

22-1257

**United States Court of Appeals
for the Sixth Circuit**

LIVINGSTON EDUCATIONAL SERVICE AGENCY
and WAYNE-WESTLAND COMMUNITY SCHOOLS,

Plaintiffs – Appellants,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JOOYEUN CHANG, in her official capacity as Assistant Secretary and Principal Deputy Assistant Secretary of the Administration for Children and Families; ADMINISTRATION FOR CHILDREN AND FAMILIES; and BERNADINE FUTRELL, in her official capacity as the director of the Office of Head Start,

Defendants – Appellees.

On Appeal from the United States District Court
for the Eastern District of Michigan
No. 2:22-cv-10127, Hon. Nancy G. Edmunds

APPELLANTS' PRINCIPAL BRIEF

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DISCLOSURE STATEMENT

Plaintiffs/Appellants are public school districts and do not issue stock or have shareholders.

TABLE OF CONTENTS

DISCLOSURE STATEMENT.....	ii
TABLE OF AUTHORITIES.....	v
JURISDICTIONAL STATEMENT	1
ISSUES FOR REVIEW	2
STATEMENT OF THE CASE AND PROCEDURAL HISTORY.....	4
Background	4
The Parties	7
Procedural History	9
SUMMARY OF THE ARGUMENT	10
ARGUMENT	13
I. Standard of Review	13
II. The district court erred in finding the Rule is authorized by the Head Start Act because the statutory authorities cited by HHS do not provide a basis for such a sweeping exercise of power.....	13
A. The Rule is not an administrative standard.....	15
B. The Rule is not a standard relating to the condition of facilities.....	17
C. The Rule does not fit within the provision permitting modification of other “appropriate” performance standards.....	20
Recent Precedent.....	20
“Appropriate” Limits: Eiusdem Generis	23
“Appropriate” Limits: No Reductions in Services	24
“Appropriate” Limits: Head Start’s History of Flexibility and Control.....	26
The District Court Did Not Appropriately Limit “Appropriate”	27

D. If OSHA’s explicit statutory delegation to protect workers was not sufficient authority for its vaccine-or-test mandate, the ostensibly implicit authority relied on by HHS here is surely inadequate. 30

E. The district court ignored fundamental principles of statutory interpretation in its ruling. 32

The Rule is unprecedented and conflicts with HHS’s longstanding deference to parents, doctors, and state and local authority. 32

The district court’s decision contradicts the major questions doctrine. 36

The district court’s decision violates the canon of federalism. 37

The district court’s decision invites a nondelegation problem. 38

F. The district court’s interpretive approach was flawed. 39

G. The district court and motions panel wrongly relied on a separate statutory provision that even HHS did not cite as authority for the mandate. 41

III. HHS lacked good cause to skip public notice and comment, and the agency’s actions demonstrate its own lack of urgency. 43

IV. The other equitable factors favor Appellants. 48

A. The district court correctly concluded that the Rule will cause Appellants to suffer irreparable harm. 48

The government lacks a compelling interest to enforce the mandate against Appellants. 49

Appellants’ irreparable harms have not expired. 50

B. The public interest and balance of harms weigh in favor of preliminary relief. 53

CONCLUSION 54

TABLE OF AUTHORITIES

Cases

<i>Ala. Ass’n of Realtors v. Dep’t of Health & Hum. Servs.</i> , 141 S. Ct. 2485 (2021)	passim
<i>Asbestos Info. Ass’n/N. Am. v. OSHA</i> , 727 F.2d 415 (5th Cir. 1984)	44
<i>Ass’n of Cmty. Cancer Ctrs. v. Azar</i> , 509 F. Supp. 3d 482 (D. Md. 2020).....	46
<i>Astrue v. Capato</i> , 566 U.S. 541 (2012)	24
<i>Bays v. City of Fairborn</i> , 668 F.3d 814 (6th Cir. 2012).	13
<i>Biden v. Missouri</i> , 142 S. Ct. 647 (2022)	12, 31, 32, 47
<i>BST Holdings, LLC v. OSHA</i> , 17 F.4th 604 (5 th Cir. 2021)	23
<i>Chamber of Commerce v. DHS</i> , 504 F. Supp. 3d 1077 (N.D. Cal. 2020)	46
<i>Church of Lukumi Babalu Aye, Inc. v. Hialeah</i> , 508 U. S. 520 (1993)	48
<i>Combier-Kapel v. Biegelson</i> , 242 F. App’x 714 (2d Cir. 2007).....	52
<i>Economic Opportunity Com., Inc. v. Weinberger</i> , 524 F.2d 393 (2d Cir. 1975).....	26
<i>Florida v. Becerra</i> , 544 F. Supp. 3d 1241 (M.D. Fla. 2021)	46
<i>Georgia v. Biden</i> , No. 1:21-cv-163, 2021 U.S. Dist. LEXIS 234032 (S.D. Ga. Dec. 7, 2021).....	16
<i>In re Babyland Family Services, Inc.</i> , HHS Dept. Appeals Bd., DAB No. 2109, 2007 HHSDAB Lexis 62 (Aug. 28, 2007)	15

In re Camden Cty. Council on Econ. Opportunity,
HHS Dept. Appeals Bd., DAB No. 2116, 2007 HHSDAB Lexis 79
(Sept. 25, 2007)..... 18

Indus. Union Dep’t, AFL-CIO v. Am. Petroleum Inst.,
448 U.S. 607 (1980) 38

Kentucky v. Biden,
23 F.4th 585 (6th Cir. 2022)..... passim

Louisiana v. Becerra, No. 3:21-CV-04370,
2022 U.S. Dist. LEXIS 1333 (W.D. La. Jan. 1, 2022) passim

Mack Trucks, Inc. v. EPA,
682 F.3d 87 (D.C. Cir. 2012)..... 44

Mass. Bldg. Trades Council v. DOL,
21 F.4th 357 (6th Cir. 2021) 33, 34

MCP No. 165 v. DOL, No. 21-7000,
2021 U.S. App. LEXIS 37024 (6th Cir. Dec. 15, 2021) 19, 33, 36, 44, 46

Michigan v. EPA,
576 U.S. 743 (2015) 42

Mourning v. Family Publications Service, Inc.,
411 U.S. 356 (1973) 27

N.C. Growers Ass’n v. UFW,
702 F.3d 755 (4th Cir. 2012) 44

NFIB v. OSHA,
142 S. Ct. 661 (2022) passim

Northport Health Servs. of Ark., LLC v. United States HHS,
14 F.4th 856 (8th Cir. 2021)..... 42

Regeneron Pharmaceuticals, Inc. v. HHS,
510 F. Supp. 3d 29 (S.D.N.Y. 2020) 46

Smiley v. Citibank (S. Dakota), N.A.,
517 U.S. 735 (1996) 45

Texas v. Becerra, No. 5:21-CV-300-H,
2021 U.S. Dist. LEXIS 248309 (N.D. Tex. Dec. 31, 2021) passim

Tiger Lily, LLC v. HUD,
5 F.4th 666 (6th Cir. 2021)..... passim

Tiger Lily, LLC v. HUD,
 992 F.3d 518 (6th Cir. 2021)..... 20, 37, 38

United Cook Inlet Drift Ass’n v. Nat’l Marine Fisheries Serv., No. 3:21-
 cv-00255-JMK,
 2022 U.S. Dist. LEXIS 109879 (D. Alaska June 21, 2022)..... 52

United States ex rel. Felten v. William Beaumont Hosp.,
 993 F.3d 428 (6th Cir. 2021) 15

United States v. Cain,
 583 F.3d 408 (6th Cir. 2009) 44, 46

Util. Air Reg. Grp. v. EPA,
 573 U.S. 302 (2014) 33

Util. Air Regulatory Grp. v. EPA,
 573 U.S. 302 (2014) 22

W. W. v. N.Y.C. Dep’t of Educ.,
 2014 U.S. Dist. LEXIS 47253 (S.D.N.Y. Mar. 31, 2014) 53

W.A. v. Hendrick Hudson Cent. Sch. Dist.,
 927 F.3d 126 (2d Cir. 2019)..... 53

Washington v. Reno,
 35 F.3d 1093, 1103 (6th Cir. 1994) 13

West Virginia v. EPA,
 597 U.S. ___, ___ (June 30, 2022)..... passim

Whitman v. Am. Trucking Ass’ns,
 531 U.S. 457 (2001) 22

Statutes

5 U.S.C. § 553 43

28 U.S.C. § 1292 1

28 U.S.C. § 1331 1

29 U.S.C. § 652 30

40 U.S.C. § 121 21

42 U.S.C. § 9836a passim

Regulations

36 Fed. Reg. 10,466 19

45 C.F.R. § 1302.41 35

45 C.F.R. § 1302.42 35

45 C.F.R. § 1302.93 35

45 C.F.R. § 1303.10 16

45 C.F.R. § 1304.53 18

45 C.F.R. § 1305.2 18

61 Fed. Reg. 57,186 35

86 Fed. Reg. 68,052 passim

Other Authorities

CDC Morbidity and Mortality Weekly Report (Dec. 11, 2020) 4, 27

Mandate FAQs (Mar. 16, 2022) 6

Mental Health and Staff Wellness: Emotionally Strong Together,
HHS/OHS webinar transcript (statement of OHS Deputy Director
Ann Linehan), July 14, 2021 5

Remarks by President Biden on Fighting the COVID-19 Pandemic
(Sept. 9, 2021)..... 6

The Federalist No. 78..... 39

Wilson Greene, *Universal Preschool: A Worthy but Costly Goal*, 35 J.L.
& Educ. 555 (2006) 26

REQUEST FOR ARGUMENT

Because this case reviews a federal rule impacting over a million Americans, because it represents the first time any circuit court of appeals will interpret this particular federal statute, and because the district court reached a different conclusion on the merits than two other federal district courts, Appellants suggest oral argument is warranted.

JURISDICTIONAL STATEMENT

The district court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, because it arises under the United States Constitution. On March 24, 2022, Appellants filed a notice of appeal of the district court's March 4, 2022 order denying Appellants' motion for a preliminary injunction. This Court has jurisdiction over this appeal pursuant to 28 U.S.C. § 1292(a)(i), which grants appellate jurisdiction over interlocutory orders granting or denying injunctions.

ISSUES FOR REVIEW

1. The Head Start Act identifies a specific set of program performance standards in areas such as administration, facilities, and financial management that the Secretary of Health & Human Services (“HHS”) is authorized to modify. Purporting to exercise that authority, the Secretary promulgated a rule with a COVID-19 vaccine mandate for all staff of Head Start programs as well as contractors and volunteers who interact with Head Start students. Did the district court improperly deny Plaintiffs’ Motion for a Preliminary Injunction, based on the incorrect determination that the rule falls within the Secretary’s delegated authority from Congress?
2. The Administrative Procedure Act requires public notice-and-comment before a new rule may be promulgated, except in the rare case when an agency has good cause to forgo that procedure. The Secretary found that he had good cause in this instance due to the urgent nature of the COVID-19 pandemic and required all Head Start programs to comply with the rule’s vaccine mandate by January 31, 2022. Despite that claimed urgency, the federal

government has since declined to appeal preliminary injunctions issued by two federal district courts six months ago, leaving the rule enjoined in 25 states. Did the district court incorrectly deny a preliminary injunction because this is not one of the rare cases when good cause permits the Secretary to forgo notice-and-comment?

STATEMENT OF THE CASE AND PROCEDURAL HISTORY

Background

Head Start was created in 1965 as part of President Lyndon Johnson’s war on poverty, premised on the idea that education and early intervention programs were keys to breaking the chain of generational poverty. Across the country, Head Start programs serve approximately 850,000 young children living in families at or below the federal poverty line, providing early childhood education and other support for families.

Nine months after the start of the COVID-19 pandemic, and a year before the program’s vaccine mandate was released, a Centers for Disease Control (“CDC”) study commended the Head Start program’s safety record, finding that “programs that successfully implemented CDC-recommended guidance for childcare programs were able to continue offering safe in-person learning,” 86 Fed. Reg. 68,052, 68,056 (Nov. 30, 2021) (the “Rule”) (citing CDC Morbidity and Mortality Weekly Report (Dec. 11, 2020)¹ (“CDC MMWR Report”)), in part by “appl[ying] other innovative approaches” and “allowing maximum program flexibility.” CDC MMWR Report (Discussion).

¹ www.cdc.gov/mmwr/volumes/69/wr/mm6949e3.htm.

In the summer of 2021, after COVID-19 vaccines had become widely available, the Office of Head Start (“OHS”)—the agency within the U.S. Department of Health & Human Services (“HHS”) that administers Head Start—told local Head Start programs during a webinar that “receiving the vaccination is a personal decision. We want to make sure that you’re doing everything you can to make sure that your staff and families have reliable information and resources to help them make this decision and in consultation with their doctor.”²

Two months later, President Biden spoke to the American people about the nation’s battle against COVID-19 and announced five federal vaccine mandates: a vaccine-or-test mandate for large employers by the Occupational Safety and Health Administration (“OSHA”); a vaccine mandate for healthcare workers whose employers participate in the Medicare or Medicaid programs by the Centers for Medicare & Medicaid Services (“CMS”); vaccine mandates for all federal employees and all employees of federal contractors; and a vaccine mandate for educators in

² *Mental Health and Staff Wellness: Emotionally Strong Together*, HHS/OHS webinar transcript (statement of OHS Deputy Director Ann Linehan), July 14, 2021, eclkc.ohs.acf.hhs.gov/video/mental-health-staff-wellness-emotionally-strong-together.

Head Start. *See* Remarks by President Biden on Fighting the COVID-19 Pandemic (Sept. 9, 2021).³

By the time the Head Start mandate was released on the last day of November 2021 as an Interim Final Rule with comment period—the final of the five mandates to launch—it had expanded to encompass the one million Head Start volunteers who interact with children in addition to the 273,000 Head Start staff across the country. Rule at 68,068-69. The Rule also requires that staff, children, and families over age two wear masks while at Head Start program sites or receiving services within their homes,⁴ though Appellants direct their challenge to the vaccine mandate aspect of the Rule. HHS accepted comments on the Interim Final Rule until December 30, 2021, but has not released a final rule.

³ www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3.

⁴ *See* Mandate FAQs (Mar. 16, 2022), <https://eclkc.ohs.acf.hhs.gov/exploring-head-start-program-performance-standards/article/universal-masking-covid-19-vaccine-requirement-faqs> (“Q: Are we requiring families and children receiving home-based services to wear masks in their homes? A: Yes, the universal masking requirement applies to all individuals 2 years of age and older when they are indoors in a setting where Head Start services are provided.”).

The Parties

Appellants are two public school districts in eastern Michigan that sponsor Head Start programs: Livingston Educational Services Agency (“Livingston”) and Wayne-Westland Community Schools (“Wayne-Westland”). They brought this case because the imposition of a vaccine mandate will irreparably harm their ability to provide services to a vulnerable population. In particular, mandating vaccination will force Appellants to terminate staff, which would close Head Start classrooms and disenroll some of the most marginalized students in their schools. *See, e.g.*, Decl. of Dr. Hubert, R. 42-8, Page ID # 11. (Due to strict child-to-teacher ratios required by Head Start, students cannot simply be combined into larger classrooms.) The Rule would also make it substantially harder to hire new staff at a time when the Head Start workforce is in crisis.⁵ Finally, because of the Rule, Livingston has had to isolate Head Start students (whose families are the most disadvantaged in the community and who are more likely to be minorities) and teachers

⁵ *See* Comment of Michigan Head Start Association (Dec. 23, 2021), R. 30-5, Page ID # 484 (“We have grave concerns regarding the impact of the current mandate on the workforce crisis we are experiencing across Michigan.”).

from the other students and teachers in the same building, further marginalizing these students. *Id.* at Page ID # 3-6.

Appellants wish to be very clear: they support staff being vaccinated against COVID-19, have encouraged staff to be vaccinated, and do not want their lawsuit to in any way diminish public confidence in the effectiveness of COVID-19 vaccines at preventing severe illness and death. For the past two years, Appellants (along with Head Start programs across the country) have faced the very difficult job of balancing at times competing commitments—trying to keep COVID-19 out of their classrooms, and continuing to provide vital services to poor children and families within their communities. Appellants found the right balance, which has not involved mandatory vaccination. In fact, although counter-intuitive, Appellants believe that, in the context of their own programs, mandating vaccination is actually counter-productive to their mission of raising families out of poverty. They filed this lawsuit not to make any statement against vaccines or the political response to the pandemic, but to avoid the heartbreaking situation of closing classrooms and denying services to children and families who need them.

Procedural History

Appellants filed their complaint on January 20, 2022. R. 1. The district court initially issued, then extended, a temporary restraining order to prevent irreparable harm. R. 20, 32. After an evidentiary hearing on February 28, 2022, the court denied Appellants' motion for a preliminary injunction in an opinion issued on March 4, 2022. The court ruled that while Livingston and Wayne-Westland would suffer irreparable harm, they were unlikely to succeed on the merits, and it found that the harm and public interest factors weighed against them. R. 46. In doing so, the district court broke from two other district courts that found a likelihood of success on the merits of very similar challenges to the same mandate. *Texas v. Becerra*, No. 5:21-CV-300-H, 2021 U.S. Dist. LEXIS 248309 (N.D. Tex. Dec. 31, 2021); *Louisiana v. Becerra*, No. 3:21-CV-04370, 2022 U.S. Dist. LEXIS 1333 (W.D. La. Jan. 1, 2022).

Appellants filed a notice of appeal of the district court's denial of a preliminary injunction on March 24, 2022. This case was docketed in this Court on March 30, 2022. A week later, Appellants filed a motion for injunction pending appeal after the district court denied Appellants' similar motion on the same day. The Government responded on April 18,

and Appellants replied on April 20. On May 20, 2022, the Motions Panel issued a brief order denying the motion, Ct. App. Dkt. 27-2, and directed the order's publication. *Id.* The Appellants promptly filed a motion for rehearing en banc, which was denied on June 21.

SUMMARY OF THE ARGUMENT

Appellants are entitled to a preliminary injunction against the Rule because they are likely to succeed on the merits; because they, along with the children and families they serve, have suffered and continue to suffer irreparable harm; and because the public interest and balance of the equities lie in their favor. To date two other federal district courts have agreed, but no Court of Appeals has yet issued a ruling.

In brief, Appellants' arguments for a preliminary injunction are:

1. Especially in light of today's Supreme Court decision *West Virginia v. EPA*, HHS's "claim[] to [have] discover[ed] in a long-extant statute an unheralded power representing a transformative expansion in its regulatory authority" must be rejected. 597 U.S. ___, ___ (June 30, 2022) (slip op. at 20). It is "telling that [Head Start], in its [more than] half-century of existence, had never relied on its authority to regulate" its

programs for impoverished preschoolers to require vaccination of either students or staff. *Id.*, slip op. at 18. As the Court stated, the “[e]xtraordinary grants of regulatory authority” necessary for such “unheralded power[s]” require more than “‘modest words,’ ‘vague terms,’ or ‘subtle devices’” of the type relied upon by HHS here. *Id.* at 18, 20. Agencies can only escape this “major questions doctrine” by pointing to “clear congressional authorization for the power it claims.” *Id.* No such clear congressional authorization exists in the Head Start Act, and the mandate therefore exceeds the agency’s delegated power.

