Preamble to the Final Rule on Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs

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Administration for Children and Families
Office of Head Start
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1302

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Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs

AGENCY: Office of Head Start (OHS), Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment (IFC) adds new provisions to the Head Start Program Performance Standards to mitigate the spread of the coronavirus disease 2019 (COVID-19) in Head Start programs. This IFC requires effective upon publication, universal masking for all individuals two years of age and older, with some noted exceptions, and all Head Start staff, contractors whose activities involve contact with or providing direct services to children and families, and volunteers working in classrooms or directly with children to be vaccinated forCOVID-19 by January 31, 2022.

DATES: *Effective date*: This IFC is effective on November 30, 2021.

Compliance date: The compliance date for the mask requirement is the date of publication of the rule, November 30, 2021. The compliance date for the vaccine requirement is January 31, 2022. For more information, *see* **SUPPLEMENTARY INFORMATION**.

Comment date: To be assured consideration, comments on this interim final rule must be received on or before December 30, 2021.

ADDRESSES: You may submit comments, identified by [docket number and/or RIN number], by any of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Office of Head Start, Attention: Director of Policy and Planning, 330 C Street, SW, 4th Floor, Washington, DC 20201.

Instructions: All submissions received must include the agency name and docket number or RIN for this rulemaking. All comments received will be posted without change to http://www.regulations.gov, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Colleen Rathgeb, OHS, at HeadStart@eclkc.info or 1-866-763-6481. Deaf and hearing-impaired individuals may call the Federal Dual Party Relay Service at 1-800-877-8339 between 8 a.m. and 7 p.m. Eastern Standard Time.

SUPPLEMENTARY INFORMATION: The compliance date for the vaccine requirement is January 31, 2022. This means staff, certain contractors and volunteers must have their second dose in a two-dose series, or first dose in a single-dose by January 31, 2022. Full vaccination requires 14 days after a two-dose series such as Pfizer or Moderna or 14 days after a single-dose series like Johnson & Johnson, but for purposes of this regulation, staff, certain contracts and volunteers will meet the requirement even if they have not yet completed the 14-day waiting period required for full vaccination. This timing flexibility applies only to the initial implementation of this IFC and has no bearing on ongoing compliance.

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I. Tribal Consultation Statement

ACF conducts an average of five tribal consultations each year for tribes operating Head Start and Early Head Start. The consultations are held in four geographic areas across the country: Southwest, Northwest, Midwest (Northern and Southern), and East. The consultations are often held in conjunction with other tribal meetings or conferences, to ensure the opportunity for most of the 150 tribes that operate Head Start and Early Head Start programs to attend and voice their concerns regarding service delivery. We complete a report after each consultation, and then we compile a final report that summarizes the consultations. We submit the report to the Secretary of Health and Human Services (the Secretary) at the end of the year. We invite public comment on this IFC if there are concerns specific to Native communities and programs.

II. Statutory Authority

ACF publishes this interim final rule under the authority granted to the Secretary by sections 641A(a)(1)(C), (D) and (E) of the Head Start Act, 42 U.S.C. 9836a(a)(1)(C)–(E)), (D) and (,),, as amended by the Improving Head Start for School Readiness Act of 2007 (Pub. L. 110-134).

III. Executive Summary

A. Purpose of the Interim Final Rule

SARS-CoV-2, the infectious agent that causes COVID-19, is considered to be mainly transmissible through exposure to respiratory droplets when a person is in close contact with someone who has COVID-19. Correct and consistent facemask use has been critical in reducing the risk of droplet transmission of SARS-CoV-2.[1,2]Vaccination is the most important measure for reducing risk for SARS-CoV-2 transmission and in avoiding severe illness, hospitalization, and death.[3]

Four primary variants of SARS-CoV-2 have emerged to date. Of these, the Delta variant has been of particular concern as it causes more infections and spreads faster than other variants.[4] While the Delta variant has increased levels of transmissibility, COVID-19 vaccination remains highly effective against hospitalization and death. Although there are cases of SARS-CoV-2 infections among vaccinated individuals,[5] fully vaccinated adults were six times less likely to become infected, twelve times less likely to be hospitalized and eleven times less likely to die from COVID-19 compared to

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[1] https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html
[2] https://www.osha.gov/coronavirus/safework
[3] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

[4] Centers for Disease Control and Prevention. "Delta Variant: What We Know About the Science." August 26, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html
[5] Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021 | MMWR

unvaccinated adults according to data from August 2021.[6,7] While studies are still ongoing, preliminary data suggest that vaccinated persons infected with the Delta variant are potentially less infectious, and infectious for shorter periods of time compared to infected unvaccinated persons.[8,9,10,11,12,13]

The purpose of this IFC is to protect the health and safety of Head Start staff, children, and families and to mitigate the spread of SARS-CoV-2 in Head Start programs. It requires: (1) universal masking for all individuals two years of age and older, with some noted exceptions, effective immediately upon publication of this rule), (2) vaccination for COVID-19 by January 31, 2022, with some noted exemptions, for all Head Start program staff, inclusive of Head Start, Early Head Start, and Early Head Start-Child Care Partnerships, certain contractors, and volunteers in classrooms or working directly with children (hereafter referred to as "Head Start staff"), and (3) for those granted an exemption to the requirement specified in (2), at least weekly testing for current SARS-CoV-2 infection. The requirements in this IFC will reduce the risk of transmission of SARS-CoV-2 in classrooms, which will protect the health and safety of children, reduce closures of Head Start programs, which can cause hardship for families,

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[6] https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status MMWR Morb Mortal Wkly Rep 2021;70:1255–1260. DOI: http://dx.doi.org/10.15585/mmwr.mm7036e2
[7] https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination

[8] Chia PY, Ong SWX, Chiew C, et al. Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study. medRxiv. 2021;https://www.medrxiv.org/content/10.1101/2021.07.28.21261295v1
[9] Shamier MC, Tostmann A, Bogers S. Virological characteristics of SARS-CoV-2 vaccine breakthrough infections in health care workers. medRxiv. 2021;https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1
[10] Kang M, Xin H, Yuan J. Transmission dynamics and epidemiological characteristics of Delta variant infections in China. medRxiv. 2021;https://www.medrxiv.org/content/10.1101/2021.08.12.21261991v1
[11] Ong SWX, Chiew CJ, Ang LW, et al. Clinical and Virological Features of SARS-CoV-2 Variants of Concern: A Retrospective Cohort Study Comparing B.1.1.7 (Alpha), B.1.315 (Beta), and B.1.617.2 (Delta). Preprints with The Lancet. 2021;https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3861566
[12] Mlcochova P KS, Dhar MS, et al. . SARS-CoV-2 B.1.617.2 Delta variant emergence and vaccine breakthrough. Research Square. 2021 https://www.researchsquare.com/article/rs-637724/v1
[13] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

and support the Administration's priority of sustained in-person early care and education that is safe for children—with all of its known benefits to children and families.[14]

Greater understanding about the spread ofSARS-CoV-2, the increased risk to certain populations, the benefits of masking, and the safety and efficacy of vaccines demonstrates the need for widespread masking and vaccination to reduce COVID-19 and its impacts. Although COVID-19 cases had begun to decline in parts of the country following the most recent COVID-19 surge, data indicate cases are beginning to rise in other parts—particular northern states where the weather has begun to turn colder ,[15] and the future trajectory of the pandemic is unclear. The Delta variant is currently the predominant variant in the United States and has resulted in greater rates of cases and hospitalizations among children than from other variants.[16,17,18] Furthermore, there is potential for the rapid and unexpected development and spread of additional new and more transmissible variants. Experience with the Delta variant suggests that we must take adequate steps to prevent transmission and protect the workforce and children to avoid serious harm.[19] It is critical that all Head Start staff get fully vaccinated for

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[14] Barr, A. C., & Gibbs, C. (2019). *Breaking the Cycle? Intergenerational Effects of an Anti-Poverty Program in Early Childhood*. EdWorkingPaper: 19-141. Retrieved from Annenberg Institute at Brown University, https://edworkingpapers.com/sites/default/files/ai19-141.pdf.; Bauer, L., & Schanzenbach, D. W. (2016). *The Long-Term Impact of the Head Start Program*. Washington, DC: The Brookings Institute. Retrieved from: https://www.hamiltonproject.org/assets/files/long_term_impact_of_head_start_program.pdf.; Ludwig, J., & Phillips, D. (2007). The Benefits and Costs of Head Start. *Social Policy Report, Vol. 21*(3), Society for Research in Child Development. Retrieved from: https://files.eric.ed.gov/fulltext/ED521701.pdf.; Garcia, J. L., Heckman, J. J., Leaf, D. E., & Prados M. J. (2019). Quantifying the Life-cycle Benefits of a Prototypical Early Childhood Program. National Bureau of Economic Research Working Paper No. 23479. Cambridge, MA: NBER. Retrieved from: https://heckmanequation.org/www/assets/2017/01/w23479.pdf.; Yoshikawa, H., Weiland, C., Brooks-Gunn, J., Burchinal, M. R., Espinosa, L. M., Gormley, W. T., Ludwig, J., Magnuson, K. A., Phillips, D., & Zaslow, M. (2013). *Investing in Our Future: The Evidence Base on Preschool Education*. Society for Research in Child Development and Foundation for Child Development. Retrieved from: http://www.fcd-us.org/assets/2013/10/Evidence20Base20on20Preschool20Education20FINAL.pdf

[15] https://covid.cdc.gov/covid-data-tracker/#trends_dailycases

[16] Delahoy, M., et al. Hospitalizations Associated with COVID-19 Among Children and Adolescents -COVID-Net, 14 States, March 1, 2020 – August 14, 2021, https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e2.htm

[17] Siegel DA, Reses HE, Cool AJ, et al. Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021.

[18] https://covid.cdc.gov/covid-data-tracker/#demographicsovertime

[19] Centers for Disease Control and Prevention. "Delta Variant: What We Know About the Science." August 26, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html

COVID-19 and consistently wear masks to protect children, staff, and families from exposure to SARS-CoV-2 and to reduce the risk of transmission to families of Head Start children and staff who may be at risk for increased morbidity and mortality from COVID-19.

