taken against a health care provider, supplier or practitioner by a Federal or State governmental agency or a health plan; which include the availability of a due process mechanism, and; are based on acts or omissions that affect or could affect the payment, provision or delivery of a health care item or service. For example, a formal or official final action taken by a Federal or State governmental agency or a health plan may include, but is not limited to, a personnel-related action such as suspensions without pay, reductions in pay, reductions in grade for cause, terminations or other comparable actions. A hallmark of any valid adjudicated action or decision is the availability of a due process mechanism. The fact that the subject elects not to use the due process mechanism provided by the authority bringing the action is immaterial, as long as such a process is available to the subject before the adjudicated action or decision is made final. In general, if an ''adjudicated action or decision'' follows an agency's established administrative procedures (which ensure that due process is available to the subject of the final adverse action), it would qualify as a reportable action under this definition. This definition specifically excludes clinical privileging actions taken by Federal or State Government agencies and similar paneling decisions made by health plans. This definition does not include overpayment determinations made by Federal or State Government programs, their contractors or health plans; and it does not include denial of claims determinations made by Government agencies or health plans. For health plans that are not Government entities, an action taken following adequate notice and the opportunity for a hearing that meets the standards of due process set out in section 412(b) of the HCQIA (42 U.S.C. 11112(b)) also would qualify as a reportable action under this definition.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State means any of the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands and Guam.

Voluntary surrender means a surrender made after a notification of investigation or a formal official request by a Federal or State licensing or certification authority for a health care provider, supplier or practitioner to surrender the license or certification (including certification agreements or contracts for participation in Federal or State health care programs). The definition also includes those instances where a health care provider, supplier or practitioner voluntarily surrenders a license or certification (including program participation agreements or contracts) in exchange for a decision by the licensing or certification authority to cease an investigation or similar proceeding, or in return for not conducting an investigation or proceeding, or in lieu of a disciplinary action.

[64 FR 57758, Oct. 26, 1999, as amended at 65 FR 70507, Nov. 24, 2000; 70 FR 53954, Sept. 13, 2005]

Subpart B—Reporting of Information

§ 61.4 How information must be reported.

Information must be reported to the HIPDB as required under §§ 61.6, 61.7, 61.8, 61.9, 61.10, 61.11 and 61.15 in such form and manner as the Secretary may prescribe.

§ 61.5 When information must be reported.

(a) Information required under §§ 61.7, 61.8, 61.9, 61.10 and 61.11 must be submitted to the HIPDB—

(1) Within 30 calendar days from the date the final adverse action was taken or the date when the reporting entity became aware of the final adverse action; or

(2) By the close of the entity's next monthly reporting cycle, whichever is later.

(b) The date the final adverse action was taken, its effective date and duration of the action would be contained in the information reported to the HIPDB under §§ 61.7, 61.8, 61.9, 61.10 and 61.11.