Sorting Through Current Trends in Federal & State Legislative and Regulatory Issues: What Medicaid Administrators Need to Know

EMPAA Meeting

August 19, 2019

ABOUT ME

Mary Jo Carden, RPh, JD

- Pharmacist and lawyer
- Pharmaceutical policy expert with more than 20 years experience
  - Consulting
  - Corporate
  - Association management

Presentation Overview

- **Federal and State Drug Pricing Initiatives**
  - Trump Administration Efforts
    - Brief Overview of 2018 Blueprint to Lower Drug Prices and Subsequent Actions
    - What happened to the proposed rebate rule?
    - Department of Health and Human Services and Food and Drug Administration (HHS/FDA) Safe Importation Action Plan released on August 1
    - International Pricing Index—Anticipated Proposed Rule
    - Price transparency in direct-to-consumer (DTC) advertisement
    - Executive Orders and Actions to Increase Transparency in Health Care Pricing and Prescription Drugs
  - Congressional Action
    - Prescription Drug Pricing Reduction Act of 2019
      - Released by Senate Finance Committee in July 2019

Presentation Overview

- **Federal and State Drug Pricing Initiatives**
  - General state trends
    - As of July 25, 2019: 49 bills enacted
      - Action by 47 states on 271 bills
    - Pharmacy benefit management oversight and gag clause prohibitions
    - Transparency and affordability legislation
    - PBM spread pricing

National Academy for State Health Policy. Legislative Actions to Lower Pharmaceutical Costs. Updated July 25, 2019. https://nashp.org/rx-legislative-tracker-2019/. Accessed August 2, 2019.

Presentation Overview

- **Medicaid, Affordable Care Act (ACA) and Other Health Care Reform Initiatives**
  - Legal actions
    - *Texas v Azar* and the future of the ACA
    - Supreme Court will hear case on risk corridors in October
  - Update on Medicaid waiver activity and existing challenges
  - Alternative payment models
    - Oklahoma
    - Michigan
    - Colorado
  - Medicaid block grants and other potential actions
  - Policy on health reimbursement accounts (HRAs) in June 2019

Presentation Overview

- **Medicare Part D and Medicare Advantage**
  - Key 2020 initiatives
    - CMS announced lower premiums for Medicare Part D
    - Enhancing tools for combating opioid epidemic
    - Supplemental benefits for chronically ill in Medicare Advantage
    - Indications-based pricing
    - Step therapy for Part B/D in Medicare Advantage
    - Restrictions on gag clauses

Presentation Overview

- **Competitive Marketplace: Biosimilars and Generics**
  - Food and Drug Administration (FDA)
    - Biosimilar naming: updated draft guidance
    - Update on actions for transitional biologics, including insulin, that will enter biologic pathway in 2020
  - Other key activities
    - Legislation to ensure access to product samples and of generics and biosimilars to promote competition
    - The battle over biologic monograph development: FDA v United States Pharmacopeia

Federal and State Drug Pricing Initiatives

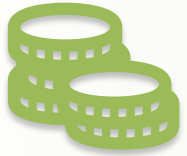
2018 Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

- Released by Administration on May 11, 2018
  - Included a request for information on ways to lower prescription drug costs for Americans
- Contained dozens of suggestions and policy proposals on how stakeholders throughout the health care system can address the issue of high drug costs
  - Medicare Part D formulary flexibility
  - Value-based contracting
  - Promoting biosimilars and generic adoption in the market
  - Rebate reform and other safe harbor changes

Pillars of the Blueprint

Increased market competition

Better Negotiation



Incentives for Lower List Prices

Lower Out-of-Pocket Costs

Trump Administration Efforts to Lower Drug Prices: Proposed Rebate Rule--Rescinded

- Proposed rule issued by the Department of Health and Human Services Office of Inspector General in April 2019
  - Sought safe harbor projections for rebates in federal government programs and replace with alternative point of sale discounts and new safe harbor for pharmacy benefit management company services
  - Criticism included
    - Increased premium cost for Medicare beneficiaries
    - Inclusion of Medicaid management care rebates
    - Did not specifically include rebates in commercial contracts
  - Rescinded in July 2019