This IFC adds provisions to the Head Start Program Performance Standards to impose three requirements:

(1) Universal masking, with some noted exceptions, for all individuals two years of age and older when there are two or more individuals in a vehicle owned, leased, or arranged by the Head Start program; when they are indoors in a setting where Head Start services are provided; and, for those not fully vaccinated, outdoors in crowded settings or during activities that involve close contact with other people. This requirement is effective immediately.

(2) Vaccination for COVID-19 for Head Start program staff, certain contractors and volunteers by January 31, 2021.

(3) For those granted an exemption to the requirement specified in (2), at least weekly testing for current SARS-CoV-2 infection.

Being fully vaccinated for COVID-19 and using a mask are two of the most effective mitigation strategies available to reduce transmission ofSARS-CoV-2.[20] Additionally, including a regular SARS-CoV-2 testing requirement for those approved for an exemption from the vaccination requirement is necessary to identify infected employees and separate them from the workplace to prevent transmission and to facilitate early medical intervention, when appropriate. Fully vaccinated staff are at much lower risk of infection and therefore, pose lower transmission risk to the young unvaccinated children

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[20] Centers for Disease Control and Prevention. "Science Brief: COVID-19 Vaccines and Vaccination." September 15, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#:~:text=Evidence%20suggests%20the%20US%20COVID,interrupting%20chains%20of%20transmission.

in their care. The CDC recommends screening testing for current infection of unvaccinated asymptomatic workers as a useful tool to detect SARS-CoV-2 and stop transmission quickly.[21]

B. Interim Final Rule Justification

Section 641A of the Head Start Act authorizes the Secretary to "modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs," including "administrative and financial management standards," "standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate) for such agencies, and programs," and "such other standards as the Secretary finds to be appropriate," 42 U.S.C. 9836a§ 9836a(a)(1)(C),(D), (E). In developing these modifications, the Secretary included relevant considerations pursuant to section 641A(a)(2) of the Head Start Act, 42 U.S.C. 9836a(a)(2). The Secretary consulted with experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and FDA. The Secretary considered the Office of Head Start's past experience with the longstanding health and safety Head Start Program Performance Standards that have sought to protect Head Start staff and participants from communicable and contagious diseases. The Secretary also considered the circumstances and challenges typically facing children and families served by Head Start agencies including the disproportionate effect of COVID-19 on low-income communities served by Head Start agencies and the potential for devastating consequences for children and families of program closures and service interruptions due to SARS-CoV-2 exposures. The Secretary finds it necessary and appropriate to set health and safety standards for the condition of Head Start facilities

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[21] Centers for Disease Control. "Overview of Testing for SARS-CoV-2 (COVID-19)" October 22, 2021.
Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

that ensure the reduction in transmission of the SARS-CoV-2 and to avoid severe illness, hospitalization, and death among program participants.

ACF initially chose, among other actions, to allow Head Start programs to decide whether or not to require staff vaccination rather than require vaccination, to provide information on the COVID-19 vaccine through its Early Childhood Learning and Knowledge Center[22], the website used to share guidance and information with Head Start grant recipients, and to emphasize that grant recipients can use COVID-19 response funds and American Rescue Plan funds to support staff in getting the COVID-19 vaccine. However, despite all of these efforts, uptake of vaccination among Head Start staff has not been as robust as hoped for and has been insufficient to create a safe environment for children and families. This is particularly true given the advent of the Delta variant and the potential for new variants and as programs continue to return to fully in-person services as the Office of Head Start expects in January 2022. The Office of Head Start (OHS) issued guidance to programs on May 20, 2021 outlining its expectations for programs in the 2021-2022 program year. This guidance prepared programs for the resumption of in-person services and informed programs that they should build toward full enrollment and provide comprehensive services for all enrolled children as soon as possible. It noted that beginning January 2022, OHS intends to reinstate pre-pandemic practices for tracking and monitoring enrollment. OHS will also resume evaluating which programs enter into the Full Enrollment Initiative in January 2022, which is a process by which OHS identifies programs that are not serving their full funded enrollment. This guidance followed a period since the onset of the pandemic of greater flexibility for programs with requirements related to enrollment, service duration,

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[22] Office of Head Start. "OHS COVID-19 Updates." Available at: https://eclkc.ohs.acf.hhs.gov/about-us/coronavirus/ohs-covid-19-updates

virtual/remote delivery of services, among others. These flexibilities were critical to programs' ability to continue providing services to children and families and to adapt services based on the changing health conditions in their communities during unprecedented times. As programs prepare for fully in-person services, it is imperative that we create conditions that support the health and safety of children and reduce program closures and service interruptions. The universal masking and vaccination requirements outlined in this IFC are critical to this effort.

The U.S. Centers for Disease Control and Prevention (CDC) issued guidance July 27, 2021.[23] The CDC stated that the rationale for this guidance was twofold: (1) an alarming rise in COVID-19 cases and hospitalization rates around the country—a reversal in what had been a steady decline since January 2021[24] and (2) new data showing the Delta variant to be highly transmissible.[25] A study covering the period from June to mid-August 2021 showed that weekly COVID-19 associated hospitalization rates among children and adolescents rose nearly five-fold during the late June to mid-August 2021 period, which coincided with increased circulation of the Delta variant.[26] In this same study, hospitalization rates were 10 times higher among unvaccinated than fully vaccinated adolescents. A separate study conducted in the United Kingdom showed that vaccination effectively reduces the risk of Delta variant infection[27] but that "vaccination

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[23] *Centers for Disease Control and Prevention. "Science Brief: COVID-19 Vaccines and Vaccination." September 15, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#:~:text=Evidence%20suggests%20the%20US%20COVID,interrupting%20chains%20of%20transmission.*

[24] Centers for Disease Control and Prevention. "COVID Data Tracker." Available at: https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalization-network

[25] Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep. ePub: 30 July 2021; https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

[26] Delahoy MJ, Ujamaa D, Whitaker M, et al. Hospitalizations Associated with COVID-19 Among Children and Adolescents — COVID-NET, 14 States, March 1, 2020–August 14, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1255–1260. DOI: http://dx.doi.org/10.15585/mmwr.mm7036e2

[27] Singanayagam, AnikaBadhan, Anjna et al. Community transmission and viral load kinetics of the SARS-CoV-2 delta (B.1.617.2) variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study. https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext

alone is not sufficient to prevent all transmission of the delta variant in the household setting, where exposure is close and prolonged." The authors recommended nonpharmaceutical interventions, such as mask wearing, as an important complementary approach alongside vaccination to minimize spread of the Delta variant.

On November 10, 2021, the CDC issued updated guidance to early childhood education and child care (ECE) programs.[28] One of the key changes in the guidance is the recommendation for universal indoor masking for ECE programs for everyone aged 2 years and older regardless of vaccination status, with limited exceptions, see section V *Provisions of the Interim Final Rule.* It also notes that ECE program staff can model consistent and correct use for children aged 2 years or older in their care. Vaccinations and masks are key strategies for reducing the transmission of SARS-CoV-2 along with other risk reduction strategies, including staying home if sick; handwashing; improving ventilation; screening and diagnostic testing, cleaning, and disinfecting; keeping physical distance; and cohorting,[29] especially because physical distancing is not always feasible in early childhood settings.[30]

The COVID-19 vaccines are the safest and most effective way to protect individuals and the people with whom they live and work from infection and from severe illness and hospitalization if they contract the virus. Data from August 2021 indicate that when compared with vaccinated adults, those who were not fully vaccinated were 6 times more likely to become infected, 12 times more likely to be hospitalized, and 11 times

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28 Centers for Disease Control. "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs." November 10, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html

29 Cohorting refers to placing children and child care providers into distinct groups who stay together throughout an entire day.

30 Centers for Disease Control and Prevention. "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs." August 25, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html; https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/transmission_k_12_schools.html

more likely to die of COVID-19.[31,32] In addition to preventing morbidity and mortality associated with COVID-19, currently available vaccines also demonstrate effectiveness against asymptomatic SARS-CoV-2 infection. A study of the period from December 14, 2020 to August 14, 2021, found that full vaccination for COVID-19 was 80 percent effective in preventing SARS-CoV-2 infection among health care workers.[33] While the scientific evidence for transmissibility of breakthrough cases (i.e., cases in fully vaccinated individuals) is still developing, fully vaccinated individuals are less likely to spread COVID-19 because they are less likely to become infected in the first place. Studies have shown that vaccinations reduce the risk of COVID-19 among unvaccinated close contacts, including children. For example, one study found that vaccination of health care workers was associated with decreased COVID-19 cases among members of their household.[34] Additionally, a study during the early months of the COVID-19 vaccine rollout in Israel found that community vaccination rates were associated with declines in infections among unvaccinated children.[35] Vaccination was also shown to be effective in lowering the risk of severe disease if infected with the Delta variant, which has emerged as a more contagious strain of the SARS-CoV-2 with a higher impact on children than previous variants.[36]

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[31] Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status — 13 U.S. Jurisdictions, April 4–July 17, 2021 Early Release / September 10, 2021 / 70

[32] Center for Disease Control and Prevention. "COVID Data Tracker." Available at: https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination

[33] Fowles, A., Gaglani, M., Groover, K., et al. Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020-August 2021, *Morbidity and Mortality Weekly Report,* August 27, 2021, Available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s_cid=mm7034e4_w

[34] Effect of Vaccination on Transmission of SARS-CoV-2. N Engl J Med 2021; 385:1718-1720 DOI: 10.1056/NEJMc2106757

[35] Milman, O., Yelin, I., Aharony, N. et al. Community-level evidence for SARS-CoV-2 vaccine protection of unvaccinated individuals. Nat Med 27, 1367–1369 (2021). https://doi.org/10.1038/s41591-021-01407-5

[36] Centers for Disease Control and Prevention. "COVID Data Tracker. Pediatric Data." Available at: https://covid.cdc.gov/covid-data-tracker/#pediatric-data; Centers for Disease Control and Prevention. "Delta Variant: What We Know About the Science." Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html; Centers for Disease Control and Prevention. Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021
Available at: https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e1.htm?s_cid=mm7036e1_w

Given that children under age 5 years are too young to be vaccinated at this time, requiring masking and vaccination among everyone who is eligible are the best defenses against COVID-19, especially cases arising from the more infectious Delta variant. These measures will also reduce program closures due to SARS-CoV-2 infection. When children or staff test positive for SARS-CoV-2 or have exposure to someone else who has tested positive for SARS-CoV-2, classrooms or entire programs close for a period of days or weeks to allow for test results and quarantining per local health department guidance. Additionally, as discussed later in this IFC, closures impose hardship on Head Start children and families by diminishing the ability to attend Head Start in person. The result is harm to early learning and development. Closures also diminish the ability of parents to work or participate in schooling.