2. Recent controlling Supreme Court authority regarding three other pandemic-era executive actions by federal agencies—all cases that focused on the proper scope of agencies’ delegated statutory power—also make clear that the vague statutory authority the government relies on here does not authorize such a novel, far-reaching rule. *See Ala. Ass’n of Realtors v. Dep’t of Health & Hum. Servs.*, 141 S. Ct. 2485 (2021) (striking down CDC eviction moratorium); *NFIB v. OSHA*, 142 S. Ct. 661 (2022) (striking down OSHA vaccine-or-test mandate); *Biden v.*

- Missouri*, 142 S. Ct. 647 (2022) (upholding CMS vaccine mandate).
3. Even if this Court were to find that this mandate can survive its statutory infirmities, the government has not met its heavy burden to show good cause to bypass the notice-and-comment requirements of the APA, especially given that the government has sat on its hands for the six months since two district courts enjoined the Head Start mandate across 25 states. *See Texas v. Becerra*, 2021 U.S. Dist. LEXIS 248309 (N.D. Tex. Dec. 31, 2021); *Louisiana v. Becerra*, 2022 U.S. Dist. LEXIS 1333 (W.D. La. Jan. 1, 2022).
 4. Imposing the vaccine mandate on Appellants would require them to terminate staff and shutter classrooms, depriving low-income children and their families of services intended by Congress to break the cycle of poverty. This constitutes irreparable harm to both Appellants and those they serve.
 5. The government cannot credibly claim harm when it has allowed the mandate to lie dormant across half the country since January. Balanced against the clear harm the mandate would

inflict on Appellants’ programs, the balance of equities lies with Appellants. Moreover, the “public interest [lies] in having governmental agencies abide by the federal laws that govern their existence and operations,” *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994), and even during a pandemic “our system does not permit agencies to act unlawfully . . . in pursuit of desirable ends.” *Alabama Realtors*, 141 S. Ct. at 2490.

ARGUMENT

I. Standard of Review

A district court’s legal conclusions as to a plaintiff’s likelihood of success on the merits are reviewed de novo. *Bays v. City of Fairborn*, 668 F.3d 814, 819 (6th Cir. 2012).

II. The district court erred in finding the Rule is authorized by the Head Start Act because the statutory authorities cited by HHS do not provide a basis for such a sweeping exercise of power.

“Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.” *NFIB v. OSHA*, 142 S. Ct. 661, 665 (2022). That authority must be especially clear when an agency asserts broad powers. *Id.* “The question, then, is whether the Act plainly authorizes the Secretary’s mandate.” *Id.* It does not.

As stated in the “Statutory Authority” section of its preamble, the Rule relies only on 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). Rule at 68,052. Section 9836a(a)(1) empowers the Secretary to modify specified types of “performance standards” for programs that receive Head Start funding. Subsection (C) provides authority to modify “administrative and financial management standards.” Subsection (D) provides authority to modify “standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate).” And Subsection (E) allows modification of “such other standards as the Secretary finds to be appropriate.”

Under Supreme Court and Sixth Circuit precedent, none of these statutory provisions authorizes a nationwide vaccine mandate for Head Start staff, contractors, and volunteers. Under a strained and constitutionally flawed reading of the statute, the district court found all three of these provisions granted authority for the Rule, while the motions panel’s decision explicitly relied only on Subsection (E). R. 46, Page ID # 8-9; Mots. Panel Order 4. These interpretations were

erroneous. They conflict with this Court’s command to “interpret a statute according to its plain meaning.” *United States ex rel. Felten v. William Beaumont Hosp.*, 993 F.3d 428, 431 (6th Cir. 2021). And they contradict the Supreme Court’s insistence that Congress speak clearly when authorizing a power as significant as a federal vaccination mandate.

A. The Rule is not an administrative standard.

A vaccination mandate is plainly not an “administrative or financial management standard,” 42 U.S.C. § 9836a(a)(1)(C), which covers things like bookkeeping and back-office compliance. For example, HHS’s Departmental Appeals Board upheld the termination of a Head Start grant for failure to observe “administrative and financial management standards” when it found misuse of funds, failure to pay employer-side taxes, lack of internal recordkeeping, and lack of an employee code of conduct. *In re Babyland Family Services, Inc.*, HHS Dept. Appeals Bd., DAB No. 2109, 2007 HHSDAB Lexis 62 (Aug. 28, 2007).

HHS itself has defined “administrative standards” issued pursuant to this authority, stating within the Head Start performance standards that the purpose of the program’s administrative requirements is to ensure

that grantees “observe standards of organization, management, and administration that will ensure, so far as reasonably possible, that all program activities are conducted in a manner consistent with the purposes of the Act.” 45 C.F.R. § 1303.10 (Purpose). *See* 42 U.S.C. § 9839(a)(1) (defining “administrative requirements and standards” using the same language).

In the *Texas* case, HHS conceded that the Rule is not a “financial management standard,” but maintained it is an “administrative standard.” 2021 U.S. Dist. LEXIS 248309, at *10-11. The *Texas* court correctly rejected this reading, concluding that “the scope of ‘administrative standards’ is informed by the term to which it is joined: ‘financial management standards.’” 2021 U.S. Dist. LEXIS 248309, at *19. In both terms, the reference is to back-end operations, not regulation of employee, volunteer, or student health. *See also Georgia v. Biden*, No. 1:21-cv-163, 2021 U.S. Dist. LEXIS 234032, at *29 (S.D. Ga. Dec. 7, 2021) (noting the federal contractor mandate “goes far beyond addressing administrative and management issues”).

The district court did not interpret the word “administrative” but instead concluded in a single paragraph that any measure that “keep[s]

the doors open” at Head Start is administrative in nature. That is not what administrative means, as shown by the statutory phrase (“administrative and financial management standards”) and past agency practice applying the term.

This Court should be wary of allowing HHS to expand the meaning of “administrative standard” to encompass the Rule. If such an interpretation were upheld, then HHS, under the guise of keeping the doors open, could override the autonomy of local school systems that operate Head Start programs on nearly any conceivable matter.

B. The Rule is not a standard relating to the condition of facilities.

Subsection (D) provides HHS the authority to modify “standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate).” A plain reading of this provision gives the Secretary the power to regulate the safety of buildings and their surrounding spaces. The term “condition and location of facilities” is limited to the physical places where Head Start happens. “Facility” is defined within Head Start’s performance standards as “a structure, such as a building or modular unit, appropriate for use in

carrying out a Head Start program and used primarily to provide Head Start services.” 45 C.F.R. § 1305.2.

The Secretary has already promulgated rules that apply this authority, requiring that “premises are . . . kept free of undesirable and hazardous materials and conditions” and that “each facility’s space, light, ventilation, heat, and other physical arrangements are consistent with the health, safety and developmental needs of children.” 45 C.F.R. § 1304.53(10). The statute authorizes action to address circumstances such as a playground with “vines with berries, cluttered trash and leaves, and a play structure with splinters and rusty nails.” *In re Camden Cty. Council on Econ. Opportunity*, HHS Dept. Appeals Bd., DAB No. 2116, 2007 HHSDAB Lexis 79 (Sept. 25, 2007).

As the *Texas* court determined, this statutory delegation concerns things like fire codes, not rules under which Head Start programs must fire teachers. *Texas*, 2021 U.S. Dist. LEXIS 248309, at *21. There is no way to read this provision to authorize the Secretary to impose a nationwide vaccine mandate on staff, contractors, and volunteers—each of whom are obviously human beings, not “facilities.”

Even though subsection (D) concerns the safety and physical space of facilities, the court below relied on this provision, reasoning that because the statute mentions “indoor air quality assessment standards” and COVID-19 is an airborne pathogen, the Rule is justified. R. 46, Page ID # 8-9. But it is an abuse of the statutory language to say that a mandate requiring individuals to be vaccinated against an airborne pathogen is an air quality standard at all, and no other court has accepted such a strained interpretation. *See Louisiana*, 2022 U.S. Dist. LEXIS 1333, at *24; *Texas*, 2021 U.S. Dist. LEXIS 248309, at *21 (“the Rule governs the conditions of people, not buildings”). By comparison, no one contests OSHA’s power to regulate air contaminants, *see, e.g.*, 36 Fed. Reg. 10,466, 10,503 (May 29, 1971) (OSHA’s original air contaminant standard following passage of the OSH Act in 1970), but that did not justify OSHA’s vaccine mandate, and indeed Chief Judge Sutton twice distinguished air pollution from communicable diseases when considering the OSHA rule. *See MCP No. 165 v. DOL*, No. 21-7000, 2021 U.S. App. LEXIS 37024, at *8 & *25 (6th Cir. Dec. 15, 2021) (Sutton, C.J., dissenting from denial of initial hearing en banc).

C. The Rule does not fit within the provision permitting modification of other “appropriate” performance standards.

Recent Precedent

As stated above, the motions panel joined the district court in relying on the final catch-all provision of the statute, which authorizes the Secretary to modify “such other standards as the Secretary finds to be appropriate.” 42 U.S.C. § 9836a(a)(1)(E). Reliance on this “catch-all” provision for “appropriate” performance standards, Mots. Panel Order 4, directly conflicts with Supreme Court and circuit precedent.

In *Alabama Realtors*, the Supreme Court ruled against a broad assertion of power by the CDC to mandate an eviction moratorium under a similar catch-all provision for any “necessary” measures. *See* 141 S. Ct. at 2489 (“[T]he Government’s read of §361(a) would give the CDC a breathtaking amount of authority.”). In *Tiger Lily I* and *II*, this Court used the same reasoning to conclude that the same agency action exceeded the CDC’s authority. *See Tiger Lily, LLC v. HUD (Tiger Lily I)*, 992 F.3d 518 (6th Cir. 2021) (denying stay of district court’s declaratory judgment against the moratorium); *Tiger Lily, LLC v. HUD (Tiger Lily II)*, 5 F.4th 666 (6th Cir. 2021) (affirming declaratory judgment). “Necessary” cannot mean “plenary authority to impose any regulation,”

this Court explained, because that interpretation would swallow up the rest of the statute and render its other provisions superfluous. *Tiger Lily II*, 5 F.4th at 671.

This Court also rejected a similar claim in the case of the federal-contractor vaccination mandate, where the government relied on its power to “prescribe policies and directives that the President considers necessary to carry out this subtitle.” 40 U.S.C. § 121(a). Just as “necessary” was not an open-ended grant in *Tiger Lily*, so too in *Kentucky*: “[W]hile [the President] may enjoy a modest valence of necessary and proper powers surrounding those powers enumerated in § 101, he cannot wield a supposedly necessary and proper power without showing how it clearly stems from a power enumerated.” *Kentucky v. Biden*, 23 F.4th 585, 606 (6th Cir. 2022). Here, too, a necessary power must closely resemble a specified power to fall within Congress’s meaning of “appropriate.” Even OSHA’s explicit statutory power to protect worker safety—the agency’s *raison d’etre*—was not enough to save a vaccine mandate that would have protected worker safety where the Supreme Court deemed the risk to workers to not be an “occupational” one. *NFIB v. OSHA*, 142 S. Ct. at 666.

In the opinion of *West Virginia v. EPA* issued today, the Supreme Court counseled, “Extraordinary grants of regulatory authority are rarely accomplished through ‘modest words,’ ‘vague terms,’ or ‘subtle device[s].’” 597 U.S. ___, ___ (June 30, 2022) (slip op. at 18) (quoting *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 468 (2001)). The Court said it was “reluctant to read into ambiguous statutory text’ the delegation claimed to be lurking there. To convince us otherwise, something more than a merely plausible textual basis for the agency action is necessary. The agency instead must point to ‘clear congressional authorization’ for the power it claims.” *Id.*, slip op. at 19 (quoting *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014)). To state the obvious, “appropriate” is not clear congressional authorization for a vaccination mandate on over a million Americans.

Indeed, the facts of *West Virginia v. EPA* also map neatly onto the Rule here. As in *EPA*, here HHS has “claimed to discover in a long-extant statute an unheralded power,” slip op. at 20, one never used before in such an ambitious way. *See Texas*, 2021 U.S. Dist. LEXIS 248309, at *11. It represents a “transformative expansion in [HHS’s] regulatory authority,” slip op. at 20, that will force Head Start classrooms to close

(in violation of the program’s authorizing statute), that invades the power of states and localities to regulate public health to which Head Start had previously deferred, and that regulates the health of staff and volunteers with a vaccine that one cannot don and doff upon starting and leaving work. HHS “located that newfound power in the vague language of an ancillary provision of the Act, one that was designed to function as a gap filler” *Id.* (cleaned up). “Appropriate” is exactly that: vague language designed to function as a gap filler. And though Congress has not “conspicuously and repeatedly declined to enact” a vaccine mandate, *id.*, this Administration pursued its September 9 package of vaccine mandates as a “workaround” to congressional opposition to such a policy. *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 612, n.14 (5th Cir. 2021). So here, as in *West Virginia*, “there is every reason to hesitate before concluding that Congress meant to confer on [HHS] the authority it claims.” Slip op. at 20.

“Appropriate” Limits: Ejusdem Generis

Three other reasons further cut against such an aggressive reading of “appropriate.” First, a statutory catch-all is informed by the terms that go before in the list. *See, e.g., Ala. Realtors*, 141 S. Ct. at 2488 (“the second

sentence informs the grant of authority by illustrating the kinds of measures that could be necessary”). Here, those terms are found in subsections (A) through (D), which address the modification of standards for non-educational services like nutrition and social services, pre-school educational standards, administrative and financial management standards, and facilities standards. Thus, when reading subsection (E) to determine what counts as “appropriate,” the Court must ask whether a nationwide Head Start workplace vaccine mandate is like the other matters for which HHS can modify standards. It is not.

“Appropriate” Limits: No Reductions in Services

Second, the Head Start Act prioritizes access for vulnerable children above all else. *See Astrue v. Capato*, 566 U.S. 541, 558 (2012) (court turns to neighboring provisions to define statutory term). The statute itself provides that no modification of a performance standard by the Secretary is lawful if it results in the elimination or reduction of Head Start services: “[T]he Secretary shall . . . ensure that any such revisions in the standards will not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services.” 42 U.S.C. § 9836a(a)(2)(C)(ii). And this makes

sense: Congress wanted to ensure maximum access to a program to serve vulnerable kids living in poverty.

The Rule violates that fundamental principle. Even the district court found that Livingston's and Wayne-Westland's compliance with the Rule would require each school district to terminate teachers, close classrooms, and deprive the most marginalized students of Head Start programs. R. 46, Page ID # 23. Indeed, the Rule itself predicted a laundry list of awful outcomes for children and families if classrooms closed on even a temporary basis: instability and stress for children and families; the disruption of children's opportunities for learning, socialization, nutrition, and continuity and routine; missed opportunities for academic instruction; children falling behind; children missing out on social interaction and play with peers; impeding Head Start families from participating in the workforce; and financial hardship on low-wage workers who may not have paid time off to care for children staying home. Rule at 68,057-58. And the National Head Start Association predicted in a letter that the Rule "could result in the closing of over 1,300 Head Start classrooms." *Texas*, 2021 U.S. Dist. LEXIS 248309, at *58. Perhaps HHS believes it is acceptable to close classrooms to fight the pandemic, to

punish poor children and their families for the choices of other adults. Congress made a different choice—no revision to a performance standard can undermine the ultimate purpose of serving vulnerable students by reducing the services available.

“Appropriate” Limits: Head Start’s
History of Local Flexibility and Control

Third, the Head Start Act favors local flexibility and local control. *Economic Opportunity Com., Inc. v. Weinberger*, 524 F.2d 393, 402 (2d Cir. 1975) (“there must be a substantial showing by HEW that removal of a program from local control is justified”); Wilson Greene, *Universal Preschool: A Worthy but Costly Goal*, 35 J.L. & Educ. 555, 562 (2006) (“Head Start, a program that receives 80% of its funding from the federal government, understands the importance of local control over preschools.”). Indeed, the Head Start Act specifically invests local Head Start agencies with the responsibility for setting standards for hiring, training, and retaining qualified employees. 42 U.S.C. § 9839(a)(1) & (3). And this approach has worked; the Head Start Program “has a documented history of success from flexible practices depending on local needs,” *Texas*, 2021 U.S. Dist. LEXIS 248309, at *47-51, including during this pandemic, as documented by the CDC and acknowledged in the

Rule's preamble. *See* CDC MMWR Report, *supra* at 8; Rule at 68,056. A performance standard is not "appropriate" when it runs so clearly counter to the program's historic norms.

The District Court Did Not Appropriately Limit "Appropriate"

The district court reasoned that an "appropriate" performance standard is one that is "reasonably related to the purposes of the enabling legislation." R. 46, Page ID # 9 (quoting *Mourning v. Family Publications Service, Inc.*, 411 U.S. 356, 365 (1973)). But the court's reasoning is mistaken for three reasons. First, the premise itself fails: the mandate is *not* related to the purpose of Head Start, but to the administration's goal of vaccinating as many adults as possible. *See* PI Mot., R. 5, Page ID # 23-24 (noting the mandate does not further purpose of Head Start). Indeed, the Rule's own preamble makes that clear, as its Regulatory Impact Analysis—the agency's comprehensive statistical estimate of the mandate's expected costs and benefits—projected that it would lead to health benefits only for adults, not kids. *See* Rule at 68,078-90; PI Mot., R. 5, Page ID # 37-38. Head Start exists to run pre-K programs for kids, not to drive down the number of unvaccinated adults. *Cf. NFIB*, 142 S. Ct. at 665 (observing that "imposing a vaccine mandate on 84 million

Americans in response to a worldwide pandemic is simply not part of what [OSHA] was built for.”).

Second, that reasoning disregards the Supreme Court’s much more recent approach in *Alabama Realtors*, where the Court held that the provision within the Public Health Services Act authorizing the Surgeon General to “provide for . . . other measures, as in his judgment may be necessary” to “prevent . . . the spread of communicable diseases” was not a delegation from Congress authorizing the CDC to enforce a nationwide eviction moratorium. 141 S. Ct. at 2487. While not contesting the government’s asserted connection between eviction and the spread of disease—the prevention of which was a core purpose of the statute—the Supreme Court noted that the “measures [that] may be necessary clause” was situated after a list of several very specific infection-control measures. As the Court said, it “strains credulity” to believe that “a decades-old statute that authorizes [the CDC] to implement measures like fumigation and pest extermination” grants the CDC the “sweeping authority” that it asserted. *Id.* at 2486. Likewise, a very similar provision in a decades-old statute following a prosaic list of categories of performance standards for Head Start programs does not permit a

sweeping vaccine mandate whose benefits flow to a population Congress did not even design the program to serve. On the contrary, because this vaccine mandate is no “everyday exercise of federal power,” it required clear statutory authorization. *NFIB v. OSHA*, 142 S. Ct. at 665.

