All written comments will be available for public inspection on *regulations.gov.* An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Dated: September 5, 2019.

David A. Shive,

Chief Information Officer.

[FR Doc. 2019–19861 Filed 9–12–19; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Drug Vial Size Report

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health & Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces the issuance of the August 2, 2019 single-source funding opportunity titled ''Drug Vial Size Report'' available solely to the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine [the Academies] to conduct a study on the Federal healthcare costs, safety, and quality concerns associated with discarded drugs that results from weight-based dosing of medicines contained in single dose vials as stated in Senate report 114–274.

DATES: The performance period of the award, in the amount of $1,200,000, to the Academies will be 18 months from the date of award.

FOR FURTHER INFORMATION CONTACT: Alisha Williams, (410) 786–7507 and Deborah Pujals Keyser, (410) 786–8096.

SUPPLEMENTARY INFORMATION:

I. Background

A 2016 report published in the British Medical Journal (BMJ) describes overspending and waste due to single-use cancer drugs being supplied in vials that contain larger dosages than needed by the average patient. The authors specifically cite examples of drug manufacturers distributing larger sizes and more limited variety of single-use vial sizes in the U.S. than they do for their overseas markets. While this may paradoxically increase physician and hospital profits when reimbursement is based on a percentage of the cost of an entire vial, this situation results in the excessive waste of highly-valuable drugs and increased Federal and private payer costs. Using claims data for the top 20 cancer drugs, the study found that the proportion of drug wasted ranged from 1 to 33 percent and was associated with an estimated $2.8 billion dollars per year in drug costs and healthcare provider markups on wasted drug.

In addition to wasting taxpayer dollars through Federal health programs like Medicare, this practice also drives up the cost for patients whose cost sharing is based on amounts of drugs that are unnecessarily large. Since Medicare Part B beneficiaries pay coinsurance of up to 20 percent for prescription drugs, seniors are paying higher out-of-pocket costs for drugs they do not need or receive.

As described in Chapter 17, Section 40.1 of the Medicare Claims Processing Manual, Medicare Part B pays for the amount of the drug or biological administered to the beneficiary as well as the remainder of drug discarded from single-use vials or other single-use package up to the amount of the drug or biological indicated on the vial or package label. The JW modifier is a Healthcare Common Procedure Coding System (HCPCS) Level II modifier used on a Medicare Part B drug claims to report the amount of drug or biological that is discarded and eligible for payment under the discarded drug policy. The modifier is only to be used for drugs in single-dose or single-use packaging. As of January 1, 2017, The Centers for Medicare and Medicaid Services (CMS) requires all physicians, hospitals and other providers to use the JW modifier when submitting claims to Medicare Administrative Contractors (MACs) for reimbursement (except claims for drugs and biologicals provided under the Competitive Acquisition Program) and to document discarded waste in the patient's medical record. This mandatory reporting nationwide will provide the data necessary to quantify the amount of drugs that are unused and the cost to taxpayers from that waste.

Further research is needed to fully illustrate system factors that lead to drug waste from single-dose vials, quantify the Federal government's and Medicare beneficiaries' costs associated with this waste, and explore waste mitigation strategies.

II. Provisions of the Notice

The Funding Opportunity offers $1,200,000 in funding for the Academies to conduct a study on the Federal healthcare costs, safety, and quality concerns associated with discarded drugs that results from weight-based dosing of medicines contained in single-dose vials. More specifically, the Academies' requirements include, but are not limited to:

- Provide a comprehensive assessment of Federal healthcare costs, both to the Medicare program and to Medicare beneficiaries, due to billing for wasted drugs and biologicals from single-dose vials. Additionally, examine Federal reimbursement and beneficiary cost-sharing policies as they relate to drug waste and the degree to which these policies may affect costs to Federal programs and beneficiaries.
- Using available data sources, quantify the amount of waste associated with single-dose injectable drugs and biologics in billing units and/or proportion of available vial sizes and calculate the associated dollar amounts.
- Identify relevant drugs, vial sizes, dosing practices, and delivery practices most associated with waste. Evaluate dosing strategies which may contribute to or mitigate excessive drug waste where possible (for example, dosing based on weight, body surface area [BSA] and institutional rounding/dose-capping protocols).
- Research the safety and quality concerns associated with the use of single-dose vials which contain excess drug from industry and regulatory perspectives. Investigate manufacturer rationale for developing particular vial sizes and safety standards (such as those from U.S. Pharmacopoeia [USP]) influencing requirements for single-dose vs multi-dose vial development and utilization. Review Federal guidelines or requirements that influence drug package types and drug supply chain factors such as manufacturing, storage, and shipment.
- Consult with Stakeholders, including CMS, FDA, CDC, DOD, IHS, VA, USP, specialty physicians [including rural practitioners], specialty clinics [including rural clinics], hospitals [including rural hospitals], patient groups, biopharmaceutical manufacturers, health insurance companies, and healthcare distributors/wholesalers.
- Comply with applicable conflict of interest standards.
- The report should include findings related to above requirements as well as provide recommendations to Congress for revising current policies and practices or other strategies to mitigate drug waste and its associated costs. Recommendations should consider collateral impact on all stakeholders' perspectives, such as Federal programs, private insurers, and beneficiaries who pay for wasted drug products, as well as pharmaceutical industry and physician,

clinic, and hospital practices that receive reimbursement for wasted drug products.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: September 6, 2019.

Seema Verma

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–19885 Filed 9–12–19; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3304]

The Special 510(k) Program; Guidance for Industry and Food and Drug Administration Staff; 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 final guidance entitled ''The Special 510(k) Program.'' FDA established the Special 510(k) Program to facilitate the submission, review, and clearance of changes to a manufacturer's own legally marketed predicate device. This guidance provides the framework that FDA uses when considering whether a premarket notification (510(k)) is appropriate for review as a Special 510(k).

DATES: The announcement of the guidance is published in the **Federal Register** on September 13, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2018–D–3304 for ''The Special 510(k) Program.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''The Special 510(k) Program'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Joshua Silverstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–5155; Angela DeMarco, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–4471; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301,