Health and Safety

The Delta variant, which in the summer of 2021 became the predominant SARS-CoV-2 strain in the United States, is more contagious – spreading twice as fast – and results in more cases and hospitalizations for children.[37] The increase in hospitalization is more acute in states with lower vaccination rates. Studies released by CDC found that the rate of hospitalization for children was nearly four times higher in states with the lowest vaccination rates when compared to states with high vaccination rates.[38] Furthermore, hospitalization rates for children in September and October 2021, while lower than other age groups, were elevated relative to other periods during the pandemic.[39] Vaccination remains the best line of defense against COVID-19. Data show

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[37] Centers for Disease Control and Prevention. "Delta Variant: What We Know About the Science." August 26, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html; https://covid.cdc.gov/covid-data-tracker/#pediatric-data

[38] Siegel DA, Reses HE, Cool AJ, et al. Trends in COVID-19 Cases, Emergency Department Visits, and Hospital Admissions Among Children and Adolescents Aged 0–17 Years — United States, August 2020–August 2021. MMWR Morb Mortal Wkly Rep 2021; 70:1249–1254. DOI: https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e1.htm.

[39] Centers for Disease Control and Prevention. "COVID Tracker Weekly Review." Available at: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html

fully vaccinated persons are less likely than unvaccinated persons to become infected with SARS-CoV-2, and infections with the Delta variant in fully vaccinated persons are associated with less severe clinical outcomes.[40] Being fully vaccinated reduces risk of the transmission of SARS-COV-2 from staff to children who are not yet eligible for the vaccine and must be protected to minimize their exposure. Reducing transmission from staff to children and between staff also reduces transmission from children and staff to their family members. Transmission of SARS-CoV-2 in child care settings has been linked to infections and hospitalizations in family members,[41] and some children and staff may return home to family members who are older or have underlying medical conditions that put them at greater risk for COVID-19-related morbidity and mortality. Studies have shown that COVID-19 has disproportionately affected some racial and ethnic minority groups such as Hispanic or Latino, Black or African American, American Indian or Alaskan Native (AIAN), and Native Hawaiian and other Pacific Islander people. [42] It is also estimated that these disparities may have long term implications for these populations: for example, it is estimated that COVID-19 morbidity and mortality impacts can reverse over 10 years of progress in reducing the gaps in life expectancy between Black and White populations.[43] Many families of Head Start children and staff are members of minority communities; 71 percent of families, and 69 percent of staff, self-identify as Hispanic/Latino, Black/African American, American Indian, or Alaska

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[40] Centers for Disease Control and Prevention. “Science Brief: COVID-19 Vaccines and Vaccination.” September 15, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#:~:text=Evidence%20suggests%20the%20US%20COVID,interrupting%20chains%20of%20transmission.

[41] Lopez AS, Hill M, Antezano J, et al. Transmission Dynamics of COVID-19 Outbreaks Associated with Child Care Facilities — Salt Lake City, Utah, April–July 2020. MMWR Morb Mortal Wkly Rep 2020;69:1319–1323. DOI: http://dx.doi.org/10.15585/mmwr.mm6937e3

[42] Centers for Disease Control and Prevention. “Introduction to COVID-19 Racial and Ethnic Health Disparities.” December 10, 2020. Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html

[43] Andrasfay, T., & Goldman, N. (2021). Reductions in 2020 US life expectancy due to COVID-19 and the disproportionate impact on the Black and Latino populations. Proceedings of the National Academy of Sciences of the United States of America, 118(5), e2014746118. https://doi.org/10.1073/pnas.2014746118

Native,[44] who have been shown to be at increased risk of exposure to SARS-CoV-2. Given the disproportionate burden of COVID-19 deaths and lower vaccination rates among racial and ethnic minority groups, requiring vaccination among Head Start staff is not only an issue of personal health, but also promotes public and community health and health equity for children and staff in Head Start programs.[45]A recent CDC study showed that during the period from May 23 to June 12, 2021, 50 percent of the children in a classroom tested positive for SARS-COV-2 infection in a Marin County, California elementary school following exposure to one unvaccinated teacher.[46] This outbreak, which began with an unvaccinated teacher who attended school for two days with symptoms and took off her mask when reading to the class, demonstrates the importance of vaccinating staff members who work closely with young children. The rate of SARS-CoV-2 positivity in the two rows closest to the teacher's desk was 80 percent (8 of 10); in the three back rows, it was 29 percent (4 of 14). Four days after the teacher reported being symptomatic, when the teacher received a positive test, additional cases of COVID-19 were reported among other staff members, students, parents, and siblings connected to the school. In addition to highlighting the importance of vaccination and masking, this study points to the Delta variant's increased transmissibility and potential for rapid spread, especially in unvaccinated populations such as children too young for vaccination.[47]

Additionally, a study covering the period from July 15 to August 31, 2021, that included public K-12 schools in Maricopa and Pima Counties, Arizona, found that

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[44] United States Department of Health and Human Services. "Head Start Program Information Report." Available at: https://eclkc.ohs.acf.hhs.gov/data-ongoing-monitoring/article/program-information-report-pir

[45] Patel KM, Malik AA, Lee A, et al. COVID-19 vaccine uptake among US child care providers. *Pediatrics.* 2021; doi: https://pubmed.ncbi.nlm.nih.gov/34452977/

[46] Lam-Hine T, McCurdy SA, Santora L, et al. Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School — Marin County, California, May–June 2021. MMWR Morb Mortal Wkly Rep 2021; 70:1214–1219. DOI: http://dx.doi.org/10.15585/mmwr.mm7035e2

[47] Lam-Hine T, McCurdy SA, Santora L, et al. Outbreak Associated with SARS-CoV-2 B.1.617.2 (Delta) Variant in an Elementary School — Marin County, California, May–June 2021. MMWR Morb Mortal Wkly Rep 2021; 70:1214–1219. DOI: http://dx.doi.org/10.15585/mmwr.mm7035e2

schools without mask requirements were 3.5 times more likely to have COVID-19 outbreaks compared with schools that started the year with mask requirements.[48] This finding is consistent with another study that included 520 counties across the United States during the period July 1 to September 4, 2021, reporting that counties without school mask requirements experienced larger increases in pediatric COVID-19 case rates after the start of school compared to counties that had school mask requirements.[49]

Prior to the availability of COVID-19 vaccines in the United States, during the period from September to October 2020, ACF collaborated with CDC to conduct a mixed-methods study in Head Start programs in eight states (Alaska, Georgia, Idaho, Maine, Missouri, Texas, Washington, and Wisconsin). The study found that implementing and monitoring adherence to recommended mitigation strategies, such as mask use, can reduce risk for SARS-COV-2 transmission in Head Start settings. It also showed that Head Start and Early Head Start programs that successfully implemented CDC-recommended guidance for childcare programs were able to continue offering safe in-person learning.[50]

A survey of the U.S. child care workforce conducted between May 26 and June 23, 2021, found that the overall COVID-19 vaccine uptake among child care providers was 78.2 percent, which was higher than the general U.S. adult population (65 percent).[51] The rate among Head Start and Early Head Start staff in center-based settings specifically was 73 percent, though lower in home-based programs. That 73 percent is a nationwide

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[48] Jehn M, McCullough JM, Dale AP, et al. Association Between K–12 School Mask Policies and School-Associated COVID-19 Outbreaks — Maricopa and Pima Counties, Arizona, July–August 2021. MMWR Morb Mortal Wkly Rep 2021;70:1372–1373. DOI: http://dx.doi.org/10.15585/mmwr.mm7039e1

[49] Budzyn SE, Panaggio MJ, Parks SE, et al. Pediatric COVID-19 Cases in Counties With and Without School Mask Requirements — United States, July 1–September 4, 2021. MMWR Morb Mortal Wkly Rep 2021;70:1377–1378. DOI: http://dx.doi.org/10.15585/mmwr.mm7039e3

[50] Coronado F, Blough S, Bergeron D, et al. Implementing Mitigation Strategies in Early Care and Education Settings for Prevention of SARS-CoV-2 Transmission — Eight States, September–October 2020. MMWR Morb Mortal Wkly Rep 2020; 69:1868-1872. DOI: http://dx.doi.org/10.15585/mmwr.mm6949e3

[51] Patel KM, Malik AA, Lee A, et al. COVID-19 vaccine uptake among US child care providers. Pediatrics. 2021; doi: https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e1.htm

figure. It could be much less in certain areas. Also, it is 73 percent of adults, but none of the children in the programs can be vaccinated. While other teachers and staff members might be protected from an unvaccinated staff, the concern remains the protection of children and families. Depending on the role in the program of the 27 percent of Head Start staff that are unvaccinated, it could result in roughly 250,000 children who are in the care of an unvaccinated adult. This IFC is critical in order to increase that percentage, given the importance of protecting young children from exposure to SARS-CoV-2, including more transmissible variants.

