This clearance covers the following requirements:

(a) FAR 52.245–1(f)(1)(ii) requires contractors to document the receipt of Government property.

(b) FAR 52.245–1(f)(1)(ii)(A) requires contractors to submit report if overages, shortages, or damages and/or other discrepancies are discovered upon receipt of Government-furnished property.

(c) FAR 52.245–1(f)(1)(iii) requires contractors to create and maintain records of all Government property accountable to the contract.

(d) FAR 52.245–1(f)(1)(iv) requires contractors to periodically perform, record, and report physical inventories during contract performance, including upon completion or termination of the contract.

(e) FAR 52.245–1(f)(1)(vii)(B) requires contractors to investigate and report all incidents of Government property loss as soon as the facts become known.

(f) FAR 52.245–1(f)(1)(viii) requires contractors to promptly disclose and report Government property in its possession that is excess to contract performance.

(g) FAR 52.245–1(f)(1)(ix) requires contractors to disclose and report to the Property Administrator the need for replacement and/or capital rehabilitation.

(h) FAR 52.245–1(f)(1)(x) requires contractors to perform and report to the Property Administrator contract property closeout.

(i) FAR 52.245–1(f)(2) requires contractors to establish and maintain source data, particularly in the areas of recognition of acquisitions and dispositions of material and equipment.

(j) FAR 52.245–1(j)(2) requires contractors to submit inventory disposal schedules to the Plant Clearance Officer via the Standard Form 1428, Inventory Disposal Schedule.

(k) FAR 52.245–9(d) requires a contractor to identify the property for which rental is requested.

B. Annual Reporting Burden

Number of Respondents: 11,375.
Responses per Respondent: 1,057.
Total Responses: 12,023,375.
Average Burden Hours per Response: .3092.
Total Burden Hours: 3,717,627.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20006, telephone 202–501–4755. Please cite OMB Control No. 9000–0075, Government Property, in all correspondence.

Edward Loeb,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Govenrmentwide Policy.

[FR Doc. 2015–25366 Filed 10–5–15; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Reporting on Health Care Quality and Patient Safety

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of Availability—New Common Formats.

SUMMARY: As authorized by the Secretary of HHS, AHRQ coordinates the development of sets of common definitions and reporting formats (Common Formats) for reporting on health care quality and patient safety. The purpose of this notice is to announce the availability of two new sets of Common Formats for public review and comment: 1) Common Formats for retail pharmacies—Common Formats for Retail Pharmacy; and 2) the healthcare associated infection (HAI) module for Common Formats for Surveillance.

DATES: Ongoing public input.

ADDRESSES: The Common Formats for Retail Pharmacy, the HAI module for Common Formats for Surveillance, and the remaining Common Formats can be accessed electronically at the following HHS Web site: *http://www.pso.ahrq.gov/common/.*

FOR FURTHER INFORMATION CONTACT: Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *PSO@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, (73 FR 70732–70814), provide for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The collection of patient safety work product allows the aggregation of data that help to identify and address underlying causal factors of patient quality and safety problems.

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other healthcare providers may assemble information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs—called ''patient safety work product''—is privileged and confidential. Patient safety work product is used to conduct patient safety activities, which may include identifying events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Act and Patient Safety Rule which can be accessed electronically at: *http://www.pso.ahrq.gov/legislation/.*

Definition of Common Formats

The term ''Common Formats'' refers to the common definitions and reporting formats, specified by AHRQ, that allow health care providers to collect and submit standardized information regarding patient quality and safety to PSOs and other entities. The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording

system; rather the formats are intended to enhance the ability of health care providers to report information that is standardized both clinically and electronically.

In collaboration with the interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF), and the public, AHRQ has developed Common Formats for three settings of care—acute care hospitals, skilled nursing facilities, and retail pharmacies—in order to facilitate standardized data collection and analysis. The scope of Common Formats applies to all patient safety concerns including: Incidents—patient safety events that reached the patient, whether or not there was harm; near misses or close calls—patient safety events that did not reach the patient; and unsafe conditions—circumstances that increase the probability of a patient safety event.

AHRQ's Common Formats for patient safety event reporting include:

• Event descriptions (definitions of patient safety events, near misses, and unsafe conditions to be reported);

• Specifications for patient safety aggregate reports and individual event summaries that derive from event descriptions;

• Delineation of data elements and algorithms to be used for collection of adverse event data to populate the reports; and

• Technical specifications for electronic data collection and reporting.

The technical specifications promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their valid values, conditional and go-to logic, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning. They also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so that the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began their development by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provided an evidence base to inform construction of the Common Formats. The inventory included many systems from the private sector,

including prominent academic settings, hospital systems, and international reporting systems (*e.g.,* from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems were included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has convened the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS— CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration—as well as the DoD and VA.

When developing Common Formats, AHRQ first reviews existing patient safety practices and event reporting systems. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment. The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues.

Since the initial release of the Common Formats in August 2008, AHRQ has regularly revised the formats based upon public comment. AHRQ solicits feedback on beta (and subsequent) versions of Common Formats from private sector organizations and individuals. Based upon the feedback received, AHRQ further revises the Common Formats. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, frameworks, and definitions.

