TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Sec. 582 of the FD&C Act; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average time per response (in hours)	Total hours
Request renewals (Waivers Guidance, sec. III)	1	1	1	16	16
Total					114,932

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL DISCLOSURE BURDEN [1]

Sec. 582 of the FD&C Act; activity	Number of respondents	Number of disclosures per respondent	Total disclosures	Average time per disclosure (in hours)	Total hours
Illegitimate product notifications to trading partners (Notifications Guidance, sec. III.B)	500	310	155,000	8	1,240,000
Illegitimate product notification terminations to trading partners (Notifications Guidance, sec. III)	500	310	155,000	4	620,000
Total					1,860,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We have reorganized the information collection by respondent activity and clarified where information collection elements are discussed in the respective guidance documents. Based on illegitimate product notifications FDA has already received, we previously estimated a total of 250 respondents. However, we have considered industry feedback indicating that more notifications may be submitted based on stakeholder understanding of FDA's recent clarification of stolen product in the ''Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act'' draft guidance (June 2021; available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/definitions-suspect-product-and-illegitimate-product-verification-obligations-under-drug-supply*). As such, we have increased our number of estimated respondents to 500 and assume 40 percent are manufacturers (200), 50 percent are wholesale distributors (250), and 10 percent are pharmacies (50). Because manufacturers, repackagers, and wholesale distributors are collectively responsible for prescription drugs from the point of manufacturing through distribution in the drug supply chain, we continue to assume that these three trading partners submit most notifications of illegitimate products.

In response to industry feedback, we have increased our estimate of the average time per response from 1 hour to 8 hours to more accurately reflect the burden respondents may incur in satisfying the information collection. We have otherwise retained the average burden per response for activities associated with consultations and waiver/exception/exemption requests. Finally, also based on public comment and industry feedback, we have increased our estimate of the average number of disclosures/notifications per respondent, as well as our assumption of the average time necessary for each disclosure notification, for an increase from 66,070 to 1,860,000 hours annually.

As a result of these adjustments, our estimated burden for the information collection reflects a cumulative increase since the last OMB review and approval. We attribute this increase to a more recent evaluation of the information collection and informal communications with industry and other interested stakeholders regarding burden estimates.

Dated: January 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Telehealth Resource Center Performance Measurement Tool, OMB No. 0915–0361—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than March 14, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Samantha Miller, the acting

HRSA Information Collection Clearance Officer at (301) 443–9094.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information collection request title for reference.

Information Collection Request Title: Telehealth Resource Center Performance Measurement Tool OMB No. 0915–0361—Extension

Abstract: HRSA requests an extension of their Telehealth Resource Center Performance Measurement Tool. The Telehealth Resource Centers (TRC) deliver telehealth technical assistance. There are two types of HRSA TRC programs:

- Two National Telehealth Resource Center Programs focus on policy and technology.
- 12 Regional Telehealth Resource Center Programs host activities and provide resources to rural and underserved areas.

The HRSA Telehealth Resource Centers:

- Provide training and support
- Publicize information and research findings
- Support collaboration and partnerships
- Promote effective partnerships
- Promote the use of telehealth by providing health care information and education to the public and medical specialists.

The TRCs share expertise through individual consults, training, webinars, conference presentations, and the web.

Need and Proposed Use of the Information: In order to evaluate existing programs, data are submitted to HRSA's Office for the Advancement of Telehealth (OAT) through HRSA's Performance Improvement Management System (PIMS). The data are used to measure the effectiveness of the technical assistance (TA). There is one data reporting period each year; during these reporting periods, data are reported for the previous twelve months of activity. Programs have approximately six weeks to enter their data into the PIMS system during each annual reporting period.

The instrument was developed with the following four goals in mind:

1. Improving access to needed services,
2. Reducing rural and underserved population practitioner isolation,
3. Improving health system productivity and efficiency, and
4. Improving patient outcomes.

The TRCs currently report on existing performance data elements using PIMS. The performance measures are designed to assess how the TRC program is meeting its goals to:

- Expand the availability of telehealth services in underserved communities;
- Improve the quality, efficiency, and effectiveness of telehealth services;
- Promote knowledge exchange and dissemination about efficient and effective telehealth practices and technology; and
- Establish sustainable TA centers providing quality, unbiased TA for the development and expansion of effective and efficient telehealth services in underserved communities.

Additionally, the PIMS tool allows OAT to:

- Determine the value added from the TRC Cooperative Agreement;
- Justify budget requests;
- Collect uniform, consistent data which enables OAT to monitor programs;
- Provide guidance to grantees on important indicators to track over time for their own internal program management;
- Measure performance relative to the mission of OAT/HRSA as well as individual goals and objectives of the program;
- Identify topics of interest for future special studies; and
- Identify changes in health care needs within rural and underserved communities, allowing programs to shift focus in order to meet those needs.

Likely Respondents: The likely respondents will be telehealth associations, telehealth providers, rural and underserved health providers, clinicians that deliver services via telehealth, technical assistance providers, research organizations and academic medical centers.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, 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

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Telehealth Resource Center Performance Measurement Tool	14	42	588	0.07	41
	14		588		41

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, Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier OS–0990–0478]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.