drugs because breast cancer in males is rare. This has resulted in limited FDA-approved treatment options for males. Clinical management of male breast cancer is generally based on experience with and data from females with breast cancer, rather than on data from prospective, randomized clinical trials.

The draft guidance recommends that eligibility criteria for clinical trials of breast cancer drugs allow for inclusion of males. When males have not been included or when inclusion of males is very limited in clinical trials for breast cancer drugs, the guidance includes clinical development recommendations for when no difference in efficacy or safety is anticipated between males and females based on the drug’s mechanism of action and for when there is a concern for differential efficacy or safety between males and females.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Male Breast Cancer: Developing Drugs for Treatment.” 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 321 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0010; the collections of information in 21 CFR part 602 have been approved under OMB control number 0910–0011; the collections of information in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910–0572.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either

- [https://www.regulations.gov](https://www.regulations.gov)

Dated: August 19, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

FOR FURTHER INFORMATION CONTACT:
[FR Doc. 2019–18363 Filed 8–26–19; 8:45 am]
BILLING CODE 4164–01–P
HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,
Director, Division of the Executive Secretariat. [FR Doc. 2019–18425 Filed 8–26–19; 8:45 am]

**SUPPLEMENTARY INFORMATION:**

**Information Collection Request Title:** Evidence-Based Telehealth Network Program Measures, OMB No. 0906–xxxx—NEW.

**Abstract:** This ICR is for a new approval of measures for the Federal Office of Rural Health Policy’s Office of Advancement of Telehealth programs. Specifically, grants administered in accordance with the following legislative statute (ii) Section 711(b) of the Social Security Act (42 U.S.C. 912(b)), as amended. The purpose of these programs is to provide grants that demonstrate how telehealth programs and networks can improve access to quality health care services in rural, frontier, and underserved communities. These grants will work to: (a) Expand access to, coordinate, and improve the quality of health care services; (b) improve and expand the training of health care providers; and (c) expand and improve the quality of health information available to health care providers and their families for decision-making. In addition, these grants will help HRSA assess the effectiveness of evidence based practices with the use of telehealth for patients, providers, and payers.

A 60-day notice was published in the Federal Register on April 08, 2019, vol. 84, No. 67; pp. 13936. There were no public comments.

**Likely Respondents:** Award recipients of the Evidence Based Telehealth Network Program.

**Burden Statement:** Burden in this context means the time expended by persons to generate, maintain, retain, review, or disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

**TOTAL ESTIMATED ANNUALIZED BURDEN HOURS**

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* Number is rounded to the nearest whole number.