Biosimilar Reimbursement

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FDA Commissioner Gottlieb's Recent Comments on Biosimilars Illustrates Agency's Commitment

FDA's Role in Ensuring a Robust Biosimilar Marketplace

"FDA is invested in making sure that the new biosimilar pathway works, and that we can help facilitate a robust market for these products. So, we take note when we see market practices that can reduce the incentive for sponsors to invest in the development of biosimilars in the first place."

Opportunity for Biosimilars to Drive Significant Savings

"Generic drug competition provided an estimated $1.46 trillion in savings to the U.S. health care system from 2005-2015"

"At the same time, biosimilars not only present opportunities for significant cost savings, they can dramatically expand patient access to therapies."

Source: Commissioner Scott Gottlieb, MD America's Health Insurance Plans' (AHIP) National Health Policy Conference "Capturing the Benefits of Competition for Patients" March 7, 2018. https://www.fda.gov/NewsEvents/Speeches/ucm590833.htm

Trump Administration Officials Recognize the Role of Biosimilars in Lowering Drug Prices

"Increased competition is one of the key strategies President Trump outlined in the American Patients First blueprint to bring down prescription drug prices. Biologics represent an increasingly common treatment option and make up 40 percent of American drug spending, competition from biosimilars is desperately needed. The challenges to building a market for biosimilars are even more complex than others in the drug space. But the FDA's announcement demonstrates the Trump Administration is unafraid to take comprehensive action to deliver more competition, more choices, and lower prices for American patients." – Secretary Alex Azar, July 2018

"We also proposed some ideas about making generics more available or biosimilars, so there's a lot of things that we're trying to do within the Part D program to hopefully create more competition and hopefully lower drug prices for our beneficiaries." – CMS Administrator, Seema Verma, December 2017

Existing Payer Landscape is a Key Challenge for Biosimilar Competition; FDA is Speaking Out

Commissioner Gottlieb continues to come out strongly against the existing landscape that is challenging for biosimilar penetration

"Current rebating and contracting practices -- combined with the increased consolidation that we're seeing in many segments of the drug supply chain -- has produced some misaligned incentives."

"…we're working closely with Secretary Alex Azar on crafting policy options that can improve competition, access, and the chance for patients to benefit from safe, effective, and lower cost biosimilar alternatives."

"…the crux of these pay for delay schemes are also taking root in the biologics market. Except this time, in these biosimilar pacts, the tactics are dressed in the guise of rebates and contracting provisions between manufacturers and PBMs that discourage biosimilar market entry."

Source: Commissioner Scott Gottlieb, MD America's Health Insurance Plans' (AHIP) National Health Policy Conference "Capturing the Benefits of Competition for Patients" March 7, 2018. https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm

What Will Drive the Market?

Small molecule generics had enablers and catalysts in retail pharmacy and A/B substitution

What or Who will be the enablers of the biosimilar market?

- Payer Push via Formulary Changes?
- Patient Incentives and Buy-In?
- Interchange-ability and Substitution?

Payer Activity on Biosimilars:

Leading PBMs have all included biosimilars on their national formularies – but have not eliminated all reference products to fully drive biosimilar utilization

Interchangeability and Reimbursement…Key Questions Remain

Part B

CMS has not indicated how they will treat interchangeable biosimilars from a coding or payment perspective under Part B

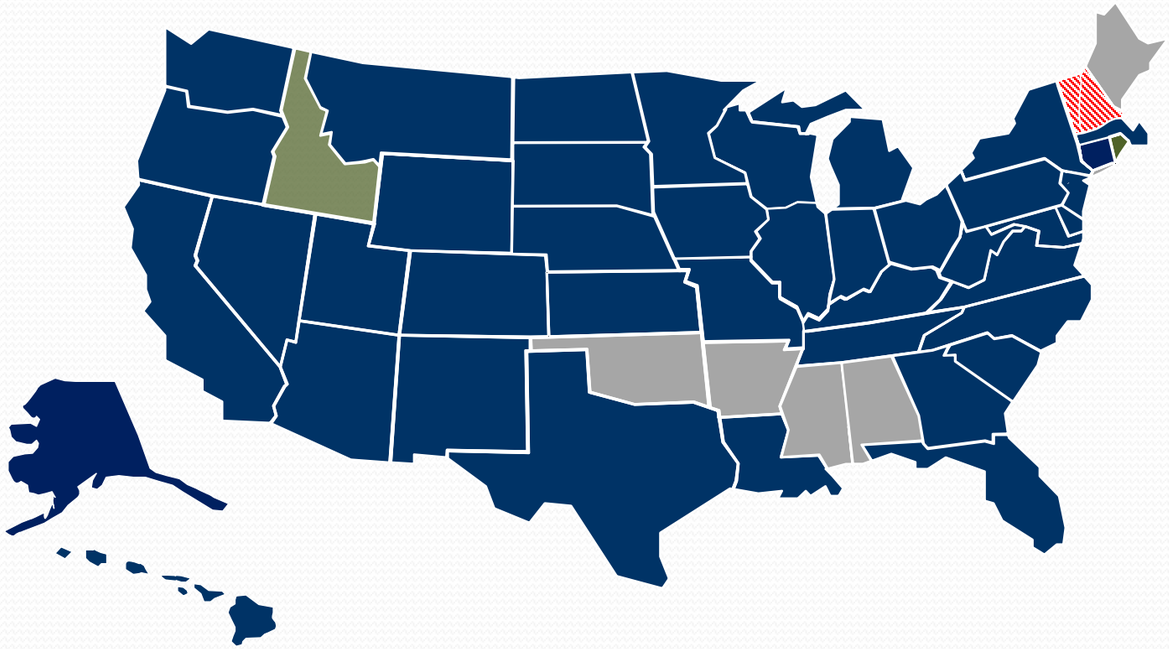
With limited authority by the Medicare Administrative Contractors – the role of IC in Part B remains unclear

Part D

CMS has not clearly outlined how the introduction of interchangeable products will be handled for Part D plans

Mid year formulary changes and changes to reference products via utilization management are potential areas of focus

Interchangeability and Automatic Substitution



Legislation enacted

Board of Pharmacy regulation and legislation enacted

Legislation is active and progressing (2)

Legislation Overview

- Legislation is required to update state pharmacy laws to allow for the automatic substitution of interchangeable biosimilars
- Physician notification requirements is the area with the most variance across states

"We're taking a hard look at how we determine interchangeability so that we can make determinations that biosimilars can be used interchangeably with the brand of drugs." - Commissioner Gottlieb, CNBC interview, March 2018