

State programs within the State; support constituent requests made to a Congressional representative, support litigation involving the agency, and facilitate research on the quality and effectiveness of care provided. We have provided background information about the proposed system in the

SUPPLEMENTARY INFORMATION section below. Although the Privacy Act requires only that the "routine use" portion of the system be published for comment, CMS invites comments on all portions of this notice. See **EFFECTIVE DATES** section for comment period.

EFFECTIVE DATES: CMS filed a new system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on August 8, 2003.

ADDRESSES: The public should address comments to: Director, Division of Privacy Compliance Data Development (DPCDD), CMS, Room N2-04-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850. Comments received will be available for review at this location, by appointment, during regular business hours, Monday through Friday from 9 a.m.-3 p.m., eastern time zone.

FOR FURTHER INFORMATION CONTACT: Wayne Smith, Finance, Systems and Budget Group, Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Room S3-18-11, Baltimore, Maryland 21244-1850, Telephone Number: (410) 786-3258.

Steven Pelovitz, Survey and Certification Group, Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Room S2-12-25, Baltimore, Maryland 21244-1850, Telephone Number: (410) 786-3160.

SUPPLEMENTARY INFORMATION:

I. Description of the Proposed System of Records

A. Glossary of Terms

ACTS—ASPEN Complaints/Incidents Tracking System.

ASPEN—Automated Survey Processing Environment.

CLIA—Clinical Laboratory Improvement Amendments of 1988.

OSCAR—Online Survey Certification and Reporting System.

B. Background

The implementation of ACTS is critical to CMS's mission of assuring that beneficiaries receive quality care in

a safe environment. Several reports in recent years have highlighted this need. In March 1999, the General Accounting Office (GAO) issued a report entitled, "Complaint Investigation Processes Often Inadequate to Protect Residents." GAO assessed the effectiveness of State complaint investigation practices and the role of CMS in establishing standards and conducting oversight. The GAO recommended stronger requirements, increased federal monitoring and improved tracking of findings for complaints. In addition, in 1999, the Office of the Inspector General (OIG) issued a report entitled "The External Review of Hospital Quality." OIG recommended that CMS hold accreditation agencies and State agencies more fully accountable for their performance in reviewing hospitals. One of the areas that OIG made specific recommendations about was the handling of complaints. ACTS is part of CMS' response to these recommendations.

The ACTS responds to the concerns and problems found by the GAO, OIG and CMS' own needs. The ability to capture data that are useful, analyze data in a meaningful way, and use the products of the analysis to make refinements and improvements is critical to continuous quality improvement. Before ACTS, complaint data was maintained in the OSCAR Complaint System. The OSCAR Complaint System collected a minimal amount of data that was the result of an onsite survey. The data in ACTS is much more comprehensive than data that was maintained in the OSCAR Complaint System. ACTS automates complaint management operations. ACTS is a windows-based, client-server application that tracks, processes, and reports on complaints/incidents made against certified health care providers and suppliers. It is designed to manage all operations associated with complaints/incidents processing, from initial intake and investigation through final disposition. It is fully integrated into the ASPEN standard system architecture. Specific fields are configurable by individual states to accommodate a variety of operations environments.

ACTS is a national tracking system used by all States. It permits the collection procedures for complaints to be timely, consistent and complete. ACTS will eliminate redundant data collection systems, and it takes advantage of new technology and open systems architecture. ACTS will be used for all certified providers and suppliers. These providers and suppliers include: Skilled nursing facilities, nursing

facilities, hospitals, home health agencies, end-stage renal disease facilities, hospices, rural health clinics, comprehensive outpatient rehabilitation facilities, outpatient physical therapy services, community mental health centers, federally qualified health centers, ambulatory surgical centers, portable X-Ray facilities, intermediate care facilities for persons with mental retardation, and CLIA laboratories. Data in ACTS is collected and entered by the State Survey Agencies and CMS Regional Offices.

C. Statutory and Regulatory Basis for System of Records

Section 1864 of the Social Security Act (the Act) states the Secretary may use State agencies to determine compliance by providers of services with the conditions of participation. Under section 1864(a) 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. Sections 1819(d) and 1919(d) of the Act require licensure under applicable State and local laws.

Sections 1864 (c) and 1865 of the Act provides the basis for conducting complaint surveys of accredited hospitals and establishes the basic framework of complaint surveys for virtually all other accredited providers and suppliers. Regulations authorizing such surveys are found in 42 CFR 488.7(a)(2). 42 CFR 488.332 authorizes investigation of complaints of violations and monitoring of compliance. 42 CFR 488.335 authorizes actions on complaints of resident neglect and abuse, and misappropriation of resident property for nursing homes. 42 CFR 482.13(f) requires a hospital to report any death that occurs while a patient is restrained or in seclusion for behavior management, or where it is reasonable to assume that a patient's death is a