

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 formats can be implemented electronically, and to PSOs, so that the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PSOPPC) 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 and updates to current versions of the Common Formats for public review and comment. The prior version of Common Formats for Event Reporting for Hospitals, Version 1.2, was released in April 2013. 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 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 formats.

Commenting on Common Formats for Event Reporting—Hospital Version 2.0

AHRQ used a tiered approach to develop Hospital Version 2.0. This approach was done in response to feedback from PSOs and the public to decrease the number of questions for each module of the formats in order to

reduce the burden on health care providers and to facilitate data transmission. These formats have two tiers, or data sets. The first tier, or national data set, contains elements that are collected for submission to the PSOPPC. The second tier, or local data set, is optional and is designed for use at the local level for additional analyses. This local data set is not meant for transmission to the PSOPPC.

The Agency is specifically interested in obtaining feedback from both the private and public sectors on the updated Common Formats for Event Reporting—Hospitals Version 2.0. At this time, only the event descriptions—which define adverse events of interest in the inpatient hospital setting—are available. Other elements of the Common Formats, including aggregate reports and technical specifications, will be developed following revision of the Common Formats for Hospital Version 2.0 based on public comment and NQF advice. Information on how to comment and provide feedback on the Common Formats for Hospital Version 2.0 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.

Further information on the Common Formats can be obtained through AHRQ's PSO Web site: <http://www.pso.ahrq.gov/>. To receive notifications about final versions of AHRQ Common Formats, please subscribe to "E-Mail Updates" at: <https://pso.ahrq.gov/about/subscribe>.

Sharon B. Arnold,
Acting Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-317, CMS-319, CMS-10166, CMS-10178, and CMS-10184]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by June 7, 2016.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number ___, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION:**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-317 State Medicaid Eligibility Quality Control Sampling Plan

CMS-319 State Medicaid Eligibility Quality Control Sample Selection Lists

CMS-10166 Payment Error Rate Measurement in Medicaid and the State Children's Health Insurance Program

CMS-10178 Medicaid and State Children's Health Insurance Plan (SCHIP) Managed Care

CMS-10184 Payment Error Rate Measurement—State Medicaid and SCHIP Eligibility

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Medicaid Eligibility Quality Control (MEQC) Sample Plans; *Use:* The Medicaid Eligibility Quality Control (MEQC) system is based on monthly State reviews of Medicaid and Medicaid expansion under Title XXI cases by States performing the traditional sampling process identified through statistically reliable statewide samples of cases selected from the eligibility files. These reviews are conducted to determine whether or not the sampled

cases meet applicable State Title XIX or XXI eligibility requirements when applicable. The reviews are also used to assess beneficiary liability, if any, and to determine the amounts paid to provide Medicaid services for these cases. In the MEQC system, sampling is the only practical method of validating eligibility of the total caseload and determining the dollar value of eligibility liability errors. Any attempt to make such validations and determinations by reviewing every case would be an enormous and unwieldy undertaking. In 1993, CMS implemented MEQC pilots in which States could focus on special studies, targeted populations, geographic areas or other forms of oversight with CMS approval. States must submit a sampling plan, or pilot proposal to be approved by CMS before implementing their pilot program. The Children's Health Insurance Program Reauthorization Act (CHIPRA) was enacted February 4, 2009. Sections 203 and 601 of the CHIPRA relate to MEQC. Section 203 of the CHIPRA establishes an error rate measurement with respect to the enrollment of children under the express lane eligibility option. The law directs States not to include children enrolled using the express lane eligibility option in data or samples used for purposes of complying with the MEQC requirements. Section 601 of the CHIPRA, among other things, requires a new final rule for the Payment Error Rate Measurement (PERM) program and aims to harmonize the PERM and MEQC programs and provides States with the option to apply PERM data resulting from its eligibility reviews for meeting MEQC requirements and vice versa, with certain conditions. We review, either directly or through its contractors, of the sampling plans helps to ensure States are using valid statistical methods for sample selection. The collection of information is also necessary to implement provisions from the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111-3) with regard to the Medicaid Eligibility Quality Control (MEQC) and Payment Error Rate Measurement (PERM) programs. *Form Number:* CMS-317 (OMB control number: 0938-0146); *Frequency:* Semi-Annually *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 20; *Total Annual Hours:* 480. (For policy questions regarding this collection contact Bridgett Rider at 410-786-2602.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of*

