''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002; Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Gregory Reaman, Oncology Center of Excellence, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2202, Silver Spring, MD 20993–0002, 301–796–0785; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs: Amendments to Sec. 505B of the FD&C Act.'' This draft guidance addresses early planning for pediatric evaluation of certain molecularly targeted oncology drugs (including biological products) for which original NDAs and BLAs are expected to be submitted to FDA on or after August 18, 2020, in accordance with the provisions of section 505B of the FD&C Act. Section 505B of the FD&C Act (21 U.S.C. 355c) (also referred to as the Pediatric Research Equity Act or PREA (Pub. L. 108–155)), was amended by FDARA.

The amendments provide a new mechanism to expedite the evaluation of certain novel drugs with the potential to address an unmet medical need of pediatric patients with cancer. Specifically, FDARA amended the requirement for pediatric investigations of certain new targeted cancer drugs to be based on molecular mechanism of action rather than clinical indication. For original NDAs and BLAs submitted on or after August 18, 2020, if the application is for a new active ingredient, and the drug or biological product that is the subject of the application is intended for treatment of an adult cancer and directed at a molecular target FDA determines to be substantially relevant to the growth or progression of a pediatric cancer, reports of molecularly targeted pediatric cancer investigations must be submitted with the marketing application, unless the required investigations are waived or deferred (section 505B(a)(1)(B) of the FD&C Act).

This draft guidance provides recommendations on regulatory considerations related to the amendments to section 505B of the FD&C Act, including information on molecular targets, factors FDA intends to consider in the determination of whether a molecular target is substantially relevant to the growth or progression of a pediatric cancer, the molecular target lists, content of the initial pediatric study plan and description of recommended studies, additional considerations for rare cancers, and considerations for planned waivers and deferrals. In addition, the draft guidance includes information regarding global implications and international collaboration.

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 ''FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs.'' 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.

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. 3501–3521). 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 312 have been approved under OMB control numbers 0910–0014. The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, or https://www.regulations.gov.*

Dated: December 9, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26877 Filed 12–12–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Bureau of Primary Health Care Uniform Data System, OMB No. 0915–0193—Revision

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than January 13, 2020.

ADDRESSES: Submit your comments, including the ICR title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Bureau of Primary Health Care (BPHC) Uniform Data System (UDS), OMB No. 0915–0193—Revision

Abstract: The Health Center Program, administered by HRSA, is authorized under section 330 of the Public Health Service (PHS) Act, most recently amended by section 50901(b) of the Bipartisan Budget Act of 2018, Public Law 115–123. Health centers are community-based and patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients regardless of their ability to pay. Nearly 1,400 health centers operate approximately 12,000 service delivery sites that provide primary health care to more than 27 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA uses the Uniform Data System (UDS) for annual reporting by certain HRSA award recipients, including Health Center Program awardees (those funded under section 330 of the PHS Act), Health Center Program look-alikes, and Nurse Education, Practice, Quality and Retention Program awardees (specifically those funded under the practice priority areas of section 831(b) of the PHS Act).

Need and Proposed Use of the Information: HRSA collects UDS data annually to ensure compliance with legislative and regulatory requirements, improve clinical and operational performance, and report overall program accomplishments. HRSA aligns several clinical measures reported in UDS with the Centers for Medicare & Medicaid Services' (CMS) electronic specified clinical quality measures (eCQM). These data help to identify trends over time, enabling HRSA to establish or expand targeted programs and to identify effective services and interventions that will improve the health of medically underserved communities. HRSA analyzes UDS data with other national health-related data sets to compare the Health Center Program patient populations and the overall U.S. population.