Data show COVID-19 vaccination requirements are effective in increasing vaccination rates among employees. Other industries that have implemented vaccine requirements have seen substantial increases in the percent of their workforce receiving the vaccine.[52, 53] Two weeks following the Governor of Washington's vaccine requirement for State workers, according to the Washington State Department of Health**,** the weekly vaccination rate increased 34 percent.[54]

Reduced Program Closures

Requiring staff to get fully vaccinated for COVID-19 is critical to reduce program closures due to SARS-CoV-2 exposures. Such closures may impose multiple hardships on Head Start children and families. The children and families served by Head Start are largely comprised of individuals who experience economic hardship and have been historically underserved and marginalized. In 2019, 80 percent of children served by

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[52] Hirsch, L. (2021, September 30). *After mandate, 91% of Tyson workers are vaccinated*. The New York Times. Retrieved November 3, 2021, from https://www.nytimes.com/2021/09/30/business/tyson-foods-vaccination-mandate-rate.html; Josephs, L. (2021, September 29). Nearly 600 United Airlines employees face termination for failing to comply with Vaccine Mandate. CNBC. Retrieved November 3, 2021, from https://www.cnbc.com/2021/09/28/unvaccinated-united-airlines-staff-faces-termination-as-early-as-today.html

[53] White House. "WHITE HOUSE REPORT: Vaccination Requirements Are Helping Vaccinate More People, Protect Americans from COVID-19, and Strengthen the Economy." Available at: https://www.whitehouse.gov/wp-content/uploads/2021/10/Vaccination-Requirements-Report.pdf

[54] White House. "Path Out of the Pandemic." Available at: https://www.whitehouse.gov/covidplan/#schools; Mikkelsen, D. (2021, August 27). *Covid-19 vaccinations increase in Washington following mandates, Spike in cases*. king5.com. Retrieved November 3, 2021, from https://www.king5.com/article/news/local/covid-19-vaccinations-increase-in-washington/281-1af4cc43-2d7f-4e77-a2fd-0fad28d0c4f3

Head Start were Black, Indigenous, or persons of color.[55] Thirty-eight percent of children were dual language learners, with a language other than English spoken in the home (sometimes in addition to English). The mean annual household income for families was $26,000. Fifty-nine percent of children had a mother with a high school diploma or less, and the majority (77 percent) had a mother who was either working full-time, working part-time, or looking for work. Fifty-seven percent and 52 percent of children's families received SNAP benefits and WIC benefits, respectively. Thirty-one percent of children lived in a household where parents reported household food would often or sometimes run out and they did not have money to purchase more. Twenty-four percent of children's mothers had moderate or severe depressive symptoms, as measured by a clinical depression screening tool.

Head Start programs provide critical services to meet the health, nutrition, and early learning needs of these children and families. Programs provide healthy nutritious meals to children and provide diapers for babies and toddlers, every day they are at the program. Programs ensure children are brushing their teeth and provide critical mental health services. Programs also provide high-quality early education services to promote the overall learning and development of children and prepare them for entry into kindergarten. If a program must close its facilities for a designated period of time due to an outbreak of SARS-CoV-2 infections, children at-risk will not receive these critical in-person services. Further, program closures limit the ability of Head Start families to work or seek educational opportunities. As summarized previously, Head Start families earning low wages and very likely do not have sick leave to care for children while they are in quarantine. Staying home for intermittent closures, rather than working, imposes

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[55] All descriptive statistics in this paragraph are from: Kopack Klein, A., Aikens, N., Li, A., Bernstein, S. Reid, N., Dang, M., Blesson, E…. Tarullo, L. (2021). Descriptive Data on Head Start Children and Families from FACES 2019: Fall 2019 Data Tables and Study Design, OPRE Report 2021-77, Washington, DC: U.S. Department of Health and Human Services.

significant financial costs on Head Start families. It also places the families at risk of losing their employment if they must take unpaid leave to care for children in quarantine. Families rely on Head Start programs to provide stable and reliable early care and education services to their children, and the effects of intermittent closures are significant.

As alluded to previously, program closures also create instability and stress for children and families. They disrupt children's opportunities for learning, socialization, nutrition, and continuity and routine. In June 2020, the Defending the Early Years organization released a survey to better understand the impact COVID-19 has had on young children, their families, and their teachers. Balancing working from home and supporting children was the number one challenge for parents. This challenge was especially acute for families with multiple children in different grade levels or with one child under the age of four years. Fifty-five percent of parents of young children reported they were somewhat-to-very concerned about financial issues (e.g., job loss) due to the COVID-19 pandemic.[56] Other issues of concern related to early childhood education program and school closures and/or virtual or remote learning have compounded to create uniquely difficult challenges for families. These compounding issues include missed opportunities for academic instruction, children falling behind, children missing out on social interaction and play with peers, challenges to safe reopening, and increase in children's stress.

Survey data from February 2021 indicates that a diminished ability to attend early childhood programs like Head Start in-person, is related to an increase in social and emotional difficulties for children, a decrease in support for children with disabilities, and

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[56] Jones, Denisha. Education Resources Information Center. "The Impact of COVID-19 on Young Children, Families, and Teachers." *Defending the Early Years* (2020). Available at: https://eric.ed.gov/?id=ED609168

an increase in parental stress due to lack of affordable child care including loss of jobs and wages.[57] The RAPID-EC Survey describes this as a "chain of hardship" where families loss of jobs results in difficulty paying for basic needs such as food and housing further negatively impacting family well-being including a rise in emotional distress for parents and children.[58] These disruptions can be particularly difficult for children and families experiencing homelessness, a population Head Start programs are required to prioritize (45 CFR §1302.15(c)). Of all families enrolled in Head Start programs, about 6.2 percent or 42,334 families experienced homelessness during the 2020-2021 program year.[59] Given the greater risks to the health and development of young children experiencing homelessness, stable Head Start services are critically important for these families.[60]

School closures, heightened stress, loss of income, and social isolation resulting from the COVID-19 pandemic are all stressors that have increased the risk for child abuse and neglect.[61] Head Start programs are required to prioritize foster children for enrollment, and there was an increase in the rate of children in foster care served in Head Start from 3.5 percent in 2019 to 3.8 percent in 2021. Program closures and remote learning during the pandemic contribute to disruption of service access for these children,

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[57] Barnett, W.S & Jung, K. Seven Impacts of the Pandemic on Young Children and their Parents: Initial Findings from NIEER's December 2020 Preschool Learning Activities Survey. February 2021. Available at: NIEER_Seven_Impacts_of_the_Pandemic_on_Young_Children_and_their_Parents.pdf

[58] Fisher,P, Lombardi, J. & Kendall Taylor, N. A day in the life of a pandemic/ https://medium.com/rapid-ec-project/a-year-in-the-life-of-a-pandemic-4c8324dda56b

[59] United States Department of Health and Human Services. "Head Start Program Information Report." Available at: https://eclkc.ohs.acf.hhs.gov/data-ongoing-monitoring/article/program-information-report-pir

[60] Kiersten: Coughlin, C. G., Sandel, M., & Stewart, A. M. (2020). Homelessness, Children, and COVID-19: A Looming Crisis. *Pediatrics*, 146(2). Available at: https://doi.org/10.1542/peds.2020-1408; Haskett, M. E., Armstrong, J. M., & Tisdale, J. (2016). Developmental Status and Social–Emotional Functioning of Young Children Experiencing Homelessness. Early Childhood Education Journal, 44(2), 119–125.
Available at: https://doi.org/10.1007/s10643-015-0691-8; Weinreb; L., Goldberg, R., Bassuk, E., & Perloff, J. (1998). Determinants of Health and Service Use Patterns in Homeless and Low-income Housed Children. Pediatrics, 102(3), 554–562. Available at: https://doi.org/10.1542/peds.102.3.554

[61] Rodriguez, C.M, Lee, S.J., Ward, K.P., & Pu, D.F. (2021). The Perfect Storm: Hidden risk of child maltreatment during the Covid-19 pandemic. Child Maltreatment, 26(2), 139-151.

who often experience trauma and are most in need of the consistent care, education and comprehensive services that Head Start provides.[62]

Supporting safe and sustained in-person services allows programs to return to fulfilling the critical functions they serve for children and families. All Head Start staff are mandated reporters and programs must have internal procedures in place for staff to report suspected cases of child abuse and neglect. Procedures also include notification to the program's Regional Office immediately if a staff member or volunteer suspects an incident. Agencies must provide training in methods for identifying and reporting suspected child abuse and neglect (45 CFR 1304.52(l)(3)(i)).[63] Research also indicates that Early Head Start can serve as a child abuse and neglect prevention program.[64] The work Head Start programs do to strengthen family economic stability and decrease parental stressors is known to help prevent child abuse. Many programs also provide supports to families experiencing domestic violence (2.5 percent or 24,000 families in 2019 OHS data[65]). This IFC is an important step in decreasing serious risks to very young children and their families.

OHS has been tracking data on the operating status of programs since the onset of the pandemic. In March and April of 2020, more than 90 percent of programs closed all in-person operations for varying lengths of time. By August of 2020, 21 percent of programs had reopened for in-person services, 26 percent remained closed for in-person services due to COVID-19, and the remainder of programs were closed for summer

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[62] Kiersten: Klain, E. J., & White, A. R. (2013). Implementing trauma-informed practices in child welfare. CITY: State Policy Advocacy Reform Center. Retrieved from http://www.centerforchildwelfare.org/kb/TraumaInformedCare/ImplementingTraumaInformedPracticesNov13.pdf

63 Office of Head Start Information Memorandum. Mandated Reporting of Child Abuse and Neglect ACF-IM-HS-15-04. September 18, 2015. Available at: https://eclkc.ohs.acf.hhs.gov/policy/im/acf-im-hs-15 04#:~:text=Staff%20who%20need%20help%20identifying,800%2D422%2D4453).&text=All%20Head%20Start%20programs%20must,of%20child%20abuse%20and%20neglect

[64] Child Trends. "How Early Head Start Prevents Child Maltreatment." November 1, 2018. Available at: https://www.childtrends.org/publications/how-early-head-start-prevents-child-maltreatment.

65 United States Department of Health and Human Services. "Head Start Program Information Report." Available at: https://eclkc.ohs.acf.hhs.gov/data-ongoing-monitoring/article/program-information-report-pir

months as regularly scheduled. In December 2020, data show the highest combined percentage (67 percent) of Head Start centers operating as solely virtual/remote or as hybrid, with an additional five percent, or 878, of centers closed. Together, these virtual/remote, hybrid, and closed centers account for over 13,500 centers nationwide. Each center represents many families for whom unpredictable closures and transitions to virtual learning come at a cost, may present difficult decisions between employment and child care responsibilities, and could result in major financial impacts on their household.

July 2021 data show that two percent of centers (393) were closed due to COVID-19, 14 percent of centers were operating in a virtual/remote service delivery model (2,861), and 45 percent of centers were operating in a hybrid service delivery model (9,181). Only 35 percent of centers (7,240) were operating fully in person.