Information Collection: State Medicaid Eligibility Quality Control (MEQC) Sample Selection Lists; *Use:* The MEQC system is based on monthly State reviews of Medicaid and Medicaid expansion under Title XXI cases by States performing the traditional sampling process identified through statistically reliable statewide samples of cases selected from the eligibility files. These reviews are conducted to determine whether or not the sampled cases meet applicable State Title XIX or XXI eligibility requirements when applicable. The reviews are also used to assess beneficiary liability, if any, and to determine the amounts paid to provide Medicaid services for these cases. In the MEQC system, sampling is the only practical method of validating eligibility of the total caseload and determining the dollar value of eligibility liability errors. Any attempt to make such validations and determinations by reviewing every case would be an enormous and unwieldy undertaking. At the beginning of each month, State agencies still performing the traditional sample are required to submit sample selection lists which identify all of the cases selected for review in the States' samples. The sample selection lists contain identifying information on Medicaid beneficiaries such as: State agency review number, beneficiary's name and address, the name of the county where the beneficiary resides, Medicaid case number, etc. The submittal of the sample selection lists is necessary for Regional Office validation of State reviews. Without these lists, the integrity of the sampling results would be suspect and the Regional Offices would have no data on the adequacy of the States' monthly sample draw or review completion status. The authority for collecting this information is Section 1903(u) of the Social Security Act. The specific requirement for submitting sample selection lists is described in regulations at 42 CFR 431.814(h). Regional Office staff review the sample selection lists to determine that States are sampling a sufficient number of cases for review. *Form Number:* CMS-319 (OMB control number: 0938-0147); *Frequency:* Monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 10; *Total Annual Responses:* 120; *Total Annual Hours:* 960. (For policy questions regarding this collection contact Bridgett Rider at 410-786-2602.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Payment Error Rate Measurement in Medicaid &

Children's Health Insurance Program (CHIP); *Use:* The Improper Payments Information Act (IPIA) of 2002 as amended by the Improper Payments Elimination and Recovery Improvement Act (IPERIA) of 2012 requires CMS to produce national error rates for Medicaid and Children's Health Insurance Program (CHIP). To comply with the IPIA, CMS will engage a Federal contractor to produce the error rates in Medicaid and CHIP. The error rates for Medicaid and CHIP are calculated based on the reviews on three components of both Medicaid and CHIP program. They are: Fee-for-service claims medical reviews and data processing reviews, managed care claims data-processing reviews, and eligibility reviews. Each of the review components collects different types of information, and the state-specific error rates for each of the review components will be used to calculate an overall state-specific error rate, and the individual state-specific error rates will be used to produce a national error rate for Medicaid and CHIP. The states will be requested to submit, at their option, test data which include full claims details to the contractor prior to the quarterly submissions to detect potential problems in the dataset to and ensure the quality of the data. These states will be required to submit quarterly claims data to the contractor who will pull a statistically valid random sample, each quarter, by strata, so that medical and data processing reviews can be performed. State-specific error rates will be based on these review results. We need to collect the fee-for-service claims data, medical policies, and other information from states as well as medical records from providers in order for the contractor to sample and review adjudicated claims in those states selected for medical reviews and data processing reviews. Based on the reviews, state-specific error rates will be calculated which will serve as part of the basis for calculating national Medicaid and CHIP error rates. *Form Number:* CMS-10166 (OMB control number: 0938-0974); *Frequency:* Annually, Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 34; *Total Annual Responses:* 34; *Total Annual Hours:* 56,100. (For policy questions regarding this collection contact Bridgett Rider at 410-786-2602.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid and Children's Health Insurance (CHIP) Managed Care Claims and Related

Information; *Use:* The Payment Error Rate Measurement (PERM) program measures improper payments for Medicaid and the State Children's Health Insurance Program (SCHIP). The program was designed to comply with the Improper Payments Information Act (IPIA) of 2002 and the Office of Management and Budget (OMB) guidance. Although OMB guidance requires error rate measurement for SCHIP, 2009 SCHIP legislation temporarily suspended PERM measurement for this program and changed to Children's Health Insurance Program (CHIP) effective April 01, 2009. See Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) Public Law 111-3 for more details. There are two phases of the PERM program, the measurement phase and the corrective action phase. The PERM measures improper payments in Medicaid and CHIP and produces State and national-level error rates for each program. The error rates are based on reviews of Medicaid and CHIP fee-for-service (FFS) and managed care payments made in the Federal fiscal year under review. States conduct eligibility reviews and report eligibility related payment error rates also used in the national error rate calculation. We created a 17 State rotation cycle so that each State will participate in PERM once every three years. Following is the list of States in which we will measure improper payments over the next three years in Medicaid. We need to collect capitation payment information from the selected States so that the federal contractor can draw a sample and review the managed care capitation payments. We will also collect State managed care contracts, rate schedules and updates to the contracts and rate schedules. This information will be used by the Federal contractor when conducting the managed care claims reviews. Sections 1902(a)(6) and 2107(b)(1) of the Social Security Act grants CMS authority to collect information from the States. The IPIA requires us to produce national error rates in Medicaid and CHIP fee-for-service, including the managed care component. The State-specific Medicaid managed care and CHIP managed care error rates will be based on reviews of managed care capitation payments in each program and will be used to produce national Medicaid managed care and CHIP managed care error rates. *Form Number:* CMS-10178 (OMB control number: 0938-0994); *Frequency:* Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 34; *Total Annual*