HRSA received comments on the BPHC UDS **Federal Register** notice published on July 26, 2019, vol. 84, No. 144; pp. 36108. We have taken the commenter's suggestions into consideration and have made appropriate adjustments to the draft instruments. The 2020 UDS data collection will be updated in the following ways:

- *Retiring CMS126 Use of Appropriate Medications for Asthma:* The CMS eCQM is no longer being updated when new asthma medications are approved for use. This measure was also retired from the Healthcare Effectiveness Data and Information Set, is no longer endorsed by the NQF, and there is currently no comparable eCQM for asthma. Thus, no replacement measure is planned at this time.
- *Retaining CMS277v0—Dental Sealants for Children Between 6–9 years:* Based upon public feedback, HRSA has decided to retain the dental sealant measure for 2020 UDS reporting. HRSA has also decided to not add the fluoride varnish measure for 2020 UDS.
- *Adding CMS159v8 Depression Remission at Twelve Months:* The addition of the CMS depression remission measure at 12 months provides complementary mental health outcome data on how well health centers help patients reach remission. Improvement in the symptoms of depression and an ongoing assessment of the current treatment plan are crucial to the reduction of symptoms and psychosocial well-being of patients. The addition of *CMS159v8* further supports HRSA's commitment to HHS' strategic objective to ''Reduce the impact of mental and substance use disorders through prevention, early intervention, treatment, and recovery support.''
- *Revising the HIV linkage to care measure:* The HIV linkage to care measure captures the percentage of patients whose first ever HIV diagnosis was made by health center staff between October 1 of the prior year and September 30 of the measurement year and who were seen for follow-up treatment within 90 days of that first-ever diagnosis. This measure will be modified to change the follow-up treatment from 90 days to 30 days aligning with Centers for Disease Control and Prevention's guidance.[1]
- *Adding CMS349v2 HIV Screening:* The addition of the CMS HIV screening measure will enable HRSA to better identify priority geographic locations, assist high risk groups among health center patients, and more effectively deploy interventions and resources in support of the ''Ending the HIV Epidemic'' Initiative.
- *Adding Prescription for Pre-Exposure Prophylaxis International Classification of Diseases (ICD) 10 Codes and Current Procedural Terminology codes:* The addition of the Prescription for Pre-Exposure Prophylaxis ICD–10 and Current Procedural Terminology codes will allow for the collection of this HIV prescription prevention data in health centers and further supports the ''Ending the HIV Epidemic'' Initiative's goal of reducing new HIV infections.
- *Refraining from including additional diabetes measures:* Based upon public feedback, HRSA will not be adding CMS131v8 Diabetes Eye Exam, CMS123v7 Diabetes Foot Exam, or CMS134v8 Diabetes Medial Attention to Nephropathy to the 2020 UDS.
- *Adding CMS125v8 Breast Cancer Screening:* There is substantial geographic and demographic variation in breast cancer death rates, suggesting that there are social and non-economic obstacles that affect breast cancer screening.[2] Preventive screening through timely access to mammograms can lead to early detection, better treatment prognosis, and potential to reduce health disparities.[3]
- *Adding a Prescription Drug Monitoring Programs (PDMPs) Question to Appendix D: Health Center Health Information Technology Capabilities:* PDMPs are effective tools for reducing prescription drug abuse and diversion. Improving provider utilization and access to real-time data has demonstrated meaningful results in

[1] *https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf.*

[2] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4540479/.*

[3] *https://www.thecommunityguide.org/findings/cancer-screening-reducing-structural-barriers-clients-breast-cancer.*

reducing over-prescribing of medication.[4]

• *Revising the Social Determinants of Health Question in Appendix D: Health Center Health Information Technology Capabilities:* There is strong evidence that social and economic factors influence an individual's health.[5] Several health care systems are exploring how to collect information on the social determinants of health (SDOH). The inclusion of these questions into Appendix D allows HRSA to see how health centers are approaching this challenge and how many of their vulnerable patients are experiencing social and economic risks associated with poor health. For health centers that are using a standardized screener, there is one additional question asking for the total number of patients that screen positive for food insecurity, housing insecurity, financial strain, and lack of transportation/access to public transportation.

• *Adding ICD–10 Codes to Capture Human Trafficking and Intimate Partner Violence:* HRSA is aware that human trafficking [6] and intimate partner violence [7] are part of the SDOH that can affect a wide range of health and quality of life outcomes. Addressing SDOH is a HRSA objective to improve the health and well-being of health center patients and the broader community in which they reside.

