DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Reduction of Issuer Burden Through Technology Grant

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

ACTION: Notice of funding opportunity.

SUMMARY: This notice announces the issuance of the March 10, 2021 (and amended on April 29, 2021) single-source funding opportunity titled “Reduction of Issuer Burden Through Technology Grant” (hereafter referred to as the “RIBTT Grant”) available solely to the National Association of Insurance Commissioners (NAIC) to build a connection between the State Electronic Rate and Form Filing (SERFF) system, owned and operated by the NAIC, and the Health Insurance Oversight System (HIOS), which is operated by the Centers for Medicare and Medicaid Services (CMS). This connection will enable health insurance issuers to enter rate justification data into the SERFF system and then have this rate justification data automatically transfer to HIOS. Currently, health insurance issuers have to enter duplicate data into both the SERFF system and HIOS in order to maintain compliance with federal and state law in 49 states and the District of Columbia.

DATES: The project period of the award, in the amount of $250,000 to the NAIC, will be 24 months from the date of award. The tentative award date is July 29, 2021.

FOR FURTHER INFORMATION CONTACT: Jim Taing, (301) 492–4182.

SUPPLEMENTARY INFORMATION:

I. Background

The Reduction of Issuer Burden Through Technology Grant (RIBTT Grant) provides a funding source to build a connection between the SERFF system and the Unified Rate Review (URR) module of HIOS. Forty-nine states and the District of Columbia currently use the SERFF system to collect and review rate data. Building a connection between SERFF and HIOS will reduce burden on health insurance issuers and decrease the potential for data mismatches between the two systems. It will enable health insurance issuers to enter rate justification data into the SERFF system and the rate justification data will automatically transfer to HIOS. Currently, health insurance issuers have to enter duplicate data into both the SERFF system and HIOS in order to maintain compliance with applicable federal and state law. Funding under the RIBTT Grant is available to the NAIC to complete their portion of the technical changes needed in order to build such a connection between the SERFF system and HIOS.

II. Provisions of the Notice

CMS is anticipating approximately a total of $250,000 will be available for the RIBTT Grant, pending availability of funds, to the NAIC to complete their portion of the technical changes needed in order to build such a connection between the SERFF system and HIOS for the transfer of rate filing information. The NAIC may use grant funds for a variety of planning, development, testing, and implementation objectives related to the technical changes needed to build the connection between the SERFF system and HIOS. This includes, but is not limited to, hiring or contracting with information technology professionals or firms to complete the work. Pending an acceptable application and budget, the CMS will recommend awarding a single source grant to the NAIC who is uniquely qualified to complete the work requested. The NAIC is uniquely positioned to perform this work as they are the only applicant under this funding opportunity to meet the objectives of this funding opportunity as they own, operate, and maintain the SERFF system and the SERFF system is what is utilized by health insurance issuers to submit rate filing justification data in 49 states and the District of Columbia. The NAIC has built previous IT connections between their SERFF system and HIOS for the submission of Qualified Health Plan certification data between SERFF and the Plan Management module of HIOS. Funds enable NAIC to establish this new IT connection between the SERFF system and the URR module of HIOS based on the prior system architecture.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynnette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the Federal Register.

Dated: July 19, 2021.

Lynnette Wilson,
Federal Register Liaison, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0703]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2022

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2022 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2018 (AGDUFA III), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2022.

FOR FURTHER INFORMATION CONTACT: Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, Lisa.Kable@fda.hhs.gov or visit FDA’s website at https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm. For general questions, you may also email the Center for Veterinary