Trump Administration Efforts to Lower Drug Prices

HHS/FDA Safe Importation Action Plan

Released on August 1, 2019

Pathway 1: States, pharmacists, and wholesalers

- Must submit plan to FDA
- Excludes controlled substances, biologics (including insulin), infused and IV products, inhalants used during surgery, parenterally administrated products and those subject to REMS
  - Plans must detail assurances related to compliance with drug quality, record keeping and product testing with further detail outlined in future notice of proposed rulemaking (NPRM)
  - Must also certify no harm to consumers will result and will result in lower costs

Pathway 2: Manufacturer importation of forfeit products with FDA equivalents in the United States

- Foreign and United States products could have different national drug codes (NDCs)

States with importation laws, including Florida, Vermont, and Maine have taken action in importation

Trump Administration Efforts to Lower Drug Prices: International Pricing Index (IPI) for Medicare Part B covered products

- Advanced notice of proposed rulemaking released in October 2018 and NPRM anticipated soon
- Seeks to benchmark United States drug prices against those in other developed markets, including certain European countries, Canada, Japan, and the United Kingdom
- Proposed as a 5-year demonstration model (2019-2023) that will include approximately 50% of the United States
- Prices in the United States would be based on 126% of the average price in other countries plus an add on for hospital and doctor fees
  - Projected to decrease costs by 30% when fully implemented

HHS Press release: What You Need to Know about Cutting Down on Foreign Freeloading. October 25, 2018.

Trump Administration Efforts to Lower Drug Prices

Transparency in Direct-to-Consumer Advertising

HHS Rule Finalized in May 2019; Federal judge invalidated in July 2019

- Would require manufacturers to disclose wholesale acquisition cost or list price of a product with a cost of $35 or more
- Challenged by pharmaceutical companies in court on First Amendment Free speech grounds
- Federal district court judge found that HHS does not have regulatory authority to compel companies to disclose prices
  - Did not rule on First Amendment provisions
- When proposed rule was released, PhRMA released voluntary guidelines for DTC price releases
  - Some companies continue to release pricing in advertisements
- Critics found that price disclosures not always reliable because consumers covered by public and private insurance do not pay list price

Heath, S. Judge rules against HHS Drug Advertising Price Transparency Rule. July 10, 2019. https://patientengagementhit.com/news/judge-rules-against-hhs-drug-advertising-price-transparency-rule. Accessed August 1, 2019.

Trump Administration Efforts to Lower Drug Prices: Executive Orders on Drug and Pricing Transparency

- In July, President signaled that he may release an executive order to lower prices on all branded products used by Medicare and other government programs unless Congress acts
  - Could be modeled after Department of Defense contract pricing
- On June 24, President released an executive order that would require public disclosures of prices by insurance companies, pharmaceutical industry, and hospitals
  - Included in NPRM for outpatient hospital systems with public comment period until September 29, 2019

Erman, M; O'Donnell C. Exclusive: White House preparing order that would cut drug prices for Medicare: sources. Reuters: July 25, 2019. https://www.reuters.com/article/us-usa-drugpricing-exclusive/exclusive-white-house-preparing-order-that-would-cut-drug-prices-for-medicare-sources-idUSKCN1UJ354. Accessed August 1, 2019.

Heath S. CMS Proposes Updates, Pitches Price Transparency Rules. July 29, 2019. https://revcycleintelligence.com/news/cms-proposes-updates-for-opps-pitches-price-transparency-rules. Accessed August 1, 2019.

Congressional Action: Prescription Drug Pricing Reduction Act of 2019

- Mark-up released by Senate Finance Committee July 2019
- Comprehensive legislation to consider changes in drug pricing for Medicare and Medicaid
- Full summary available at https://www.finance.senate.gov
- House Ways and Means and Energy and Commerce Committees also working on bills

Prescription Drug Pricing Reduction Act of 2019: Medicare Part D

- Restructures Part D beginning in 2022 to limit enrollee cost sharing in the initial coverage limit and coverage gap
  - Total out-of-pocket spending capped at $3,100
- Significantly restructures coverage gap (donut hole) and catastrophic coverage
  - Provides incentives to use lower cost medications for both the patient and plans
    - $0 cost sharing for biosimilars
    - Shifts primary responsibility for catastrophic coverage from federal government to plans and brand name manufacturers
      - Eliminates current manufacturer discount in coverage gap

Prescription Drug Pricing Reduction Act of 2019: Medicare Part D Reinsurance Proposed Restructuring by 2024