September 2021 center operating status data shows 73 percent (14,917) of the centers are open for in-person only services, 14 percent (2,892) are operating in a hybrid model of in-person and virtual/remote services, and 4 percent (835) are open for virtual/remote only. Two percent (324) of centers remain entirely closed due to COVID-19 and the remaining 7 percent of centers are unreported, closed for the season, or closed due to a natural disaster. The increase in the number of programs delivering services in-person only is consistent with the expectations OHS outlined in May 2021 that programs move toward fully in-person services as soon as possible by January 2022, factoring in local health conditions.[66] This data also show that while closures declined, at least 20 percent of programs are closed, operating a virtual/remote service delivery model only, or in a hybrid model. Programs need to be able to resume fully in-person services to meet the needs of children and families, for all the reasons discussed in this section of the IFC.

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[66] Office of Head Start. Office of Head Start (OHS) Expectations for Head Start Programs in Program Year (PY) 2021–2022. May 20, 2021. Available at: https://eclkc.ohs.acf.hhs.gov/policy/pi/acf-pi-hs-21-04

A vaccination requirement and consistent and correct mask use are critical in mitigating SARS-CoV-2 transmission and keeping Head Start programs open. Program closures impede Head Start families from participating in the workforce, impose financial hardship on low wage workers who may not have paid time off to care for children who are in quarantine, create instability for children and families who depend on the Head Start program, and delay a full economic recovery for the nation.

HHS Secretary's Extension of Public Health Emergency

On January 31, 2020, Health and Human Services Secretary Alex M. Azar II determined that a public health emergency (PHE) exists retroactive to January 27, 2020,[67] under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. This declaration has been extended every 90 days since then and most recently on October 18, 2021. The current PHE declaration extends until mid-January 2022.

C. Waiver of Proposed Rulemaking

In accordance with the Administrative Procedure Act (APA), 5 U.S.C. 553, ACF ordinarily publishes a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule before the provisions of the rule take effect. . Specifically, 5 U.S.C. 553(b) generally requires the agency to publish a notice of the proposed rule in the Federal Register that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Section 553(c) further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Section 553(b)(B) authorizes the agency to waive these procedures, however, if the agency finds good cause

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[67] United States Department of Health and Human Services. "Public Health Emergency." January 31, 2020. Available at: https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVDI-15Oct21.aspx

that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

The 2021 outbreaks associated with the SARS-Cov-2 Delta variant have shown that current levels of COVID-19 vaccination coverage up until now have been inadequate to protect Head Start staff, children, and families. The data showing the effectiveness of vaccination indicate to us that we cannot delay taking this action in order to protect the health and safety of children and families, and the staff providing care.

We recognize that newly reported COVID-19 cases, hospitalizations, and deaths have begun to trend downward at a national level; nonetheless, they remain substantially elevated relative to numbers seen in May and June 2021, just before the Delta variant became the predominant strain circulating in the U.S.[68] And while cases are trending downward in some states, there are emerging indications of potential increases in others—particularly northern states where the weather has begun to turn colder.[69] The United States experienced a large COVID-19 wave in the winter of 2020. As of November 18, 2021, over 30 percent of people aged 12 years and older in the United States remain not fully vaccinated—and this situation could pose a threat to the country's progress on the COVID-19 pandemic, potentially incurring a fifth wave of COVID-19 cases.[70]

The efficacy of COVID-19 vaccinations has been demonstrated.[71] An ASPE report published on October 5, 2021, found that COVID-19 vaccines are a key component in controlling the COVID-19 pandemic. Clinical data show vaccines are

[68] https://covid.cdc.gov/covid-data-tracker/#datatracker-home.

[69] https://www.cdc.gov/flu/professionals/acip/background-epidemiology.htm.

[70] Centers for Disease Control. "COVID Data Tracker." November 18, 2021. Available at: https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total
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[71] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.

highly effective in preventing COVID-19 cases and severe outcomes including hospitalization and death. Vaccines continue to be effective in preventing COVID-19 associated with the now-dominant Delta variant.[72, 73]

In addition to preventing morbidity and mortality associated with COVID-19, the vaccines also appear to be effective against asymptomatic SARS-CoV-2 infection. A recent study of health care workers in 8 states found that, from December 14, 2020, through August 14, 2021, full vaccination with COVID-19 vaccines was 80 percent effective in preventing RT-PCR–confirmed SARS-CoV-2 infection among frontline workers.74 Emerging evidence also suggests that vaccinated people who become infected with Delta have the potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk.75 For example, in a study of breakthrough infections among health care workers in the Netherlands, SARS-CoV-2 infectious virus shedding was lower among vaccinated individuals with breakthrough infections than among unvaccinated individuals with primary infections.76

As noted earlier in this section, a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to children from unvaccinated staff, continuing strain on the health care system, and known efficacy and safety of available vaccines, have persuaded us that a vaccine requirement for Head Start staff, certain contractors, and volunteers is an essential component of the nation's COVID-19 response. Further, it would endanger the health and safety of staff, children and families, and be contrary to the public interest to delay imposing the vaccine mandate. Therefore, we believe it would be impracticable and contrary to the public interest for us to undertake normal

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[72] https://www.nejm.org/doi/full/10.1056/nejmoa2108891.
[73] https://www.mayoclinic.org/coronavirus-covid-19/covid-variant-vaccine.
[74] https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm?s_cid=mm7034e4_w.
[75] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#ref43.
[76] https://www.medrxiv.org/content/10.1101/2021.08.20.21262158v1.full.pdf.

notice and comment procedures and to thereby delay the effective date of this IFC. We find good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. §§ 552(d), 553(b)(B). For those same reasons, as authorized by subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act or CRA), 5 U.S.C. 808(2), we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under the CRA. Therefore, we find there is good cause to waive the CRA's delay in effective date pursuant to 5 U.S.C. 808(2).

IV. Background

Since its inception in 1965, Head Start has been a leader in supporting children from low-income families in reaching kindergarten healthy and ready to thrive in school and life. The program was founded on research showing that health and wellbeing are pre-requisites to maximum learning and improved short- and long-term outcomes. In fact, OHS identifies health as the foundation of school readiness.

The Head Start Program Performance Standards require children to be up to date on immunizations and their state's Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) schedule (45 CFR 1302.42(b)(1)(i)). When children are behind on immunizations or other care, Head Start programs are required to ensure they get on a schedule to catch up. Additionally, education, family service, nutrition, and health staff help children learn healthy habits, monitor each child's growth and development, and help parents access needed health care. It is vitally important that enrolled pregnant women and children from birth to five years can access in-person services. When children are able to participate in their regular, in-person program options, they form a secure attachment to and relationship with their Head Start teachers. A large body of research demonstrates that a secure attachment with caregivers is a critical foundation for

children to learn and explore their environment.[77] Furthermore, education staff who see children in person are better able to monitor their progress and individualize teaching and learning. The youngest children, children from birth to five years, need physical interaction with materials and in-person support for optimal learning. Screen based learning is much less effective and necessarily limited in the number of hours. Finally, as many parents return to work, they need the assurance that their children are in a safe and high-quality learning environment.

It is equally important that the Head Start program itself is safe for all children, families, and staff. For this reason, the Head Start Program Performance Standards specify that the program must ensure staff do not pose a significant risk of communicable disease (45 CFR 1302.93(a)). Ensuring that children and families can benefit from program services as safely as possible is OHS' highest priority. While this is always important, the COVID-19 pandemic highlights the need to ensure staff are as protected as possible so that children under age 5 years, who cannot yet be vaccinated, are also protected. Fully vaccinated staff are at much lower risk of infection and therefore, pose lower transmission risk to the young unvaccinated children in their care.[78] Young children who get the virus can also spread it to others in their homes and communities. Ensuring Head Start staff are fully vaccinated significantly reduces the possibility of the program playing an unwitting part in community spread of SARS-CoV-2.

On October 29, 2021 the U.S. Food and Drug Administration authorized the Pfizer-BioNTech mRNA vaccine for COVID-19 for use in children ages five to 11. On November 2, 2021, CDC adopted the CDC Advisory Committee on Immunization

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[77] Bergin, C., & Bergin, D. (2009). Attachment in the classroom. *Educational Psychology Review, 21*(2), 141-170.; Rees, C. (2007). Childhood attachment. *British Journal of General Practice, 57*(544), 920-922.; Sierra, P. G. (2012). Attachment and preschool teacher: An opportunity to develop a secure base. *International Journal of Early Childhood Special Education (INT-JECSE), 4*(1), 1-16.

[78] Centers for Disease Control and Prevention. "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs." November 10, 2021.
Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html

Practices' (ACIP) recommendation that children 5 to 11 years old be vaccinated for COVID-19 with the Pfizer-BioNTech pediatric vaccine. While Head Start does serve some children who are currently eligible for a vaccine, children five and older only represented 1.11 percent of children enrolled in Head Start programs during the 2020-2021 program year (Office of Head Start - Program Information Report [PIR] Enrollment Statistics Report - 2021 - National Level). As of November 11, 2021, there is no pediatric COVID-19 vaccine available for children younger than age five years in the United States.

To the extent a court may enjoin any part of the rule, the Department intends that other provisions or parts of provisions should remain in effect. Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

V. Provisions of the Interim Final Rule

This interim final rule (IFR) adds new provisions to the Head Start Program Performance Standards to require: (1) effective immediately, and with exceptions discussed below, universal masking for all individuals two years of age and older regardless of program option, (2) all Head Start staff, certain contractors, and volunteers in classrooms or working directly with children to be fully vaccinated for COVID-19, with exemptions discussed below, and (3) for those granted an exemption to the requirement specified in (2) at least weekly testing for current SARS-CoV-2 infection.

The definition of *staff* in §1305.2 is "paid adults who have responsibilities related to children and their families who are enrolled in programs." Consistent with that

definition, "all staff" as noted in this IFC, refers to all staff who work with enrolled Head Start children and families in any capacity regardless of funding source. The term "Head Start" is inclusive of Head Start, Early Head Start, and Early Head Start-Child Care Partnerships.

