



State of California—Health and Human Services Agency
California Department of Public Health



TOMÁS J. ARAGÓN, MD, DrPH
Director and State Public Health Officer

GAVIN NEWSOM
Governor

**NOTICE OF 15-DAY PUBLIC AVAILABILITY OF PROPOSED CHANGES
DPH-11-023 ADVERSE EVENTS REPORTING
DATE POSTED: March 23, 2021**

PUBLIC PROCEEDINGS

Pursuant to Government Code section 11346.8(c) and Title 1 California Code of Regulations, Section 44, notice is hereby given that the California Department of Public Health (Department) has changed the text for the proposed regulations regarding Adverse Events Reporting, DPH-11-023, and is making the changed text available for public comment prior to adoption, amendment or repeal of the resulting regulations.

In addition to the modified text, the following documents are being added to the rulemaking record:

1. Methodology to Indicate Changes to the Proposed Regulatory Text
2. Supplemental Statement of Reasons
3. A copy of the changed proposed text is enclosed. This notice document, the proposed text, supplemental statement of reasons, and methodology of the changes are available online at the [Office of Regulation's webpage for proposed regulations](https://www.cdph.ca.gov/Programs/OLS/Pages/Proposed-Regulations.aspx) (<https://www.cdph.ca.gov/Programs/OLS/Pages/Proposed-Regulations.aspx>) by clicking the link for [DPH-11-023 Adverse Events Reporting](#).

These documents are also available for inspection upon request at: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, between the hours of 8:00 a.m. to 5:00 p.m.

WRITTEN COMMENT PERIOD

Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by April 6, 2021, which is hereby designated as the close of the written comment period. Comments received after this date may not be considered timely.

Written comments may be submitted as follows:

1. By email: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "**Adverse Events Reporting DPH-11-023**" in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission: (916) 636-6220;
3. By Postal Service: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814; or

CDPH Office of Regulations • 1415 L Street, Suite 500 • Sacramento, CA 95814
(916) 558-1710 • (916) 636-6220 FAX
[Department Website \(www.cdph.ca.gov\)](http://www.cdph.ca.gov)



4. Hand-delivered: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier “**Adverse Events Reporting DPH-11-023**,” author’s name, and mailing address.

To request a copy of this notice, the regulation text, and any of the regulatory documents or an alternate format of these documents be mailed to you, please call (916) 440-7807, or the California Relay Service at 711, or write to the Office of Regulations, 1415 L Street, Suite 500, Sacramento CA 95814, or send an email to regulations@cdph.ca.gov. Upon specific request, these documents will be made available in Braille, large print, or on computer disk.

INQUIRES

Inquiries regarding the subject matter in this notice may be directed to Linda M. Cortez, Office of Regulations, at (916) 440-7807.