Responses: 28,050; *Total Annual Hours:* 28,050. (For policy questions regarding this collection contact Bridgett Rider at 410-786-2602.)

5. Type of Information Collection

Request: Extension of a currently approved collection; *Title of Information Collection:* Eligibility Error Rate Measurement in Medicaid and the Children's Health Insurance Program; *Use:* The Improper Payments Information Act (IPIA) of 2002 requires CMS to produce national error rates for Medicaid and the Children's Health Insurance Program (CHIP). To comply with the IPIA, CMS will use a national contracting strategy to produce error rates for Medicaid and CHIP fee-for-service and managed care improper payments. The federal contractor will review States on a rotational basis so that each State will be measured for improper payments, in each program, once and only once every three years. Subsequent to the first publication, we determined that we will measure Medicaid and CHIP in the same State. Therefore, States will measure Medicaid and CHIP eligibility in the same year measured for fee-for-service and managed care. We believe this approach will advantage States through economies of scale (e.g. administrative ease and shared staffing for both programs reviews). We also determined that interim case completion timeframes and reporting are critical to the integrity of the reviews and to keep the reviews on schedule to produce a timely error rate. Lastly, the sample sizes were increased slightly in order to produce an equal sample size per strata each month. Periodically, CMS will conduct Federal

re-reviews of States' PERM files to ensure the accuracy of States' review findings and the validity of the review process. CMS will select a random subsample of Medicaid and CHIP cases from the sample selection lists provided by each State. States will submit all pertinent information related to the review of each sampled case that is selected by CMS. *Form Number:* CMS-10184 (OMB control number: 0938-1012); *Frequency:* Annually, Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 34; *Total Annual Responses:* 1,583; *Total Annual Hours:* 946,164. (For policy questions regarding this collection contact Bridgett Rider at 410-786-2602.)

Dated: April 5, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: National Survey of Child and Adolescent Well-Being-Third Cohort (NSCAW III): Agency Recruitment.

OMB No.: 0970-0202.

Description: The Administration for Children and Families (ACF) within the U.S. Department of Health and Human

Services (HHS) intends to collect data on a third cohort of children and families for the National Survey of Child and Adolescent Well-Being (NSCAW). NSCAW is the only source of nationally representative, longitudinal, firsthand information about the functioning and well-being, service needs, and service utilization of children and families who come to the attention of the child welfare system. The first two cohorts of NSCAW were collected beginning in 1999 and 2008 and studied children who had been the subject of investigation by Child Protective Services. Children were sampled from child welfare agencies nationwide. The proposed data collection plan for the third cohort of NSCAW includes two phases: Phase 1 includes child welfare agency recruitment and collection of files for sampling children, and Phase 2 includes baseline data collection and an 18-month follow-up data collection. The current data collection plan calls for selecting a new cohort of 4,565 children and families and repeating similar data collection procedures as the previous two cohorts. This Notice is specific to Phase 1. The overall goal is to recruit child welfare agencies in 83 primary sampling units nationwide. Child welfare agencies will be selected with probability proportional to size, based on the current distributions in the child welfare system. Child welfare agency recruitment will include: mail, email, phone calls, and site visits with child welfare agency administrators.

Respondents: Child welfare agency administrators and other personnel. Data collection will take place over a 2-year period.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents (rounded)	Number of responses per respondent	Average burden hours per response	Annual burden hours
Information package for agency administrators	83	42	1	.25	11
Initial visit or call with agency staff	83	42	1	1	42
Visit or call with agency staff explaining the sample file process	83	42	1	2	84
Agency staff monthly sample file generation and transmission	83	42	15	1	630

Estimated Total Annual Burden Hours: 767.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be

identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the