

97410 Decisions on Data Applications

(a)

Timelines for Decisions. (1) The Department shall notify applicants in writing of its decision on the data application within 120 days of the complete submission of the data application unless one or more of the following occur: (A) A longer period is agreed to by the applicant; or (B) A Data Release Committee recommendation is required for the application as stated in Section 97402; or (C) The Department requests input from the Data Release Committee for the application under Section 97836(b); or (D) The data request includes data subject to review by the Department of Health Care Services under Section 97408; or (E) The data request includes confidential data, which requires approval from the Committee for the Protection of Human Subjects; or (F) If the Department has good cause to extend time. (2) If there is an extension of time under this section, the Department shall notify the applicant in writing of the extension, including the reason for the extension and the anticipated length of extension. The Department shall send this notice to applicant at least 10 days before the Department is required to issue a decision notice.

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The data request includes data subject to review by the Department of Health Care Services under Section 97408; or

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The data request includes confidential data, which requires approval from the Committee for the Protection of Human Subjects; or

(F)

If the Department has good cause to extend time.

(2)

If there is an extension of time under this section, the Department shall notify the applicant in writing of the extension, including the reason for the extension and the anticipated length of extension. The Department shall send this notice to applicant at

least 10 days before the Department is required to issue a decision notice.

(b)

Decision Notice. (1) If the application is denied, in whole or in part, the Department shall state in the notice the scope of denial and the reasons for denial. (2) If the application is approved, in whole or in part: (A) The Department shall state in the notice the scope of the approval, the price for the data as set by the Department, and how the data will be provided to the applicant; and (B) If a data use agreement is required pursuant to section 97412, the Department shall provide the required data use agreements with the decision notice, and the reason why data use agreements are required.

(1)

If the application is denied, in whole or in part, the Department shall state in the notice the scope of denial and the reasons for denial.

(2)

If the application is approved, in whole or in part: (A) The Department shall state in the notice the scope of the approval, the price for the data as set by the Department, and how the data will be provided to the applicant; and (B) If a data use agreement is required pursuant to section 97412, the Department shall provide the required data use agreements with the decision notice, and the reason why data use agreements are required.

(A)

The Department shall state in the notice the scope of the approval, the price for the data as set by the Department, and how the data will be provided to the applicant; and

(B)

If a data use agreement is required pursuant to section 97412, the Department shall provide the required data use agreements with the decision notice, and the reason why data use

agreements are required.