SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and, with certain exceptions, labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ORTHO-CEPT (desogestrel-ethinyl estradiol) 21- and 28-day oral tablets, 0.15 mg/0.03 mg, is the subject of NDA 020301, held by Janssen Pharmaceuticals, Inc., and initially approved on December 14, 1992. ORTHO-CEPT is indicated for the prevention of pregnancy in women who elect to use oral contraceptives as a method of contraception.

In a letter dated October 7, 2014, Janssen Pharmaceuticals, Inc., notified FDA that ORTHO-CEPT (desogestrel-ethinyl estradiol) 21- and 28-day oral tablets, 0.15 mg/0.03 mg, were being discontinued, and FDA moved the drug product to the ''Discontinued Drug Product List'' section of the Orange Book.

Arnall Golden Gregory LLP submitted a citizen petition dated March 11, 2021 (Docket No. FDA–2021–P–0292), under 21 CFR 10.30, requesting that the Agency determine whether ORTHO-CEPT (desogestrel-ethinyl estradiol) oral tablets, 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 ORTHO-CEPT (desogestrel-ethinyl estradiol) 21- and 28-day oral tablets, 0.15 mg/0.03 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ORTHO-CEPT (desogestrel-ethinyl estradiol) 21- and 28-day oral tablets, 0.15 mg/0.03 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ORTHO-CEPT (desogestrel-ethinyl estradiol) 21- and 28-day oral tablets, 0.15 mg/0.03 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ORTHO-CEPT (desogestrel-ethinyl estradiol) 21- and 28-day oral tablets, 0.15 mg/0.03 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 also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. 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: August 17, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–17990 Filed 8–20–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–XXXX]

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: COVID–19 Provider Relief Programs Application and Attestation Portal, and Claims Reimbursement Submission Activities

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

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 October 22, 2021.

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 Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

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

Information Collection Request Title: COVID–19 Provider Relief Programs Application and Attestation Portal, and Claims Reimbursement Submission Activities, OMB No. 0906–XXXX.

Abstract: HRSA administers the Provider Relief Programs (which includes the Provider Relief Fund (PRF), the American Rescue Plan Act Rural (ARPA–R) payments, the COVID–19 Coverage Assistance Fund (CAF), and the COVID–19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured (Uninsured Program or UIP). The

Provider Relief Programs disbursed, and are continuing to disburse, funds to eligible healthcare providers through two pathways: (1) Direct provider payments via the PRF and ARPA–R payments, and (2) claims reimbursement via the CAF and the UIP. This information collection includes four components: (1) The PRF and ARPA–R application portal; (2) the PRF and ARPA–R attestation portal; (3) the CAF application portal; and (4) the UIP application portal. To date, information for these programs has been collected under a Paperwork Reduction Act waiver executed pursuant to public health emergency authorities. HRSA is seeking comments regarding the CAF and the UIP for the first time. These information collections support administration of the Provider Relief Programs including the PRF, the Uninsured Program, and the CAF (funds for these three programs were appropriated under the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), Paycheck Protection Program and Health Care Enhancement Act (Pub. L. 116–139), Coronavirus Response and Relief Supplemental Appropriations Act (Division M of Pub. L. 116–260)), and the ARPA–R payments (funds were appropriated under the American Rescue Plan Act of 2021, Pub. L. 117–2).

Need and Proposed Use of the Information: Providers who apply for Provider Relief Programs (*i.e.,* PRF, ARPA–R, CAF, and UIP payments) must apply for direct provider payments or claims reimbursement and attest to a set of Terms and Conditions to enable HRSA's appropriate disbursement and oversight of recipients' use of funds.

Information collected will allow for (1) assessing if recipients have met statutory and programmatic requirements; (2) conducting audits; (3) gathering data required to calculate, disburse, and report on PRF, ARPA–R, CAF, and UIP payments; and (4) program evaluation. HRSA staff may also use information collected to identify and report on trends in the effect of the COVID–19 pandemic on health care providers and uninsured or underinsured patients throughout the United States.

HHS makes publicly available the names of payment recipients and the aggregate amounts received, for all providers who attest to receipt of a payment and acceptance of the Terms and Conditions or who retain payments for more than 90 days and are deemed to have accepted the Terms and Conditions. By accepting funds, the recipient consents to HHS publicly disclosing the payments that recipient has received.

Likely Respondents: Health care providers that apply to receive, or have applied to receive, PRF, ARPA–R, CAF, or UIP payments, and attested to the associated Terms and Conditions.

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
Attestation Portal	130,000	1	130,000	0.25	32,500
Application Portal	130,000	1	130,000	1.00	130,000
CAF Application	15,000	1	15,000	1.00	15,000
UIP Application	280,000	1	280,000	5.60	1,568,000
Total	555,000	.....	555,000	.....	1,745,500

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. 2021–18018 Filed 8–20–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Information Technology Advisory Committee 2021 Schedule of Meetings

AGENCY: Office of the National Coordinator for Health Information Technology (ONC), HHS.

ACTION: Notice of meetings.

SUMMARY: The Health Information Technology Advisory Committee (HITAC) was established in accordance with the 21st Century Cures Act and the Federal Advisory Committee Act. The HITAC, among other things, identifies priorities for standards adoption and makes recommendations to the National Coordinator for Health Information Technology (National Coordinator). The HITAC will hold public meetings throughout 2021. See list of public meetings below.

FOR FURTHER INFORMATION CONTACT: Michael Berry, Designated Federal Officer, at *Michael.Berry@hhs.gov,* (202) 701–0795.

SUPPLEMENTARY INFORMATION: Section 4003(e) of the 21st Century Cures Act (Pub. L. 114–255) establishes the Health Information Technology Advisory Committee (referred to as the ''HITAC''). The HITAC will be governed by the provisions of the Federal Advisory Committee Act (FACA) (Pub. L. 92–463), as amended, (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

Composition

The HITAC is comprised of at least 25 members, of which: