

that the NNV impurity can be controlled within the acceptable intake limit by sponsors of varenicline products within the context of their particular applications.

CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, is currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Medley Pharmaceuticals Ltd. submitted a citizen petition dated June 6, 2022 (Docket No. FDA–2022–P–1013), under 21 CFR 10.30, requesting that the Agency determine whether CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, has not been withdrawn for reasons of safety or effectiveness to the extent that the drug can be manufactured or formulated in a manner that satisfies any applicable acceptable intake limit for nitrosamine impurities.

Accordingly, the Agency will continue to list CHANTIX (varenicline tartrate) tablets, 0.5 mg and 1 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs, including satisfying any applicable acceptable intake limit for nitrosamine impurities. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–03947 Filed 2–24–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

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

ACTION: Notice.

SUMMARY: HRSA is publishing an updated monetary amount of the average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

FOR FURTHER INFORMATION CONTACT: CDR George Reed Grimes, Director, Division of Injury Compensation Programs, Health Systems Bureau, HRSA, by mail at 5600 Fishers Lane, 08N186B, Rockville, Maryland 20857; or call (301) 443–9350.

SUPPLEMENTARY INFORMATION: Section 100.2 of the VICP’s implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary of Health and Human Services (the Secretary), is effective upon its delivery by the Secretary to the United States Court of Federal Claims (the Court) and will be published periodically in a notice in the **Federal Register**. The Secretary delegated this responsibility to the HRSA Administrator. This figure is calculated using the most recent Medical Expenditure Panel Survey–Insurance Component data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation (KFF) Employer Health Benefits Survey.

In 2022, Medical Expenditure Panel Survey–Insurance Component, available at www.meps.ahrq.gov, published the annual 2021 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was \$7,380. This figure is divided by 12 to determine the cost per month of \$615.00. The \$615.00 figure is increased or decreased by the percentage change reported by the most recent KFF Employer Health Benefits Survey, available at www.kff.org. The increase from 2021 to 2022 was 2.2 percent. By adding this percentage increase, the calculated average monthly

cost of a health insurance policy for a 12-month period is \$628.53.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is \$628.53 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the Secretary to the Court. Such notice was delivered to the Court on February 21, 2023.

Carole Johnson,
Administrator.

[FR Doc. 2023–03919 Filed 2–24–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Office for the Advancement of Telehealth Outcome Measures, OMB No. 0915–0311—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 April 28, 2023.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail 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 HRSA Information Collection Clearance Officer, at 301–594–4394.

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

Information Collection Request Title: Office for the Advancement of Telehealth Outcome Measures OMB No. 0915–0311—Extension.

Abstract: This clearance request is for extending the approval of the Office for Advancement of Telehealth Outcome Measures that are currently approved under OMB No. 0915–0311, with an expiration date of October 31, 2023. To help carry out its mission, HRSA created this set of performance measures that grantees of the Telehealth Network Grant Program can use to evaluate the effectiveness of their services programs and monitor their progress using performance reporting data.

Need and Proposed Use of the Information: As required by the Government Performance and Review Act of 1993, all federal agencies must develop strategic plans describing their overall goal and objectives. HRSA has

worked with grantees of the Telehealth Network Grant Program to develop performance measures to be used to evaluate and monitor the progress of the grantees. Grantee goals are to improve access to needed services; reduce rural practitioner isolation; improve health system productivity and efficiency; and improve patient outcomes. In each of these categories, specific indicators were designed to be reported through a performance monitoring website. Measures for the Telehealth Network Grant Program capture awardee-level and aggregate data that illustrate the impact and scope of federal funding along with assessing these efforts. The measures speak to the Office for Advancement of Telehealth's progress toward meeting the goals, specifically telehealth services delivered through Emergency Departments.

Likely Respondents: Telehealth Network Grant Program Grantees.

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
Performance Improvement Measurement System	29	1	29	7	203
Total	29	29	203

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.

[FR Doc. 2023–03912 Filed 2–24–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

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 April 28, 2023.

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 HRSA Information Collection Clearance Officer, at (301) 594–4394.

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

Information Collection Request Title: Enhancing HIV Care of Women, Infants, Children and Youth Building Capacity through Communities of Practice OMB No. 0915–xxxx–New.

Abstract: HRSA aims to increase delivery of evidence-based interventions that enhance client outcomes, increase the skill level of the HIV workforce providing care and treatment to Women, Infants, Children and Youth, and involve partnerships for dissemination of best practices to Ryan White HIV/AIDS Program (RWHAP) Part D participants. To that end, HRSA seeks to implement a Communities of Practice (CoP) platform for RWHAP Part D recipients. A CoP engages recipient teams in improvement learning sessions using subject matter experts along with application experts who help recipient teams select, test, and implement changes on the front line of care. Through organizational self-assessments, didactic learning on specific care topics, goals setting, and work plan development, each team can strategically benefit their organization. CoPs afford participants the opportunity to work in a group to solve a recognized challenge related to a CoP domain and support dialogue among participants and the consultant/subject matter experts. Recipient teams commit to