• *Utilizing the Uniform Data System Test Cooperative (UTC):* As part of HRSA's efforts to modernize the UDS HRSA is establishing the UTC as an enduring testing and piloting capability. The UTC consists of three main components: (1) A steering committee, (2) a coordinating entity, and (3) health center test participants. Through this cooperative, HRSA will be able to pilot test innovative information technology and software, streamlining of clinical quality measures, and alternative data collection methodologies to reduce reporting burden and improve data quality and integrity.

The total number of estimated respondents changed from 2,075 to 2,134. The reason for the increase in the number of respondents for the UDS Report from 1,471 to 1,503 is because this number was previously based on 2018 UDS data that HRSA had available in July 2019. Since then, HRSA has been able to update the respondents that we anticipate for 2019 UDS reporting due to the incremental increase of awardees in the Health Center Program. The increase in the number of Grant Reports for Vulnerable Populations from 504 to 531 is due to an increase in a subset of awardees who receive Migrant Health Center, Health Care for the Homeless, and Health Centers for Residents of Public Housing funding.

The average burden hours per response changed from 223 to 238 as a result of comments received on the 60-day **Federal Register** Notice and additional consultation with external stakeholders. These stakeholders stated that the inclusion of additional clinical quality measures in the UDS would slightly increase the reporting burden. While these measures are already included in most electronic health records, there is some additional work that health centers will need to do in order to incorporate the measures into their workflows and their annual reporting. In addition to these changes, the names of the forms *Universal Report* and *Grant Report* were updated to provide greater specificity.

Likely Respondents: Likely respondents will include Health Center Program award recipients, Health Center Program look-alikes, and Nurse Education, Practice, Quality and Retention Program awardees funded under the practice priority areas of section 831(b) of the PHS Act.

Burden Statement: Burden includes 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 use technology and systems for the purpose of: Collecting, validating, and verifying information, processing and maintaining information, disclosing and providing information. It also accounts for time to train personnel, respond to a collection of information, search data sources, complete and review the collection of information, and transmit or otherwise disclose the information. It will also include testing information necessary to support the UTC. No more than three tests would be conducted each calendar year and no more than one hundred health centers would participate in one test. Participation is voluntary and will not affect health centers' funding status. This sample size is sufficient to conduct a pilot test and determine if proposed innovations should be scaled across the Health Center Program.

The total annual burden hours estimated for this Information Collection Request 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
Uniform Data System (UDS) Report	1,503	1	1,503	238	357,714
Grant Report for Vulnerable Populations	531	1	531	30	15,930
UTC Tests	100	3	300	80	24,000
Total	2,134	.....	2,334	.....	397,644

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2019–26876 Filed 12–12–19; 8:45 am]

BILLING CODE 4165–15–P

[4] *https://www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.*

[5] *https://www.countyhealthrankings.org/explore-health-rankings/measures-data-sources/county-health-rankings-model/health-factors/social-and-economic-factors.*

[6] *https://www.acf.hhs.gov/otip/about/what-is-human-trafficking.*

[7] *https://www.hrsa.gov/sites/default/files/hrsa/HRSA-strategy-intimate-partner-violence.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Opportunity to Co-Sponsor Office of Disease Prevention and Health Promotion Healthy Aging Summit and Regional Workshops

AGENCY: Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Office of Disease Prevention and Health Promotion (ODPHP) announces the opportunity for non-Federal public and private sector organizations and entities to co-sponsor the 2020 Healthy Aging Regional Workshops (Workshops) and/or the 2021 Healthy Aging Summit (HAS).

Opportunity A: 2020 Healthy Aging Regional Workshop co-sponsorship will involve executing a single or series of financially self-sustaining (no federal funds will be provided to the co-sponsor) meetings or workshops to convene healthy-aging stakeholders to support regional action planning and dissemination of information on healthy aging, aging in place, and age-friendly public health systems.

Opportunity B: 2021 Healthy Aging Summit co-sponsorship will involve executing a single financially self-sustaining (no federal funds will be provided to the co-sponsor) conference and related activities focused on health promotion and disease prevention research across the lifespan. This Summit will identify critical research needs and highlight the latest science of creating livable communities and improving healthy aging.

