REFORMING MEDICARE

Option: Allow Faster Market Access to Generic Versions of Biologic Drugs

Expensive biologic drugs (medications made from living organisms) are used to treat conditions like cancer, rheumatoid arthritis and multiple sclerosis. These types of drugs currently provide manufacturers with 12 years of exclusive market access before generic versions (known as biosimilars) can enter the market. This proposal would reduce the exclusivity period to seven years. Because generic medications have a lower retail cost, this would save money for Medicare and its beneficiaries.

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Biologics are drugs used to treat many complex and chronic diseases—such as cancer, multiple sclerosis, and rheumatoid arthritis—that often affect older populations. The U.S. Food and Drug Administration was only recently granted the authority to approve generic versions of biologic drugs as part of the new health law. There are currently no generic versions of biologic drugs on the market in the United States. In developing generic versions of the drug, one important issue is how long the brand-name biologic drug company is allowed to sell its product without any competition, known as market exclusivity. During the market exclusivity period, no competing generic drug can enter the market. Under the new health law, brand-name biologic drug manufacturers have 12 years of market exclusivity.

Argument for:

Generic versions of biologics—commonly known as biosimilars—will give consumers access to more affordable biologics. Biologics are some of the fastest-growing, and higher-priced, drugs in the market. A brand-name biologic drug can cost as much as $1.5 million annually. A generic version of that drug would be considerably less expensive.

Many support a reduction of the exclusivity period to no more than seven years. (Nonbiologic brand name drugs today generally have only a five-year exclusivity period). Reducing the market exclusivity period to seven years would allow biosimilars to enter the market much sooner, and the increased competition would likely lead to considerable savings for consumers. It would also mean savings for federal programs like Medicare and Medicaid (a federal-state program that provides assistance to low-income people). Allowing seven years of market exclusivity is more than enough time to give manufacturers a monopoly to recoup their development costs.
Argument against:

Drug companies have raised concerns that reducing the market exclusivity period could slow the development of new biologic drugs. Biologics are made from living organisms and are typically very expensive to test and develop. Shortening the period when the brand manufacturer is the only seller of the biologic will reduce the number of years that the manufacturer is able to make money from the product to recover its research and development costs. The concern is that drug companies would have less incentive to spend the money needed to research and develop new biologics if they do not believe they can recoup their costs. This could reduce the incentive to develop biologics that could be used to treat many of the diseases faced by Medicare enrollees.

**Avalere Health, LLC** is a leading advisory company focused on health care business strategy and public policy.