

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 no fewer than 90 days prior to the
8 time the Drug is commercialized in California, unless the agency agrees to shortened time.

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 CIRM after a public hearing conducted by
13 CIRM that provides for receipt of public comment..

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 a successor statewide prescription drug discount program) to eligible
20 Californians under this program.

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 a successor statewide prescription drug discount program.

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

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

11 Reference: Section 125290.30, Health and Safety Code.