This co-sponsorship opportunity is not a grant or contract award program and each partner will be responsible for financially supporting its own activities. Potential co-sponsors must have demonstrated interest in and experience with coordinating healthy aging-focused activities, be capable of managing the day-to-day operations associated with the proposed activities, and be willing to participate substantively in the execution of the co-sponsored activity.

DATES: To receive consideration, proposals for co-sponsoring Healthy Aging Regional Workshops and/or the 2021 Healthy Aging Summit must be received via email or postmarked mail at the addresses listed below, by 5:00 p.m. EST on January 17, 2020. Proposals will meet the deadline if they are either (1) received on or before the deadline date; or (2) postmarked on or before the deadline date. Private metered postmarks will not be accepted as proof of timely mailing. Hand-delivered proposals must be received by 5:00 p.m. EST on January 17, 2020. Proposals that are received after the deadline will not be considered.

ADDRESSES: Expressions of interest for healthy-aging co-sponsorships should be submitted via email to *HP2030@hhs.gov* with the subject line ''Co-sponsorship Opportunity for Healthy Aging'' or by mail to Ayanna Johnson, Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ayanna Johnson, Office of Disease Prevention and Health Promotion, Office of the Assistant Secretary for Health, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Telephone: (240) 453–8280; Email: *HP2030@hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

ODPHP is a program office within the Office of the Assistant Secretary for Health (OASH), Office of the Secretary of the U.S. Department of Health and Human Services (HHS). ODPHP was established by Congress in 1976 with a mission to provide leadership for disease prevention and health promotion efforts for all Americans. To promote the health of the country, ODPHP sets national health goals and supports programs, services, and educational activities. ODPHP leads Healthy People 2020/2030, Dietary Guidelines for Americans, Physical Activity Guidelines for Americans, National Clinical Care Commission, National Youth Sports Strategy, President's Council on Sports, Fitness and Nutrition, and *healthfinder.gov.*

The percentage of the population age 65 or older in the United States is growing. It is estimated that by 2050, 20.9% of the population will be over age 65, compared to 13.7% in 2012. This group is living and working longer, redefining later life, and enriching our communities and society in new and vital ways. Improvements in the delivery of preventive services and care coordination, and a greater understanding of the social, environmental and emotional factors that influence health in the later years of life could help reduce health care costs and improve quality of life for older Americans.

Preparing regional public health and aging services leaders, to ensure that our public health system is equipped to support the unique health needs of older Americans, is of utmost importance. To further address the health needs of Americans as they age, ODPHP organized Healthy Aging Summits in 2015 and 2018. The Summits provided an opportunity to share the state-of-the-science in healthy aging, identify knowledge gaps, promote prevention and support livable communities for aging in place. Following the Summits, one-day national workshops convened state aging directors and state health officers to develop state-level priorities and action plans to promote healthy aging. The 2018 workshop expanded convened both state and local public health leaders to explore issues affecting older adults.

Building on the Healthy People model, ODPHP projects use a social-determinants-of-health (SDOH) framework to strengthen public health. The framework calls for looking at upstream conditions that impact health. The SDOH framework was adapted to each of the Summits through the conference tracks which included: Maximizing Quality of Life, Social and Community Context, Health and Health Care, and Neighborhood and Built Environment.

Requirements of the Co-Sponsorship

Consistent with ODPHP's mission and the applicable statutory authority, Title XVII of the Public Health Service Act, the Healthy Aging Regional Workshops and Healthy Aging Summit aim to support the dissemination of relevant information and convene experts to share best practices for disease prevention and health promotion. The Workshops convene over 1 day, and typically have 50 attendees. The Summit convenes over 3 days, and typically has 600 attendees.

ODPHP is seeking organizations capable of managing the development and execution of healthy aging research-sharing conferences or workshops and programming. Co-sponsors will assist with workshop and/or summit and agenda development, coordination, financial management, and meeting logistics in conjunction with ODPHP staff.

Approved proposals will require a co-sponsorship agreement signed by both the co-sponsor and ODPHP that outlines the terms and parameters of the agreement. The co-sponsorship will be