introduced in Congress

Bipartisan legislation titled The Childhood Cancer Survivorship, Treatment, Access, and Research (STAR) Act of 2015 has been introduced in both the House and the Senate. The bill has five main sections: 1) expanding opportunities for childhood cancer research; 2) improving childhood cancer surveillance; 3) improving quality of life for childhood cancer survivors; 4) ensuring patients' access to publicly available compassionate use policies; and 5) ensuring pediatric expertise at the National Institutes for Health (NIH). Members of the Childhood Cancer Caucus in Congress are among those who have signed on to the legislation.

> "A child is diagnosed with cancer every three minutes – and one in five children of these children do not survive. With cancer as the leading cause of death among young people in our country, we must do more. As part of that effort, the bipartisan Childhood Cancer STAR Act will help accelerate research for pediatric cancer and improve the care for childhood cancer patients."
>
> - Rep. Van Hollen

Cancer Care Bill Discussed at Medicare Payment Reform Hearing on Capitol Hill

On October 1, the House Committee on Energy& Commerce Subcommittee on Health held a hearing entitled "Examining Potential Ways to Improve the Medicare Program" to discuss three bills, including a cancer care bill. Bruce Gould, President of the Community Oncology Alliance, testified in favor of the Cancer Care Payment Reform Act of 2015. (H.R.1934), which would establish a national Oncology Medical Home Demonstration Project. In his testimony, Gould suggested that the payment reform model under H.R. 1934 would lower costs and improve quality of cancer care. He further explained that community oncology practices are struggling as a result of major Medicare reimbursement cuts. The result is a consolidation of cancer care, which is increasing costs and reducing access. Gould testified that H.R. 1934 is a solution for the problem because it builds upon prior successful demonstrations with the concept of an Oncology Medical Home model.

CENTERS FOR MEDICARE & MEDICAID SERVICES NEWS

CMS Publishes Proposed Payment Rule for Physician Fee Schedule and Part B for 2016

On July 15, CMS published a proposed rule, "Medicare Program: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016," and accepted comments on it under September 8. This rule contains a host of important provisions, yet one that has garnered significant attention is the proposed policy by CMS of grouping biosimilar products together for the same payment calculation, for purposes of reimbursement. In other words, average sales prices (ASPs) of biosimilars for the same reference product would be blended together within the code they share. Sen. Ron Wyden (D-OR), ranking Member of the Senate Finance Committee, recently sent a letter to CMS in support of the CMS proposal to group biosimilar products associated with a reference biologic into a single code, along with a separate billing code for the innovator biologic product.

Stakeholders Express Concerns About Rising Medicare Part B Patient Cost-Sharing

In late September, 70 stakeholders sent a group letter to key leaders in both the House and Senate urging action to prevent estimated increases in the Medicare Part B premium and deductible for 2016. According to the 2015 Medicare Trustees Report, Part B premiums will increase by 52% per month, from $104.90 to $159.30, for 30% of beneficiaries. The report also estimates that the Part B deductible will increase from $147 to $223, which will affect all beneficiaries. The letter lays out a few options for potentially mitigating these cost increases. Given open enrollment begins on October 15, the group letter urges swift action by Congress.

OTHER LEGISLATIVE AND REGULATORY NEWS

Presidential Candidate Hillary Clinton Unveils Drug Pricing Proposals

Democratic Presidential candidate Hillary Clinton recently released a package of proposals aimed at lowering the costs of prescription drugs. The proposals supported by Hillary Clinton include:1) eliminating federal tax breaks for drug companies for direct-to-consumer advertising; 2) allowing drug re-importation; 3) requiring Medicaid rebates for low-income Medicare enrollees; 4) authorizing HHS to negotiate Medicare Part D drug prices; 5) requiring drug companies to disclose research costs; 6) prohibiting brand and generic drug company patent settlements; 7) reducing the exclusivity period for biologics to seven years; and 8) capping certain out-of-pocket drug costs, among other proposals. In a statement on the Clinton plan, the Pharmaceutical Research and Manufacturers of America (PhRMA) suggests that it would hurt medical innovation, curb progress in treating serious diseases, threaten drug safety (with re-importation), and result in fewer coverage options under Medicare Part D. Read more about the proposal by visiting: www.hillaryclinton.com, then click on "Get the Facts" box at the bottom right of the page. Filter the Briefings "Factsheets". The Factsheet title is "Hillary Clinton's Plan for Lowering Prescription Drug Costs". To read more from John Castellani, President and CEO of PhRMA, visit www.phrma.org and search for "Clinton Proposal". The Media Release is titled "PhRMA: Clinton Proposal Would Turn Back the Clock on Medical Innovation".