Government (Current law 80%)	**Part D plans (Current law 15%) and Brand Name Manufacturers (Current law 0%)**
20% Brand drugs 40% Generic Drugs	60% Plan responsibility for brand and generic drugs 20% Brand manufacturer

Beneficiary 5% catastrophic phase cost sharing eliminated by 2022

Prescription Drug Pricing Reduction Act of 2019: Medicare Part D PBM Reporting and Direct and Indirect Renumeration (DIR)

- Would require HHS to publicly disclose aggregate price concessions including rebates and discounts based on the aggregate discount that the PBM pays retail and mail order pharmacies
  - Does not require disclosure of specific contract terms
  - Requires Part D plans to report to pharmacies any sale adjustments for price concessions at the point of sale
  - Part D plans must included actual and projected DIR fees in Part D bids
  - Beginning in 2020, requires Part D plans to report DIR fees, discounts, chargebacks, and rebates to CMS within 6 months after the close of the plan year
    - HHS must provide an independent third-party audit of DIR fees and publicly report discrepancies

Prescription Drug Pricing Reduction Act of 2019: Medicare Part D Efforts to Control Price Increases and Improve Transparency

- Would establish a mandatory Part D rebate if a manufacturer increases list price for a Part D brand or biologic product above inflation
- Rebates provided to Medicare every 6 months
- Rebate is equal to the quantity of each drug covered during he rebated period and the amount by which the actually average daily list price exceed the inflation-adjusted list price
- Beginning in 2022, would require plans to justify price increases for drugs and biologics as measured by wholesale acquisition cost
  - HHS Secretary identifies need for price justification and notifies manufacturer within 60 days and then manufacturer has 180 days to respond

Prescription Drug Pricing Reduction Act of 2019: Other Medicare Part D Provisions

- Would require Part D to provide a real-time benefit tool as adopted by CMS to enable transmission of formulary information
  - Would enable physicians to receive credit for using the tool under the Merit-based Incentive Payment System
- Would allow Part D plans to use fee-for-service claims data for Part D coverage determinations beginning in 2021

Prescription Drug Pricing Reduction Act of 2019: Medicaid

- Would require enhancements to Medicaid Pharmacy & Therapeutics Committees in states using a formulary system
  - Must include physicians and pharmacists and other individuals appointed by the governor
    - At least one practicing pharmacist and one physician must be free of manufacturer, Medicaid plan, and PBM conflicts and must have expertise in at least one Medicaid-specific beneficiary population
  - Must include a publicly accessible conflict of interest policy that requires committee member disclosure and recusal processes
- Average manufacturer price (AMP) initiatives
  - Exclude authorized generics from AMP calculation for Medicaid rebate program
  - Increases the maximum rebate amount to 125% of converge drugs AMP for the periods beginning October 1, 2022
    - Manufacturer AMP increases beyond inflation would be subject to all rebate obligations if there was no cap

Prescription Drug Pricing Reduction Act of 2019: Medicaid Spread Pricing Prohibitions

- Require PBMs to provide pass-through pricing
- Limits pharmacy management services to be limited to ingredient cost and processional dispending fee not less than professional dispensing fee that state plan or waiver would pay and must be pass through to the pharmacy in its entirety
- PBM administrative feeds would be limited to “reasonable administrative fee”
- Prohibits spread pricing for purposes of federal matching
- Mandates a report to Congress examining specialty drug coverage and Medicaid reimbursement

Prescription Drug Pricing Reduction Act of 2019: Risk-Sharing Value-Based Arrangements

- Would apply to curative and gene therapies
- Allows for the use of installment-based payments with state payments of equal installments at equal intervals
- HHS must provide a report to Congress assessing the impact within 5 years assessing the impact on enrollees, federal and state spending, and pricing

Prescription Drug Pricing Reduction Act of 2019: Medicare Part B

ASP Calculation

- Expands average sales price (ASP) reporting provisions to manufacturers that do not have a Medicaid drug rebate agreement
- Requires manufacturers to pay Medicare Part B rebates if price increases exceed consumer price index for urban consumers
- Beginning in July 2021, would require manufacturers to exclude the value of coupons from the calculation of ASP because if the value of coupons is high, ASP for purposes of Medicare Part B payments could be higher