Consistent with CDC's guidance, in general, fully vaccinated[79] means

(i) a person's status 2 weeks after completing primary vaccination with a COVID-19 vaccine with, if applicable, at least the minimum recommended interval between doses in accordance with the approval, authorization, or listing that is:

(A) Approved or authorized for emergency use by the Food and Drug Administration (FDA);

(B) Listed for emergency use by the World Health Organization (WHO); or

(C) Administered as part of a clinical trial at a U.S. site, if the recipient is documented to have primary vaccination with the "active" (not placebo) COVID-19 vaccine candidate, for which vaccine efficacy has been independently confirmed (e.g., by a data and safety monitoring board) or if the clinical trial participant at U.S. sites had received a COVID-19 vaccine that is neither approved nor authorized for use by FDA but is listed for emergency use by WHO; or

(ii) A person's status 2 weeks after receiving the second dose of any combination of two doses of a COVID-19 vaccine that is approved or authorized by the FDA, or listed as a two-dose series by WHO (i.e., a heterologous primary series of such vaccines, receiving doses of different COVID-19 vaccines as part of one primary series). The second dose of the series must not be received earlier than 17 days (21 days with a 4-day grace period) after the first dose.

A. Masking Requirement

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[79] Centers for Disease Control and Prevention. "When You've Been Fully Vaccinated." October 15, 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html

This IFC adds a new provision to part1302, subpart D – Health Program Services in § 1302.47, Safety practices. Section 1302.47(b)(5), Safety practices, specifies the appropriate practices all staff and consultants follow to keep children safe during all activities. This IFC creates a new paragraph (vi) that requires universal masking for all individuals aged 2 years and older when there are two or more individuals in a vehicle owned, leased, or arranged by the Head Start program; indoors in a setting when Head Start services are provided; and for those not fully vaccinated, outdoors in crowded settings or during activities that involve sustained close contact with other people. The Office of Head Start notes that being outdoors with children inherently includes sustained close contact for the purposes of caring for and supervising children.

There are different types of masks. Head Start staff should choose a mask that is comfortable to wear and fits snugly. It must cover one's mouth, nose, and chin. It can fasten around the ears or the back of the head, as long as it stays in place when one talks and moves. Masks with vents or exhalation valves are not allowed because they allow unfiltered breath to escape the mask. For more information on masks, programs can consult Your Guide to Masks | CDC .

Purchasing masks needed for staff to fulfill their duties and responsibilities and for children is considered an allowable use of Head Start program funds, as well as the COVID-19 response funds and the American Rescue Plan funds.[80] Programs should have masks available to provide to children when they do not have their own mask.

This requirement is effective immediately upon publication of this IFC. Exceptions are noted for when individuals are eating or drinking; for children when they are napping; for the narrow subset of persons who cannot wear a mask, or cannot safely wear a mask, because of a disability as defined by the Americans with Disabilities Act

[80] Office of Head Start. "FY 2021 American Rescue Plan Funding Increase for Head Start Programs." May 4, 2021. Available at: **https://eclkc.ohs.acf.hhs.gov/policy/pi/acf-pi-hs-21-03**

(ADA), consistent with CDC guidance on disability exemptions[81]; and for children with special health care needs, for whom programs should work together with parents and follow the advice of the child's health care provider for the best type of face covering. It should be noted that like all new skills, children will need to be taught the proper way to put a mask on and keep a mask on. While children are adaptable, they are still in the early stages of development and may need reminders and reinforcements to comply with this new practice. It is imperative that Head Start staff abide by the Standards of Conduct outlined in 1302.90 Personnel Policies in the Head Start Program Performance Standards namely that staff, consultants, contractors, and volunteers implement positive strategies to support children's well-being and do not use harsh disciplinary practices that could endanger the health or safety of children.

B. Vaccination Requirement

This IFC adds four new provisions to part 1302, subpart I – Human Resources Management in § 1302.93, Staff health and wellness, and § 1302.94, Volunteers. Section 1302.93(a), Staff health and wellness, states that "the program must ensure staff do not, because of communicable diseases, pose a significant risk to the health or safety of others in the program that cannot be eliminated or reduced by reasonable accommodation, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act." This IFC adds a new paragraph (a)(1) to § 1302.93 requiring all staff, and those contractors whose activities involve contact with or providing direct services to children and families, to be fully vaccinated for COVID-19, except for those (i) for whom a vaccine is medically contraindicated, (ii) for whom medical necessity requires a delay in vaccination,[82] or (iii) who are legally entitled to an accommodation

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[81] Centers for Disease Control. Order: Wearing of face masks while on conveyances and at transportation hubs. January 21, 2021. Available at: **Order: Wearing of face masks while on conveyances and at transportation hubs | Quarantine | CDC**

[82] As defined by CDC's informational document, Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (CDC, September 29, 2021).

with regard to the COVID-19 vaccination requirement based on an applicable Federal law. It also adds a new paragraph (a)(2) indicating that those who are granted an exemption outlined in (a)(1)(i) through (iii) must undergo testing at least weekly for current SARS COV-2 infection..

The additions made to § 1302.94, Volunteers, mirrors that of § 1302.93, Staff health and wellness. This IFC also adds a new paragraph (a)(1) to § 1302.94, Volunteers, that requires all volunteers who are in classrooms or working directly with children other than their own must be fully vaccinated for COVID-19, except for those (i) for whom a vaccine is medically contraindicated, (ii) for whom medical necessity requires a delay in vaccination,[83] or (iii) who are legally entitled to an accommodation with regard to the COVID-19 vaccination requirement based on an applicable Federal law. It also adds a new paragraph (a)(2) indicating that those who are granted an exemption outlined in paragraphs (a)(1)(i) through (iii) must undergo testing at least weekly for current SARS-CoV-2 infection. The costs associated with regular testing for those granted an exemption are an allowable use of Head Start funds so long as it is included in a program's policies and procedures. While paying for the costs associated with regular testing is allowable use of Head Start funds, it is not a requirement. Programs should consider whether they can sustain continued funding for testing if/when the COVID-19 funds are exhausted. Finally, we have also revised § 1302.94 to remove the word "regular" from paragraph (a). We believe it is important for all volunteers to adhere to these requirements not just those who regularly volunteer in the program.

Programs may use SARS-CoV-2 testing for all staff, regardless of vaccination status, as an additional mitigation strategy with the COVID-19 vaccines, and those granted exemptions are required to undergo testing, but testing alone is not an alternative

[83] As defined by CDC's informational document, Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States (CDC, September 29, 2021).

to the COVID-19 vaccination requirement specified in §1302.93 and §1302.94. This is a key difference between this IFC and the COVID-19 Vaccination and Testing; Emergency Temporary Standard, published, by the Occupational Safety and Health Administration (OSHA) on November 5, 2021, which requires employers with 100 or more employees to develop, implement, and enforce a mandatory COVID-19 vaccination policy, unless they adopt a policy requiring employees to choose to either be vaccinated or undergo regular SARS-Cov-2 testing and wear a face covering. Whereas OSHA allows employers to offer an option for testing and face coverings, this IFC does not permit a testing and face coverings option for individuals without an approved vaccine exemption. The rationale for the difference is that ACF is acting under statutory and regulatory standards that are different from OSHA's. In general, the Head Start Act requires standards for a safe environment for staff, children, and other participants.

Documentation of Vaccination Status

The Head Start Act at section 647 (42 USC 9842) has a provision on record-keeping, which allows the Secretary to require certain records be kept and to support OHS in conducting its oversight of programs through monitoring. Pursuant to the statutory recordkeeping requirement in section 647 of the Head Start Act (42 U.S.C. 9842) and in order to ensure programs are complying with the vaccination requirements of this IFC, we are requiring that they track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination, such as recent receipt of monoclonal antibodies or convalescent plasma. Vaccination exemption requests and outcomes must also be documented, discussed further in section II.A.5. of this IFC. This documentation will be an ongoing process as new staff are onboarded.

While program staff may not have personal medical records on file with their employer, all staff COVID-19 vaccines must be appropriately documented by the

provider or supplier. All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files, pursuant to the ADA and the Rehabilitation Act.

Examples of acceptable forms of proof of vaccination include:

- CDC COVID-19 vaccination record card (or a legible photo of the card),
- Documentation of vaccination from a health care provider or electronic health record, or
- State immunization information system record.

If vaccinated outside of the United States, a reasonable equivalent of any of the previous examples would suffice.

Programs have the flexibility to use the appropriate tracking tools of their choice. For those who would like to use it, CDC provides a staff vaccination tracking tool that is available on the NHSN website (https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html). This is a generic Excel-based tool available for free to anyone, not just NHSN participants, that facilities can use to track COVID-19 vaccinations for staff members.

Exemption Process

Under Federal law, including the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964, staff, contractors, and volunteers who cannot be vaccinated because of a disability under the ADA, medical condition, or sincerely held religious beliefs, practice, or observance may in some circumstances be granted an exemption, as discussed in II.B of this IFC. Head Start staff included in this IFC must be able to request an exemption from these COVID-19 vaccination requirements. Additionally, programs following CDC guidelines and the new requirements in this IFC may also be required to provide reasonable accommodations, to the extent required by federal law, for employees who request and receive exemption from vaccination because

of a disability, medical condition, or sincerely held religious belief, practice, or observance.

In support of the new requirements in §§ 1302.93 and 1302.94, it is the responsibility of Head Start programs to establish a process for reviewing and reaching determinations regarding exemption requests (e.g., disability, medical conditions, sincerely held religious beliefs, practices, or observances). Programs must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the program's decision on the request, and any accommodations that are provided. Requests for exemptions based on an applicable federal law must be documented and evaluated in accordance with applicable Federal law and each program's policies and procedures. As is relevant here, this IFC preempts the applicability of any state or local law providing for exemptions to the extent such law provides broader exemptions than provided for by federal law and are inconsistent with this IFC.

For staff members, contractors, and volunteers who request a medical exemption from vaccination, all documentation confirming recognized clinical contraindications to COVID-19 vaccines or medical need for delay, and which supports the request, must be signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws. Such documentation must contain all information specifying which of the authorized or approved COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications or the recognized clinical reasons necessitating delay in vaccination; and a statement by the authenticating practitioner recommending that the staff member be exempted from the program's COVID-19 vaccination requirements based on the recognized clinical contraindications or allowed to delay vaccination.