Finally, “appropriate” cannot mean “plenary authority to impose any regulation” related to the Act, or else the rest of the statute enumerating several discrete categories of performance standards the Secretary may modify would be superfluous. *Tiger Lily II*, 5 F.4th at 671. Under the district court’s reading, Congress could have passed a much shorter law: a purpose statement in § 9831 and an authorization statement allowing any rules the Secretary thinks are appropriate to accomplish that purpose. But that is not the law Congress passed. Rather, the law Congress passed includes a list of specified standards the Secretary shall set; standards regarding staff and volunteer health are not on the list. And the Act also tells the Secretary not to adopt rules that would reduce access to services or to undermine local flexibility, both of which this Rule does. The Rule is not “appropriate.”

D. If OSHA’s explicit statutory delegation to protect workers was not sufficient authority for its vaccine-or-test mandate, the ostensibly implicit authority relied on by HHS here is surely inadequate.

It is difficult to imagine a clearer delegation of authority to regulate health and safety than Congress’ 1970 passage of the Occupational Safety and Health Act, creating the Occupational Safety and Health Administration, which Congress authorized to enforce occupational safety and health standards in order “to provide safe or healthful employment” for workers. 29 U.S.C. § 652(8). And whereas the OSH Act’s focus is workers, who were both the target and beneficiaries of OSHA’s mandate, the Head Start Act’s focus is low-income children, who are neither the target nor main beneficiaries (by the preamble’s own accounting) of Head Start’s mandate. Notably, the Supreme Court never once disputed that OSHA’s mandate would have protected workers in the workplace—the very purpose of OSHA and the OSH Act.

But despite this alignment between the core purpose of the statute, agency, and the vaccine-or-test mandate, the Supreme Court still struck down the OSHA vaccine mandate, finding that the risk of COVID-19 was not an “occupational hazard” of the kind OSHA is authorized to regulate but an everyday risk to public health. 142 S. Ct. at 665-66. If Congress’s

clear delegation to protect workers—and decades of agency rulemaking to do the same—was not sufficient to save the OSHA mandate, a vague delegation relying on the word “appropriate” cannot justify a vaccine mandate for Head Start.

The Supreme Court’s decision upholding the CMS vaccine mandate does not lead to a contrary result, for two reasons. First, the Court found that perhaps the “most basic” function of CMS was to issue regulations necessary to protect the “health and safety of individuals who are furnished services” by the Medicare or Medicaid programs. *Biden v. Missouri*, 142 S. Ct. at 650. But the “most basic” function of Head Start is providing education and other services to kids in poverty, not protecting the health of their teachers.

Second, none of the facts salient to the CMS decision apply in the context of Head Start: the Court noted that Medicare and Medicaid patients “are often elderly, disabled, or otherwise in poor health” such that “transmission of COVID-19 to such patients is particularly dangerous,” *id.* at 651, whereas young children are not high risk; the Court noted that vaccination is both consistent with “the fundamental principle of the medical profession: first, do no harm,” and with other

agency action targeting infection control within Medicare and Medicaid facilities, *id.* at 652-53, whereas Head Start does not provide healthcare to vulnerable populations; and finally the Court observed that mandatory vaccination is a “common feature of the provision of healthcare in America,” such that American healthcare workers “are ordinarily required to be vaccinated,” *id.* at 653, yet mandatory vaccination of teachers and staff is rare—even after COVID-19. *See* PI Mot., R. 5, Page ID # 26-27 (only two states and D.C. require staff vaccination against COVID-19).

E. The district court ignored fundamental principles of statutory interpretation in its ruling.

Were there any doubt as to the meaning of the statutory provisions on which the Secretary relied, several “canons of interpretation” would “foreclose construing [any] ambiguity in the government’s favor.” *Kentucky*, 23 F.4th at 606. These canons and principles are numerous.

The Rule is unprecedented and conflicts with HHS’s longstanding deference to parents, doctors, and state and local authority.

In *Kentucky*, this Court confronted “the imposition of an irreversible medical procedure without precedent in the history of the Property Act’s application,” 23 F.4th at 610, finding that “[t]he dearth of analogous historical examples is strong evidence that § 101 does not contain such a

power,” *id.* at 608. *Accord MCP No. 165 v. USDOL*, 20 F.4th 264, 284 (6th Cir. 2021) (Sutton, J., dissenting from denial of initial hearing en banc) (“A lack of historical precedent tends to be the most telling indication that no authority exists.”); *Mass. Bldg. Trades Council v. DOL*, 21 F.4th 357, 397 (6th Cir. 2021) (Larsen, J., dissenting) (“[W]e should be skeptical when an agency suddenly discovers ‘in a long-extant statute an unheralded power.’”) (quoting *Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 324 (2014)). *See also NFIB*, 142 S. Ct. at 666 (observing that the “lack of historical precedent” for OSHA’s vaccine-or-test mandate is a “telling indication that [it] extends beyond the agency’s legitimate reach.”).

Here, “this is the first time that Head Start has ever mandated a medical procedure as a precondition to new or ongoing employment.” *Texas*, 2021 U.S. Dist. LEXIS 248309, at *11. *Accord Louisiana*, 2022 U.S. Dist. LEXIS 1333, at *31 (noting the statute relied upon by defendants “has never been used to impose a mandatory specific medical treatment upon individuals”).

In asserting that the Rule conforms to past agency practice, the district court and motions panel relied on the fact that HHS has imposed one health-related requirement on Head Start program staff and

volunteers (routine physical screenings) and another on students (checks for compliance with CDC-recommended vaccinations⁶). R. 46, Page ID # 3-4; Mots. Panel Order 4-5. But, as this Court concluded in *Kentucky*, “none of those comes even close to the deployment of [a federal statute] to mandate a medical procedure . . .” 23 F.4th at 607.

A vaccine mandate for staff and volunteers under threat of termination is far more invasive than an annual physical exam. *See Mass. Bldg. Trades Council*, 21 F.4th at 398 (Larsen, J., dissenting) (considering “not only . . . the *kind* of power but also the *scope* or *degree*”). It is also different in kind from a routine physical exam or a records check for recommended vaccinations.

Moreover, both of those regulations recognize that parents, providers, and state and local governments, not the federal government, have the ultimate say in the health decisions of teachers and students. The regulation requiring staff health screenings states that such screenings may be done only “as recommended by [the] health care provider in

⁶ The district court also mentioned Head Start’s rule for HIV-positive children. R. 46, Page ID # 3. However, this is hardly authority for a vaccination mandate for staff and volunteers. The HIV rule simply sets standards for how the local Head Start programs must treat students with a particular type of disability under various other federal laws.

accordance with state, tribal, or local requirements.” 45 C.F.R. § 1302.93(a). Furthermore, after HHS published a proposed rule that would have required tuberculosis screening for Head Start volunteers in 1996, many commenters expressed concern that it “would be costly, create a barrier to parent volunteers, and make no sense in communities with low incidences of tuberculosis.” 61 Fed. Reg. 57,186, 57,189 (Nov. 5, 1996) (HHS “belie[ves] that overly prescriptive Federal regulations should be avoided in order to provide flexibility to [local programs] to enable them to make programmatic decisions based on the needs of the children and families they serve and of the communities in which they are located.”). HHS accordingly modified the final rule so that it required screening for regular volunteers only when “State, Tribal, or local law” required it (in other words, adding no burden beyond that already in place locally). *Id.*

As for the regulation pertaining to students’ vaccination status, HHS directs programs only to assist parents who desire to bring their children up to date on immunizations. *See* 45 C.F.R. §§ 1302.41(b)(1)-1302.42(b)(1) (programs must “[a]ssist parents with making arrangements to bring the child up-to-date . . . with parent consent”). In

other words, the cited regulations reflect HHS’s longstanding practice of deferring to parental, state, and local authority in health decisions—a practice that the Rule completely upsets.

The district court’s decision
contradicts the major questions doctrine.

In *Kentucky*, this Court insisted on “a clear statement from Congress that it intended the President to use a property-and-services procurement act, for a purpose never-before recognized, to effect major changes in the administration of public health.” 24 F.4th at 607. *Accord MCP No. 165*, 20 F.4th at 268 (Sutton, C.J., dissenting) (“[B]road assertions of administrative power demand unmistakable legislative support.”); *Tiger Lily II*, 5 F.4th at 671; *see also Alabama Realtors*, 141 S. Ct. at 2489 (“We expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance.”); *NFIB*, 142 S. Ct. at 665 (same).

The Supreme Court underscored this holding in *West Virginia v. EPA*, 597 U.S. ____ (2022), issued today. There, the Court said the doctrine applies to “agencies asserting highly consequential power beyond what Congress could reasonably be understood to have granted.” Slip op. at 20. That is precisely what we have here—an unprecedented assertion of

power and a “significant encroachment into the lives—and health—of a vast number” of Americans, *NFIB*, 142 S. Ct. at 665, that extends beyond what Congress could reasonably be understood to have granted for a pre-kindergarten program for low-income students. This is especially so when the Rule is rightly viewed in the context of the package of administration initiatives announced on September 9.

The district court’s decision
violates the canon of federalism.

Beyond the specific commitment to local autonomy in the Head Start Act, courts also presume a commitment to federalism when interpreting federal statutory authority. In *Tiger Lily I*, this Court insisted on “clear, unequivocal textual evidence of Congress’s intent” to grant such broad agency authority in the face of the traditional state power over property matters. 992 F.3d at 523. Similarly, in *Tiger Lily II* this Court said “Congress must enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power.” 5 F.4th at 671 (cleaned up); *see also Alabama Realtors*, 141 S. Ct. at 2489 (“Our precedents require Congress to enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power and the power of the Government over private property.”). This Rule

overrides these federalism principles by substituting the Secretary’s judgment for state and local authority over both health and education.

The district court’s decision invites a nondelegation problem.

By construing the statute so broadly as to delegate to the Secretary authority to impose a nationwide vaccine mandate, the district court (and the motions panel) open up the statute to a significant separation-of-powers concern. In *Tiger Lily I*, the Court said “the broad construction of § 264 the government proposes raises . . . concerns about the delegation of legislative power to the executive branch.” 992 F.3d at 523. In *Tiger Lily II*, the Court again raised the nondelegation problem. 5 F.4th at 672. The Court quoted a plurality opinion from the U.S. Supreme Court: “A construction of the statute that avoids this kind of open-ended grant [of power] should certainly be favored.” 5 F.4th at 672 (quoting *Indus. Union Dep’t, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 645-46 (1980)). See generally *Tiger Lily II* at 674-75 (Thapar, J., concurring) (presenting an in-depth discussion of doctrine, observing that Congress alone “wields the formidable power of prescribing the rules by which the duties and rights of every citizen are to be regulated” because “Congress is the [branch of government] most responsive to the will of the people”) (cleaned up)

(quoting *The Federalist* No. 78, at 465). The district court favored just such an open-ended grant of power when it should have been avoided.

These recent rulings by the Supreme Court and this Court required the district court to construe the statutory authority that HHS relies on narrowly to avoid serious constitutional concerns. Yet the district court paid them no heed.

F. The district court's interpretive approach was flawed.

The district court did not cite or apply any of the foregoing principles this Court applied in its recent on-point cases; instead, it asserted that “the present case is more analogous” to the Supreme Court’s decision on the CMS mandate, and that the Head Start mandate therefore should also be upheld. *See* R. 46, Page ID # 13-14. For at least three reasons, this analysis is mistaken.

First, the district court distinguished *NFIB* because it concerned a regulation on private employers rather than recipients of public funds. R. 46, Page ID # 13. But Appellants are not pressing a constitutional argument in this appeal, so any distinction between Congress’s constitutional Commerce and Spending powers is irrelevant. The key question is whether the statute the Secretary relied on actually

authorized the power the Secretary claims to possess, not whether Congress has the authority to set conditions on receipt of federal funds.

Second, the district court stripped language from *NFIB* out of context. In *NFIB*, the Supreme Court signaled that, unlike the broad vaccinate-or-test mandate at issue in that case, more “targeted regulations” “where the virus poses a special danger because of the particular features of an employee’s job or workplace” would “plainly [be] permissible” under the OSH Act. R. 46, Page ID # 13-14 (quoting 142 S. Ct. at 665-66). Yet the Supreme Court’s discussion of OSHA’s power under the OSH Act to regulate dangers particular to a specific occupational safety and health risk says nothing about whether HHS may adopt vaccine mandates under the Head Start Act. Moreover, the Rule suffers from the same flaw as OSHA’s mandate: it is not targeted or tailored based on places where the virus poses a special danger but instead applies in blanket fashion across all Head Start programs to all staff and contractors and volunteers who interact with students, whether indoors or outdoors. Finally, Head Start classrooms do not pose a “special danger” to students or staff. *See* PI Mot., R. 5, Page ID # 28-29 (noting pre-school age children, even unvaccinated, are safest demographic in pandemic; CDC study from

spring 2020 finding that working in early childhood education facilities did not increase risk of COVID-19 infection; Rule itself assumed “that Head Start staff face similar exposure to [COVID-19] risks as other adults”) (quoting Rule at 68,074).

Third, the district court threw out a final lifeline, saying that even if all the foregoing is wrong, it’s not so wrong as to violate *Chevron*. R. 46, Page ID # 14. But deference is no refuge here, as the *Texas* Court rightly concluded. *Texas*, 2021 U.S. Dist. LEXIS 248309, at *16 (“Under step two of the *Chevron* framework, . . . The plain language of the defendants’ cited authority, the statutory context, and the existing regulations all confirm that the Secretary’s interpretation of ‘performance standards’ is not a permissible construction of the statute.”). And the district court’s analysis of past agency practice is mistaken; a mandatory vaccination on all staff is unlike anything HHS has done before, as explained above.

G. The district court and motions panel wrongly relied on a separate statutory provision that even HHS did not cite as authority for the mandate.

Aside from briefly addressing the statutory justification actually asserted by HHS in the Rule, the district court and motions panel also concluded that the Rule fit within a separate statutory provision that

“gives the Secretary the power to remedy deficiencies . . . ‘if the Secretary finds that the deficiency threatens the *health or safety* of staff or program participants.’” R. 46, Page ID # 10; Mots. Panel Order 4 (quoting 42 U.S.C. § 9836a(e)(1)(B)(i)). But HHS did not cite this provision as a source of authority in the Rule. And “a court may uphold agency action only on the grounds that the agency invoked when it took the action.” *Michigan v. EPA*, 576 U.S. 743, 758 (2015). That rule applies to statutory grounds as much as scientific or policy rationales. See *Northport Health Servs. of Ark., LLC v. United States HHS*, 14 F.4th 856, 870 n.6 (8th Cir. 2021). Therefore, the statute’s “deficiency” provision cannot provide a basis for upholding the Rule.

Moreover, the “deficiency” provision does not support the Rule. Under a plain reading of the statutory scheme, the Secretary’s ability to correct “deficiencies” under § 9836a(e)(1) cannot expand the Secretary’s separate authority to modify specific performance standards under § 9836a(a)(1). Instead, the authority to correct deficiencies is tied to HHS’s power to review individual programs; it is not a basis for issuing a nationwide mandate. 42 U.S.C. § 9836a(e)(1) (permitting HHS to require correction of deficiencies only “on the basis of a review pursuant to subsection (c)”);

§ 9836a(c) (permitting HHS to conduct routine reviews, follow-up reviews, and unannounced inspections of individual Head Start programs for compliance with performance standards).

Such reviews for deficiencies would unsurprisingly relate to health and safety when, for example, HHS finds fault with a program's use of poorly ventilated facilities, which ties to an express performance standard under § 9836a(a)(1)(D). But HHS's authority to review individual programs does not equate to an open-ended delegation to issue additional nationwide standards on whatever health or safety topic HHS chooses. *See also Texas*, 2021 U.S. Dist. LEXIS 248309, at *25-*29 (rebutting Defendants' "deficiency" arguments). Any other reading would render the statute's earlier specification of particular standards superfluous.

III. HHS lacked good cause to skip public notice and comment, and the agency's actions demonstrate its own lack of urgency.

Notice-and-comment rulemaking is the cornerstone of federal administrative procedure. Thus, the APA permits agencies to skip notice-and-comment only when they have "good cause." 5 U.S.C. § 553. Here, the agency asserted that good cause existed to issue the Rule without

notice and comment based on the COVID-19 Delta variant wave and data on the effectiveness of vaccination. Rule at 68,058–59.

The “good cause” exception is one for which the government bears a heavy burden, and which is “narrowly construed and only reluctantly countenanced.” *United States v. Cain*, 583 F.3d 408, 420 (6th Cir. 2009). “There is a high bar to invoke the exception.” *N.C. Growers Ass’n v. UFW*, 702 F.3d 755, 767 (4th Cir. 2012). These are “rare circumstances” such as emergencies or other situations where serious harm would result from a delay. *Id.* (quoting *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012)). And the bar is especially high here, as “the default rule in agency rulemaking should be the notice-and-comment process, particularly when a rule imposes highly consequential new regulations . . . and when the agency has never invoked such a power before.” *MCP No. 165*, 20 F.4th at 284 (Sutton, C.J., dissenting). “The more expansive a rule’s reach, the greater the necessity for public comment.” *Id.* at 278 (Sutton, C.J., dissenting).

Although not dispositive, an agency’s delay is “evidence that a situation is not a true emergency.” *Asbestos Info. Ass’n/N. Am. v. OSHA*, 727 F.2d 415, 423 (5th Cir. 1984). In any event, the COVID-19 pandemic

has been ongoing in the United States since approximately March 2020, with vaccinations available for a large portion of the intervening time. In that context, HHS lacked good cause to impose the mandate without following notice-and-comment procedures. HHS's stated reasoning that a delay would be contrary to the public interest is unavailing.

In addition, the APA's notice-and-comment procedures are designed to assure due deliberation. *Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 741 (1996). HHS's failure to adhere to notice-and-comment procedures deprived crucial stakeholders of their opportunity to engage in the rulemaking process. Head Start staff, volunteers, and parents were excluded. It cannot be credibly asserted that it would have been "impracticable and contrary to the public interest" to allow these individuals the opportunity to provide comment. In fact, after issuing the Rule, HHS accepted comments until December 30, 2021. Rule at 68,052. The importance of deliberation is evidenced by the nearly 2,800 comments submitted—comments that are now largely meaningless given that the agency has still not issued a final rule and the key requirements of the Rule have been in effect for months. HHS did not, and could not,

demonstrate “good cause” to justify its failure to comply with its notice-and-comment obligations under the APA.

Indeed, numerous courts have rejected the COVID-19 pandemic as a justification for bypassing notice-and-comment. *Florida v. Becerra*, 544 F. Supp. 3d 1241, 1295 (M.D. Fla. 2021) (CDC rule on cruise ships); *Regeneron Pharmaceuticals, Inc. v. HHS*, 510 F. Supp. 3d 29, 48 (S.D.N.Y. 2020) (CMS’s rule on drug prices); *Chamber of Commerce v. DHS*, 504 F. Supp. 3d 1077, 1094 (N.D. Cal. 2020) (DHS rule for visa program); *Ass’n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482, 496 (D. Md. 2020) (CMS rule on Medicare Part B). “Good cause” cannot mean stopping something bad sooner rather than later, “unless we wish to sideline the notice-and-comment process . . . with respect to every future medical innovation concerning COVID-19 for this federal agency and other ones too.” *MCP No. 165*, 20 F.4th at 279 (Sutton, C.J., dissenting). “Otherwise the good cause exception would swallow the rule.” *United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009).

