

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency’s estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Sec. 1110, Social Security Act, 42 U.S.C. 1310.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Head Start Program Performance Standard (Office of Management and Budget #: 0970–0148)

AGENCY: Office of Head Start, Administration for Children and

Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the information collection requirements under the Head Start Program Performance Standards (Office of Management and Budget (OMB) #0970–0148, expiration August 31, 2024). At this time, there are no changes to the approved recordkeeping requirements under this OMB number. However, a Notice of Proposed Rulemaking on Supporting the Head Start Workforce and Consistent Quality Programming was published and if any of the proposed changes are made final, this information collection will be updated to reflect those changes.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Section 641A of the Head Start Act, 42 U.S.C. 9836A, directs the U.S. Department of Health and Human

Services (HHS) to develop “scientifically based and developmentally appropriate education performance standards related to school readiness” and “ensure that any such revisions in the standards do not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services.” This information collection is entirely record keeping and does not contain any standardized instruments to provide flexibility for local programs. These records are intended to act as a tool for grantees and delegate agencies to be used in their day-to-day operations. For example, this includes the requirement that programs maintain a waiting list of eligible families. There are currently no changes to the record keeping requirements. However, if any proposed changes from the Notice of Proposed Rulemaking on Supporting the Head Start Workforce and Consistent Quality Programming (88 FR 80818), this information collection will be updated to reflect those changes.

Respondents: Head Start grant recipients. Depending on the standard, the calculated burden hours is based on the individual enrollee, family, grant, program, or staff. In a few cases, only a proportion of one of these may apply.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average annual burden hours per response	Annual burden hours
Impasse procedures	2,900	1	0.7	2,030
Documenting eligibility	260,000	1	0.166	43,160
Maintain a waiting list	2,900	1	2	5,800
Track attendance	2,900	1	5	14,500
Written plan to support program participation following temporary suspension	150	1	1	150
Child developmental screenings and assessment	800,000	1	1	800,000
Dual Language Learners Assessment	269,000	1	2	538,000
Obtain child health status, source of health care, and nutritional health needs	800,000	1	0.66	528,000
Documents lack of available funds for assessment and treatment	2,900	1	0.5	1,450
Maintaining records on the administration of medication	2,900	1	0.5	1,450
Joint agreements, procedures, or contracts with community organizations and memorandum of understanding with local entity	2,900	1	0.166	481
Criminal record checks	74,000	1	0.33	24,420
Ensure staff initial health examination and periodic re-examination	25,000	1	0.25	6,250
Volunteer screening for tuberculosis	2,900	1	0.166	481
Maintain automated accounting and recordkeeping system and collect and use data to monitor program performance and continuous improvement, and conduct a self-assessment and community assessment	2,900	1	79	229,100
Quality Improvement Plan	100	1	10	1,000
Submit proof of coverage	2,900	1	0.166	481
Parental Consent, Annual Notice, and Recordkeeping of PII Disclosure	723,000	1	0.33	238,590

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Annual number of responses per respondent	Average annual burden hours per response	Annual burden hours
Applications for the purchase, construction, or renovation of facilities; record retention and submission of documents on facilities	250	1	40	10,000
Waiver request	200	1	1	200
Up-to-date child rosters and lists of adults each child is authorized to be released to are maintained	2,900	1	2	5,800
Agencies required to compete will have to complete an application for each grant competed	75	1	60	4,500
Each Head Start or Early Head Start agency wishing to be renewed for 5 years without competition shall request that status from ACF	400	1	0.25	100
Updating program and personnel policies and procedures that promote implementation of Head Start standards	2,900	1	7	20,300

Estimated Total Annual Burden Hours: 2,476,243.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Section 641A of the Head Start Act, 42 U.S.C. 9836A.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1584]

Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to Coronavirus Disease

2019 (COVID-19). FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorization follows the February 4, 2020, determination by the Secretary of Health and Human Services (HHS), as amended on March 15, 2023, that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad and that involves the virus that causes COVID-19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the

SUPPLEMENTARY INFORMATION section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Kim Sapsford-Medintz, Office of Product Evaluation and Quality, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3216, Silver Spring, MD 20993-0002, 301-796-0311 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for