Payment Changes

- Effective January 2019, establishes a wholesale acquisition cost (WAC) plus 3% for Medicare Part B drugs and biologics that do not have an ASP in the first 2 quarters of availability
- Biosimilars would be paid at the lesser of WAC plus 3% or ASP plus 6% of the reference product beginning in July 2020
- Changes biosimilar reimbursement to ASP plus 8% for a five year period beginning January 2020
- Maximum add-on for physician administration would be capped at $1,000
- Would pay for administration of drugs and biologics at the physician fee schedule rate

2019 State Trends in Drug Pricing and Transparency: Enacted or Vetoed by Governors

Gag Clause Prohibitions	PBM Spread Pricing and Other Reimbursement Issues	PBM Registration and Oversight
AL ME MN NE NM (plus adequate pharmacy reimbursement) NV (plus oversight of rebates) SC	AR (plus appeals for pharmacies) LA (pharmacist may decline prescription if reimbursement less than acquisition price MT—vetoed by governor NE SD TN	AL DE (plus MAC pricing provisions) LA MN (plus rebate price information disclosure and MAC pricing) SC UT (PBM fiduciary and reporting)

National Academy for State Health Policy. Legislative Actions to Lower Pharmaceutical Costs. Updated July 25, 2019. https://nashp.org/rx-legislative-tracker-2019/. Accessed August 2, 2019.

2019 State Trends in Drug Pricing and Transparency: Ohio

- Passed comprehensive legislation to regulate and evaluate PBMs and state purchasing of prescription drugs
  - Medicaid director will select a third party administrator and will identify a single rate to PBMs
  - Must ensure appropriate cost sharing
  - Creates a Prescription Drug Transparency and Affordability Advisory Council within the Department of Administrative Services that will provide report to the General Assembly and Governor within 6 months that evaluates the following
    - Drug price transparency
    - New payment models
    - Improving efficiency across health systems
    - Leverage state purchasing power and measures to improve outcomes to improve purchasing
    - Maximizing federal, state, and local resources to lower drug prices

National Academy for State Health Policy. Legislative Actions to Lower Pharmaceutical Costs. Updated July 25, 2019. https://nashp.org/rx-legislative-tracker-2019/. Accessed August 2, 2019.

California Drug Pricing Transparency Law

- On August 1, 2019, federal judge allows pharmaceutical industry to move forward with lawsuit against CA statute that requires advance notice to the state on drug price increases
  - Lawsuit can proceed on First Amendment Issues and violations of interstate commerce clause

Source: Kaiser Health News. August 2, 2019. https://khn.org/. Accessed August 2, 2019.

State Activity on Utilization Management

State Medicaid Managed Care: Proposals include those which look at eligibility for state Medicaid and/or work requirements; carving in or carving out pharmacy benefits in the state Medicaid managed care program; implementing a standard process for prior authorizations; and proposals which look at Medicaid formularies

Formulary Management: Several states are looking at proposals which prohibit formulary changes during a plan year or require notice to prescribers in advance of changes

Prior Auth/Step Therapy: A majority of states in session have at least one bill looking into prior authorization including looking at e-PA, standard formats for PA, and setting timeframes for responses; another proposal looks to make step therapy and PA protocols readily accessible online for prescribers

