

Inside Drug Pricing

Sen. Rosen Unveils Bill To Boost Nonprofit Pharmaceutical Sector

By Gabrielle Wanneh / June 30, 2021 at 1:54 PM

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Sen. Jacky Rosen (D-NV) introduced legislation designed to help nonprofit pharmaceutical companies by making it easier for them to acquire nonprofit tax-exempt status, providing them grants and low-interest loans, and waiving FDA user fees.

“Whether it’s access to cancer-treating medication or insulin pumps, my legislation would help reduce costs and improve the domestic supply chain by providing support to nonprofit pharmaceutical and medical device manufacturers in an effort to bring more medications and devices to market at a reasonable price, while creating jobs right here at home,” [Rosen said in an announcement Friday \(June 25\)](#).

Nonprofit drug companies historically have provided affordable drugs in low- and middle-income countries, but as Americans increasingly can’t afford their medications and hospitals run out of common generic injectables, a nonprofit drug sector is forming in the United States.

But nonprofit drug makers say there are barriers to establishing a strong nonprofit drug making sector that Congress should remove. To that end, Rosen’s bill would provide guidance to the Internal Revenue Service (IRS) on the qualifications drug makers must meet to be classified as nonprofits. The criteria [are designed to accommodate the wide variety of models](#) employed by the nonprofit pharma sector.

Additionally, the bill would authorize a program to make available \$5 million in cooperative agreements to help nonprofits introduce eligible drugs and devices to the market within five years. The bill also would provide revolving loans of up to \$5 million each.

For nonprofit drug companies that don’t participate in the cooperative agreement or loan programs, the bill also would waive FDA user fees.

Medicines360, a nonprofit drug maker focused on women’s health, praised the bill.

“As a nonprofit, Medicines360 has long worked to remove cost as a barrier to health by developing and providing quality, affordable women’s health products,” Medicines360 Executive Vice President of Policy and Strategic Market Access Autumn Ehnou said. “But, like other nonprofit pharmaceutical organizations, we’ve faced challenges to achieving our mission in the current policy landscape, which largely benefits for-profit companies.”

Medicines360 relies on a research-based status for its tax exemption despite developing and selling its own product, Liletta, a drug that prevents pregnancy for up to six years and is available at a low cost to public health clinics in the 340B drug discount program. The bill would make the process of acquiring tax-exempt status more straightforward, Ehnou said.

It's unclear whether the bill will make it into the reconciliation package that Democrats are preparing or whether it will gain traction as a stand-alone bill. As the bill's sole sponsor, Rosen had mentioned the bill briefly during a previous hearing for the Senate Homeland Security & Governmental Affairs Committee.

"We need multiple solutions for lowering drug prices in the U.S. healthcare system, drug pricing is a major issue in Congress right now, and I think we have a unique way of adding to those goals while increasing real access to medicines," Ehnou said. -- *Gabrielle Wanneh* (gwanneh@iwppnews.com)

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