> "Researchers and scientists across the biopharmaceutical industry have dedicated their lives to the search for new treatments and cures for patients. They do this against seemingly insurmountable odds, knowing that despite years of work on potential medicines nine out of ten will fail during clinical trials and the process will start over. This persistence and dedication to patients has resulted in tremendous advances against some of life's biggest enemies, including cancer, hepatitis c, heart disease and other terrible diseases."
>
> - John J. Castellani,
> President and CEO , PhRMA

FDA Releases Biosimilar Naming Information

In late August, the Food and Drug Administration (FDA) released highly-anticipated draft guidance on naming of biosimilars, and also published a proposed rule indicating that the proposed naming structure would apply to six currently-licensed biosimilar products. Under the FDA draft naming guidance, all biologic reference products and their biosimilars will share the same drug substance name, yet every product, including the reference product, will also get a unique FDA-designated suffix made up of four lowercase letters. The proposal is intended to prevent inadvertent substitution of biologics not deemed interchangeable, and also help track the safety and utilization once they are available.

OIG Releases Advisory Opinion on Free Supply of Cancer Drug During Insurance Delay

The HHS Office of the Inspector General (HHS OIG) recently published an Advisory Opinion regarding a program that provides a cancer drug for free for a limited time, for patients experiencing insurance approval process delays and who have federal health care program coverage. The Advisory Opinion concludes that the OIG will not impose sanctions under the Anti-Kickback Statute or Civil Monetary Penalties Statute for this particular program.

E-mail **INFO@OMNICARESCG.COM** to receive the **REIMBURSEMENT & COVERAGE POLICY UPDATES** or to provide topic suggestions for future Omnicare SCG publications.

FDA Awards New Grants to Spur Drug Development for Rare Diseases

The FDA recently announced it has awarded 10 new research grants, totaling over $19 million, to spur development of treatments for rare diseases. These new grants were awarded to principal investigators in ten states. Ten of the awards fund studies that enroll pediatric patients, and the grants will support research in 17 different rare diseases, several of which have little or no available treatment options.

Some of the grant recipients for fiscal year 2015 include:

- Albert Einstein College of Medicine (Bronx, New York), Deepa Manwani, Phase 2 Study of Gamunex (Intravenous Gammaglobulin) for the Treatment of Sickle Cell Acute Pain — about $1.6 million over four years
- Baylor College of Medicine (Houston, Texas), Andrew Sikora, Phase 2 Study of ADXS11-001 Vaccine for the Treatment of HPV-Related Oropharyngeal Cancer —about $1.2 million over three years
- Beckman Research Institute of the City of Hope (Duarte, California), Behnam Badie, Phase 1 Study of Cellular Immunotherapy Using Optimized IL13Ra2 Specific CAR T Cells for the Treatment of Malignant Glioma —$600,000 over three years

To read about more of the recipients, visit www.fda.gov and search for "research grants 2015".

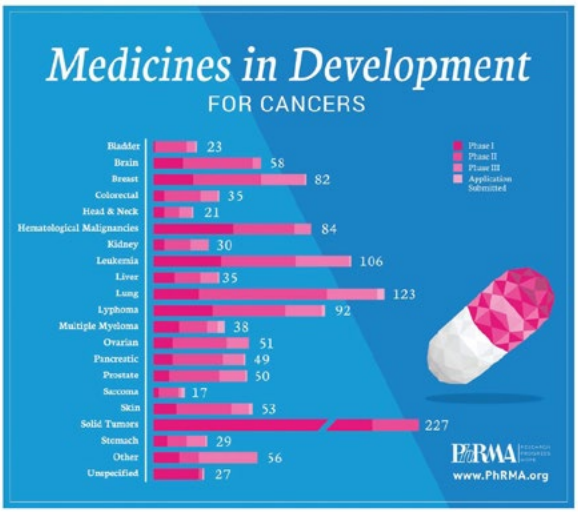
California Drug Pricing Ballot Initiative Set for November 2016 Vote

A statewide ballot measure in California, which recently qualified to be voted on during the November 2016 elections, would require California state programs to pay no more for prescription drugs than the prices negotiated by the U.S. Department of Veterans Affairs (as permissible under federal law). An effort is underway in Ohio to get a similar ballot measure to appear on the November 2016 presidential election ballot.

IN OTHER NEWS

Over 800 Cancer Treatments in Pipeline

A new report from PhRMA shows that there are currently 836 medicines and vaccines for various cancers in the pipeline. A chart highlighting the specific cancers targeted with these medicines accompanied the announcement. PhRMA also notes that 73% of the medicines being development have the potential to be used as personalized medicine. The PhRMA report highlights the American Association for Cancer Research (AACR) annual Cancer Progress Report. To access the report, visit http://phrma.org/sites/default/files/pdf/oncology-report-2015.pdf.



From the American Association for Cancer Research (AACR) annual Cancer Progress Report.

Omnicare Specialty Care Group (SCG) provides integrated services starting with the manufacturer and continuing through to the patient. Our team of experts designs product-specific solutions that improve access and increase speed to therapy, solve for affordability issues and support compliance and adherence.

- BRAND SUPPORT
- PROGRAM PHARMACY
- THIRD PARTY LOGISTICS
- SPECIALTY PHARMACY

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