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Title 22@ Social Security

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Division 5@ Licensing and Certification of Health Facilities, Home Health Agencies, Clinics, and Referral Agencies

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Chapter 1@ General Acute Care Hospitals

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Article 11@ Adverse Event Reporting Requirements

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Section 70973@ Adverse Event Investigation

70973 Adverse Event Investigation

(a)

The hospital shall provide the requisite information, as outlined in section 70972, necessary for the Department to determine if an adverse event is substantiated or unsubstantiated, pursuant to the following process: (1) If the reported adverse event or complaint is determined by the Department to be an ongoing threat of imminent danger of death or serious bodily harm, the hospital shall be subject to an onsite investigation, initiated within 48 hours or two (2) business days of receipt of the report or complaint, whichever is greater. (2) If the Department determines there is no ongoing threat of imminent danger of death or serious bodily harm, the hospital shall be subject to one or both of the following: (A) An onsite inspection. (B) An offsite investigation that includes but is not limited to interviews and records reviews.

(1)

If the reported adverse event or complaint is determined by the Department to be an ongoing threat of imminent danger of death or serious bodily harm, the hospital shall be subject to an onsite investigation, initiated within 48 hours or two (2) business days of receipt of the report or complaint, whichever is greater.

(2)

If the Department determines there is no ongoing threat of imminent danger of death or serious bodily harm, the hospital shall be subject to one or both of the following:

(A) An onsite inspection. (B) An offsite investigation that includes but is not limited to interviews and records reviews.

(A)

An onsite inspection.

(B)

An offsite investigation that includes but is not limited to interviews and records reviews.