The lone exception is in the CMS vaccine-mandate case, where the Supreme Court acknowledged that it could not “say that in this instance the two months the agency took to prepare a 73-page rule constitutes

‘delay’ inconsistent with the Secretary’s finding of good cause.” *Missouri*, 142 S. Ct. at 654. But the case for the Secretary’s good-cause finding here is significantly weaker than the Secretary’s good-cause justification for the CMS mandate.

The President announced the Head Start Rule on September 9, but it was not published until November 30, almost a month after the CMS and OSHA mandates, even though it’s only two-thirds the length of the CMS rule and one-third the length of the OSHA rule. In other words, HHS took longer to issue a shorter, less complex rule than the one the Supreme Court reluctantly countenanced in *Missouri*. No wonder two other district courts rejected the good-cause defense. *See Texas*, 2021 U.S. Dist. LEXIS 248309, at *41; *Louisiana*, 2022 U.S. Dist. LEXIS 1333 at *37.

In addition, HHS’s subsequent actions have not been consistent with an agency that believes the Rule requires immediate implementation. In twenty-five states, the Rule is preliminarily enjoined. Those sweeping injunctions have been in force for over five months, and because the federal government has waived its right to appeal the injunctions, they will remain in place for the duration of the district courts’ proceedings in each case. HHS’s credibility on its good cause finding is severely

compromised by its lack of alacrity in pursuing its interest in these cases. *See Church of Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U. S. 520, 547 (1993) (“A law cannot be regarded as protecting an interest of the highest order when it leaves appreciable damage to that supposedly vital interest unprohibited.” (cleaned up)). “The government’s actions undercut its representations of great urgency in implementation of the [Head Start] mandate.” *Kentucky*, 23 F.4th at 610.

IV. The other equitable factors favor Appellants.

A. The district court correctly concluded that the Rule will cause Appellants to suffer irreparable harm.

The district court initially issued a temporary restraining order to prevent irreparable harm, and then extended it. R. 20, 32. Ruling on the preliminary injunction, the court concluded that Appellants were irreparably harmed by immediate imposition of the Rule. R. 46, Page ID # 23. The district court was especially mindful of the impact of the staffing crisis for students. *Id.* (“Students’ loss of in-person learning time and related hardships on students’ families and Plaintiffs constitute ‘irreparable harm.’”).

Even the Secretary recognized these harms, identifying the negative consequences of temporary classroom closures in the Rule itself: “The

children and families served by Head Start are largely comprised of individuals who experience economic hardship and have been historically underserved and marginalized.” “Head Start programs provide critical services to meet the health, nutrition, and early learning needs of these children and families.” “[P]rogram closures . . . create instability and stress for children and families. They disrupt children’s opportunities for learning, socialization, nutrition, and continuity and routine.” Moreover, “[p]rogram closures impede Head Start families from participating in the workforce, impos[ing] financial hardship on low wage workers who may not have paid time off to care for children . . .” Rule at 68,057.

These same harms will occur, and be far greater and permanent, if the Rule is not enjoined and the Appellants are forced to make long-term or permanent classroom closures. Head Start has strict student-teacher ratio requirements, so students cannot simply be shifted into another classroom. Classrooms will close and students will be unenrolled if the Appellants are forced to fire their teachers.

The government lacks a compelling interest
to enforce the mandate against Appellants.

Appellants’ showing of irreparable harm is even stronger when weighed against the Government’s lackadaisical attitude toward its

supposedly compelling interest in this rule. Again, HHS did not move for interlocutory appellate review after losing in two other district courts, such that the Head Start Rule is not effective in 25 states. HHS cannot credibly claim that it cannot wait to enforce its mandate against two additional Head Start providers, given its lack of urgency in pursuing its interests elsewhere.

Appellants' irreparable harms have not expired.

Weeks after the district court denied Appellants' motion for preliminary injunction, the district court also denied a motion for injunction pending appeal. R. 58. At that point, the district court changed its view of irreparable harm, finding that the irreparable harm it had previously recognized had dissipated because Appellants failed to "mak[e] good faith efforts to secure or hire vaccinated individuals to replace staff members who are unwilling to be vaccinated." R. 58, Page ID # 5. The district court did not explain why its view had changed in the four weeks since its ruling on the preliminary injunction, nor were Appellants given the opportunity to brief the issue. Furthermore, the district court's revised ruling on irreparable harm contradicts the very purpose of Appellants' preliminary injunction motion—to avoid the

irreparable harm of terminating and replacing staff. Regardless, the record below indicates the difficulty Appellants face in hiring new, vaccinated staff in a tight labor market, especially for educators, *see* R. 30-5 (comment letter by Michigan Head Start Association); R. 42-8 and R. 55, Page ID # 75-80 (written and live testimony of Livingston superintendent), and especially in a part of the country where overall vaccination rates are lower than average.⁷ As this Court has recognized, “[s]erious resistance” from a workforce and consequent “serious [educational] disruption” weigh in favor of a stay. *Kentucky*, 2022 U.S. App. LEXIS 267, at *52.

The district court’s cavalier attitude towards firing current staff also fails to appreciate the articles in the Administrative Record filed in other courts for this rule showing the importance of child-teacher bonding and consistency during a school year for the child’s learning and sense of safety and stability. *Etherton v. Biden*, 1:22-cv-00195-LMB-JFA (E.D.Va.), AR 00999, AR 01030, AR 01033.⁸

⁷ According to the most recent CDC data, 60% of residents of Livingston County, Michigan, and 55% of residents of Wayne County, Michigan, are fully vaccinated. This is compared to 67% of the U.S. population overall.

⁸ Attachment in the Classroom (Bergin & Bergin, Educational Psychology Review); Childhood Attachment (Rees, British Journal of General

The district court also failed to recognize the irreparable harm of isolating Head Start students from other preschool children. Dr. Michael Hubert, the superintendent of Livingston, explained in his testimony that the Rule caused Livingston to make the “tremendously difficult” decision to restructure its Head Start program so that its Head Start students are isolated from the other pre-kindergarten children the school district serves, who tend to be from a higher socioeconomic background. Livingston did this in order to limit the number of staff who would be subject to the mandate and thus subject to termination if this litigation fails. Decl. of Dr. Hubert, R. 42-8, Page ID # 3-5. Dr. Hubert also testified that the isolation of Head Start students and staff from the rest of the school population has “significantly harmed” the Head Start students, and has “negatively impact[ed] the diversity in our school community.” *Id.* His professional opinion on such a matter “is precisely a question on

Practice); Attachment and preschool teacher: An opportunity to develop a secure base (Sierra, *International Journal of Early Childhood Special Education*).

See Combier-Kapel v. Biegelson, 242 F. App’x 714, 715 (2d Cir. 2007) (appropriate to take judicial notice of administrative record); *United Cook Inlet Drift Ass’n v. Nat’l Marine Fisheries Serv.*, No. 3:21-cv-00255-JMK, 2022 U.S. Dist. LEXIS 109879, at *15 (D. Alaska June 21, 2022) (the same administrative record exists for all cases filed against a single rule).

which we defer to educational experts.” *See W.A. v. Hendrick Hudson Cent. Sch. Dist.*, 927 F.3d 126, 147 (2d Cir. 2019). “[T]h[e] Court is not qualified to second-guess these educational experts’ opinions.” *W. W. v. N.Y.C. Dep’t of Educ.*, 2014 U.S. Dist. LEXIS 47253, at *35 (S.D.N.Y. Mar. 31, 2014). The failure to recognize the ongoing irreparable harm of segregating low-income students from the general preschool population was a mistake in the district court’s analysis on the injunction pending appeal.

B. The public interest and balance of harms weigh in favor of preliminary relief.

Though HHS is rightly concerned about the impact of COVID-19 spread on Head Start program participants and the general public, the government is not entitled to automatically prevail in every request for injunctive relief against a measure aimed at combatting the pandemic. *See, e.g., NFIB*, 142 S. Ct. at 666 (invalidating OSHA’s vaccine-or-test mandate even though OSHA claimed it made workplaces safer).

Two ultimate equitable principles hold sway here. First, it is “the responsibility of those chosen by the people through democratic processes” to “weigh such tradeoffs” between public health and other interests. *NFIB*, 142 S. Ct. at 666. Here, the school boards of Appellants

have found that the goal of vaccination does not justify mass layoffs across its workforce. Certainly their judgment as to the health and safety of their students and staff is entitled to consideration as an accurate reflection of the public interest in their community.

Second, “the public’s true interest lies in the correct application of the law.” *Kentucky*, 2022 U.S. App. LEXIS 267, at *56. Because the Appellants are likely to succeed on the law, the public interest weighs in their favor.

CONCLUSION

HHS lacks the statutory authority to impose this rule, and a pandemic is not an automatic trump card for avoiding notice-and-comment rulemaking. The district court’s decision is incompatible with the Supreme Court’s decisions in *NFIB* and *Alabama Realtors* and this Court’s decisions in *Tiger Lily I* and *II* and *Kentucky*. It should be reversed and an injunction entered so that Appellants can continue serving poor children and their families without threat of government interference.

Dated: June 30, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief was prepared in Century Schoolbook font, size 14, double-spaced, and is 10,508 words, which is under the limit of 13,000 words for such a petition. See Fed. R. App. P. 35. /s/ Daniel R. Suhr

22-1257

**United States Court of Appeals
for the Sixth Circuit**

LIVINGSTON EDUCATIONAL SERVICE AGENCY
and WAYNE-WESTLAND COMMUNITY SCHOOLS,

Plaintiffs – Appellants,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JOOYEUN CHANG, in her official capacity as Assistant Secretary and Principal Deputy Assistant Secretary of the Administration for Children and Families; ADMINISTRATION FOR CHILDREN AND FAMILIES; and BERNADINE FUTRELL, in her official capacity as the director of the Office of Head Start,

Defendants – Appellees.

On Appeal from the United States District Court
for the Eastern District of Michigan
No. 2:22-cv-10127, Hon. Nancy G. Edmunds

ADDENDUM TO APPELLANTS' PRINCIPAL BRIEF

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ADDENDUM**Statutes and Regulations**

	Description	Addendum Page
1	Excerpts from Head Start Act: 42 U.S.C. §§ 9836a and 9831	Addendum 1
2	Current Head Start Performance Standards, 81 Fed. Reg. 61,412 (Sept. 2016)	Addendum 11
3	Vaccine and Mask Requirements to Mitigate the Spread of COVID-19 in Head Start Programs, 86 Fed. Reg. 68,052 (Nov. 30, 2021)	Addendum 54

Pleadings, Motions, and Orders in the District Court

	Dkt. #	Description	Page ID #
4	1	Verified Complaint	1-47
5	5	Plaintiffs' Motion for Preliminary Injunction	122-173
6	20	Order Granting in Part and Denying in Part Plaintiffs' Motion for Temporary Restraining Order	411-420
7	30	Michigan House of Representatives and Senate Amicus Brief in support of Plaintiffs	455-486
8	32	Order Granting Motion to Extend Temporary Restraining Order	502-504
9	35	Defendants' Opposition to PI Motion	572-633
10	39	Plaintiffs' Reply in Support of PI Motion	761-780
11	46	Order Denying Plaintiffs' Motion for Preliminary Injunction	1154-1178
12	49	Notice of Appeal	1185-1186
13	50	Plaintiffs' Motion for Injunction Pending Appeal	1187-1197

14	56	Defendants' Opposition to Motion for Injunction Pending Appeal	1285-1295
15	58	Order Denying Plaintiffs' Motion for Injunction Pending Appeal	1298-1306

Other Parts of the Record in the District Court
(in chronological order)

	Dkt. #	Description	Page ID #
16	39-3	Excerpts from 1975 Head Start Performance Standards	799-804, 817-832
17	5-2	American Academy of Pediatrics: Under the Right Conditions, Center-Based Child Care is an Unlikely Covid-19 Threat to Staff (Oct. 13, 2020)	266-267
18	5-2	CDC: MMWR on Head Start and COVID-19 Mitigation (Dec. 11, 2020) <i>(cited in FN 50 of Rule)</i>	290-294
19	42-5	CDC Science Brief: Transmission of SARS-CoV-2 in K-12 Schools and Early Care and Education Programs (July 9, 2021) <i>(cited in FN 30 of Rule)</i>	951-964
20	5-2	The New York Times: Kids, Covid, and Delta (Sept. 9, 2021)	243-245
21	1-2	Remarks by President Biden on Fighting the COVID-19 Pandemic (Sept. 9, 2021)	35-44
22	5-2	CDC: COVID-19 Guidance for Operating Early Care and Education / Child Care Programs (Nov. 10, 2021) <i>(cited in FN 28 of Rule)</i>	296-310
23	5-2	CDC: Risk for COVID-19 Infection, Hospitalization and Death By Age Group (Nov. 22, 2021)	239

24	5-2	Press Release: NHSA Sounds Alarm to Secretary Becerra on Vaccine and Mask Mandate (Dec. 17, 2021)	353-354
25	30-5	Michigan Head Start Association comment letter regarding Vaccine Mandate (Dec. 23, 2021)	483-486
26	5-2	OHS Vaccine Mandate FAQs (Dec. 23, 2021)	334-344
27	5-2	CDC: Provisional COVID-19 Deaths by Sex and Age (Jan. 15, 2022)	240-241
28	39-4	Joint NHSA / AASA Letter re: Vaccine Mandate (Feb. 8, 2022)	870-871
29	55	Transcript of Preliminary Injunction Hearing (Feb. 28, 2022)	1204-1284

Exhibit 1

7/7/22, 2:31 PM

42 USC 9831: Statement of purpose

◀ Current ▶

[Back to Original Document](#)

<< Previous [TITLE 42 / CHAPTER 105 / SUBCHAPTER II / § 9831](#) Next >>

[Print] [Print selection]

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42 USC 9831: Statement of purpose

Text contains those laws in effect on July 6, 2022

From Title 42-THE PUBLIC HEALTH AND WELFARE

CHAPTER 105-COMMUNITY SERVICES PROGRAMS

SUBCHAPTER II-HEAD START PROGRAMS

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[Miscellaneous](#)

[Amendments](#)

[Effective Date](#)

[Short Title](#)

§9831. Statement of purpose

It is the purpose of this subchapter to promote the school readiness of low-income children by enhancing their cognitive, social, and emotional development-

(1) in a learning environment that supports children's growth in language, literacy, mathematics, science, social and emotional functioning, creative arts, physical skills, and approaches to learning; and

(2) through the provision to low-income children and their families of health, educational, nutritional, social, and other services that are determined, based on family needs assessments, to be necessary.

(Pub. L. 97–35, title VI, §636, Aug. 13, 1981, 95 Stat. 499 ; Pub. L. 101–501, title I, §102, Nov. 3, 1990, 104 Stat. 1224 ; Pub. L. 105–285, title I, §102, Oct. 27, 1998, 112 Stat. 2703 ; Pub. L. 110–134, §2, Dec. 12, 2007, 121 Stat. 1363 .)

EDITORIAL NOTES

AMENDMENTS

2007-Pub. L. 110–134 amended section generally. Prior to amendment, text read as follows: "It is the purpose of this subchapter to promote school readiness by enhancing the social and cognitive development of low-income children through the provision, to low-income children and their families, of health, educational, nutritional, social, and other services that are determined, based on family needs assessments, to be necessary."

1998-Pub. L. 105–285 amended section catchline and text generally. Prior to amendment, text read as follows:

"(a) In recognition of the role which Project Head Start has played in the effective delivery of comprehensive health, educational, nutritional, social, and other services to economically disadvantaged children and their families, it is the purpose of this subchapter to extend the authority for the appropriation of funds for such program.

"(b) In carrying out the provisions of this subchapter, the Secretary of Health and Human Services shall continue the administrative arrangement responsible for meeting the needs of migrant, non-English language background, and Indian children and shall assure that appropriate funding is provided to meet such needs."

1990-Subsec. (b). Pub. L. 101–501 inserted ", non-English language background," after "migrant".

STATUTORY NOTES AND RELATED SUBSIDIARIES

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42 USC 9836a: Standards; monitoring of Head Start agencies and programs

Text contains those laws in effect on July 6, 2022

From Title 42-THE PUBLIC HEALTH AND WELFARE

CHAPTER 105-COMMUNITY SERVICES PROGRAMS

SUBCHAPTER II-HEAD START PROGRAMS

Jump To:[Source Credit](#)[Miscellaneous](#)[References In Text](#)[Amendments](#)[Effective Date](#)**§9836a. Standards; monitoring of Head Start agencies and programs****(a) Standards****(1) Content of standards**

The Secretary shall modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs under this subchapter, including-

(A) performance standards with respect to services required to be provided, including health, parental involvement, nutritional, and social services, transition activities described in section 9837a of this title, and other services;

(B) scientifically based and developmentally appropriate education performance standards related to school readiness that are based on the Head Start Child Outcomes Framework to ensure that the children participating in the program, at a minimum, develop and demonstrate-

(i) language knowledge and skills, including oral language and listening comprehension;

(ii) literacy knowledge and skills, including phonological awareness, print awareness and skills, and alphabetic knowledge;

(iii) mathematics knowledge and skills;

(iv) science knowledge and skills;

(v) cognitive abilities related to academic achievement and child development;

(vi) approaches to learning related to child development and early learning;

(vii) social and emotional development related to early learning, school success, and social problemsolving;

(viii) abilities in creative arts;

(ix) physical development; and

(x) in the case of limited English proficient children, progress toward acquisition of the English language while making meaningful progress in attaining the knowledge, skills, abilities, and development described in clauses (i) through (ix), including progress made through the use of culturally and linguistically appropriate instructional services;

(C) administrative and financial management standards;

(D) standards relating to the condition and location of facilities (including indoor air quality assessment standards, where appropriate) for such agencies, and programs, including regulations that require that the facilities used by Head Start agencies (including Early Head Start agencies and any delegate agencies) for regularly scheduled center-based and combination program option classroom activities-

(i) shall meet or exceed State and local requirements concerning licensing for such facilities; and

(ii) shall be accessible by State and local authorities for purposes of monitoring and ensuring compliance, unless State or local laws prohibit such access; and

(E) such other standards as the Secretary finds to be appropriate.

(2) Considerations regarding standards

In developing any modifications to standards required under paragraph (1), the Secretary shall-

(A) consult with experts in the fields of child development, early childhood education, child health care, family services (including linguistically and culturally appropriate services to non-English speaking children and their families), administration, and financial management, and with persons with experience in the operation of Head Start programs;

(B) take into consideration-

(i) past experience with use of the standards in effect under this subchapter on December 12, 2007;

(ii) changes over the period since October 27, 1998, in the circumstances and problems typically facing children and families served by Head Start agencies;

7/7/22, 2:30 PM

- (iii) recommendations from the study on Developmental Outcomes and Assessments for Young Children by the National Academy of Sciences, consistent with section 9844(j) of this title;
- (iv) developments concerning research-based practices with respect to early childhood education and development, children with disabilities, homeless children, children in foster care, and family services, and best practices with respect to program administration and financial management;
- (v) projected needs of an expanding Head Start program;
- (vi) guidelines and standards that promote child health services and physical development, including participation in outdoor activity that supports children's motor development and overall health and nutrition;
- (vii) changes in the characteristics of the population of children who are eligible to participate in Head Start programs, including country of origin, language background, and family structure of such children, and changes in the population and number of such children who are in foster care or are homeless children;
- (viii) mechanisms to ensure that children participating in Head Start programs make a successful transition to the schools that the children will be attending;
- (ix) the need for Head Start agencies to maintain regular communications with parents, including conducting periodic meetings to discuss the progress of individual children in Head Start programs; and
- (x) the unique challenges faced by individual programs, including those programs that are seasonal or short term and those programs that serve rural populations;

- (C)(i) review and revise as necessary the standards in effect under this subsection; and
- (ii) ensure that any such revisions in the standards will not result in the elimination of or any reduction in quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services required to be provided under such standards as in effect on December 12, 2007; and
- (D) consult with Indian tribes, including Alaska Natives, experts in Indian, including Alaska Native, early childhood education and development, linguists, and the National Indian Head Start Directors Association on the review and promulgation of standards under paragraph (1) (including standards for language acquisition and school readiness).