Participation by the private sector in the development and subsequent revision of the Common Formats is achieved through working with the NQF. The Agency engages the NQF, a non-profit organization focused on health care quality, to solicit comments and advice regarding proposed versions of the Common Formats. AHRQ began this process with the NQF in 2008, receiving feedback on AHRQ's 0.1 Beta release of the Common Formats for Event Reporting—Hospital. After receiving public comment, the NQF

solicits the review and advice of its Common Formats Expert Panel and subsequently provides feedback to AHRQ. The Agency then revises and refines the Common Formats and issues them as a production version. AHRQ has continued to employ this process for all subsequent versions of the Common Formats.

Beginning in 2013, AHRQ began development of Common Formats for Surveillance for hospitals which are also called the Quality and Safety Review System (QSRS). These formats are different than previously-developed Common Formats because they do not support event reporting in hospitals or other settings. QSRS supports retrospective review or audit of medical records in hospitals, and data are entered by medical record coders/ abstractors. While Common Formats that support event reporting are of great importance to the quality improvement process, by informing users on the nature and causes of patient safety events, they do not support collection of populations at risk and hence do not allow generation of rates. QSRS allows generation of rates of adverse events and benchmarking and trending of performance in hospitals, including documentation of improvement over time. The principle immediate use planned for QSRS is to update and expand on the scope of the Medicare Patient Safety Monitoring System (MPSMS) that is currently in use by HHS to audit a sample of U.S. medical records for purposes of establishing national adverse event rates.

Commenting on Common Formats for Retail Pharmacy

In 2014, representatives from U.S. retail pharmacies approached AHRQ regarding collaboration to develop Common Formats for the retail pharmacy setting. Development of the new Formats began using the existing AHRQ Common Formats Medication module from the AHRQ Common Formats for Event Reporting—Hospital, version 1.2, as a starting point. AHRQ, in conjunction with retail pharmacy representatives, designed Common Formats for Retail Pharmacy for use in U.S. retail pharmacies. These formats will facilitate improved detection and understanding of medication-related events originating in pharmacies and, if implemented as specified, will allow aggregation of medication-related data across different pharmacy providers.

The Agency is specifically interested in obtaining feedback from both the private and public sectors on the new Common Formats for Retail Pharmacy. At this time, only the Event

Description—which defines adverse events of interest in the retail pharmacy setting—is available. Other elements of the Common Formats, including aggregate reports and technical specifications, will be developed following revision of the Common Formats for Retail Pharmacy based on public comment and NQF advice. Information on how to comment and provide feedback on the Common Formats for Retail Pharmacy is available at the NQF Web site: *http://www.quality forum.org/Project_Pages/Common_ Formats_for_Patient_Safety_Data.aspx.*

Commenting on HAI Module for Common Formats for Surveillance

Common Formats addressing all QSRS modules—except for those for HAIs—were made available for public comment in 2014. During the intervening time, AHRQ was able to consult with CDC in order to refine the HAI module. When integrated with the remaining modules of QSRS, the HAI module will allow completion of the first version of QSRS.

The Agency is specifically interested in obtaining feedback from both the private and public sectors on the HAI module for Common Formats for Surveillance. Only the Event Description—which defines six HAI adverse events of interest—is available. Based on public comment and NQF advice, AHRQ will finalize this module,

which will be incorporated into QSRS software. Information on how to comment and provide feedback on the HAI module is available at the NQF Web site: *http://www.qualityforum.org/ Project_Pages/Common_Formats_for_ Patient_Safety_Data.aspx.*

AHRQ appreciates the time and effort individuals invest in providing comments. The Agency will review and consider all feedback received to help guide the development of a revised version. The process for updating and refining the formats will continue to be an iterative one.

Future versions of the Common Formats are planned to be developed for additional ambulatory settings, such as ambulatory surgery centers and physician and practitioner offices. More information on the Common Formats can be obtained through AHRQ's PSO Web site: *http://www.pso.ahrq.gov/.*

Sharon B. Arnold,
AHRQ Deputy Director.
[FR Doc. 2015–25364 Filed 10–5–15; 8:45 am]
BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: National Youth in Transition Database and Youth Outcome Survey.
OMB No.: 0970–0340.
Description: The Foster Care Independence Act of 1999 (42 U.S.C. 1305 *et seq.*) as amended by Public Law 106–169 requires State child welfare agencies to collect and report to the Administration on Children and Families (ACF) data on the characteristics of youth receiving independent living services and information regarding their outcomes. The regulation implementing the National Youth in Transition Database, listed in 45 CFR 1356.80, contains standard data collection and reporting requirements for States to meet the law's requirements. ACF will use the information collected under the regulation to track independent living services, assess the collective outcomes of youth, and potentially to evaluate State performance with regard to those outcomes consistent with the law's mandate.

Respondents: State agencies that administer the John H. Chafee Foster Care Independence Program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Youth Outcome Survey	20,667	1	0.50	10,334
Data File	52	2	1,849	192,296

Estimated Total Annual Burden Hours: 202,630

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment

is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@ OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
[FR Doc. 2015–25370 Filed 10–5–15; 8:45 am]
BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–3378]

Acceptability of Draft Labeling To Support Abbreviated New Drug Application Approval; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "Acceptability of Draft Labeling to Support ANDA Approval."