recommended level. Further, the issues of whether or not to adjust fluoride in drinking water, as well as the recommended level to which fluoride should be adjusted, have previously been addressed in the **Federal Register** and are not part of this request.[8]

Note: Public water systems must continue to comply with Environmental Protection Agency (EPA) requirements for a special notice for exceedance of the secondary standard of 2 mg/L (40 CFR 141.208) (*https://www.epa.gov/dwregdev/drinking-water-regulations-and-contaminants*).

CDC is seeking public comment on the following:

1. Are there any evidence-based concerns about the appropriateness of the proposed operational control range and criteria for adherence based on measurement capacity or feasibility of maintaining the target level?

References

1. U.S. Public Health Service Recommendations for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. *Public Health Reports.* 2015 July–Aug;130(4):318–331.
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3. Barker LK, Duchon KK, Lesaja S, et al. Adjusted Fluoride Concentrations in 34 States: 2006–2010 and 2015. Journal AWWA. 2017;109(8):2–17.
4. Engineering and Administrative Recommendations for Water Fluoridation, MMWR Sept 29,1995/44(RR–13:1–40. Fluoride Recommendations Work Group. Recommendations for using fluoride to prevent and control dental caries in the United States. MMWR Recomm Rep. 2001;50(RR–14):1–42.
5. Heller KE, Eklund SA, Burt BA. Dental caries and dental fluorosis at varying water fluoride concentrations. J Public Health Dent. 1997;57:136–43.
6. Brown R, McTigue N, Graf K. Monitoring fluoride: how closely do utilities match target versus actual levels? Opflow, 40;7:10. *https://doi.org/10.5991/OPF.2014.40.0042.*
7. Teefy S. Managing fluoridation within a stringent regulatory framework. Proc 2013 AWWA Water Quality Technology Conference, Oakland, Calif.
8. Public Health Service Recommendation for Fluoride Concentration in Drinking Water for the Prevention of Dental Caries. *Fed Regist.* 2015;80(84):24936–24947. Available at: *https://www.federalregister.gov/documents/2015/05/01/2015-10201/public-health-service-recommendation-for-fluoride-concentration-in-drinking-water-for-prevention-of.* Accessed 5/11/2018.

Dated: July 9, 2018.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2018–14968 Filed 7–12–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10531, CMS–R–43, CMS–10102, CMS–10143, CMS–10261, CMS–10500, and CMS–855I]

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

AGENCY: Centers for Medicare & Medicaid 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 August 13, 2018.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395–5806 *OR*

Email: OIRA_submission@omb.eop.gov

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 *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: 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:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD); Use: The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, ''Transcatheter Mitral Valve Repair (TMVR)''. The TMVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all-cause mortality and quality of life. In order to remove the data collection requirement under this coverage with evidence development (CED) NCD or make any other changes to the existing policy, we

must formally reopen and reconsider the policy. We are continuing to review and analyze the data collected since this NCD was effective in 2014

We find that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TMVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TMVR technologies for the treatment of mitral regurgitation (MR).

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TMVR is reasonable and necessary (*e.g.,* improves health outcomes) for Medicare beneficiaries under section 1862(a)(1)(A) of the Act. The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ–10) to assess heath status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0–100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ–10 is pursuant to Section 1142 of the Social Security Act (the ACT) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries. *Form Number:* CMS–10531 (OMB control number: 0938–1274); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 3,897; *Total Annual Responses:* 15,588; *Total Annual Hours:* 5,456. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Coverage for Portable X-ray Suppliers and Supporting Regulations; *Use:* The requirements contained in this information collection request are classified as conditions of participation or conditions for coverage. Portable X-rays are basic radiology studies (predominately chest and extremity X-rays) performed on patients in skilled nursing facilities, residents of long-term care facilities and homebound patients. The CoPs are based on criteria described in the law, and are designed to ensure that each portable X-ray supplier has properly trained staff and provides the appropriate type and level of care for patients. We use these conditions to certify suppliers of portable X-ray services wishing to participate in the Medicare program. This is standard medical practice and is necessary in order to help to ensure the well-being, safety and quality professional medical treatment accountability for each patient. There is a significant increase in the burden due to burden that was not accounted for in the previous information collection request. *Form Number:* CMS–R–43 (OMB Control number: 0938–0338); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 5,986,509; *Total Annual Responses:* 5,987,018; *Total Annual Hours:* 532,959. (For policy questions regarding this collections contact Sonia Swancy at 410–786–8445.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* National Implementation of the Hospital CAHPS Survey; *Use:* The HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey, also known as the CAHPS® Hospital Survey or Hospital CAHPS®, is a standardized survey instrument and data collection methodology that has been in use since 2006 to measure patients' perspectives of hospital care. While many hospitals collect information on patient satisfaction, HCAHPS created a national standard for the collection and public reporting of information that enables valid comparisons to be made across all hospitals to support consumer choice. *Form Number:* CMS–10102 (OMB control number 0938–0981); *Frequency:* Occasionally; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 4,200; *Total Annual Responses:* 3,100,000; *Total Annual Hours:* 413,230. (For policy questions regarding this collection contact William Lehrman at 410–786–1037.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Data for the Medicare Modernization Act (MMA); *Use:* The monthly data file is provided to CMS by states on dual eligible beneficiaries. The phase-down process requires a monthly count of all full benefit dual eligible beneficiaries with an active Part D plan enrollment in the month. CMS will make this selection of records using dual eligibility status codes contained in the person-month record to identify all full-benefit dual eligible beneficiaries (codes 02, 04 and 08). In the case where in a given month, multiple records were submitted for the same beneficiary in multiple file submittals, the last record submitted for that beneficiary shall be used to determine the final effect on the phase-down count. *Form Number:* CMS–10143 (OMB Control Number: 0938–0958); *Frequency:* Monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 612; *Total Annual Hours:* 4,896. (For policy questions regarding this collection contact Linda King at 410–786–1312.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Part C Medicare Advantage Reporting Requirements and Supporting Regulations in 42 CFR 422.516(a); *Use:* Medicare Advantage Organizations (MAOs) must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to: The cost of its operations; the patterns of service utilization; the availability, accessibility, and acceptability of its services; to the extent practical, developments in the health status of its enrollees; information demonstrating that the MAO has a fiscally sound operation; and other matters that CMS may require. CMS also has oversight authority over cost plans which includes establishment of reporting requirements. The changes for the 2019 reporting requirements under Organization Determinations and Reconsiderations (ODR) will add 18 new data elements to the reporting section. The new data elements will