(3) Standards relating to obligations to delegate agencies

In developing any modifications to standards under paragraph (1), the Secretary shall describe the obligations of a Head Start agency to a delegate agency to which the Head Start agency has delegated responsibility for providing services under this subchapter.

(b) Measures

(1) In general

The Secretary, in consultation with representatives of Head Start agencies and with experts in the fields of early childhood education and development, family services, and program management, shall use the study on Developmental Outcomes and Assessments for Young Children by the National Academy of Sciences and other relevant research to inform, revise, and provide guidance to Head Start agencies for utilizing, scientifically based measures that support, as appropriate-

- (A) classroom instructional practices;
- (B) identification of children with special needs;
- (C) program evaluation; and
- (D) administrative and financial management practices.

(2) Characteristics of measures

The measures under this subsection shall-

- (A) be developmentally, linguistically, and culturally appropriate for the population served;
- (B) be reviewed periodically, based on advances in the science of early childhood development;
- (C) be consistent with relevant, nationally recognized professional and technical standards related to the assessment of young children;
- (D) be valid and reliable in the language in which they are administered;
- (E) be administered by staff with appropriate training for such administration;
- (F) provide for appropriate accommodations for children with disabilities and children who are limited English proficient;
- (G) be high-quality research-based measures that have been demonstrated to assist with the purposes for which they were devised; and
- (H) be adaptable, as appropriate, for use in the self-assessment of Head Start agencies, including in the evaluation of administrative and financial management practices.

(3) Use of measures; limitations on use

(A) Use

The measures shall be designed, as appropriate, for the purpose of-

- (i) helping to develop the skills, knowledge, abilities, and development described in subsection (a)(1)(B) of children participating in Head Start programs, with an emphasis on measuring skills that scientifically valid research has demonstrated are related to children's school readiness and later success in school;

7/7/22, 2:30 PM

- (ii) improving classroom practices, including reviewing children's strengths and weaknesses and individualizing instruction to better meet the needs of the children involved;
- (iii) identifying the special needs of children; and
- (iv) improving overall program performance in order to help programs identify problem areas that may require additional training and technical assistance resources.

(B) Limitations

Such measures shall not be used to exclude children from Head Start programs.

(4) Confidentiality

(A) In general

The Secretary, through regulation, shall ensure the confidentiality of any personally identifiable data, information, and records collected or maintained under this subchapter by the Secretary and any Head Start agency. Such regulations shall provide the policies, protections, and rights equivalent to those provided to a parent, student, or educational agency or institution under section 1232g of title 20.

(B) Prohibition on nationwide database

Nothing in this subsection shall be construed to authorize the development of a nationwide database of personally identifiable data, information, or records on children resulting from the use of measures under this subsection.

(5) Special rule

(A) Prohibition

The use of assessment items and data on any assessment authorized under this subchapter by any agent of the Federal Government is prohibited for the purposes of-

- (i) ranking, comparing, or otherwise evaluating individual children for purposes other than research, training, or technical assistance; and
- (ii) providing rewards or sanctions for individual children or teachers.

(B) Results

The Secretary shall not use the results of a single assessment as the sole method for assessing program effectiveness or making agency funding determinations at the national, regional, or local level under this subchapter.

(c) Monitoring of local agencies and programs

(1) In general

To determine whether Head Start agencies meet standards described in subsection (a)(1) established under this subchapter with respect to program, administrative, financial management, and other requirements, and in order to help the programs identify areas for improvement and areas of strength as part of their ongoing self-assessment process, the Secretary shall conduct the following reviews of Head Start agencies, including the Head Start programs operated by such agencies:

- (A) A full review, including the use of a risk-based assessment approach, of each such agency at least once during each 3-year period.
- (B) A review of each newly designated Head Start agency immediately after the completion of the first year such agency carries out a Head Start program.
- (C) Followup reviews, including-
 - (i) return visits to Head Start agencies with 1 or more findings of deficiencies, not later than 6 months after the Secretary provides notification of such findings, or not later than 12 months after such notification if the Secretary determines that additional time is necessary for an agency to address such a deficiency prior to the review; and
 - (ii) a review of Head Start agencies with significant areas of noncompliance.

(D) Other reviews, including unannounced site inspections of Head Start centers, as appropriate.

(2) Conduct of reviews

The Secretary shall ensure that reviews described in subparagraphs (A) through (C) of paragraph (1)-

- (A) are conducted by review teams that-
 - (i) include individuals who are knowledgeable about Head Start programs and, to the maximum extent practicable, individuals who are knowledgeable about-
 - (I) other early childhood education and development programs, personnel management, financial accountability, and systems development and monitoring; and
 - (II) the diverse (including linguistic and cultural) needs of eligible children (including children with disabilities, homeless children, children in foster care, and limited English proficient children) and their families;

7/7/22, 2:30 PM

- (ii) include, to the maximum extent practicable, current or former employees of the Department of Health and Human Services who are knowledgeable about Head Start programs; and
- (iii) shall receive periodic training to ensure quality and consistency across reviews;

(B) include as part of the reviews, a review and assessment of program strengths and areas in need of improvement;

(C) include as part of the reviews, a review and assessment of whether programs have adequately addressed population and community needs (including those of limited English proficient children and children of migrant or seasonal farmworker families);

(D) include as part of the reviews, an assessment of the extent to which the programs address the communitywide strategic planning and needs assessment described in section 9835(g)(1)(C) of this title;

(E) include information on the innovative and effective efforts of the Head Start agencies to collaborate with the entities providing early childhood and development services or programs in the community and any barriers to such collaboration that the agencies encounter;

(F) include as part of the reviews, a valid and reliable research-based observational instrument, implemented by qualified individuals with demonstrated reliability, that assesses classroom quality, including assessing multiple dimensions of teacher-child interactions that are linked to positive child development and later achievement;

(G) are conducted in a manner that evaluates program performance, quality, and overall operations with consistency and objectivity, are based on a transparent and reliable system of review, and are conducted in a manner that includes periodic interrater reliability checks, to ensure quality and consistency, across and within regions, of the reviews and of noncompliance and deficiency determinations;

(H) in the case of reviews of Early Head Start agencies and programs, are conducted by a review team that includes individuals who are knowledgeable about the development of infants and toddlers;

(I) include as part of the reviews a protocol for fiscal management that shall be used to assess compliance with program requirements for-

- (i) using Federal funds appropriately;

- (ii) using Federal funds specifically to purchase property (consistent with section 9839(f) of this title) and to compensate personnel;

- (iii) securing and using qualified financial officer support; and

- (iv) reporting financial information and implementing appropriate internal controls to safeguard Federal funds;

(J) include as part of the reviews of the programs, a review and assessment of whether the programs are in conformity with the eligibility requirements under section 9840(a)(1) of this title, including regulations promulgated under such section and whether the programs have met the requirements for the outreach and enrollment policies and procedures, and selection criteria, in such section, for the participation of children in programs assisted under this subchapter;

(K) include as part of the reviews, a review and assessment of whether agencies have adequately addressed the needs of children with disabilities, including whether the agencies involved have met the 10 percent minimum enrollment requirement specified in section 9835(d) of this title and whether the agencies have made sufficient efforts to collaborate with State and local agencies providing services under section 619 or part C of the Individuals with Disabilities Education Act (20 U.S.C. 1419, 1431 et seq.); and

(L) include as part of the reviews, a review and assessment of child outcomes and performance as they relate to agency-determined school readiness goals described in subsection (g)(2), consistent with subsection (b)(5).

(3) Standards relating to obligations to delegate agencies

In conducting a review described in paragraph (1)(A) of a Head Start agency, the Secretary shall determine whether the agency complies with the obligations described in subsection (a)(3). The Secretary shall consider such compliance in determining whether to renew financial assistance to the Head Start agency under this subchapter.

(4) Use of review findings

The findings of a review described in paragraph (1) of a Head Start agency shall, at a minimum-

- (A) be presented to the agency in a timely, transparent, and uniform manner that conveys information of program strengths and weaknesses and assists with program improvement; and

- (B) be used by the agency to inform the development and implementation of its plan for training and technical assistance.

(d) Evaluations and corrective action for delegate agencies

(1) Procedures

Each Head Start agency shall establish, subject to paragraph (4), procedures relating to its delegate agencies, including-

- (A) procedures for evaluating delegate agencies;

- (B) procedures for defunding delegate agencies; and

- (C) procedures for a delegate agency to appeal a defunding decision.

(2) Evaluation

7/7/22, 2:30 PM

Each Head Start agency-

(A) shall evaluate its delegate agencies using the procedures established under this subsection; and

(B) shall inform the delegate agencies of the deficiencies identified through the evaluation that are required to be corrected.

(3) Remedies to ensure corrective actions

In the event that the Head Start agency identifies a deficiency for a delegate agency through the evaluation, the Head Start agency shall take action, which may include-

(A) initiating procedures to terminate the designation of the agency unless the agency corrects the deficiency;

(B) conducting monthly monitoring visits to such delegate agency until all deficiencies are corrected or the Head Start agency decides to defund such delegate agency; and

(C) releasing funds to such delegate agency-

(i) only as reimbursements except that, upon receiving a request from the delegate agency accompanied by assurances satisfactory to the Head Start agency that the funds will be appropriately safeguarded, the Head Start agency shall provide to the delegate agency a working capital advance in an amount sufficient to cover the estimated expenses involved during an agreed upon disbursing cycle; and

(ii) only if there is continuity of services.

(4) Termination

The Head Start agency may not terminate a delegate agency's contract or reduce a delegate agency's service area without showing cause or demonstrating the cost-effectiveness of such a decision.

(5) Rule of construction

Nothing in this subsection shall be construed to limit the powers, duties, or functions of the Secretary with respect to Head Start agencies or delegate agencies that receive financial assistance under this subchapter.

(e) Corrective action for Head Start agencies

(1) Determination

If the Secretary determines, on the basis of a review pursuant to subsection (c), that a Head Start agency designated pursuant to this subchapter fails to meet the standards described in subsection (a)(1) or fails to address the communitywide strategic planning and needs assessment, the Secretary shall-

(A) inform the agency of the deficiencies that shall be corrected and identify the assistance to be provided consistent with paragraph (3);

(B) with respect to each identified deficiency, require the agency-

(i) to correct the deficiency immediately, if the Secretary finds that the deficiency threatens the health or safety of staff or program participants or poses a threat to the integrity of Federal funds;

(ii) to correct the deficiency not later than 90 days after the identification of the deficiency if the Secretary finds, in the discretion of the Secretary, that such a 90-day period is reasonable, in light of the nature and magnitude of the deficiency; or

(iii) in the discretion of the Secretary (taking into consideration the seriousness of the deficiency and the time reasonably required to correct the deficiency), to comply with the requirements of paragraph (2) concerning a quality improvement plan; and

(C) initiate proceedings to terminate the designation of the agency unless the agency corrects the deficiency.

(2) Quality improvement plan

(A) Agency and program responsibilities

To retain a designation as a Head Start agency under this subchapter, or in the case of a Head Start program to continue to receive funds from such agency, a Head Start agency that is the subject of a determination described in paragraph (1), or a Head Start program that is determined to have a deficiency under subsection (d)(2) (excluding an agency required to correct a deficiency immediately or during a 90-day period under clause (i) or (ii) of paragraph (1)(B)) shall-

(i) develop in a timely manner, a quality improvement plan that shall be subject to the approval of the Secretary, or in the case of a program, the sponsoring agency, and that shall specify-

(I) the deficiencies to be corrected;

(II) the actions to be taken to correct such deficiencies; and

(III) the timetable for accomplishment of the corrective actions specified; and

(ii) correct each deficiency identified, not later than the date for correction of such deficiency specified in such plan (which shall not be later than 1 year after the date the agency or Head Start program that is determined to have a deficiency received notice of the determination and of the specific deficiency to be corrected).

(B) Secretarial responsibility

Not later than 30 days after receiving from a Head Start agency a proposed quality improvement plan pursuant to subparagraph (A), the Secretary shall either approve such proposed plan or specify the reasons why the proposed plan cannot be approved.

7/7/22, 2:30 PM

(C) Agency responsibility

Not later than 30 days after receiving from a Head Start program a proposed quality improvement plan pursuant to subparagraph (A), the Head Start agency involved shall either approve such proposed plan or specify the reasons why the proposed plan cannot be approved.

(3) Training and technical assistance

The Secretary shall provide training and technical assistance to Head Start agencies and programs with respect to the development or implementation of such quality improvement plans to the extent the Secretary finds such provision to be feasible and appropriate given available funding and other statutory responsibilities.

(f) Summaries of monitoring outcomes

(1) In general

Not later than 120 days after the end of each fiscal year, the Secretary shall publish a summary report on the findings of reviews conducted under subsection (c) and on the outcomes of quality improvement plans implemented under subsection (e), during such fiscal year.

(2) Report availability

Such report shall be made widely available to-

(A) parents with children receiving assistance under this subchapter-

- (i) in an understandable and uniform format; and
- (ii) to the extent practicable, in a language that the parents understand; and

(B) the public through means such as-

- (i) distribution through public agencies; and
- (ii) posting such information on the Internet.

(3) Report information

Such report shall contain detailed data-

- (A) on compliance with specific standards and measures; and
- (B) sufficient to allow Head Start agencies to use such data to improve the quality of their programs.

(g) Self-assessments

(1) In general

Not less frequently than once each program year, with the consultation and participation of policy councils and, as applicable, policy committees and, as appropriate, other community members, each Head Start agency, and each delegate agency, that receives financial assistance under this subchapter shall conduct a comprehensive self-assessment of its effectiveness and progress in meeting program goals and objectives and in implementing and complying with standards described in subsection (a)(1).

(2) Goals, reports, and improvement plans

(A) Goals

An agency conducting a self-assessment shall establish agency-determined program goals for improving the school readiness of children participating in a program under this subchapter, including school readiness goals that are aligned with the Head Start Child Outcomes Framework, State early learning standards as appropriate, and requirements and expectations of the schools the children will be attending.

(B) Improvement plan

The agency shall develop, and submit to the Secretary a report containing, an improvement plan approved by the governing body of the agency to strengthen any areas identified in the self-assessment as weaknesses or in need of improvement.

(3) Ongoing monitoring

Each Head Start agency (including each Early Head Start agency) and each delegate agency shall establish and implement procedures for the ongoing monitoring of their respective programs, to ensure that the operations of the programs work toward meeting program goals and objectives and standards described in subsection (a)(1).

(h) Reduction of grants and redistribution of funds in cases of underenrollment

(1) Definitions

In this subsection:

(A) Actual enrollment

The term "actual enrollment" means, with respect to the program of a Head Start agency, the actual number of children enrolled in such program and reported by the agency (as required in paragraph (2)) in a given month.

(B) Base grant

The term "base grant" has the meaning given the term in section 9835(a)(7) of this title.

7/7/22, 2:30 PM

(C) Funded enrollment

The term "funded enrollment" means, with respect to the program of a Head Start agency in a fiscal year, the number of children that the agency is funded to serve through a grant for the program during such fiscal year, as indicated in the grant agreement.

(2) Enrollment reporting requirement

Each entity carrying out a Head Start program shall report on a monthly basis to the Secretary and the relevant Head Start agency-

(A) the actual enrollment in such program; and

(B) if such actual enrollment is less than the funded enrollment, any apparent reason for such enrollment shortfall.

(3) Secretarial review and plan

The Secretary shall-

(A) on a semiannual basis, determine which Head Start agencies are operating with an actual enrollment that is less than the funded enrollment based on not less than 4 consecutive months of data;

(B) for each such Head Start agency operating a program with an actual enrollment that is less than its funded enrollment, as determined under subparagraph (A), develop, in collaboration with such agency, a plan and timetable for reducing or eliminating underenrollment taking into consideration-

(i) the quality and extent of the outreach, recruitment, and communitywide strategic planning and needs assessment conducted by such agency;

(ii) changing demographics, mobility of populations, and the identification of new underserved low-income populations;

(iii) facilities-related issues that may impact enrollment;

(iv) the ability to provide full-working-day programs, where needed, through funds made available under this subchapter or through collaboration with entities carrying out other early childhood education and development programs, or programs with other funding sources (where available);

(v) the availability and use by families of other early childhood education and development options in the community served; and

(vi) agency management procedures that may impact enrollment; and

(C) provide timely and ongoing technical assistance to each agency described in subparagraph (B) for the purpose of assisting the Head Start agency to implement the plan described in such subparagraph.

(4) Implementation

Upon receipt of the technical assistance described in paragraph (3)(C), a Head Start agency shall immediately implement the plan described in paragraph (3)(B). The Secretary shall, where determined appropriate, continue to provide technical assistance to such agency.

(5) Secretarial review and adjustment for chronic underenrollment**(A) In general**

If, after receiving technical assistance and developing and implementing the plan as described in paragraphs (3) and (4) for 12 months, a Head Start agency is operating a program with an actual enrollment that is less than 97 percent of its funded enrollment, the Secretary may-

(i) designate such agency as chronically underenrolled; and

(ii) recapture, withhold, or reduce the base grant for the program by a percentage equal to the percentage difference between funded enrollment and actual enrollment for the program for the most recent year for which the agency is determined to be underenrolled under paragraph (3)(A).

(B) Waiver or limitation of reductions

The Secretary may, as appropriate, waive or reduce the percentage recapturing, withholding, or reduction otherwise required by subparagraph (A), if, after the implementation of the plan described in paragraph (3)(B), the Secretary finds that-

(i) the causes of the enrollment shortfall, or a portion of the shortfall, are related to the agency's serving significant numbers of highly mobile children, or are other significant causes as determined by the Secretary;

(ii) the shortfall can reasonably be expected to be temporary; or

(iii) the number of slots allotted to the agency is small enough that underenrollment does not create a significant shortfall.

(6) Redistribution of funds**(A) In general**

Funds held by the Secretary as a result of recapturing, withholding, or reducing a base grant in a fiscal year shall be redistributed by the end of the following fiscal year as follows:

(i) **Indian Head Start programs**

7/7/22, 2:30 PM

If such funds are derived from an Indian Head Start program, then such funds shall be redistributed to increase enrollment by the end of the following fiscal year in 1 or more Indian Head Start programs.

(ii) Migrant and seasonal Head Start programs

If such funds are derived from a migrant or seasonal Head Start program, then such funds shall be redistributed to increase enrollment by the end of the following fiscal year in 1 or more programs of the type from which such funds are derived.

