

1 Amend 17 Cal. Code of Regs. section 100407 to read:

2 **§ 100407. Access Requirements for Products Developed by For-Profit Grantees.**

3 (a) A Grantee (or, by terms of an Exclusive License, its exclusive licensee) must submit  
4 a plan to afford uninsured Californians access to a Drug, as defined in Title 17, California Code  
5 of Regulations, section 100401, subdivision (e), the development of which was in whole or in  
6 part the result of CIRM-funded Research.

7 (1) A Grantee must submit this access plan to CIRM ~~prior to the time the Drug is~~  
8 commercialized.

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9 (2) The access plan must be consistent with industry standards at the time of  
10 commercialization accounting for the size of the market for the Drug and the resources of the  
11 Grantee or its exclusive licensee.

12 (3) ~~The plan shall be subject to the approval of the CIRM after a public hearing and~~  
13 ~~opportunity for public comment is held.~~

Deleted: will review the access plan and may make it available for review by the ICOC and the public

14 (4) The Grantee or its exclusive licensee is responsible only for providing the Drug itself,  
15 not any costs of administering the Drug or other attendant care.

16 (b) A Grantee (or its exclusive licensee) must provide a Drug, the development of which  
17 was in whole or in part the result of CIRM-funded Research, at a price as provided in the  
18 California Discount Prescription Drug Program (commencing with California Health and Safety  
19 Code section 130500) ~~(or if repealed a benchmark price described in the California Discount~~  
20 ~~Prescription Drug Program on the last day it is in effect),~~ or a successor statewide prescription  
21 drug discount program, to eligible Californians under this program.

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1 (c) A Grantee or its exclusive licensee must sell a Drug, the development of which is in  
2 whole or in part the result of CIRM-funded Research, and which is purchased in California with  
3 Public Funds (as defined in Title 17, California Code of Regulations, section 100401,  
4 subdivision (q)) at any benchmark price described in the California Discount Prescription Drug  
5 Program (or if repealed a benchmark price described in the California Discount Prescription  
6 Drug Program on the last day it is in effect) or a successor statewide prescription drug discount  
7 program.

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

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

13 Reference: Section 125290.30, Health and Safety Code.