allow CMS to obtain more information about who is submitting requests for ODR and whether the service or claim is being provided by a contract or non-contract provider. The timeliness requirement for ODR will also be eliminated to be consistent with Part D reporting. In addition, the number of data reporting elements of grievances is reduced from 23 to 19. The reporting sections for Private Fee For Service (PFFS) Payment Dispute Resolution Process and Mid-Year Network Changes will also be suspended. *Form Number:* CMS–10261 (OMB control number: 0938–1054); *Frequency:* Yearly and semi-annually; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 432; *Total Annual Responses:* 3,024; *Total Annual Hours:* 127,329. (For policy questions regarding this collection contact Maria Sotirelis at 410–786–0552.)

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey; *Use:* The information collected in the national implementation of Outpatient/Ambulatory Surgery Patient Experience of Care Survey (A/ASPECS) will be used to: (1) Provide a source of information from which selected measures can be publicly reported to beneficiaries to help them make informed decisions for outpatient surgery facility selection; (2) aid facilities with their internal quality improvement efforts and external benchmarking with other facilities; and (3) provide us with information for monitoring and public reporting purposes. *Form Number:* CMS–10500 (OMB control number: 0938–1240); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 633,304; *Total Annual Responses:* 633,304; *Total Annual Hours:* 153,592. (For policy questions regarding this collection contact Memuna Ifedirah at 410–786–6849).

7. *Type of Information Collection Request:* New collection (Request for new OMB control number); *Title of Information Collection:* Medicare Enrollment Application for Physician and Non-Physician Practitioners; *Use:* The application is used by Medicare contractors to collect data to ensure that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare, including information that allows the Medicare contractor to correctly price, process and pay the applicant's claims. This application collects information to ensure that only legitimate physicians, non-physician practitioners, and other eligible professionals are enrolled in the Medicare program. It is meant to be the first line defense to protect our beneficiaries from illegitimate providers and to protect the Medicare Trust Fund against fraud. It also gathers information that allows Medicare contractors to ensure that the provider/supplier is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, suspended or excluded from any other Federal agency or program. *Form Number:* CMS–855i (OMB control number: 0938–NEW); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); *Number of Respondents:* 513,872; *Total Annual Responses:* 1,370,078; *Total Annual Hours:* 1,000,167. For policy questions regarding this collection contact Kimberly McPhillips at (410)-786–5374.

Dated: July 10, 2018.

William N. Parham, III,

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

[FR Doc. 2018–15038 Filed 7–12–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1156]

Q3D(R1) Elemental Impurities; International Council for Harmonisation; 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 ''Q3D(R1) Elemental Impurities.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance revises the existing ICH guidance for industry ''Q3D Elemental Impurities'' and provides an updated permitted daily exposure (PDE) for the cadmium inhalation route of exposure. The updated PDE of 3 micrograms (µg)/day is based on a modifying factor approach like that used for calculating the PDEs for the cadmium oral and parenteral routes of exposure. The draft guidance is intended to correct a calculation error in the PDE for cadmium by the inhalation route of exposure. Following deliberations within the Q3D Expert Working Group, the revised calculation is based on a modifying factor approach that is consistent with the oral and parenteral PDE calculations.

DATES: Submit either electronic or written comments on the draft guidance by August 13, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–1156 for ''Q3D(R1) Elemental Impurities.'' Received comments will be placed in the docket and, except for