(iii) Early Head Start programs

If such funds are derived from an Early Head Start program in a State, then such funds shall be redistributed to increase enrollment by the end of the following fiscal year in 1 or more Early Head Start programs in that State. If such funds are derived from an Indian Early Head Start program, then such funds shall be redistributed to increase enrollment by the end of the following fiscal year in 1 or more Indian Early Head Start programs.

(iv) Other Head Start programs

If such funds are derived from a Head Start program in a State (excluding programs described in clauses (i) through (iii)), then such funds shall be redistributed to increase enrollment by the end of the following fiscal year in 1 or more Head Start programs (excluding programs described in clauses (i) through (iii)) that are carried out in such State.

(B) Adjustment to funded enrollment

The Secretary shall adjust as necessary the requirements relating to funded enrollment indicated in the grant agreement of a Head Start agency receiving redistributed funds under this paragraph.

(Pub. L. 97–35, title VI, §641A, as added Pub. L. 103–252, title I, §108, May 18, 1994, 108 Stat. 631 ; amended Pub. L. 105–285, title I, §108, Oct. 27, 1998, 112 Stat. 2713 ; Pub. L. 110–134, §8, Dec. 12, 2007, 121 Stat. 1385 .)

EDITORIAL NOTES

REFERENCES IN TEXT

The Individuals with Disabilities Education Act, referred to in subsec. (c)(2)(K), is title VI of Pub. L. 91–230, Apr. 13, 1970, 84 Stat. 175 . Part C of the Act is classified generally to subchapter III (§1431 et seq.) of chapter 33 of Title 20, Education. Section 619 of the Act is classified to section 1419 of Title 20. For complete classification of this Act to the Code, see section 1400 of Title 20 and Tables.

AMENDMENTS

2007—Pub. L. 110–134 amended section generally. Prior to amendment, section related to, in subsec. (a), quality standards, in subsec. (b), results-based performance measures, in subsec. (c), monitoring of local agencies and programs, in subsec. (d), corrective action and termination, and, in subsec. (e), summaries of monitoring outcomes.

1998—Subsec. (a)(1). Pub. L. 105–285, §108(a)(1)(A), inserted ", including minimum levels of overall accomplishment," after "regulation standards" in introductory provisions.

Subsec. (a)(1)(A). Pub. L. 105–285, §108(a)(1)(B), struck out "education," after "including health,".

Subsec. (a)(1)(B) to (E). Pub. L. 105–285, §108(a)(1)(C), (D), added subpar. (B) and redesignated former subpars. (B) to (D) as (C) to (E), respectively.

Subsec. (a)(2). Pub. L. 105–285, §108(a)(2), (3), redesignated par. (3) as (2) and struck out heading and text of former par. (2). Text read as follows: "The regulations promulgated under this subsection shall establish the minimum levels of overall accomplishment that a Head Start agency shall achieve in order to meet the standards specified in paragraph (1)."

Subsec. (a)(2)(B)(iii). Pub. L. 105–285, §108(a)(4)(A), substituted "early childhood education and" for "child".

Subsec. (a)(2)(C)(i). Pub. L. 105–285, §108(a)(4)(B)(i), struck out "not later than 1 year after May 18, 1994," before "review" and substituted "this subsection; and" for "section 9846(b) of this title on the day before May 18, 1994; and".

Subsec. (a)(2)(C)(ii). Pub. L. 105–285, §108(a)(4)(B)(ii), substituted "October 27, 1998" for "November 2, 1978".

Subsec. (a)(3). Pub. L. 105–285, §108(a)(5), substituted "to a delegate agency" for "to an agency (referred to in this subchapter as the 'delegate agency')".

Pub. L. 105–285, §108(a)(3), redesignated par. (4) as (3). Former par. (3) redesignated (2).

Subsec. (a)(4). Pub. L. 105–285, §108(a)(3), redesignated par. (4) as (3).

Subsec. (b). Pub. L. 105–285, §108(b)(1), inserted "Results-based" in heading.

Subsec. (b)(1). Pub. L. 105–285, §108(b)(2), substituted "The Secretary" for "Not later than 1 year after May 18, 1994, the Secretary", "early childhood education and" for "child", and "results-based

7/7/22, 2:30 PM

performance measures" for "performance measures" and inserted ", and the impact of the services provided through the programs to children and their families" before "(referred".

Subsec. (b)(2). Pub. L. 105–285, §108(b)(3)(A), (B), (F), substituted "Characteristics" for "Design" in heading and "shall-" for "shall be designed-" in introductory provisions and inserted concluding provisions.

Subsec. (b)(2)(A). Pub. L. 105–285, §108(b)(3)(C), substituted "be used to assess the impact of" for "to assess".

Subsec. (b)(2)(B). Pub. L. 105–285, §108(b)(3)(D), substituted "be adaptable" for "to be adaptable" and ", peer review, and program evaluation" for "and peer review" and inserted ", not later than July 1, 1999" before semicolon.

Subsec. (b)(2)(C). Pub. L. 105–285, §108(b)(3)(E), inserted "be developed" before "for other".

Subsec. (b)(3)(A). Pub. L. 105–285, §108(b)(4), substituted ", regionally, and locally" for "and by region".

Subsec. (b)(4), (5). Pub. L. 105–285, §108(b)(5), added pars. (4) and (5).

Subsec. (c)(1). Pub. L. 105–285, §108(c)(1), inserted "and results-based performance measures developed by the Secretary under subsection (b) of this section" after "standards established under this subchapter".

Subsec. (c)(2)(B). Pub. L. 105–285, §108(c)(2)(A), struck out "and" at end.

Subsec. (c)(2)(C). Pub. L. 105–285, §108(c)(2)(B), inserted "(including children with disabilities)" after "eligible children" and substituted semicolon for period at end.

Subsec. (c)(2)(D), (E). Pub. L. 105–285, §108(c)(2)(C), added subpars. (D) and (E).

Subsec. (d)(1). Pub. L. 105–285, §108(d)(1)(A), inserted "or results-based performance measures developed by the Secretary under subsection (b) of this section" after "subsection (a) of this section" in introductory provisions.

Subsec. (d)(1)(B). Pub. L. 105–285, §108(d)(1)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "with respect to each identified deficiency, require the agency-

"(i) to correct the deficiency immediately; or

"(ii) at the discretion of the Secretary (taking into consideration the seriousness of the deficiency and the time reasonably required to correct the deficiency), to comply with the requirements of paragraph (2) concerning a quality improvement plan; and".

Subsec. (d)(2)(A). Pub. L. 105–285, §108(d)(2), substituted "required to correct a deficiency immediately or during a 90-day period under clause (i) or (ii) of paragraph (1)(B)" for "able to correct a deficiency immediately" in introductory provisions.

Subsec. (e). Pub. L. 105–285, §108(e), inserted at end "Such report shall be widely disseminated and available for public review in both written and electronic formats."

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective May 18, 1994, but not applicable to Head Start agencies and other recipients of financial assistance under the Head Start Act (42 U.S.C. 9831 et seq.) until Oct. 1, 1994, see section 127 of Pub. L. 103–252, set out as an Effective Date of 1994 Amendment note under section 9832 of this title.

Exhibit 2



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Chapter XIII

RIN 0970-AC63

Head Start Performance Standards

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

ACTION: Final rule.

SUMMARY: This final rule modernizes the Head Start Program Performance Standards, last revised in 1998. In the Improving Head Start for School Readiness Act of 2007, Congress instructed the Office of Head Start to update its performance standards and to ensure any such revisions to the standards do not eliminate or reduce quality, scope, or types of health, educational, parental involvement, nutritional, social, or other services programs provide. This rule responds to public comment, incorporates extensive findings from research and from consultation with experts, reflects best practices, lessons from program input and innovation, integrates recommendations from the Secretary's Advisory Committee Final Report on Head Start Research and Evaluation, and reflects the Obama Administration's deep commitment to improve the school readiness of young children. These performance standards will improve program quality, reduce burden on programs, and improve regulatory clarity and transparency. They provide a clear road map for current and prospective grantees to support high-quality Head Start services and to strengthen the outcomes of the children and families Head Start serves.

DATES: *Effective Date:* Provisions of this final rule become effective November 7, 2016.

Compliance Date(s): To allow programs reasonable time to implement certain performance standards, we phase in compliance dates over several years after this final rule becomes effective. In the **SUPPLEMENTARY INFORMATION** section below, we provide a table, Table 1: Compliance Table, which lists dates by which programs must implement specific standards.

FOR FURTHER INFORMATION CONTACT: Colleen Rathgeb, Division Director of Early Childhood Policy and Budget, Office of Early Childhood Development, at OHS_Final_Rule@acf.hhs.gov or (202)

401-1195 (not a toll free call). 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 Time.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
- II. Tables
 - Table 1: Compliance Table
 - Table 2: Redesignation Table
- III. Background
 - a. Statutory Authority
 - b. Purpose of This Rule
 - c. Rulemaking and Comment Processes
 - d. Overview of Major Changes From the NPRM
- IV. Discussion of General Comments on the Final Rule
- V. Discussion of Section by Section Comments on the Final Rule
 - a. Program Governance
 - b. Program Operations
 - 1. Subpart A Eligibility, Recruitment, Selection, Enrollment and Attendance
 - 2. Subpart B Program Structure
 - 3. Subpart C Education and Child Development Program Services
 - 4. Subpart D Health Program Services
 - 5. Subpart E Family and Community Engagement Program Services
 - 6. Subpart F Additional Services for Children With Disabilities
 - 7. Subpart G Transition Services
 - 8. Subpart H Services to Enrolled Pregnant Women
 - 9. Subpart I Human Resources Management
 - 10. Subpart J Program Management and Quality Improvement
 - c. Financial and Administrative Requirements
 - 1. Subpart A Financial Requirements
 - 2. Subpart B Administrative Requirements
 - 3. Subpart C Protections for the Privacy of Child Records
 - 4. Subpart D Delegation of Program Operations
 - 5. Subpart E Facilities
 - 6. Subpart F Transportation
 - d. Federal Administrative Procedures
 - 1. Subpart A Monitoring, Suspension, Termination, Denial of Refunding, Reduction in Funding and Their Appeals
 - 2. Subpart B Designation Renewal
 - 3. Subpart C Selection of Grantees Through Competition
 - 4. Subpart D Replacement of American Indian and Alaska Native Grantee
 - 5. Subpart E Head Start Fellows Program
 - e. Definitions
 - VIII. Regulatory Process Matters
 - a. Regulatory Flexibility Act
 - b. Regulatory Planning and Review Executive Order 12866
 - 1. Need for Regulatory Action: Increasing the Benefits to Society of Head Start
 - 2. Cost and Savings Analysis
 - i. Structural Program Option Provisions
 - ii. Educator Quality Provisions
 - iii. Curriculum and Assessment Provisions
 - iv. Administrative/Managerial Provisions
 - 3. Benefit Analysis
 - 4. Accounting Statement

- 5. Distributional Effects
- 6. Regulatory Alternatives
- c. Unfunded Mandates Reform Act
- d. Treasury and General Government Appropriations Act of 1999
- e. Federalism Assessment Executive Order 13132
- f. Congressional Review
- g. Paperwork Reduction Act of 1995
- Tribal Consultation Statement

I. Executive Summary

Head Start currently provides comprehensive early learning services to more than 1 million children from birth to age five each year through more than 60,000 classes, home visitors, and family child care partners nationwide.¹ Since its inception in 1965, Head Start has been a leader in helping children from low-income families enter kindergarten more prepared to succeed in school and in life. Head Start is a central part of this Administration's effort to ensure all children have access to high-quality early learning opportunities and to eliminate the education achievement gap. This regulation is intended to improve the quality of Head Start services so that programs have a stronger impact on children's learning and development. It also is necessary to streamline and reorganize the regulatory structure to improve regulatory clarity and transparency so that existing grantees can more easily run a high-quality Head Start program and so that Head Start's operational requirements will be more transparent and seem less onerous to prospective grantees. In addition, this regulation is necessary to reduce the burden on local programs that can interfere with high-quality service delivery. We believe these regulatory changes will help ensure every child and family in Head Start receives high-quality services that will lead to greater success in school and in life.

In 2007, Congress mandated the Secretary to revise the program performance standards and update and raise the education standards.² Congress also prohibited elimination of, or any reduction in, the quality, scope, or types of services in the revisions.³ Thus, these regulatory revisions are additionally intended to meet the statutory requirements Congress put forth in the bipartisan reauthorization of Head Start in 2007.

¹ U.S. Department of Health and Human Services, Administration for Children and Families (2015). *Office of Head Start Program Information Report, 2014-2015*. Washington, DC: Author.

² See <https://www.congress.gov/congressional-report/110th-congress/house-report/439/1> and 42 U.S.C. 9836A(a)(1)(B).

³ 42 U.S.C. 9836A(a)(2)(C)(ii).

Approved: June 10, 2016.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

Sylvia M. Burwell,

Secretary.

For the reasons set forth in the preamble, under the authority at 42 U.S.C. 9801 *et seq.*, subchapter B of 45 CFR chapter XIII is revised to read as follows:

SUBCHAPTER B—THE ADMINISTRATION FOR CHILDREN AND FAMILIES, HEAD START PROGRAM

PART 1300—[Reserved]

PART 1301—PROGRAM GOVERNANCE

PART 1302—PROGRAM OPERATIONS

PART 1303—FINANCIAL AND ADMINISTRATIVE REQUIREMENTS

PART 1304—FEDERAL ADMINISTRATIVE PROCEDURES

PART 1305—DEFINITIONS

PART 1300—[Reserved]

PART 1301—PROGRAM GOVERNANCE

Sec.

1301.1 Purpose.

1301.2 Governing body.

1301.3 Policy council and policy committee.

1301.4 Parent committees.

1301.5 Training.

1301.6 Impasse procedures.

Authority: 42 U.S.C. 9801 *et seq.*

§ 1301.1 In general.

An agency, as defined in part 1305 of this chapter, must establish and maintain a formal structure for program governance that includes a governing body, a policy council at the agency level and policy committee at the delegate level, and a parent committee. Governing bodies have a legal and fiscal responsibility to administer and oversee the agency's Head Start and Early Head Start programs. Policy councils are responsible for the direction of the agency's Head Start and Early Head Start programs.

§ 1301.2 Governing body.

(a) *Composition.* The composition of a governing body must be in accordance with the requirements specified at section 642(c)(1)(B) of the Act, except where specific exceptions are authorized in the case of public entities at section 642(c)(1)(D) of the Act.

Agencies must ensure members of the governing body do not have a conflict of interest, pursuant to section 642(c)(1)(C) of the Act.

(b) *Duties and responsibilities.* (1) The governing body is responsible for activities specified at section 642(c)(1)(E) of the Act.

(2) The governing body must use ongoing monitoring results, data on school readiness goals, other information described in § 1302.102, and information described at section 642(d)(2) of the Act to conduct its responsibilities.

(c) *Advisory committees.* (1) A governing body may establish advisory committees as it deems necessary for effective governance and improvement of the program.

(2) If a governing body establishes an advisory committee to oversee key responsibilities related to program governance, it must:

(i) Establish the structure, communication, and oversight in such a way that the governing body continues to maintain its legal and fiscal responsibility for the Head Start agency; and,

(ii) Notify the responsible HHS official of its intent to establish such an advisory committee.

§ 1301.3 Policy council and policy committee.

(a) *Establishing policy councils and policy committees.* Each agency must establish and maintain a policy council responsible for the direction of the Head Start program at the agency level, and a policy committee at the delegate level. If an agency delegates operational responsibility for the entire Head Start or Early Head Start program to one delegate agency, the policy council and policy committee may be the same body.

(b) *Composition.* (1) A program must establish a policy council in accordance with section 642(c)(2)(B) of the Act, or a policy committee at the delegate level in accordance with section 642(c)(3) of the Act, as early in the program year as possible. Parents of children currently enrolled in each program option must be proportionately represented on the policy council and on the policy committee at the delegate level.

(2) The program must ensure members of the policy council, and of the policy committee at the delegate level, do not have a conflict of interest pursuant to sections 642(c)(2)(C) and 642(c)(3)(B) of the Act. Staff may not serve on the policy council or policy committee at the delegate level except parents who occasionally substitute as staff. In the case of tribal grantees, this

exclusion applies only to tribal staff who work in areas directly related to or which directly impact administrative, fiscal, or programmatic issues.

(c) *Duties and responsibilities.* (1) A policy council is responsible for activities specified at section 642(c)(2)(D) of the Act. A policy committee must approve and submit to the delegate agency its decisions in each of the following areas referenced at section 642(c)(2)(D)(i) through (vii) of the Act.

(2) A policy council, and a policy committee at the delegate level, must use ongoing monitoring results, data on school readiness goals, other information described in § 1302.102, and information described in section 642(d)(2) of the Act to conduct its responsibilities.

(d) *Term.* (1) A member will serve for one year.

(2) If the member intends to serve for another year, s/he must stand for re-election.

(3) The policy council, and policy committee at the delegate level, must include in its bylaws how many one-year terms, not to exceed five terms, a person may serve.

(4) A program must seat a successor policy council, or policy committee at the delegate level, before an existing policy council, or policy committee at the delegate level, may be dissolved.

(e) *Reimbursement.* A program must enable low-income members to participate fully in their policy council or policy committee responsibilities by providing, if necessary, reimbursements for reasonable expenses incurred by the low-income members.

§ 1301.4 Parent committees.

(a) *Establishing parent committees.* A program must establish a parent committee comprised exclusively of parents of currently enrolled children as early in the program year as possible. This committee must be established at the center level for center-based programs and at the local program level for other program options. When a program operates more than one option, parents may choose to have a separate committee for each option or combine membership. A program must ensure that parents of currently enrolled children understand the process for elections to the policy council or policy committee and other leadership opportunities.

(b) *Requirements of parent committees.* Within the parent committee structure, a program may determine the best methods to engage families using strategies that are most effective in their community, as long as

the program ensures the parent committee carries out the following minimum responsibilities:

(1) Advise staff in developing and implementing local program policies, activities, and services to ensure they meet the needs of children and families;

(2) Have a process for communication with the policy council and policy committee; and

(3) Within the guidelines established by the governing body, policy council or policy committee, participate in the recruitment and screening of Early Head Start and Head Start employees.

§ 1301.5 Training.

An agency must provide appropriate training and technical assistance or orientation to the governing body, any advisory committee members, and the policy council, including training on program performance standards and training indicated in § 1302.12(m) to ensure the members understand the information they receive and can effectively oversee and participate in the programs in the Head Start agency.

§ 1301.6 Impasse procedures.

(a) To facilitate meaningful consultation and collaboration about decisions of the governing body and the policy council, each agency's governing body and policy council jointly must establish written procedures for resolving internal disputes between the governing board and policy council in a timely manner that include impasse procedures. These procedures must:

(1) Demonstrate that the governing body considers proposed decisions from the policy council and that the policy council considers proposed decisions from the governing body;

(2) If there is a disagreement, require the governing body and the policy council to notify the other in writing why it does not accept a decision; and,

(3) Describe a decision-making process and a timeline to resolve disputes and reach decisions that are not arbitrary, capricious, or illegal.