For more information, Head Start programs can refer to a resource produced by the Equal Employment Opportunity Commission (EEOC), which is responsible for enforcing federal laws that prohibit employment-related discrimination based on a person's race, color, religion, sex (including pregnancy, gender identity, and sexual orientation), national origin, age (40 or older), disability, or genetic information. The EEOC resource, What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, available at What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws | U.S. Equal Employment Opportunity Commission (eeoc.gov), should be helpful in navigating employees' requests for accommodations (EEOC, October 25, 2021).

In granting such exemptions or accommodations, programs must ensure that they minimize the risk of transmission of SARS-CoV-2 to at-risk individuals, in keeping with their obligation to protect the health and safety of staff, children and families. To that end, it is a reasonable alternative that staff, contractors, and volunteers granted an accommodation be required to undergo testing at least weekly for current SARS-CoV-2 infection. Because unvaccinated employees are at higher risk of SARS-CoV-2 infection, and SARS-CoV-2 transmission among individuals without symptoms is a significant driver of COVID-19, ACF has determined it is necessary to prevent the pre-symptomatic and asymptomatic transmission of SARS-CoV-2 from unvaccinated staff, contractors and volunteers, through a requirement for a weekly screening test.[84] Although more regular screening testing (e.g., twice weekly) may identify even more cases, ACF has decided to require a minimum testing of only on a weekly basis, which is in line with CDC recommendations.

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[84] OSHA. "COVID-19 Vaccination and Testing; Emergency Temporary Standard." November 5, 2021. Available at: **https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard**

In support of this requirement, programs should develop and implement a written SARS-CoV-2 testing protocol for those staff, contractors, and volunteers granted vaccine exemptions. Programs should consult with their Health Services Advisory Committee (HSAC) and local public health officials, along with recommendations from their agency's legal counsel and Human Resources department in the development of a SARS-CoV-2 testing protocol. Programs are encouraged to review guidance from CDC and FDA about selecting SARS-CoV-2 tests and developing related protocols. The costs of regular testing for those granted an exemption are an allowable use of Head Start funds so long as it is included in a program's policies and procedures. While using Head Start funds is allowable, it is not a requirement. It is at the program's discretion to decide if they will pay for the cost of testing, considering such factors as the number of approved exemptions, whether they can sustain continued funding for testing if/when the COVID-19 funds are exhausted, any incentives associated with allowing the use of funds for testing, and whether employees can cover the expenses of testing.

D. Implementation Dates

Due to the urgent nature of the vaccination requirements established in this IFC, we have not issued a proposed rule, as discussed in section C of this IFC. While some IFCs, or provisions within IFCs, are effective immediately upon publication, such as the mask requirement, we understand that instantaneous compliance, or compliance within days, with the vaccine requirement is not possible. Vaccination requires time, especially vaccines delivered in a series. Programs' updates to their policies and procedures also take time to develop. However, in order to provide protection to staff, children, and families, we believe it is necessary to begin staff vaccinations as quickly as reasonably possible. Therefore, we have set the January 31, 2022 as the compliance date for staff to be vaccinated. Although an individual is not considered fully vaccinated until 14 days (2 weeks) after the final dose, staff, certain contractors and volunteers who have received

the final dose of a primary vaccination series by January 31, 2022 are considered to have met the vaccination requirement, even if they have not yet completed the 14-day waiting period. This timing flexibility applies only to the initial implementation of this IFC and has no bearing on ongoing compliance.

The rationale for a different timeline for compliance with the vaccine requirement in this rule relative to the CMS or the OSHA rule is because this timeline in this rule is coordinated with OHS's expectation, communicated through guidance in May 2021, for programs' return to full in-person services. Beginning January 2022, Head Start programs are expected to resume fully in-person services after a period of increased flexibility with virtual and remote services during the pandemic. At this time, OHS will reinstate pre-pandemic practices for tracking and monitoring enrollment as part of the Full Enrollment Initiative. This means that during the first week of February, OHS will evaluate reported enrollment on the last day of January for purposes of the under-enrollment process. Requiring that staff receive their second dose in a two-dose vaccine series, or a single dose in a one-dose vaccine series, by January 31 is consistent with this return to fully in-person services.

VI. Regulatory Process Matters

Treasury and General Government Appropriations Act of 1999

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires federal agencies to determine whether a policy or regulation may negatively affect family well-being. If the agency determines a policy or regulation negatively affects family well-being, then the agency must prepare an impact assessment addressing seven criteria specified in the law. ACF believes it is not necessary to prepare a family policymaking assessment, *see* Pub. L. 105–277, because the action it takes in this interim final rule will not have any impact on the autonomy or integrity of the family as an

institution. However, ACF invites public comment on whether the actions set forth in this interim final rule would have a negative effect on family well-being.

Federalism Assessment Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule would preempt some State laws that prohibit employers from requiring their employees to be vaccinated for COVID–19. Consistent with the Executive Order, we find that State and local laws that forbid employers in the State or locality from imposing vaccine requirements on employees directly conflict with this exercise of our statutory authority to protect the health and safety of Head Start participants and their families and ensure the continuation of services by requiring vaccinations for staff, certain contractors, and volunteers and universal masking. As is relevant here, this IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader grounds for exemptions than provided for by Federal law and are inconsistent with this IFC. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule. The agency has considered other alternatives (for example, relying entirely on measures such as voluntary vaccination, source control alone, and physical distancing) and has concluded that the mandate established by this rule is the minimum regulatory action necessary to achieve the objectives of the statute. Given the transmission rates of the existing strains of coronavirus and their disproportionate impacts on low-income communities served by Head Start programs, we believe that vaccination of almost all staff, certain contractors, and volunteers is necessary to promote and protect program participants and ensure program continuity. The agency has examined case studies from

other employers and concludes that vaccine mandates are vastly more effective than other measures at achieving ideal vaccination rates and the resulting protections. Given the emergency situation with respect to the Delta variant detailed more fully above, time did not permit usual consultation procedures. We are, however, inviting comments on the substance as well as legal issues presented by this rule.

Congressional Review Act

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act or CRA) allows Congress to review "major" rules issued by federal agencies before the rules take effect, *see* 5 U.S.C. 801(a). The CRA defines a major rule as one that has resulted, or is likely to result, in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, or innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets, see 5 U.S.C. 804(2). The Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this action is a major rule because it will have an annual effect on the economy of $100 million or more.

Paperwork Reduction Act of 1995

The Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501 et seq., minimizes government-imposed burden on the public. In keeping with the notion that government information is a valuable asset, it also is intended to improve the practical utility, quality, and clarity of information collected, maintained, and disclosed.

The PRA requires that agencies obtain OMB approval, which includes issuing an OMB number and expiration date, before requesting most types of information from the public. Regulations at 5 CFR part 1320 implemented the provisions of the PRA and

§ 1320.3 of this part defines a “collection of information,” “information,” and “burden.” PRA defines “information” as any statement or estimate of fact or opinion, regardless of form or format, whether numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic, or other media (5 CFR 1320.3(h)). This includes requests for information to be sent to the government, such as forms, written reports and surveys, recordkeeping requirements, and third-party or public disclosures (5 CFR 1320.3(c)). “Burden” means the total time, effort, or financial resources expended by persons to collect, maintain, or disclose information.

This IFC establishes new recordkeeping requirements under the PRA. Head Start grant recipients are required as part of this IFC to maintain records on staff vaccination rates. Additionally, Head Start programs are required to develop their own written SARS-CoV-2 testing protocol for current infection for individuals granted vaccine exemptions. To promote flexibility for local programs, there is no standardized instrument associated with the new recordkeeping requirement. As required under the PRA, ACF will submit a request for approval of these recordkeeping requirements. We will initially request approval through an emergency clearance process, allowing for 6 months of approval under the PRA. We will follow the initial approval with a full request, including two public comment periods, to extend approval of the recordkeeping requirement. A separate notice inviting comments on these new recordkeeping requirements will be published in the Federal Register.

In addition to these new recordkeeping requirements, Head Start grant recipients are expected to update their program policies and procedures to ensure costs associated with regular testing for those granted an exemption are an allowable use of Head Start funds. The recordkeeping activity of maintaining program policies and procedures including the associated burden with updating them on an annual basis is already approved under an existing OMB information collection (Control Number 0970-0148).

The separate Federal Register notice will also invite comments on this existing recordkeeping requirement.

VII. Economic Analysis of Impacts

Introduction

We have examined the impacts of this interim final rule under Executive Order 12866, Executive Order 13563, and the Regulatory Flexibility Act (5 U.S.C. 601-612). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We believe, and OIRA determined, that this interim final rule is an economically significant regulatory action as defined by Executive Order 12866. Thus, this rule has been reviewed by the Office of Information and Regulatory Affairs.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the impacts to small entities attributable to the interim final rule are limited in nature, we certify that the interim final rule will not have a significant economic impact on a substantial number of small entities. These impacts are discussed in detail in the Final Small Entity Analysis.

Summary of Costs and Benefits

This interim final rule establishes vaccine, record keeping, and mask requirements to mitigate the spread of SARS-CoV-2 in Head Start programs. We have evaluated the likely impacts of the interim final rule in comparison to a baseline scenario of no new regulation that incorporates projections of COVID-19 vaccine coverage, cases, deaths, and hospital admissions. We anticipate that the requirement that all Head Start staff get fully vaccinated for COVID-19 will induce a substantial portion of unvaccinated staff to get fully vaccinated. We also estimate that the regulation will induce a similar number,

but smaller share, of unvaccinated Head Start volunteers to get fully vaccinated in response to the interim final rule. Some Head Start volunteers are likely also covered by other regulatory actions, which complicates attributing changes in vaccine coverage to any particular regulatory action. We discuss this in greater detail in the Baseline Section and Benefits Section.

