

result of restraint or seclusion. 42 CFR 483.13 also requires nursing homes to ensure that all alleged violations involving mistreatment, neglect, abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures, including to the State survey and certification agency. Section 353 of the Public Health Service Act (42 U.S.C. 263a) authorizes collection of information from any person or entity seeking certification under CLIA.

The Privacy Act of 1974 requires Federal agencies to implement and publish procedures for the collection, maintenance, and storage of personal information. It requires that the information be gathered only for lawful purposes and that the disclosure of personally identifiable records must be limited and safeguarded. The Privacy Act allows disclosure of an individual's data without consent, given that the data will be used for a purpose that is compatible with the purpose for which the information was collected.

II. Collection and Maintenance of Data in the System

A. Scope of the Data Collected

ACTS tracks allegations of complaints made against providers and suppliers. ACTS includes demographic data for identification of providers/suppliers, such as the Medicare identification number, name of the facility, address, city, state and ZIP code. ACTS contains data for identification of complainants, residents/patients, contacts/witnesses, alleged perpetrators, survey team members, laboratory directors, and laboratory owners. Complainant information includes: Name, title, address, city, state, ZIP code, telephone numbers, e-mail address, and relationship to beneficiary, if applicable. Contacts/Witnesses information includes: Name, title, address, city, state, ZIP code, telephone numbers, fax, and a field to indicate if the individual is a possible witness. Resident/patient information includes: Name, title, date of birth, gender, date admitted, date discharged, location, and room. ACTS also contains information related to any resident/patient deaths that are associated with the use of restraints or seclusion. This information includes: Name, death type (restraint or seclusion) and date of death. Alleged Perpetrator information includes: Name, title, address, city, state, ZIP code, telephone numbers, license number, social security number and Alias name, if any.

Survey Team information includes: Name, title, and surveyor identification number. Contact/Witnesses, Resident/Patient and Alleged Perpetrator are not mandatory fields in the ACTS database. These are optional data fields. ACTS will also maintain information for CLIA laboratories. Identifiable information for CLIA laboratories includes: Laboratory director's name, laboratory owner's name and Federal Tax Identification Number.

ACTS will maintain Federal complaint information, as well as state licensure complaint information. State licensure information is both relevant and necessary to meet CMS' purposes. Under section 1864(a) of the Social Security Act (the Act), the Secretary uses the help of State health agencies, or other appropriate agencies, when determining whether health care entities meet Federal Medicare standards. Also, section 1902(a)(9)(A) of the Act requires that a State use this same agency to set and maintain additional standards for the State Medicaid program. Section 1902(a)(33)(B) requires that the State use the agency utilized for Medicare or, if such agency is not the State agency responsible for licensing health institutions, the State use the agency responsible for such licensing to determine whether institutions meet all applicable Federal health standards for Medicaid participation, subject to validation by the Secretary. The State survey agencies perform both Federal certification and State licensure functions, including the investigation of complaints and entity-reported incidents. In fact, sections 1819(d) and 1919(d) of the Act require licensure under applicable State and local laws. In order to encourage efficiency in State operations, ACTS permits collection of Federal and State information, so that the States may maintain only one database, instead of multiple systems. CMS does seek to eliminate duplicative processes and unnecessary burden, to the extent possible, so that the States can achieve more effective management of their certification and licensure responsibilities.

There are mechanisms in ACTS that allow users to distinguish between information that is collected for the purpose of meeting the 1864 Agreement from information that is collected for State licensure purposes. ACTS supports the entry of both Federal and State licensure information, thus reflecting the actual business practices of State agencies as they track complaints and incidents. In many areas, ACTS allows entry of both types of information while still maintaining discrete records to support separate and

different views, reports and statistics. Federal and State licensure data are stored in the same tables in the database. However, Federal and State licensure data is easily discernable and separate. For reporting purposes, ACTS allows users to exclude complaint and incidents against state licensure only facilities using Facility Type filters. Report customization features in ACTS also allow users to include or exclude complaints or incidents that contain only State-licensure elements.

B. Agency Policies, Procedures, and Restrictions on the Routine Use

The Privacy Act permits us to disclose information without an individual's consent if the information is to be used for a purpose, which is compatible with the purpose(s) for which the information was collected. Any such disclosure of data is known as a "routine use." CMS has the following policies, procedures and restrictions on routine use disclosures of information that will be maintained in the system. In general, disclosure of information from the system of records will be approved only for the minimum information necessary to accomplish the purpose of the disclosure after CMS:

(a) Determines that the use or disclosure is consistent with the reason that the data is being collected, e.g., track and process complaints and incidents reported against Medicare/Medicaid/CLIA providers and suppliers, and to maintain information on laboratory directors and owners.

(b) Determines:

(1) That the purpose for which the disclosure is to be made can only be accomplished if the record is provided in individually identifiable form;

(2) That the purpose for which the disclosure is to be made is of sufficient importance to warrant the effect and/or risk on the privacy of the individual that additional exposure of the record might bring; and

(3) That there is a strong probability that the proposed use of the data would in fact accomplish the stated purpose(s).

(c) Requires the information recipient to:

(1) Establish administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record;

(2) Remove or destroy at the earliest time all patient-identifiable information; and

(3) Agree not to use or disclose the information for any purpose other than the stated purpose under which the information was disclosed.

(d) Determines that the data are valid and reliable.