(b) If the agency's decision-making process does not result in a resolution and an impasse continues, the governing body and policy council must select a mutually agreeable third party mediator and participate in a formal process of mediation that leads to a resolution of the dispute.

(c) For all programs except American Indian and Alaska Native programs, if no resolution is reached with a mediator, the governing body and policy council must select a mutually agreeable arbitrator whose decision is final.

PART 1302—PROGRAM OPERATIONS

Sec.

1302.1 Overview.

Subpart A—Eligibility, Recruitment, Selection, Enrollment, and Attendance

1302.10 Purpose.

1302.11 Determining community strengths, needs, and resources.

1302.12 Determining, verifying, and documenting eligibility.

1302.13 Recruitment of children.

1302.14 Selection process.

1302.15 Enrollment.

1302.16 Attendance.

1302.17 Suspension and expulsion.

1302.18 Fees.

Subpart B—Program Structure

1302.20 Determining program structure.

1302.21 Center-based option.

1302.22 Home-based option.

1302.23 Family child care option.

1302.24 Locally-designed program option variations.

Subpart C—Education and Child Development Program Services

1302.30 Purpose.

1302.31 Teaching and the learning environment.

1302.32 Curricula.

1302.33 Child screenings and assessments.

1302.34 Parent and family engagement in education and child development services.

1302.35 Education in home-based programs.

1302.36 Tribal language preservation and revitalization.

Subpart D—Health Program Services

1302.40 Purpose.

1302.41 Collaboration and communication with parents.

1302.42 Child health status and care.

1302.43 Oral health practices.

1302.44 Child nutrition.

1302.45 Child mental health and social and emotional well-being.

1302.46 Family support services for health, nutrition, and mental health.

1302.47 Safety practices.

Subpart E—Family and Community Engagement Program Services

Subpart F—Additional Services for Children With Disabilities

1302.60 Full participation in program services and activities.

1302.61 Additional services for children.

1302.62 Additional services for parents.

1302.63 Coordination and collaboration with the local agency responsible for implementing IDEA.

Subpart G—Transition Services

1302.70 Transitions from Early Head Start.

1302.71 Transitions from Head Start to kindergarten.

1302.72 Transitions between programs.

Subpart H—Services to Enrolled Pregnant Women

1302.80 Enrolled pregnant women.

1302.81 Prenatal and postpartum information, education, and services.

1302.82 Family partnership services for enrolled pregnant women.

Subpart I—Human Resources Management

1302.90 Personnel policies.

1302.91 Staff qualification and competency requirements.

1302.92 Training and professional development.

1302.93 Staff health and wellness.

1302.94 Volunteers.

Subpart J—Program Management and Quality Improvement

1302.100 Purpose.

1302.101 Management system.

1302.102 Achieving program goals.

1302.103 Implementation of program performance standards.

Authority: 42 U.S.C. 9801 *et seq.*

§ 1302.1 Overview.

This part implements these statutory requirements in Sections 641A, 645, 645A, and 648A of the Act by describing all of the program performance standards that are required to operate Head Start, Early Head Start, American Indian and Alaska Native and Migrant or Seasonal Head Start programs. The part covers the full range of operations from enrolling eligible children and providing program services to those children and their families, to managing programs to ensure staff are qualified and supported to effectively provide services. This part also focuses on using data through ongoing program improvement to ensure high-quality service. As required in the Act, these provisions do not narrow the scope or quality of services covered in previous regulations. Instead, these regulations raise the quality standard to reflect science and best practices, and streamline and simplify requirements so programs can better understand what is required for quality services.

Subpart A—Eligibility, Recruitment, Selection, Enrollment, and Attendance

§ 1302.10 Purpose.

This subpart describes requirements of grantees for determining community strengths, needs and resources as well as recruitment areas. It contains requirements and procedures for the eligibility determination, recruitment, selection, enrollment and attendance of children and explains the policy concerning the charging of fees.

§ 1302.11 Determining community strengths, needs, and resources.

(a) *Service area.* (1) A program must propose a service area in the grant application and define the area by county or sub-county area, such as a municipality, town or census tract or

jurisdiction of a federally recognized Indian reservation.

(i) A tribal program may propose a service area that includes areas where members of Indian tribes or those eligible for such membership reside, including but not limited to Indian reservation land, areas designated as near-reservation by the Bureau of Indian Affairs (BIA) provided that the service area is approved by the tribe's governing council, Alaska Native Villages, Alaska Native Regional Corporations with land-based authorities, Oklahoma Tribal Statistical Areas, and Tribal Designated Statistical Areas where federally recognized Indian tribes do not have a federally established reservation.

(ii) If the tribe's service area includes any area specified in paragraph (a)(1)(i) of this section, and that area is also served by another program, the tribe may serve children from families who are members of or eligible to be members of such tribe and who reside in such areas as well as children from families who are not members of the tribe, but who reside within the tribe's established service area.

(2) If a program decides to change the service area after ACF has approved its grant application, the program must submit to ACF a new service area proposal for approval.

(b) *Community wide strategic planning and needs assessment (community assessment)*. (1) To design a program that meets community needs, and builds on strengths and resources, a program must conduct a community assessment at least once over the five-year grant period. The community assessment must use data that describes community strengths, needs, and resources and include, at a minimum:

(i) The number of eligible infants, toddlers, preschool age children, and expectant mothers, including their geographic location, race, ethnicity, and languages they speak, including:

(A) Children experiencing homelessness in collaboration with, to the extent possible, McKinney-Vento Local Education Agency Liaisons (42 U.S.C. 11432 (6)(A));

(B) Children in foster care; and

(C) Children with disabilities, including types of disabilities and relevant services and resources provided to these children by community agencies;

(ii) The education, health, nutrition and social service needs of eligible children and their families, including prevalent social or economic factors that impact their well-being;

(iii) Typical work, school, and training schedules of parents with eligible children;

(iv) Other child development, child care centers, and family child care programs that serve eligible children, including home visiting, publicly funded state and local preschools, and the approximate number of eligible children served;

(v) Resources that are available in the community to address the needs of eligible children and their families; and,

(vi) Strengths of the community.

(2) A program must annually review and update the community assessment to reflect any significant changes including increased availability of publicly-funded pre-kindergarten- (including an assessment of how the pre-kindergarten available in the community meets the needs of the parents and children served by the program, and whether it is offered for a full school day), rates of family and child homelessness, and significant shifts in community demographics and resources.

(3) A program must consider whether the characteristics of the community allow it to include children from diverse economic backgrounds that would be supported by other funding sources, including private pay, in addition to the program's eligible funded enrollment. A program must not enroll children from diverse economic backgrounds if it would result in a program serving less than its eligible funded enrollment.

§ 1302.12 Determining, verifying, and documenting eligibility.

(a) *Process overview*. (1) Program staff must:

(i) Conduct an in-person interview with each family, unless paragraph (a)(2) of this section applies;

(ii) Verify information as required in paragraphs (h) and (i) of this section; and,

(iii) Create an eligibility determination record for enrolled participants according to paragraph (k) of this section.

(2) Program staff may interview the family over the telephone if an in-person interview is not possible or convenient for the family.

(3) If a program has an alternate method to reasonably determine eligibility based on its community assessment, geographic and administrative data, or from other reliable data sources, it may petition the responsible HHS official to waive requirements in paragraphs (a)(1)(i) and (ii) of this section.

(b) *Age requirements*. (1) For Early Head Start, except when the child is transitioning to Head Start, a child must be an infant or a toddler younger than three years old.

(2) For Head Start, a child must:

(i) Be at least three years old or, turn three years old by the date used to determine eligibility for public school in the community in which the Head Start program is located; and,

(ii) Be no older than the age required to attend school.

(3) For Migrant or Seasonal Head Start, a child must be younger than compulsory school age by the date used to determine public school eligibility for the community in which the program is located.

(c) *Eligibility requirements*. (1) A pregnant woman or a child is eligible if:

(i) The family's income is equal to or below the poverty line; or,

(ii) The family is eligible for or, in the absence of child care, would be potentially eligible for public assistance; including TANF child-only payments; or,

(iii) The child is homeless, as defined in part 1305; or,

(iv) The child is in foster care.

(2) If the family does not meet a criterion under paragraph (c)(1) of this section, a program may enroll a child who would benefit from services, provided that these participants only make up to 10 percent of a program's enrollment in accordance with paragraph (d) of this section.

(d) *Additional allowances for programs*. (1) A program may enroll an additional 35 percent of participants whose families do not meet a criterion described in paragraph (c) of this section and whose incomes are below 130 percent of the poverty line, if the program:

(i) Establishes and implements outreach, and enrollment policies and procedures to ensure it is meeting the needs of eligible pregnant women, children, and children with disabilities, before serving pregnant women or children who do not meet the criteria in paragraph (c) of this section; and,

(ii) Establishes criteria that ensure pregnant women and children eligible under the criteria listed in paragraph (c) of this section are served first.

(2) If a program chooses to enroll participants who do not meet a criterion in paragraph (c) of this section, and whose family incomes are between 100 and 130 percent of the poverty line, it must be able to report to the Head Start regional program office:

(i) How it is meeting the needs of low-income families or families potentially eligible for public assistance, homeless children, and children in foster care, and include local demographic data on these populations;

(ii) Outreach and enrollment policies and procedures that ensure it is meeting

the needs of eligible children or pregnant women, before serving over-income children or pregnant women;

(iii) Efforts, including outreach, to be fully enrolled with eligible pregnant women or children;

(iv) Policies, procedures, and selection criteria it uses to serve eligible children;

(v) Its current enrollment and its enrollment for the previous year;

(vi) The number of pregnant women and children served, disaggregated by the eligibility criteria in paragraphs (c) and (d)(1) of this section; and,

(vii) The eligibility criteria category of each child on the program's waiting list.

(e) *Additional allowances for Indian tribes.* (1) Notwithstanding paragraph (c)(2) of this section, a tribal program may fill more than 10 percent of its enrollment with participants who are not eligible under the criteria in paragraph (c) of this section, if:

(i) The tribal program has served all eligible pregnant women or children who wish to be enrolled from Indian and non-Indian families living within the approved service area of the tribal agency;

(ii) The tribe has resources within its grant, without using additional funds from HHS intended to expand Early Head Start or Head Start services, to enroll pregnant women or children whose family incomes exceed low-income guidelines or who are not otherwise eligible; and,

(iii) At least 51 percent of the program's participants meet an eligibility criterion under paragraph (c)(1) of this section.

(2) If another program does not serve the approved service area, the program must serve all eligible Indian and non-Indian pregnant women or children who wish to enroll before serving over-income pregnant women or children.

(3) A program that meets the conditions of this paragraph (e) must annually set criteria that are approved by the policy council and the tribal council for selecting over-income pregnant women or children who would benefit from program services.

(4) An Indian tribe or tribes that operates both an Early Head Start program and a Head Start program may, at its discretion, at any time during the grant period involved, reallocate funds between the Early Head Start program and the Head Start program in order to address fluctuations in client populations, including pregnant women and children from birth to compulsory school age. The reallocation of such funds between programs by an Indian tribe or tribes during a year may not serve as a basis for any reduction of the

base grant for either program in succeeding years.

(f) *Migrant or Seasonal eligibility requirements.* A child is eligible for Migrant or Seasonal Head Start, if the family meets an eligibility criterion in paragraphs (c) and (d) of this section; and the family's income comes primarily from agricultural work.

(g) *Eligibility requirements for communities with 1,000 or fewer individuals.* (1) A program may establish its own criteria for eligibility provided that it meets the criteria outlined in section 645(a)(2) of the Act.

(2) No child residing in such community whose family is eligible under criteria described in paragraphs (c) through (f) of this section, may be denied an opportunity to participate in the program under the eligibility criteria established under this paragraph (g).

(h) *Verifying age.* Program staff must verify a child's age according to program policies and procedures. A program's policies and procedures cannot require families to provide documents that confirm a child's age, if doing so creates a barrier for the family to enroll the child.

(i) *Verifying eligibility.* (1) To verify eligibility based on income, program staff must use tax forms, pay stubs, or other proof of income to determine the family income for the relevant time period.

(i) If the family cannot provide tax forms, pay stubs, or other proof of income for the relevant time period, program staff may accept written statements from employers, including individuals who are self-employed, for the relevant time period and use information provided to calculate total annual income with appropriate multipliers.

(ii) If the family reports no income for the relevant time period, a program may accept the family's signed declaration to that effect, if program staff describes efforts made to verify the family's income, and explains how the family's total income was calculated or seeks information from third parties about the family's eligibility, if the family gives written consent. If a family gives consent to contact third parties, program staff must adhere to program safety and privacy policies and procedures and ensure the eligibility determination record adheres to paragraph (k)(2) of this section.

(iii) If the family can demonstrate a significant change in income for the relevant time period, program staff may consider current income circumstances.

(2) To verify whether a family is eligible for, or in the absence of child care, would be potentially eligible for

public assistance, the program must have documentation from either the state, local, or tribal public assistance agency that shows the family either receives public assistance or that shows the family is potentially eligible to receive public assistance.

(3) To verify whether a family is homeless, a program may accept a written statement from a homeless services provider, school personnel, or other service agency attesting that the child is homeless or any other documentation that indicates homelessness, including documentation from a public or private agency, a declaration, information gathered on enrollment or application forms, or notes from an interview with staff to establish the child is homeless; or any other document that establishes homelessness.

(i) If a family can provide one of the documents described in this paragraph (i)(3), program staff must describe efforts made to verify the accuracy of the information provided and state whether the family is eligible because they are homeless.

(ii) If a family cannot provide one of the documents described in this paragraph (i)(3) to prove the child is homeless, a program may accept the family's signed declaration to that effect, if, in a written statement, program staff describe the child's living situation that meets the definition of homeless in part 1305 of this chapter.

(iii) Program staff may seek information from third parties who have firsthand knowledge about a family's living situation, if the family gives written consent. If the family gives consent to contact third parties, program staff must adhere to program privacy policies and procedures and ensure the eligibility determination record adheres to paragraph (k) of this section.

(4) To verify whether a child is in foster care, program staff must accept either a court order or other legal or government-issued document, a written statement from a government child welfare official that demonstrates the child is in foster care, or proof of a foster care payment.

(j) *Eligibility duration.* (1) If a child is determined eligible under this section and is participating in a Head Start program, he or she will remain eligible through the end of the succeeding program year except that the Head Start program may choose not to enroll a child when there are compelling reasons for the child not to remain in Head Start, such as when there is a change in the child's family income and there is a child with a greater need for Head Start services.

(2) Children who are enrolled in a program receiving funds under the authority of section 645A of the Act remain eligible while they participate in the program.

(3) If a child moves from an Early Head Start program to a Head Start program, program staff must verify the family's eligibility again.

(4) If a program operates both an Early Head Start and a Head Start program, and the parents wish to enroll their child who has been enrolled in the program's Early Head Start, the program must ensure, whenever possible, the child receives Head Start services until enrolled in school, provided the child is eligible.

(k) *Records.* (1) A program must keep eligibility determination records for each participant and ongoing records of the eligibility training for staff required by paragraph (m) of this section. A program may keep these records electronically.

(2) Each eligibility determination record must include:

(i) Copies of any documents or statements, including declarations, that are deemed necessary to verify eligibility under paragraphs (h) and (i) of this section;

(ii) A statement that program staff has made reasonable efforts to verify information by:

(A) Conducting either an in-person, or a telephone interview with the family as described under paragraph (a)(1)(i) or (a)(2) of this section; and,

(B) Describing efforts made to verify eligibility, as required under paragraphs (h) through (i) of this section; and, collecting documents required for third party verification that includes the family's written consent to contact each third party, the third parties' names, titles, and affiliations, and information from third parties regarding the family's eligibility.

(iii) A statement that identifies whether:

(A) The family's income is below income guidelines for its size, and lists the family's size;

(B) The family is eligible for or, in the absence of child care, potentially eligible for public assistance;

(C) The child is a homeless child or the child is in foster care;

(D) The family was determined to be eligible under the criterion in paragraph (c)(2) of this section; or,

(E) The family was determined to be eligible under the criterion in paragraph (d)(1) of this section.

(3) A program must keep eligibility determination records for those currently enrolled, as long as they are enrolled, and, for one year after they

have either stopped receiving services; or are no longer enrolled.

(l) *Program policies and procedures on violating eligibility determination regulations.* A program must establish written policies and procedures that describe all actions taken against staff who intentionally violate federal and program eligibility determination regulations and who enroll pregnant women and children that are not eligible to receive Early Head Start or Head Start services.

(m) *Training on eligibility.* (1) A program must train all governing body, policy council, management, and staff who determine eligibility on applicable federal regulations and program policies and procedures. Training must, at a minimum:

(i) Include methods on how to collect complete and accurate eligibility information from families and third party sources;

(ii) Incorporate strategies for treating families with dignity and respect and for dealing with possible issues of domestic violence, stigma, and privacy; and,

(iii) Explain program policies and procedures that describe actions taken against staff, families, or participants who attempt to provide or intentionally provide false information.

(2) A program must train management and staff members who make eligibility determinations within 90 days of hiring new staff.

(3) A program must train all governing body and policy council members within 180 days of the beginning of the term of a new governing body or policy council.

(4) A program must develop policies on how often training will be provided after the initial training.

§ 1302.13 Recruitment of children.

In order to reach those most in need of services, a program must develop and implement a recruitment process designed to actively inform all families with eligible children within the recruitment area of the availability of program services, and encourage and assist them in applying for admission to the program. A program must include specific efforts to actively locate and recruit children with disabilities and other vulnerable children, including homeless children and children in foster care.

§ 1302.14 Selection process.

(a) *Selection criteria.* (1) A program must annually establish selection criteria that weigh the prioritization of selection of participants, based on community needs identified in the

community needs assessment as described in § 1302.11(b), and including family income, whether the child is homeless, whether the child is in foster care, the child's age, whether the child is eligible for special education and related services, or early intervention services, as appropriate, as determined under the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1400 *et seq.*) and, other relevant family or child risk factors.

(2) If a program serves migrant or seasonal families, it must select participants according to criteria in paragraph (a)(1) of this section, and give priority to children whose families can demonstrate they have relocated frequently within the past two-years to pursue agricultural work.

(3) If a program operates in a service area where Head Start eligible children can enroll in high-quality publicly funded pre-kindergarten for a full school day, the program must prioritize younger children as part of the selection criteria in paragraph (a)(1) of this section. If this priority would disrupt partnerships with local education agencies, then it is not required. An American Indian and Alaska Native or Migrant or Seasonal Head Start program must consider whether such prioritization is appropriate in their community.

(4) A program must not deny enrollment based on a disability or chronic health condition or its severity.

(b) *Children eligible for services under IDEA.* (1) A program must ensure at least 10 percent of its total funded enrollment is filled by children eligible for services under IDEA, unless the responsible HHS official grants a waiver.

(2) If the requirement in paragraph (b)(1) of this section has been met, children eligible for services under IDEA should be prioritized for the available slots in accordance with the program's selection criteria described in paragraph (a) of this section.

(c) *Waiting lists.* A program must develop at the beginning of each enrollment year and maintain during the year a waiting list that ranks children according to the program's selection criteria.

§ 1302.15 Enrollment.

(a) *Funded enrollment.* A program must maintain its funded enrollment level and fill any vacancy as soon as possible. A program must fill any vacancy within 30 days.