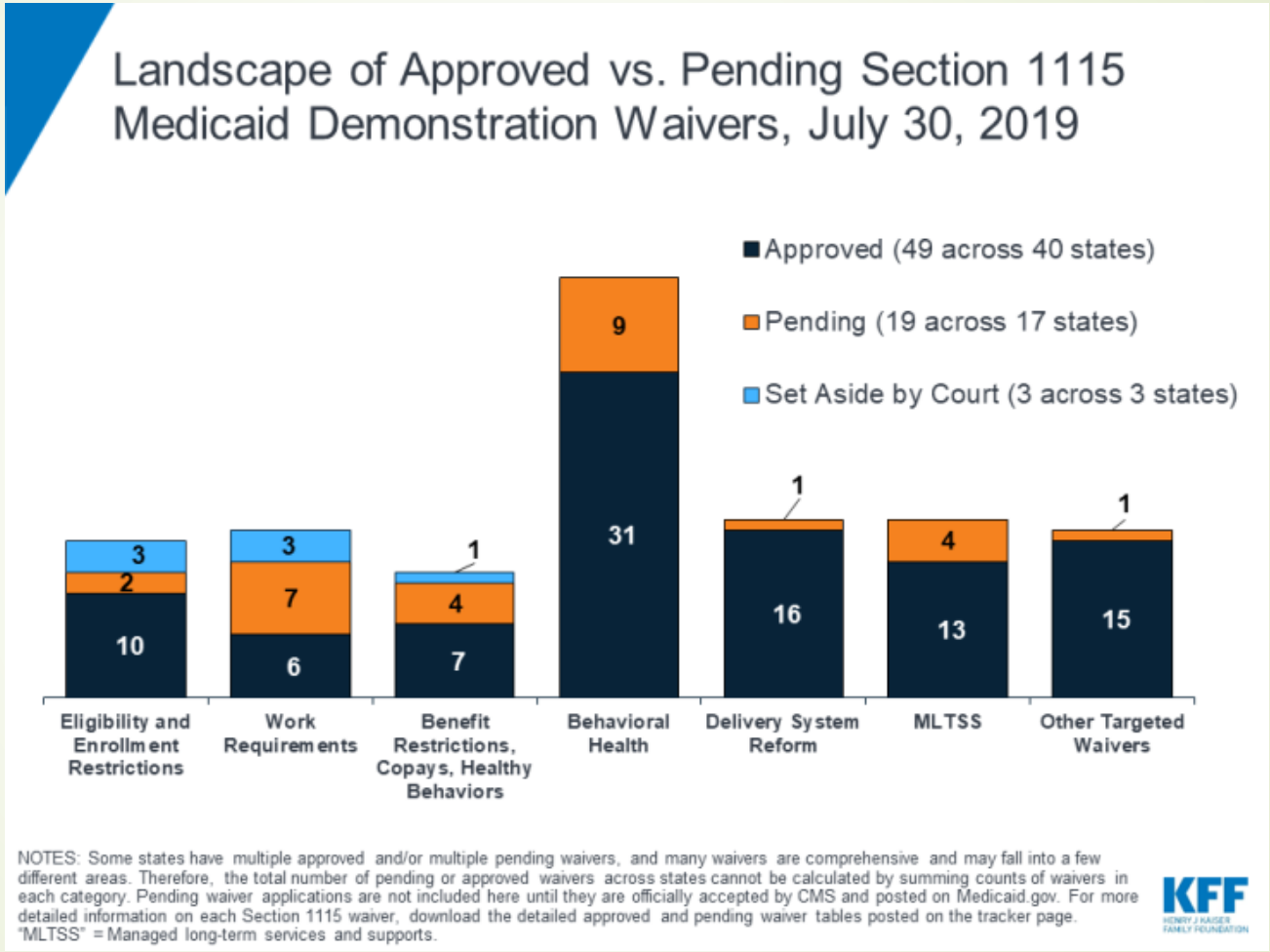
Medicaid, Affordable Care Act (ACA) and Other Health Care Reform Initiatives

Texas v. Azar Challenges Constitutionality of Entire ACA

- Initially filed by 20 Republican state attends general and governors and 2 individuals claiming that when Congress invalidated the individual mandate in a 2017 law, the ACA is no longer enforceable
  - Supreme Court previously held that the individual mandate is key to constitutionality of the ACA
  - In May 2019, 17 Democratic attorneys general intervened to defend the ACA in its entirety
  - In June 2018, Department of Justice declined to define the constitutionality of the mandate and requested that major portions of ACA be stricken, including preexisting condition coverage
- In December 2018, a federal judge in the Northern District of Texas found that the entire ACA is invalid
  - DOJ and Democratic attorneys general appealed in January 2019
  - Oral arguments heard in July 2019 and Supreme Court could hear case

Source: Zhou, L. The latest legal challenge to the Affordable Care Act, explained. Vox.com: July 10, 2019. https://www.vox.com/policy-and-politics/2019/7/9/20686224/affordable-care-act-constitutional-lawsuit-fifth-circuit-court-texas-district-court. Accessed August 2, 2019.

Update and Trends in Medicaid Waivers



Source: Medicaid Waiver Tracker: Approved and Pending Medicaid Waivers by State. KFF: July 30,2019. https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/. Accessed August 2, 2019.

