DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–5513–N]

Medicare Program; Announcement of Request for Applications for the Million Hearts® Cardiovascular Risk Reduction Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS

ACTION: Notice.

SUMMARY: This notice informs interested parties of an opportunity to apply for participation in the Million Hearts® Cardiovascular Risk Reduction Model. The primary goal of this model is to test whether encouraging physician practices to calculate risk for all of the practice's eligible Medicare beneficiaries, using the American College of Cardiology/American Heart Association (ACC/AHA) Atherosclerotic Cardiovascular Disease (ASCVD) 10-year pooled cohort risk calculator will prevent the occurrence of first-time heart attacks and strokes.

DATES: Applications will be considered timely if they are received on or before September 4, 2015 as outlined in the Request for Applications (RFA).

Note: Interested applicants will be required to submit a non-binding Letter of Intent (LOI) to apply for the model.

ADDRESSES: All LOIs must be submitted electronically through the Center for Medicare and Medicaid Innovation Web site at: *http://innovation.cms.gov/initiatives/Million-Hearts-CVDRRM/.* LOIs will be accepted throughout the entire application period, ending September 4, 2015. Applicants will need to use their LOI confirmation number to access the RFA. All applicants will receive a RFA submission confirmation number; it is the applicant's responsibility to retain a copy of the confirmation number for proof of submission.

FOR FURTHER INFORMATION CONTACT: Nina Brown at (410) 786–6103 or email address: *mhmodel@cms.hhs.gov.* The Center for Medicare and Medicaid Innovation Web site is at *http://innovation.cms.gov/.*

SUPPLEMENTARY INFORMATION:

I. Background

The Center for Medicare and Medicaid Innovation (Innovation Center), within the Centers for Medicare & Medicaid Services (CMS), was created to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and Children's Health Insurance Program beneficiaries.

We are interested in models designed to improve care for specific populations. One population is Medicare fee-for service (FFS) beneficiaries 18 to 79 years of age who have never had a heart attack or stroke and who are not under hospice care. Current evidence suggests that preventive cardiovascular disease interventions can significantly reduce both adverse cardiovascular-related outcomes and death. The Million Hearts® Cardiovascular Risk Reduction Model (hereinafter referred to as ''CVD Risk Reduction Model'') seeks to test whether providing incentives for physician practices to calculate absolute 10-year cardiovascular risk reduction, measured by the American College of Cardiology/American Heart Association (ACC/AHA) 10-year pooled cohort risk calculator, is effective in reducing heart attacks and strokes among Medicare FFS beneficiaries. Intervention group practices will engage in shared decision making, team-based care, and population health management to reduce beneficiaries' absolute risk. Intervention group practices will be required to submit quality data to CMS supported by a per-beneficiary-per-month payment.

The Innovation Center is operating this model under the authority of section 1115A of the Social Security Act (the act) (42 U.S.C. 1315a) (as added by section 3021 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), (collectively known as Affordable Care Act)). We will evaluate whether this model reduces the occurrence of heart attacks and strokes as well as Medicare expenditures and enhances the quality of care furnished to Medicare beneficiaries.

II. Provisions of the Notice

The RFA is directed to physician practices that include private practices, hospital-owned physician practices, large medical networks, hospital/physician organization, or independent practice associations. Up to 720 practices are expected to participate. Participating practices must meet the following requirements:

- Practices must have at least one practitioner. Practitioners are defined as Medical Doctors, Doctors of Osteopathic Medicine, Physician Assistants, and Nurse Practitioners.
- Practices must be using an Office of the National Coordinator for Health Information Technology (ONC) certified electronic health record (EHR) system.
- Participating physicians or other eligible professionals within the practice must have met the criteria for the Medicare EHR Incentive Programs in performance year 2015, also known as ''meaningful use,'' of an ONC certified electronic health record.

Practices selected to participate will be randomized to the intervention group or the control group. Practices randomized to the control group will be required to submit data to CMS at the beginning of the first, second, third and fifth years of the model. Control group practices will receive a one-time payment of $20 per-beneficiary following the successful transmission of data to CMS on eligible beneficiaries within their practices. Practices randomized to the control group will receive no further funding beyond this one-time payment.

Practices randomized to the intervention group will be paid a one-time upfront payment of $10 per-beneficiary to conduct initial risk stratification for eligible beneficiaries in addition to a $10 per-beneficiary-per-month fee for ongoing monitoring of high-risk FFS Medicare beneficiaries. Starting in the second year of the model, the $10 per-beneficiary-per-month ongoing fee is gradually placed at risk based on a practice's performance managing its ''high-risk'' beneficiaries.

Intervention group practices in the CVD Risk Reduction Model will use the ACC/AHA Atherosclerotic Cardiovascular Disease (ASCVD) 10-year pooled cohort risk calculator to risk stratify Medicare FFS beneficiaries 18 to 79 years of age meeting the inclusion criteria. Practices will further identify whether beneficiaries are ''high-risk'' defined by their 10-year ASCVD risk score: A ''high risk,'' beneficiary is defined as a beneficiary with an ACC/AHA 10-year ASCVD risk score greater than or equal to 30 percent. Once the high risk beneficiaries have been identified, intervention group practices will engage in risk modification and report process and outcome measures of their results. Practices will be required to submit annual data to CMS through a certified Data Registry, which will be provided to participating practices by CMS.

The CVD Risk Reduction Model period of performance is 5 years. Selected practices will enter into Model Participant Agreements with CMS. Applicants must present evidence that the applicant practices are capable of successfully identifying beneficiaries who meet the CVD Risk Reduction Model eligibility requirements.

Applicants must also demonstrate their plans for engaging in shared decision making activities with their beneficiaries. Applicants are required to submit to CMS general beneficiary data, the clinical indicators needed to calculate the 10-year ASCVD risk score, and the cardiovascular Physician Quality Reporting System (PQRS) measures as outlined in the RFA. Eligible practices will be selected on a first come, first served basis until all 720 spots have been filled. Applications must be submitted timely in the standard format outlined in the CVD Risk Reduction Model RFA in order to be considered for review. Applications that are not received in this format will not be considered for review.

For more specific details regarding the CVD Risk Reduction Model (including the RFA), we refer applicants to the informational materials on the Innovation Center Web site at: *http://innovation.cms.gov/initiatives/Million-Hearts-CVDRRM/.* Applicants are responsible for monitoring the Web site to obtain the most current information available.

III. Collection of Information Requirements

Section 1115A(d)(3) of the Social Security Act states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of the models under this section. Consequently, there is no need for this document to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: May 15, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–1804]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Studies To Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach To Establish an Acute Reference Dose; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #232 entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)'' (VICH GL54). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to address the nature and types of data that can be useful in determining an ARfD for residues of veterinary drugs, the studies that may generate such data, and how the ARfD may be calculated based on these data.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), 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 on the draft guidance by July 31, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Tong Zhou, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0826, *Tong.Zhou@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #232 entitled ''Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: General Approach to Establish an Acute Reference Dose (ARfD)'' (VICH GL54). In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Six observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one