

on and managing the insurance affordability programs for eligible individuals, performing oversight and quality control activities, combatting fraud, and responding to any concerns about the security or confidentiality of the information. *Form Number:* CMS-10440 (OMB control number: 0938-1191); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 4,662,000; *Total Annual Responses:* 4,662,000; *Total Annual Hours:* 946,386. (For policy questions regarding this collection contact Anne Pesto at 410-786-3492.)

Dated: February 8, 2019.

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

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-R-284, CMS-R-305, CMS-10455 and CMS-10520]

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 the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by April 15, 2019.

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' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>

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: William N. Parham at (410) 786-4669.

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-R-284 Transformed—Medicaid Statistical Information System (T-MSIS)
- CMS-R-305 External Quality Review (EQR) of Medicaid Managed Care Organizations (MCOs) and Supporting Regulations
- CMS-10455 Report of a Hospital Death Associated with Restraint or Seclusion
- CMS-10520 Marketplace Quality Standards

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.

Information Collection

1. Type of Information Collection

Request: Revision of a currently approved collection; *Title of Information Collection:* Transformed—Medicaid Statistical Information System (T-MSIS); *Use:* The data reported in T-MSIS are used by federal, state, and local officials, as well as by private researchers and corporations to monitor past and projected future trends in the Medicaid program. The data provide the only national level information available on enrollees, beneficiaries, and expenditures. It also provides the only national level information available on Medicaid utilization. The information is the basis for analyses and for cost savings estimates for the Department's cost sharing legislative initiatives to Congress. The collected data are also crucial to our actuarial forecasts. *Form Number:* CMS-R-284 (OMB control number: 0938-0345); *Frequency:* Quarterly and monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 55; *Total Annual Responses:* 660; *Total Annual Hours:* 6,600. (For policy questions regarding this collection contact Connie Gibson at 410-786-0755.)

2. Type of Information Collection

Request: Revision of a currently approved collection; *Title of Information Collection:* External Quality Review (EQR) of Medicaid Managed Care Organizations (MCOs) and Supporting Regulations; *Use:* State agencies must provide to the external quality review organization (EQRO) information obtained through methods consistent with the protocols specified by CMS. This information is used by the EQRO to determine the quality of care furnished by an MCO. Since the EQR results are made available to the general public, this allows Medicaid/CHIP enrollees and potential enrollees to make informed choices regarding the

selection of their providers. It also allows advocacy organizations, researchers, and other interested parties access to information on the quality of care provided to Medicaid beneficiaries enrolled in Medicaid/CHIP MCOs. States use the information during their oversight of these organizations. *Form Number:* CMS–R–305 (OMB control number 0938–0786); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 629; *Total Annual Responses:* 4,869; *Total Annual Hours:* 426,492. (For policy questions regarding this collection contact Jennifer Sheer at 410–786–1769.)

3. Type of Information Collection
Request: Revision of a currently approved collection; *Title of Information Collection:* Report of a Hospital Death Associated with Restraint or Seclusion; *Use:* The final rule, which finalized the regulations at 42 CFR 482.13(g), published on May, 16, 2012 (77 FR 29074) included a reduction in the reporting requirements related to hospital deaths associated with the use of restraint or seclusion. Section § 482.13(g) requires that hospitals must use form CMS–10455 to report those deaths associated with restraint and/or seclusion directly to the Centers for Medicare & Medicaid Services (CMS) Regional Office (RO). This requirement also applies to rehabilitation or psychiatric distinct part units (DPUs) in Critical Access Hospitals (CAHs). Currently, the hospital, CAH, or psychiatric DPU must submit the form CMS–10455 to the CMS RO via fax or email, based on RO's preference. Beginning on May 9, 2014, hospitals were no longer required to report to CMS, those deaths that were not associated with the use of seclusion and where the only restraints used were 2-point soft wrist restraints. This reporting requirement change resulted in no necessary edits to the form CMS–10455. It was estimated that this would reduce the volume of reports that must be submitted by 90 percent for hospitals. In addition, the final rule replaced the previous requirement for reporting via telephone to CMS, which proved to be cumbersome for both CMS and hospitals, with a requirement that allows the submission of reports on the form CMS–10455 via facsimile or electronically, as determined by CMS. In this PRA package, CMS is seeking OMB approval for an electronically submitted version of the currently approved paper version of form CMS–10455. *Form Number:* CMS–10455 (OMB control number: 0938–1210); *Frequency:* Occasionally; *Affected*

Public: Private Sector; *Number of Respondents:* 6,389; *Number of Responses:* 6,389; *Total Annual Hours:* 6,389. (For policy questions regarding this collection contact Caroline Gallaher at 410–786–8705.)

4. Type of Information Collection
Request: Revision of a currently approved collection. *Title of Information Collection:* Marketplace Quality Standards; *Use:* The Patient Protection and Affordable Care Act establishes requirements to support the delivery of quality health care coverage for health insurance issuers offering Qualified Health Plans (QHPs) in Exchanges. Section 1311(c)(3) of the Patient Protection and Affordable Care Act directs the Secretary to develop a system to rate QHPs on the basis of quality and price and requires Exchanges to display this quality rating information on their respective websites. Section 1311(c)(4) of the Patient Protection and Affordable Care Act requires the Secretary to develop an enrollee satisfaction survey system to assess enrollee experience with each QHP (with more than 500 enrollees in the previous year) offered through an Exchange. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards.

This collection of information is necessary to provide adequate and timely health care quality information for consumers, regulators, and Exchanges as well as to collect information to appropriately monitor and provide a process for a survey vendor to appeal HHS' decision to not approve a QHP Enrollee Survey vendor application. *Form Number:* CMS–10520 (OMB control number: 0938–1249) *Frequency:* Annually. *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions). *Number of Respondents:* 264. *Total Annual Responses:* 264. *Total Annual Hours:* 348,764. (For policy questions regarding this collection contact Nidhi Singh Shah at 301–492–5110.)

Dated: February 8, 2019.

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

Food and Drug Administration

[Docket No. FDA–2018–D–4417]

Center for Drug Evaluation and Research's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “CDER's Program for the Recognition of Voluntary Consensus Standards Related to Pharmaceutical Quality.” This guidance describes a proposed program at FDA's Center for Drug Evaluation and Research (CDER) to make public a comprehensive listing of informally recognized voluntary consensus standards related to pharmaceutical quality. This program, once established, will facilitate submissions by external stakeholders and CDER staff proposing voluntary consensus standards related to pharmaceutical quality for informal recognition. CDER believes that this informal program, which is different than the formal recognition standards program in FDA's Center for Devices and Radiological Health, will help promote innovation in pharmaceutical development and manufacturing and streamline the compilation and assessment of marketing applications for products regulated by CDER. CDER is issuing this draft guidance to obtain public comments on the proposed program.

DATES: Submit either electronic or written comments on the draft guidance by April 15, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by April 15, 2019.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically,