

regarding this collection contact Jennifer Tate at 410-786-0428).

**2. 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:** Provisions implementing this statutory reporting requirement for hospitals participating in Medicare are found at 42 CFR 482.13(g), as revised in the final rule that published on May 16, 2012 (77 FR 29034). This regulation also applies to Critical Access Hospitals (CAHs) with distinct part units (DPUs); since CAH DPUs are subject to the Hospital Conditions of Participation. The regulation at 42 CFR 482.13(g) requires that hospitals and CAHs with DPUs report deaths associated with the use of restraint and/or seclusion directly to the CMS locations. This regulation requires that information about patient deaths associated with the use of restraint and/or seclusion must be reported to the CMS Locations using the online CMS-10455 form titled “*Report Of A Hospital Death Associated With The Use Of Restraint Or Seclusion.*”

When a death occurs in a hospital (including Critical Access Hospital (CAH) with a rehabilitation or psychiatric Distinct Part Unit (DPU)) that is associated with the use of restraints and/or seclusion, the hospital staff must complete the online Form CMS-10455 (42 CFR 482.13(g)(1)). The hospital staff must also document the date and time that CMS was notified of the death in the patient’s medical record (42 CFR 482.13(g)(3)(i)).

When a death occurs during the use of 2-point soft cloth wrist restraints with no seclusion, or within 24 hours after the patient was removed from such restraints, the hospital must document the information required by 42 CFR 482.13(g)(4)(ii) into a hospital log or internal system within 7 days from the date of death (42 CFR 482.13(g)(4)(i)). The hospital is not required to submit this log or internal records to the CMS Location, however, they must be made available in either written or electronic form to CMS immediately upon request (42 CFR 482.13(g)(4)(iii)). In addition, the hospital staff must also document the date and time that the required information was entered into the hospital’s log or internal system in the patient’s medical record (42 CFR 482.13(g)(3)(ii)). **Form Number:** CMS-10455 (OMB control number: 0938-1210); **Frequency:** Occasionally; **Affected Public:** Private Sector; **Number of Respondents:** 3,137; **Number of Responses:** 3,137; **Total Annual Hours:** 1,210. (For policy questions regarding

this collection contact Caroline Gallaher at 410-786-8705.)

Dated: June 8, 2022.

**William N. Parham, III,**

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

[FR Doc. 2022-12721 Filed 6-10-22; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10520]

#### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by July 13, 2022.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

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: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

#### FOR FURTHER INFORMATION CONTACT:

William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

**1. 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:* 314; *Total Annual Responses:* 314; *Total Annual Hours:* 384,014. (For policy questions regarding this collection contact Nidhi Singh Shah at 301-492-5110.)

Dated: June 7, 2022

**William N. Parham, III,**

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

[FR Doc. 2022-12651 Filed 6-10-22; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-D-0362]

#### **Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Draft Guidance for Industry; Correction**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability; correction.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is correcting a notice that appeared in the **Federal Register** of Tuesday, May 24, 2022. The document announced the availability of a draft guidance entitled "Blood Pressure and Pulse Donor Eligibility Requirements: Compliance Policy; Draft Guidance for Industry." The draft guidance document was published with incorrect information of a comment period due date. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of May 24, 2022 (87 FR 31567), in FR Doc. 2022-11118, on page 31567, the following correction is made:

1. On page 3156, in the first column, the **DATES** caption is corrected to read:

**DATES:** Submit either electronic or written comments on the draft guidance by July 25, 2022, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

Dated: June 3, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022-12619 Filed 6-10-22; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-0686]

#### **Advisory Committee; Science Advisory Board to the National Center for Toxicological Research; Renewal**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; renewal of Federal advisory committee.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the renewal of the Science Advisory Board to the National Center for Toxicological Research (NCTR) by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Science Advisory Board to the National Center for Toxicological Research for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the June 2, 2024, expiration date.

**DATES:** Authority for the Science Advisory Board to the National Center for Toxicological Research will expire on June 2, 2024, unless the Commissioner formally determines that renewal is in the public interest.

**FOR FURTHER INFORMATION CONTACT:** Donna L. Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993-0002, 301-796-8892, [Donna.Mendrick@fda.hhs.gov](mailto:Donna.Mendrick@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services pursuant to and by the General Services Administration, FDA is announcing the renewal of the Science Advisory Board to the National Center for Toxicological Research (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee

in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee advises the Director, NCTR, in establishing, implementing, and evaluating research programs that assist the Commissioner in fulfilling his regulatory responsibilities. The Committee provides an extra-agency review in ensuring that the research programs at NCTR are scientifically sound and pertinent.

The Committee shall consist of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of toxicological research. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. Federal members will be appointed as Regular Government Employees or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, an additional non-voting representative member of consumer interests will be included in addition to the voting members.