

JAN 17 2020

A BILL FOR AN ACT

RELATING TO MEDICAID.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

1 SECTION 1. Chapter 346, Hawaii Revised Statutes, is
2 amended by adding a new section to part II to be appropriately
3 designated and to read as follows:

4 "§346- Coverage for approved clinical trials. (a)
5 Beginning on January 1, 2021, the State's medicaid managed care
6 and fee-for-service programs shall provide coverage for the
7 routine costs of care of an enrollee participating in an
8 approved clinical trial.

9 (b) Nothing in this section shall be construed to
10 otherwise limit or modify any existing requirements under this
11 chapter or prevent application of any copayment or deductible
12 provisions in a contracted health plan.

13 (c) A contracted health plan that provides coverage
14 required by this section is not, based upon that coverage,
15 liable for any adverse effects of the approved clinical trial.

16 (d) For purposes of this section:

17 "Approved clinical trial" means a trial that is:



- 1 (1) Funded by the National Institutes of Health, Centers
2 for Disease Control and Prevention, Agency for
3 Healthcare Research and Quality, Centers for Medicare
4 and Medicaid Services, United States Department of
5 Defense, or United States Department of Veterans
6 Affairs;
- 7 (2) Supported by a center or cooperative group that is
8 funded by the National Institutes of Health, Centers
9 for Disease Control and Prevention, Agency for
10 Healthcare Research and Quality, Centers for Medicare
11 and Medicaid Services, United States Department of
12 Defense, or United States Department of Veterans
13 Affairs;
- 14 (3) Conducted as an investigational new drug application,
15 an investigational device exemption, or a biologics
16 license application subject to approval by the United
17 States Food and Drug Administration; or
- 18 (4) Exempt by federal law from the requirement to submit
19 an investigational new drug application to the United
20 States Food and Drug Administration.



1 "Routine costs of care" means all medically necessary
2 conventional care, items, or services consistent with the
3 coverage provided by the contracted health plan if typically
4 provided to an enrollee who is not participating in an approved
5 clinical trial. "Routine costs of care" does not include:

6 (1) Drugs or devices that have not been approved by the
7 federal Food and Drug Administration and that are
8 associated with the approved clinical trial;

9 (2) Items or services required solely for the provision of
10 the drug, device, or service being tested in the
11 approved clinical trial;

12 (3) Items or services required solely for the clinically
13 appropriate monitoring of the drug, device, or service
14 being tested in the approved clinical trial;

15 (4) Items or services that are provided solely to satisfy
16 data collection and analysis needs and that are not
17 used in the direct clinical management of the
18 enrollee;

19 (5) Items or services customarily provided by a clinical
20 trial sponsor free of charge to any participant in the
21 approved clinical trial; or



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1 (6) Items or services that are not covered by the
 2 contracted health plan if provided outside of the
 3 approved clinical trial."

4 SECTION 2. New statutory material is underscored.

5 SECTION 3. This Act shall take effect on July 1, 2020;
 6 provided that section 1 shall take effect upon approval of the
 7 Hawaii medicaid state plan by the Centers for Medicare and
 8 Medicaid Services.

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INTRODUCED BY:

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S.B. NO. 2324

Report Title:

Medicaid; Approved Clinical Trials; Routine Costs of Care

Description:

Beginning January 1, 2021, requires contracted health plans under the State's medicaid managed care and fee-for-service programs to cover routine costs of care of enrollees participating in an approved clinical trial.

The summary description of legislation appearing on this page is for informational purposes only and is not legislation or evidence of legislative intent.

