



PRICING REQUIREMENTS¹

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

A CIRM awardee, an exclusive licensee of a CIRM awardee, or a collaborator* that commercializes a drug arising from a CIRM-funded invention or technology (including data) is required to abide by any statewide prescription drug discount program in effect at the time of commercialization. When CIRM adopted this regulation, the Legislature had created a discount drug program known as CalRX (Health & Safety Code section 130500). However, the program was never funded and has since been repealed. 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 an awardee, exclusive licensee, or collaborator* to sell the drug to publicly-funded purchasers at one of the benchmarks described in CalRx (even though the program itself is defunct). The 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 apply only if the product is self-commercialized by the CIRM awardee or if the product is commercialized by an exclusive licensee (as opposed to a non-exclusive licensee) or a collaborator* and their successors and assigns. Also, the pricing requirements do not apply to products sold outside of California.

*A collaborator is an entity that receives CIRM funding and has an ownership interest in the CIRM-funded invention or technology from which the product arose.

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.

