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Enforcement Policy Regarding Federal VCPR Requirements to Facilitate Veterinary Telemedicine During the COVID-19 Outbreak

Guidance for Industry

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1140 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/coronavirus-disease-2019-covid-19>, the FDA webpage titled "Search for FDA Guidance Documents," available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, and the Center for Veterinary Medicine webpage titled "Guidance for Industry," available at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>. You may also send an e-mail request to AskCVM@fda.hhs.gov to receive a copy of the guidance. Please include the document number FDA-2020-D-1140 and complete title of the guidance in the request.

Questions

For questions about this document, contact AskCVM@fda.hhs.gov.

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Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from threats, including emerging infectious diseases such as the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support continuity and response efforts during this pandemic. On January 31, 2020, the Department of Health and Human Services (HHS) issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

FDA is issuing this guidance to facilitate veterinarians' ability to provide veterinary medical services during the COVID-19 pandemic.

Given this public health emergency, this guidance is being implemented without prior public comment because the FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally

¹ Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

Contains Nonbinding Recommendations

enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Discussion

FDA recognizes the vital role veterinarians play in protecting public health. FDA is aware that during the COVID-19 outbreak some States are modifying their requirements for veterinary telemedicine, including State requirements regarding the veterinarian-client-patient relationship (VCPR). Given that the Federal VCPR definition requires animal examination and/or medically appropriate and timely visits to the premises where the animal(s) are kept,³ the Federal VCPR definition cannot be met solely through telemedicine. To further facilitate veterinarians' ability to utilize telemedicine to address animal health needs during the COVID-19 outbreak, FDA intends to temporarily suspend enforcement of a portion of the Federal VCPR requirements. Specifically, FDA generally intends not to enforce the animal examination and premises visit VCPR requirements relevant to FDA regulations governing Extralabel Drug Use in Animals (21 CFR part 530) and Veterinary Feed Directive Drugs (21 CFR 558.6). Given the temporary nature of this policy, we plan to reassess it periodically and provide revision or withdrawal of this guidance as necessary.

³ See 21 CFR 530.3(i) for the Federal definition of a "valid veterinarian-client-patient relationship."