

**§ 100607. Access Requirements for Products Developed by Grantees.**

(a) A Grantee, a Collaborator or an Exclusive Licensee that is commercializing a Drug, as defined in Title 17, California Code of Regulations, section 100601, subdivision (i), that resulted in whole or in part from CIRM-Funded Research must submit a plan to afford uninsured Californians access to such a Drug.

(b) A Grantee, a Collaborator or an Exclusive Licensee that commercializes a Drug must submit the access plan described in subdivision (a) of this regulation to CIRM no fewer than 90 calendar days prior to the time the Drug is commercialized in California, unless CIRM agrees to shortened time.

(c) The access plan must be consistent with industry standards at the time of commercialization accounting for the size of the market for the Drug and the resources of the Grantee, the Collaborator or its Exclusive Licensee. Grantees, Collaborators and/or their Exclusive Licensees shall have the burden of establishing that the proposed access plan satisfies the requirements of this Section.

(d) The access plan shall be subject to the approval of CIRM after a public hearing conducted by CIRM that provides for receipt of public comment. CIRM may adopt appropriate procedures to protect proprietary information submitted by Grantees, Collaborators and Exclusive Licensees in connection with said public hearing. Approval shall not be unreasonably withheld. Overall, CIRM shall not require that proposed Access plans exceed industry standards for such plans at the time of commercialization in California.

(e) Access plans approved hereunder shall make Grantees, Collaborators and Exclusive Licensees that commercialize a Drug responsible only for providing the Drug itself. Nothing herein shall require the Grantee, Collaborator or Exclusive Licensee to be responsible for any costs of administering the Drug nor for any associate costs of medical procedures or protocols for the Drug therapy, nor for any costs for attendant care.

(f) A Grantee, Collaborator, or an Exclusive Licensee that is commercializing the Drug must provide a Drug, that resulted in whole or in part from CIRM-Funded Research, at a price as provided in the California Discount Prescription Drug Program (commencing with California Health and Safety Code section 130500) (or a successor statewide prescription drug discount program) to eligible Californians under said program.

(g) A Grantee, Collaborator or its Exclusive Licensee that is commercializing the Drug must sell a Drug, that resulted in whole or in part from CIRM-Funded Research, and which is purchased in California with Public Funds (as defined in Title 17, California Code of Regulations, section 100601, subdivision (q)) at any benchmark price described in the California Discount Prescription Drug Program or a successor statewide prescription drug discount program.

(h) This regulation is not intended, and this regulation shall not be construed, to preempt or prevent any other requirement under state or federal law or regulation, or agreement or contract, that would result in selling a Drug at a lower price than provided hereunder.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code.

Reference: Section 125290.30, Health and Safety Code.