The increase in vaccine coverage attributable to the interim final rule will result in substantial health benefits from reductions in COVID-19 mortality and morbidity. We monetize these impacts using a Value per Statistical Life (VSL) for fatal cases, and estimates of the Value per Statistical Case (VSC) that vary by case severity for non-fatal cases. We also predict that reductions in COVID-19 cases among Head Start staff will result in lower absenteeism, including fewer missed days of work for staff infected with SARS-CoV-2 or recovering from COVID-19 and unvaccinated staff quarantining after a close contact tested positive for SARS-CoV-2. We monetize these impacts using a value of time that accounts for time savings for parents and other caregivers for children enrolled at Head Start centers. We estimate a range of total monetized benefits between $200 million and $296 million under a 7% discount rate, and a range between $196 million and $288 million under a 3% discount rate. These monetized benefits cover a time period between the publication date of the interim final rule and March 1, 2022, when our underlying COVID-19 projections end. For our main analysis, we assume that the requirements will be effective for this time horizon, but also consider a scenario in which the requirements are lifted at an earlier date, such as by the COVID-19 Public Health Emergency expiring. The choice of discount rate impacts the benefit estimates through the VSC, which is based on estimates of the Value per Quality-Adjusted Life Year that vary by discount rate.

In addition to the impacts that we monetize in this analysis, we anticipate that the increase in vaccine coverage attributable to the interim final rule will result in indirect

health benefits from reduced transmission of SARS-COV-2, the virus that causes COVID-19. These impacts include reductions in secondary infections from Head Start staff and volunteers to other staff and volunteers, children, and families. We anticipate that the masking requirement will also reduce transmission SARS-COV-2 from individuals covered by the requirement. This impact includes a reduction in transmission from children to Head Start teachers, staff, and other children. We also discuss a mechanism and valuation approach for monetizing benefits from Head Start centers reopening. We discuss these impacts in greater detail in the Benefits Section, and note that they are embedded in a quantitative approach in the Net Benefits section.

We have identified several costs that are attributable to the interim final rule. We monetize the costs of vaccination, which incorporates a value of time for staff and volunteers, and the cost of doses and administration; the costs of the masking requirement; the costs of testing unvaccinated staff and volunteers; and the costs of recordkeeping associated with the interim final rule. We also consider a scenario where a share of unvaccinated Head Start staff quit rather than get fully vaccinated. Under this scenario, these costs would include training replacement staff, and the costs to parents and other caregivers for children enrolled at Head Start center resulting from staff vacancies. We estimate a range of costs between $16 million and $83 million, which cover a time period between the publication of the interim final rule and March 1, 2022, which is consistent with the time horizon adopted for our benefits estimates. These cost estimates do not vary with the discount rate. We also discuss potential additional costs of masking and testing associated with Head Start centers reopening as a result of the interim final rule.

Table 1 presents a summary of the monetized impacts attributable to the interim final rule. All dollar estimates are presented in millions of 2020 dollars. We request comments on these benefit and cost estimates.

Table 1. Summary of Benefits, Costs and Distributional Effects of Interim final rule

<table>
<tr><th rowspan="2" colspan="2">Category</th><th rowspan="2">Primary Estimate</th><th rowspan="2">Low Estimate</th><th rowspan="2">High Estimate</th><th colspan="3">Units</th><th rowspan="2">Notes</th></tr>
<tr><th>Year Dollars</th><th>Discount Rate</th><th>Period Covered</th></tr>
<tr><td rowspan="5">Benefits</td><td rowspan="2">Annualized Monetized $millions/year</td><td>$247,964,991</td><td>$200,294,622</td><td>$295,635,335</td><td>2020</td><td>7%</td><td>3 months</td><td></td></tr>
<tr><td>$242,185,591</td><td>$195,986,161</td><td>$288,384,996</td><td>2020</td><td>3%</td><td>3 months</td><td></td></tr>
<tr><td rowspan="2">Annualized Quantified</td><td></td><td></td><td></td><td></td><td>7%</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td>3%</td><td></td><td></td></tr>
<tr><td>Qualitative</td><td colspan="3"></td><td></td><td></td><td></td><td></td></tr>
<tr><td rowspan="5">Costs</td><td rowspan="2">Annualized Monetized $millions/year</td><td>$49,456,037</td><td>$15,612,352</td><td>$83,299,721</td><td>2020</td><td>7%</td><td>3 months</td><td rowspan="2"></td></tr>
<tr><td>$49,456,037</td><td>$15,612,352</td><td>$83,299,721</td><td>2020</td><td>3%</td><td>3 months</td></tr>
<tr><td rowspan="2">Annualized Quantified</td><td></td><td></td><td></td><td></td><td>7%</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td>3%</td><td></td><td></td></tr>
<tr><td>Qualitative</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td rowspan="6">Transfers</td><td rowspan="2">Federal Annualized Monetized $millions/year</td><td></td><td></td><td></td><td></td><td>7%</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td>3%</td><td></td><td></td></tr>
<tr><td>From/To</td><td colspan="3">From:</td><td colspan="3">To:</td><td></td></tr>
<tr><td rowspan="2">Other Annualized Monetized $millions/year</td><td></td><td></td><td></td><td></td><td>7%</td><td></td><td></td></tr>
<tr><td></td><td></td><td></td><td></td><td>3%</td><td></td><td></td></tr>
<tr><td>From/To</td><td colspan="3">From:</td><td colspan="3">To:</td><td></td></tr>
<tr><td>Effects</td><td colspan="8">State, Local or Tribal Government:
Small Business:
Wages:
Growth:</td></tr>
</table>

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. [insert reference number]). We request comments on this analysis.

VIII. Alternatives Considered

In making the decision to require vaccination and mask use, ACF considered whether to require other mitigation strategies or combinations of mitigation strategies. The CDC's recently issued guidance on November 10, 2021 reiterates the importance of using multiple prevention strategies in ECE programs.[85] In addition to vaccinations and masks, other strategies noted in this IFC include staying home if sick; handwashing; improving ventilation; screening and diagnostic testing; cleaning and disinfecting; keeping physical distance; and cohorting.

There are two primary reasons that ACF decided to mandate vaccination and mask use. First, Head Start programs have a broad set of program performance standards that already include requirements for infection control, exclusion policies, cleaning, sanitizing and disinfecting. The requirement for staying home when sick is part of § 1302.47(b)(4)(i)(A); hand hygiene (handwashing) is included at § 1302.47(b)(6)(i); cleaning, sanitizing, and disinfecting is at § 1302.47(b)(2)(i); and physical distancing is part of § 1302.47(b)(4)(i)(A), which OHS sees as a strategy for a program's infection control practices). In addition, § 1302.47(b)(1)(iii) states that facilities need to be "free from pollutants, hazards and toxins that are accessible to children and could endanger children's safety," though it is difficult be overly prescriptive about ventilation given the range of facilities and spaces used by center-based and family child care programs.

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[85] Centers for Disease Control and Prevention. "COVID-19 Guidance for Operating Early Care and Education/Child Care Programs." November 10, 2021.
Available at: https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/child-care-guidance.html

Second, as discussed in this IFC, being fully vaccinated forCOVID-19 and using a mask are two of the most effective mitigation strategies available to reduce transmission of COVID-19.[86] With this in mind, ACF determined a federal requirement is necessary. While some agencies and localities have implemented vaccine and masking requirements, many have not. Additionally, vaccine uptake among Head Start staff has not been as robust as hoped for and has been insufficient to protect the health and safety of children and families receiving Head Start services. Combined, these factors leave certain children and families with fewer mitigation strategies in place to protect them than others. It is ACF's responsibility to make sure the environment is as safe as possible for Head Start programs uniformly across all 1,600 grant recipients.

Additionally, although less effective and efficient than vaccination, the CDC has recognized regularly testing unvaccinated individuals for SARS-CoV-2 as a useful tool for identifying asymptomatic and/or pre-symptomatic infected individuals so that they can be isolated,[87] which informed the decision to include in this IFC a testing policy for those granted an exemption. It is also consistent with the CDC's guidance on November 11, 2021, which added screening testing information to its prevention strategies. This guidance notes that in ECE programs, screening testing can help promptly identify and isolate cases, quarantine those who may have been exposed to SARS-CoV-2 and are not fully vaccinated, and identify clusters to reduce the risk to in-person education. The inclusion of a requirement for masking, vaccination and testing, for those staff, contractors and volunteers granted an exemption, ensures the Head Start Program Performance Standards reflect the current science with respect to reducing the spread of SARS-CoV-2 and reducing COVID-19.

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[86] Centers for Disease Control and Prevention. "Science Brief: COVID-19 Vaccines and Vaccination." September 15, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html#:~:text=Evidence%20suggests%20the%20US%20COVID,interrupting%20chains%20of%20transmission.
[87] Centers for Disease Control and Prevention. "Overview of Testing for SARS-CoV-2 (COVID-19). October 22, 2021. Available at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html

ACF also deliberated on the question of whether to require Head Start programs to cover the cost of testing for those granted an exemption or to shift those costs to staff. Head Start staff are not high wage earners, and we recognize it could create hardship for staff granted an exemption to absorb the cost of weekly testing. That said, if programs have many staff who are approved for exemptions, it could be difficult for the program to bear the cost of weekly testing, particularly when their COVID-19 response funds are exhausted. Given these various factors, ACF determined that it is important to make it allowable to use funds at this time, including both COVID-19 response funds and ongoing program funds, for the purpose of testing but allow programs the discretion to make the decision based on budgetary factors, the number of staff approved for an exemption, incentives or other factors. We invite comment on this decision.

ACF also considered whether to tie the universal masking requirement and the testing requirement to SARS-CoV-2 transmission rates. For example, the requirement could make masking voluntary once community transmission drops below a certain level, consistent with CDC guidance. There are more than 1600 Head Start grant recipients, many of which serve multiple communities, cross state lines or serve an entire state. Transmission rates could be significantly different across service areas. For example, one grant recipient in Michigan covers 21 different counties. It would be burdensome for this program to issue separate guidance across its service area to account for changing transmission levels across those counties. Another grant recipient, Alabama Department of Resources, has a partnership that covers the entire state of Alabama. Again, it would be burdensome for this grant recipient to change its mask guidance for different centers through the state as transmission rates change. ACF values CDC guidance that localities should monitor community transmission in making decisions and has relied on the importance of local health conditions in issuing guidance to Head Start programs. However, in the case of mask use, ACF is prioritizing a clear and transparent policy that

is easy for grantees to follow across their service areas. Additionally, children benefit from routine and predictability. ACF determined that the best course of action was not to provide an end date on the universal masking and testing requirement. ACF invites comment on this decision to leave an undetermined end date or whether we should set a finite end date, such as 6 months from the effective date of the rule.