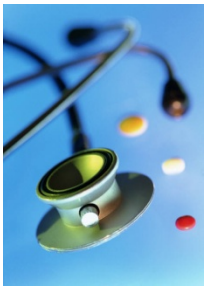
Biosimilars Approved!



*A **biosimilar** (also known as follow-on biologic or subsequent entry biologic) is a biologic medical product which is copy of an original product that is manufactured by a different company.*

On Friday, March 6, 2015, the U.S. Food and Drug Administration, using the authority provided in the Affordable Care Act, approved the first biosimilar product in the United States. Since the introduction of biosimilar products to the market could yield measurable cost savings & greater access to therapeutic treatment for chronic conditions, the following information may be relevant to the patients and populations you serve.

Biosimilars are a type of biological product that is licensed (approved) by the FDA because they are highly similar to an already FDA-approved biological product, known as the biological reference product (reference product) and have been shown to have no clinically meaningful differences from the reference product. Minor differences in clinically inactive components are allowed. But there must be no clinically meaningful differences between the biosimilar and the reference product it was compared to in terms of the safety, purity, and potency of the product

Health care professionals can prescribe biosimilars just as they would prescribe other medications - by writing the proprietary name or nonproprietary name of the biosimilar on the prescription.

A biosimilar can be approved only for those indications and condition(s) of use previously approved for the reference product, but a biosimilar can be approved for fewer than all the indications and condition(s) of use approved for the reference product. Therefore, it is important for health care professionals to review the product labeling (prescribing information) to determine which conditions of use and routes of administration the biosimilar was approved for.

The FDA has developed a website about biosimilars specifically for providers, which you are encouraged to share broadly.

Shoshana Shapiro
Federal Office of Rural Health Policy
U.S. Department of Health and Human Services
SShapiro-Baruch@hrsa.gov
301-443-4518