



**PRICING REQUIREMENTS¹ under
CIRM Regulations effective September 6, 2018**

Participation in Statewide Prescription Drug Discount Program for Low-Income, Uninsured Californians:

A Commercializing Entity is required to abide by any statewide prescription drug discount program in effect at the time of commercialization. As of the date of this writing, there is NO statewide prescription drug discount program in effect.

INSTITUTIONS USING PUBLIC FUNDS:

CIRM's regulation also requires the Commercializing Entity to sell the drug to publicly-funded purchasers at one of the benchmarks described in CalRx (even though the program itself is defunct) or a successor statewide prescription drug discount program. The CalRx benchmarks are:

- (1) Eighty-five percent of the average manufacturer price for a drug, as published by the Centers for Medicare and Medicaid Services.
- (2) The lowest price provided to any nonpublic entity in the state by a manufacturer to the extent that the Medicaid best price exists under federal law.
- (3) The Medicaid best price, to the extent that this price exists under Federal law.

LIMITATIONS:

The pricing requirements do not apply to products sold outside of California.

¹ This primer is intended to introduce the reader to concepts contained in CIRM's IP revenue sharing regulations. It is a summary only, and does not override or replace the regulations and should not be relied upon as legal advice regarding the operation of the regulations. Please review CIRM regulations and contact CIRM if you have questions about our rules or their application.