§ 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 access to such a Drug to Californians who have no other means to purchase the Drug. As used in this section, "no other means" means Californians who are not covered by a prescription drug benefit provided by any third-party payer (private or public) covering the particular Drug, and whose family incomes are below 300 percent of the federal poverty level. 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.

(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 within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless, within that timeframe, the Grantee, Collaborator or Exclusive Licensee seeks an extension from CIRM. If CIRM grants an extension, the access plan must be submitted no later than 30 business days following final approval of the Drug by the federal Food and Drug Administration.

(c) 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.

(d) 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.

(e) The Independent Citizens Oversight Committee ("ICOC") may waive the requirement in subdivision (a) of this section if the ICOC determines, after a public hearing, that in the absence of the waiver, development and broad delivery of the Drug will be unreasonably hindered or that the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to subdivision (a) of this section. To invoke this waiver provision, a Grantee, Collaborator or Exclusive Licensee must deliver a written request to the Chair of the ICOC within 10 business days following final approval of the Drug by the federal Food and Drug Administration, unless the Chair of the ICOC agrees to an extension. The request must be accompanied by materials describing how development and broad delivery of the Drug will be unreasonably hindered by compliance with subdivision (a) of this section, and/or how the waiver will provide significant benefits that equal or exceed the benefits that would otherwise flow to the state pursuant to subdivision (a) of this section. The request shall be posted on CIRM's website no fewer than ten (10) business days prior to the ICOC's consideration. The ICOC may meet in closed session to review confidential or proprietary material, or other material as allowed by Health and Safety Code section 125290.30, subdivision (d).

(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 (cc)) 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; and Section 125290.40(j), Health and Safety Code.

Reference: Sections 125290.30 and 125290.80, Health and Safety Code.