

The State of Washington has agreed to pay the state's pro rata share of the anticipated overhead costs and costs of actual validation (including complaint investigation surveys). A final reconciliation for all laboratories and all expenses will be made. We will reimburse the state for any overpayment or bill it for any balance.

II. Approval

In light of the foregoing, we grant approval of the State of Washington's laboratory licensure program under subpart E. All laboratories located in and licensed by the State of Washington under the Medical Test Site law, Chapter 70.42 of the Revised Code of Washington, are CLIA-exempt for all specialties and subspecialties until October 2, 2023.

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 12, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019-21062 Filed 9-27-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Performance Review Board Membership

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice of Performance Review Board Membership.

FOR FURTHER INFORMATION CONTACT:

Kathy Vaughn, 410-786-1050 or katherine.vaughn@cms.hhs.gov.

5 U.S.C. 4314(c)(1) through (5) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more Senior Executive Service (SES) Performance Review Boards.

The PRB shall review and evaluate the initial summary rating of a senior executive's performance, the executive's response, and the higher-level official's comments on the initial summary

rating. In addition, the PRB will review and recommend executive performance bonuses and pay increases.

5 U.S.C. 4314(c)(4) requires the appointment of board members to be published in the **Federal Register**. The following persons comprise a standing roster to serve as members of the SES PRB for the Centers for Medicare & Medicaid Services:

Jennifer Main, Chief Operating Officer (serves as the Chair)

Kimberly Brandt, Principal Deputy Administrator for Policy and Operations

Scott Giberson, Acting Director, Office of Human Capital

Nancy O'Connor, Acting Consortium Administrator, Consortium for Medicare Health Plans Operations

Randy Pate, Deputy Administrator and Director, Center for Consumer Information and Insurance Oversight

Elizabeth Richter, Deputy Center Director, Center for Medicare

Arrah Tabe-Bedward, Deputy Director, Center for Medicare and Medicaid Innovation

Jeffrey, Deputy Director for Operations, Center for Consumer Information and Insurance Oversight

Dated: September 5, 2019.

Jennifer Main,

Chief Operating Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3361]

Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs; 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 (GFI) #261 entitled "Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs." This draft guidance is intended for persons interested in pursuing conditional approval of new animal drugs for certain major uses in major species. Eligibility for conditional approval has been expanded beyond minor uses in major species and minor species to include certain major uses. The Center for Veterinary Medicine

(CVM) refers to the process for conditionally approving new animal drugs that are not minor use and minor species (MUMS) drugs as "expanded conditional approval." The purpose of expanded conditional approval is to incentivize development of new animal drugs for serious or life-threatening conditions or unmet animal or human health needs under circumstances where a demonstration of effectiveness would require a complex or particularly difficult study or studies. This draft guidance defines certain terms, clarifies the eligibility criteria for expanded conditional approval, and describes the criteria CVM intends to consider when determining expanded conditional approval eligibility.

DATES: Submit either electronic or written comments on the draft guidance by January 28, 2020 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.