Medicaid Alternative Payment Models

- Colorado, Michigan, and Oklahoma's state plan amendments allow for Medicaid alternative payment models (APMs) using outcomes-based contracts for pharmaceuticals
- Performance contracts allow for payment based on pre-established outcomes and measurement
  - Payments for successful interventions paid as a supplemental rebate by manufacturer
  - Sample contract is available at the State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)

    https://centerforevidencebasedpolicy.org/our-approach/smart-d/
- Information from the National Academy for State Health Policy suggests that APMs might provide some benefit but prescription drug prices remain a barrier and contracts are time-consuming and difficult to implement
- Colorado expected to produce one-year data results soon

Source: Reck J. A New State Tool to Manage Drug Costs: Experts Share Insights into Outcome-Based Contracts for Medicaid Pharmacy Claims. NASHP: May 27, 2019. https://nashp.org/a-new-state-tool-to-manage-drug-costs-experts-share-insights-into-outcome-based-contracts-for-medicaid-pharmacy-claims/. Accessed August 2, 2019.

Are Medicaid Block Grants Coming?

- Proposal included in the President's 2020 budget plan
  - Not approved by Congress and unlikely to be approved given Democratic-controlled House
- Centers for Medicare and Medicaid Services has sought ways to use waiver program for states to use block grants
  - Proposal sent to Office of Management and Budget in June
  - Trump Administration in discussions with states, such as Alaska to use the block grant process
  - Tennessee, Utah, and Texas have all considered block grants in legislation or study
- Use of waiver authority for block grants may prove challenging because of legal interpretations related to whether they meet the definition of "furnishing medical assistance" and recent HHS defeats on whether work requirements constitute health care may also be a barrier

Source: Sachs R. Huberfeld N. The Problematic Law and Policy of Block Grants. Health Affairs Blog: July 24, 2019. https://www.healthaffairs.org/do/10.1377/hblog20190722.62519/full/. Accessed August 2, 2019.

Executive Order on Health Reimbursement Accounts, June 2019

- Joint policy by HHS, Labor Department, and Treasury Department to allow employers to offer health reimbursement accounts for individuals to purchase in the market beginning in January 2020
- Designed to help more than 2 million uninsured individuals receive access to health insurance in the short term

Source: U.S. Departments of Health and Human Services, Labor, and The Treasury Expand Access to Quality, Affordable Health Coverage Through Health Reimbursement Arrangements. HHS Press Office: https://www.hhs.gov/about/news/2019/06/13/hhs-labor-treasury-expand-access-quality-affordable-health-coverage.html. Accessed August 2, 2019.

Medicare Part D and Medicare Advantage in 2020

CMS Announces Lower Medicare Part D Premiums and Subsidies for 2020 and Increased Transparency for Beneficiaries

- Premiums will average $30 per month in 2020, part of a 3-year reduction in premiums and subsidies will also decrease by $6 billion
- CMS also has noted ways to that has taken other effort to increase transparency to beneficiaries, including prohibiting gag clauses and requiring explanation of benefits to include information on therapeutic alternatives that may lower costs

Source: Trump Administration Drives Down Costs for Seniors. CMS.gov Newsroom: July 3e0, 2019. https://www.cms.gov/newsroom/press-releases/trump-administration-drives-down-drug-costs-seniors. Accessed August 2, 2019.

Medicare Part D: Enhancing Opioid Management Tools

- Encouraging access to medication assisted treatment for addiction at lower cost sharing levels and reminding plans that substance abuse treatment may be a disability and must cover these agents
- Implementing additional benefits under Medicare Advantage that allow beneficiaries to receive cost reductions for pain management that does not include use of opioids or opioid potentiator agents and other integrated therapies at lower cost
- Testing star ratings that measure plan management associated with use of high dose opioids and concurrent use of opioids and opioid potentiator agents, such as benzodiazepines

Source: 2020 Medicare Advantage and Medicare Part D rate Announcement and Final Call Letter Fact Sheet. CMS Media Relations: April 1, 2019. https://www.cms.gov/newsroom/fact-sheets/2020-medicare-advantage-and-part-d-rate-announcement-and-final-call-letter-fact-sheet Accessed August 2, 2019.

Medicare Advantage Supplemental Benefits for Chronically Ill Beneficiaries

- Implements a provision of a law enacted in 2018 that modifies that requirement that Medicare Advantage Plans offer "primarily health related" supplemental benefits to allow provision of meals, transportation services and other home-based services on a limited basis to potentially help improve the health of chronically ill Medicare beneficiaries
  - May help reduce the burden on some Medicaid departments that often cover benefits for some indigent Medicare beneficiaries

Source: 2020 Medicare Advantage and Medicare Part D rate Announcement and Final Call Letter Fact Sheet. CMS Media Relations: April 1, 2019. https://www.cms.gov/newsroom/fact-sheets/2020-medicare-advantage-and-part-d-rate-announcement-and-final-call-letter-fact-sheet Accessed August 2, 2019.

Medicare Part D Formulary Management and Plan Administration for 2020

- Allows Medicare Advantage to have limited authority to use step therapy and prior authorization to have flexibility to cover certain medications under Part B or Part D
  - Medicare Advantage plans generally must follow Medicare Part B requirements, this provision waives this authority to cover some products, such as biosimilars, under Medicare Part D
- Allows for formulary indications-based pricing and negotiation
- Did not implement a proposed provision to prohibit plans from placing generics on a brand tier and requiring plans to place generics on generic tiers
- Implements a statutory requirement that Part D plans do not prohibit pharmacists and pharmacies from discussing lower cost alternatives with patients at the point of sale

Source: 2020 Medicare Advantage and Medicare Part D rate Announcement and Final Call Letter Fact Sheet. CMS Media Relations: April 1, 2019. https://www.cms.gov/newsroom/fact-sheets/2020-medicare-advantage-and-part-d-rate-announcement-and-final-call-letter-fact-sheet Accessed August 2, 2019.

Competitive Marketplace: Biosimilars and Generics

FDA Updated Draft Naming Guidance for Biological Products

- March 8, 2019 updated guidance indicates that FDA will not retroactively name legacy biologic products with a random four letter hyphenated suffix as described in a January 2017 final guidance on naming
  - FDA indicated that it will include a hyphenated suffix with all new innovator biologic products and biosimilars moving forward
  - Status of insulin and other "grandfathered" biologic product names in question

Source: Food and Drug Administration: Nonproprietary Naming of Biologics Products: Update; Draft Guidance for Industry. Federal Register: March 8, 2019. https://www.govinfo.gov/content/pkg/FR-2019-03-08/pdf/2019-04242.pdf. Accessed August 2, 2019.

Status of Transitional Products that Will Enter the Biologics Pathway in March 2020

- Transitional products include growth hormones and insulins
- These are biologic products approved under the *Public Health Service Act* and integration into the biologics pathway was delayed until March 2020 by the *Biologics Price Competition and Innovation Act of 2009*
- Beginning in March 2020, these agents will be deemed to be included in the biologics pathway and thus listed in the FDA “Purple Book” rather than the ”Orange Book”
- FDA announced that all agents will be incorporated as originator biologics and may later be subject to biosimilar competition
- Questions persist on how this change will impact pricing and competition, particularly for insulins

Source: Statement from FDA Commission Scott Gottlieb, MD, on new actions advancing the agency’s biosimilars policy framework. FDA Statement: December 11, 2018. https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-actions-advancing-agencys-biosimilars-policy. Accessed August 2, 2019.

Other Key Actions on Generics and Biosimilars

- Creating and Restoring Equal Access to Equivalent Samples Act (CREATES Act)
  - S. 340 introduced in February by Sen. Leahy (D-VT) and H.R. 965 introduced by Rep. Cecilline (D-RI)
  - To create competition in the market for biological products by facilitating the entry of lower-cost generic and biosimilar versions
  - To help developers of generic drugs and biosimilar biological products obtain quantities of the reference drug or biological product to support their application
  - Creates a civil cause of action for failure to provide sufficient quantities of a covered product
  - Director of the FDA Center for Drug Evaluation and Research testified that some manufacturers have used REMS and internal distribution restrictions as a reason not to sell product samples to developers
- Recent draft legislation from Senate Health, Education, Labor and Pensions included a provision to remove the United States Pharmacopeia as the standard-setting organization for biologic monographs
  - Innovator companies and FDA have expressed support while pharmacy groups and others expressed concern
  - There is a question on whether standardization in monographs help or hurt access to biologics and the impact moving forward

Source: Welch AR. The Debate on Biologic Standards Heats Up. Biosimilar Development: July 11, 2019. https://www.biosimilardevelopment.com/doc/the-debate-on-standards-in-biologics-development-heats-up-0001. Accessed August 2 2019.

Thank You!

Contact information
Maryjo.carden@gmail.com
202-744-2773