(b) *Continuity of enrollment.* (1) A program must make efforts to maintain enrollment of eligible children for the following year.

(2) Under exceptional circumstances, a program may maintain a child's enrollment in Head Start for a third year, provided that family income is verified again. A program may maintain a child's enrollment in Early Head Start as described in § 1302.12(j)(2).

(3) If a program serves homeless children or children in foster care, it must make efforts to maintain the child's enrollment regardless of whether the family or child moves to a different service area, or transition the child to a program in a different service area, as required in § 1302.72(a), according to the family's needs.

(c) *Reserved slots.* If a program determines from the community assessment there are families experiencing homelessness in the area, or children in foster care that could benefit from services, the program may reserve one or more enrollment slots for pregnant women and children experiencing homelessness and children in foster care, when a vacancy occurs. No more than three percent of a program's funded enrollment slots may be reserved. If the reserved enrollment slot is not filled within 30 days, the enrollment slot becomes vacant and then must be filled in accordance with paragraph (a) of this section.

(d) *Other enrollment.* Children from diverse economic backgrounds who are funded with other sources, including private pay, are not considered part of a program's eligible funded enrollment.

(e) *State immunization enrollment requirements.* A program must comply with state immunization enrollment and attendance requirements, with the exception of homeless children as described in § 1302.16(c)(1).

(f) *Voluntary parent participation.* Parent participation in any program activity is voluntary, including consent for data sharing, and is not required as a condition of the child's enrollment.

§ 1302.16 Attendance.

(a) *Promoting regular attendance.* A program must track attendance for each child.

(1) A program must implement a process to ensure children are safe when they do not arrive at school. If a child is unexpectedly absent and a parent has not contacted the program within one hour of program start time, the program must attempt to contact the parent to ensure the child's well-being.

(2) A program must implement strategies to promote attendance. At a minimum, a program must:

- (i) Provide information about the benefits of regular attendance;
- (ii) Support families to promote the child's regular attendance;

(iii) Conduct a home visit or make other direct contact with a child's parents if a child has multiple unexplained absences (such as two consecutive unexplained absences); and,

(iv) Within the first 60 days of program operation, and on an ongoing basis thereafter, use individual child attendance data to identify children with patterns of absence that put them at risk of missing ten percent of program days per year and develop appropriate strategies to improve individual attendance among identified children, such as direct contact with parents or intensive case management, as necessary.

(3) If a child ceases to attend, the program must make appropriate efforts to reengage the family to resume attendance, including as described in paragraph (a)(2) of this section. If the child's attendance does not resume, then the program must consider that slot vacant. This action is not considered expulsion as described in § 1302.17.

(b) *Managing systematic program attendance issues.* If a program's monthly average daily attendance rate falls below 85 percent, the program must analyze the causes of absenteeism to identify any systematic issues that contribute to the program's absentee rate. The program must use this data to make necessary changes in a timely manner as part of ongoing oversight and correction as described in § 1302.102(b) and inform its continuous improvement efforts as described in § 1302.102(c).

(c) *Supporting attendance of homeless children.* (1) If a program determines a child is eligible under § 1302.12(c)(1)(iii), it must allow the child to attend for up to 90 days or as long as allowed under state licensing requirements, without immunization and other records, to give the family reasonable time to present these documents. A program must work with families to get children immunized as soon as possible in order to comply with state licensing requirements.

(2) If a child experiencing homelessness is unable to attend classes regularly because the family does not have transportation to and from the program facility, the program must utilize community resources, where possible, to provide transportation for the child.

§ 1302.17 Suspension and expulsion.

(a) *Limitations on suspension.* (1) A program must prohibit or severely limit the use of suspension due to a child's behavior. Such suspensions may only be temporary in nature.

(2) A temporary suspension must be used only as a last resort in extraordinary circumstances where there is a serious safety threat that cannot be reduced or eliminated by the provision of reasonable modifications.

(3) Before a program determines whether a temporary suspension is necessary, a program must engage with a mental health consultant, collaborate with the parents, and utilize appropriate community resources—such as behavior coaches, psychologists, other appropriate specialists, or other resources—as needed, to determine no other reasonable option is appropriate.

(4) If a temporary suspension is deemed necessary, a program must help the child return to full participation in all program activities as quickly as possible while ensuring child safety by:

(i) Continuing to engage with the parents and a mental health consultant, and continuing to utilize appropriate community resources;

(ii) Developing a written plan to document the action and supports needed;

(iii) Providing services that include home visits; and,

(iv) Determining whether a referral to a local agency responsible for implementing IDEA is appropriate.

(b) *Prohibition on expulsion.* (1) A program cannot expel or unenroll a child from Head Start because of a child's behavior.

(2) When a child exhibits persistent and serious challenging behaviors, a program must explore all possible steps and document all steps taken to address such problems, and facilitate the child's safe participation in the program. Such steps must include, at a minimum, engaging a mental health consultant, considering the appropriateness of providing appropriate services and supports under section 504 of the Rehabilitation Act to ensure that the child who satisfies the definition of disability in 29 U.S.C. 705(9)(b) of the Rehabilitation Act is not excluded from the program on the basis of disability, and consulting with the parents and the child's teacher, and:

(i) If the child has an individualized family service plan (IFSP) or individualized education program (IEP), the program must consult with the agency responsible for the IFSP or IEP to ensure the child receives the needed support services; or,

(ii) If the child does not have an IFSP or IEP, the program must collaborate, with parental consent, with the local agency responsible for implementing IDEA to determine the child's eligibility for services.

(3) If, after a program has explored all possible steps and documented all steps taken as described in paragraph (b)(2) of this section, a program, in consultation with the parents, the child's teacher, the agency responsible for implementing IDEA (if applicable), and the mental health consultant, determines that the child's continued enrollment presents a continued serious safety threat to the child or other enrolled children and determines the program is not the most appropriate placement for the child, the program must work with such entities to directly facilitate the transition of the child to a more appropriate placement.

§ 1302.18 Fees.

(a) *Policy on fees.* A program must not charge eligible families a fee to participate in Head Start, including special events such as field trips, and cannot in any way condition an eligible child's enrollment or participation in the program upon the payment of a fee.

(b) *Allowable fees.* (1) A program must only accept a fee from families of enrolled children for services that are in addition to services funded by Head Start, such as child care before or after funded Head Start hours. A program may not condition a Head Start child's enrollment on the ability to pay a fee for additional hours.

(2) In order to support programs serving children from diverse economic backgrounds or using multiple funding sources, a program may charge fees to private pay families and other non-Head Start enrolled families to the extent allowed by any other applicable federal, state or local funding sources.

Subpart B—Program Structure

§ 1302.20 Determining program structure.

(a) *Choose a program option.* (1) A program must choose to operate one or more of the following program options: Center-based, home-based, family child care, or an approved locally-designed variation as described in § 1302.24. The program option(s) chosen must meet the needs of children and families based on the community assessment described in § 1302.11(b). A Head Start program serving preschool-aged children may not provide only the option described in § 1302.22(a) and (c)(2).

(2) To choose a program option and develop a program calendar, a program must consider in conjunction with the annual review of the community assessment described in § 1302.11(b)(2), whether it would better meet child and family needs through conversion of existing slots to full school day or full working day slots, extending the program year, conversion of existing

Head Start slots to Early Head Start slots as described in paragraph (c) of this section, and ways to promote continuity of care and services. A program must work to identify alternate sources to support full working day services. If no additional funding is available, program resources may be used.

(b) *Comprehensive services.* All program options must deliver the full range of services, as described in subparts C, D, E, F, and G of this part, except that §§ 1302.30 through 1302.32 and § 1302.34 do not apply to home-based options.

(c) *Conversion.* (1) Consistent with section 645(a)(5) of the Head Start Act, grantees may request to convert Head Start slots to Early Head Start slots through the re-funding application process or as a separate grant amendment.

(2) Any grantee proposing a conversion of Head Start services to Early Head Start services must obtain policy council and governing body approval and submit the request to their regional office.

(3) With the exception of American Indian and Alaska Native grantees as described in paragraph (c)(4) of this section, the request to the regional office must include:

(i) A grant application budget and a budget narrative that clearly identifies the funding amount for the Head Start and Early Head Start programs before and after the proposed conversion;

(ii) The results of the community assessment demonstrating how the proposed use of funds would best meet the needs of the community, including a description of how the needs of eligible Head Start children will be met in the community when the conversion takes places;

(iii) A revised program schedule that describes the program option(s) and the number of funded enrollment slots for Head Start and Early Head Start programs before and after the proposed conversion;

(iv) A description of how the needs of pregnant women, infants, and toddlers will be addressed;

(v) A discussion of the agency's capacity to carry out an effective Early Head Start program in accordance with the requirements of section 645A(b) of the Head Start Act and all applicable regulations;

(vi) Assurances that the agency will participate in training and technical assistance activities required of all Early Head Start grantees;

(vii) A discussion of the qualifications and competencies of the child development staff proposed for the Early Head Start program, as well as a

description of the facilities and program infrastructure that will be used to support the new or expanded Early Head Start program;

(viii) A discussion of any one-time funding necessary to implement the proposed conversion and how the agency intends to secure such funding; and,

(ix) The proposed timetable for implementing this conversion, including updating school readiness goals as described in subpart J of this part.

(4) Consistent with section 645(d)(3) of the Act, any American Indian and Alaska Native grantee that operates both an Early Head Start program and a Head Start program may reallocate funds between the programs at its discretion and at any time during the grant period involved, in order to address fluctuations in client populations. An American Indian and Alaska Native program that exercises this discretion must notify the regional office.

(d) *Source of funding.* A program may consider hours of service that meet the Head Start Program Performance Standards, regardless of the source of funding, as hours of planned class operations for the purposes of meeting the Head Start and Early Head Start service duration requirements in this subpart.

§ 1302.21 Center-based option.

(a) *Setting.* The center-based option delivers the full range of services, consistent with § 1302.20(b). Education and child development services are delivered primarily in classroom settings.

(b) *Ratios and group size.* (1) Staff-child ratios and group size maximums must be determined by the age of the majority of children and the needs of children present. A program must determine the age of the majority of children in a class at the start of the year and may adjust this determination during the program year, if necessary. Where state or local licensing requirements are more stringent than the teacher-child ratios and group size specifications in this section, a program must meet the stricter requirements. A program must maintain appropriate ratios during all hours of program operation, except:

(i) For brief absences of a teaching staff member for no more than five minutes; and,

(ii) During nap time, one teaching staff member may be replaced by one staff member or trained volunteer who does not meet the teaching qualifications required for the age.

(2) An Early Head Start or Migrant or Seasonal Head Start class that serves children under 36 months old must have two teachers with no more than eight children, or three teachers with no more than nine children. Each teacher must be assigned consistent, primary responsibility for no more than four children to promote continuity of care for individual children. A program must minimize teacher changes throughout a

child’s enrollment, whenever possible, and consider mixed age group classes to support continuity of care.

(3) A class that serves a majority of children who are three years old must have no more than 17 children with a teacher and teaching assistant or two teachers. A double session class that serves a majority of children who are three years old must have no more than

15 children with a teacher and teaching assistant or two teachers.

(4) A class that serves a majority of children who are four and five years old must have no more than 20 children with a teacher and a teaching assistant or two teachers. A double session class that serves a majority of children who are four and five years old must have no more than 17 children with a teacher and a teaching assistant or two teachers.

TABLE TO § 1302.21(b)—CENTER-BASED GROUP SIZE

4 and 5 year olds	No more than 20 children enrolled in any class. No more than 17 children enrolled in any double session class.
3 year olds	No more than 17 children enrolled in any class. No more than 15 children enrolled in any double session class.
Under 3 years old	No more than 8 or 9 children enrolled in any class, depending on the number of teachers.

(c) *Service duration*—(1) *Early Head Start.* (i) By August 1, 2018, a program must provide 1,380 annual hours of planned class operations for all enrolled children.

(ii) A program that is designed to meet the needs of young parents enrolled in school settings may meet the service duration requirements in paragraph (c)(1)(i) of this section if it operates a center-based program schedule during the school year aligned with its local education agency requirements and provides regular home-based services during the summer break.

(2) *Head Start.* (i) Until a program is operating all of its Head Start center-based funded enrollment at the standard described in paragraph (c)(2)(iv) or (v) of this section, a program must provide, at a minimum, at least 160 days per year of planned class operations if it operates for five days per week, or at least 128 days per year if it operates four days per week. Classes must operate for a minimum of 3.5 hours per day.

(ii) Until a program is operating all of its Head Start center-based funded enrollment at the standard described in paragraph (c)(2)(iv) or (v) of this section, if a program operates a double session variation, it must provide classes for four days per week for a minimum of 128 days per year and 3.5 hours per day. Each double session class staff member must be provided adequate break time during the course of the day. In addition, teachers, aides, and volunteers must have appropriate time to prepare for each session together, to set up the classroom environment, and to give individual attention to children entering and leaving the center.

(iii) By August 1, 2019, a program must provide 1,020 annual hours of planned class operations over the course of at least eight months per year for at

least 50 percent of its Head Start center-based funded enrollment.

(iv) By August 1, 2021, a program must provide 1,020 annual hours of planned class operations over the course of at least eight months per year for all of its Head Start center-based funded enrollment.

(v) A Head Start program providing fewer than 1,020 annual hours of planned class operations or fewer than eight months of service is considered to meet the requirements described in paragraphs (c)(2)(iii) and (iv) of this section if its program schedule aligns with the annual hours required by its local education agency for grade one and such alignment is necessary to support partnerships for service delivery.

(3) *Secretarial determination.* (i) On or before February 1, 2018, the Secretary may lower the required percentage described in paragraph (c)(2)(iii) of this section, based on an assessment of the availability of sufficient funding to mitigate a substantial reduction in funded enrollment; and,

(ii) On or before February 1, 2020, the Secretary may lower the required percentage described in paragraph (c)(2)(iv) of this section, based on an assessment of the availability of sufficient funding to mitigate a substantial reduction in funded enrollment.

(4) *Extension.* If an extension is necessary to ensure children enrolled in the program on November 7, 2016 are not displaced from the Early Head Start or Head Start program, a program may request a one-year extension from the responsible HHS official of the requirements outlined in paragraphs (c)(1) and (c)(2)(iii) of this section.

(5) *Exemption for Migrant or Seasonal Head Start programs.* A Migrant or Seasonal program is not subject to the

requirements described in § 1302.21(c)(1) or (2), but must make every effort to provide as many days and hours of service as possible to each child and family.

(6) *Calendar planning.* A program must:

(i) Plan its year using a reasonable estimate of the number of days during a year that classes may be closed due to problems such as inclement weather; and,

(ii) Make every effort to schedule makeup days using existing resources if hours of planned class operations fall below the number required per year.

(d) *Licensing and square footage requirements.* (1) The facilities used by a program must meet state, tribal, or local licensing requirements, even if exempted by the licensing entity. When state, tribal, or local requirements vary from Head Start requirements, the most stringent provision takes precedence.

(2) A center-based program must have at least 35 square feet of usable indoor space per child available for the care and use of children (exclusive of bathrooms, halls, kitchen, staff rooms, and storage places) and at least 75 square feet of usable outdoor play space per child.

(3) A program that operates two or more groups within an area must ensure clearly defined, safe divisions to separate groups. A program must ensure such spaces are learning environments that facilitate the implementation of the requirements in subpart C of this part. The divisions must limit noise transfer from one group to another to prevent disruption of an effective learning environment.

§ 1302.22 Home-based option.

(a) *Setting.* The home-based option delivers the full range of services, consistent with § 1302.20(b), through

visits with the child's parents, primarily in the child's home and through group socialization opportunities in a Head Start classroom, community facility, home, or on field trips. For Early Head Start programs, the home-based option may be used to deliver services to some or all of a program's enrolled children. For Head Start programs, the home-based option may only be used to deliver services to a portion of a program's enrolled children.

(b) *Caseload*. A program that implements a home-based option must maintain an average caseload of 10 to 12 families per home visitor with a maximum of 12 families for any individual home visitor.

(c) *Service duration*—(1) *Early Head Start*. By August 1, 2017, an Early Head Start home-based program must:

(i) Provide one home visit per week per family that lasts at least an hour and a half and provide a minimum of 46 visits per year; and,

(ii) Provide, at a minimum, 22 group socialization activities distributed over the course of the program year.

(2) *Head Start*. A Head Start home-based program must:

(i) Provide one home visit per week per family that lasts at least an hour and a half and provide a minimum of 32 visits per year; and,

(ii) Provide, at a minimum, 16 group socialization activities distributed over the course of the program year.

(3) *Meeting minimum requirements*. A program that implements a home-based option must:

(i) Make up planned home visits or scheduled group socialization activities that were canceled by the program, and to the extent possible attempt to make up planned home visits canceled by the family, when this is necessary to meet the minimums described in paragraphs (c)(1) and (2) of this section; and,

(ii) Not replace home visits or scheduled group socialization activities for medical or social service appointments for the purposes of meeting the minimum requirements described in paragraphs (c)(1) and (2) of this section.

(d) *Safety requirements*. The areas for learning, playing, sleeping, toileting, preparing food, and eating in facilities used for group socializations in the home-based option must meet the safety standards described in § 1302.47(1)(ii) through (viii).

§ 1302.23 Family child care option.

(a) *Setting*. The family child care program option delivers the full range of services, consistent with § 1302.20(b). Education and child development services are primarily delivered by a

family child care provider in their home or other family-like setting. A program may choose to offer the family child care option if:

(1) The program has a legally binding agreement with one or more family child care provider(s) that clearly defines the roles, rights, and responsibilities of each party, or the program is the employer of the family child care provider, and ensures children and families enrolled in this option receive the full range of services described in subparts C, D, E, F, and G of this part; and,

(2) The program ensures family child care homes are available that can accommodate children and families with disabilities.

(b) *Ratios and group size*. (1) A program that operates the family child care option where Head Start children are enrolled must ensure group size does not exceed the limits specified in this section. If the family child care provider's own children under the age of six are present, they must be included in the group size.

(2) When there is one family child care provider, the maximum group size is six children and no more than two of the six may be under 24 months of age. When there is a provider and an assistant, the maximum group size is twelve children with no more than four of the twelve children under 24 months of age.

(3) One family child care provider may care for up to four children younger than 36 months of age with a maximum group size of four children, and no more than two of the four children may be under 18 months of age.

(4) A program must maintain appropriate ratios during all hours of program operation. A program must ensure providers have systems to ensure the safety of any child not within view for any period. A program must make substitute staff and assistant providers available with the necessary training and experience to ensure quality services to children are not interrupted.

(c) *Service duration*. Whether family child care option services are provided directly or via contractual arrangement, a program must ensure family child care providers operate sufficient hours to meet the child care needs of families and not less than 1,380 hours per year.

(d) *Licensing requirements*. A family child-care provider must be licensed by the state, tribal, or local entity to provide services in their home or family-like setting. When state, tribal, or local requirements vary from Head Start requirements, the most stringent provision applies.

(e) *Child development specialist*. A program that offers the family child care option must provide a child development specialist to support family child care providers and ensure the provision of quality services at each family child care home. Child development specialists must:

(1) Conduct regular visits to each home, some of which are unannounced, not less than once every two weeks;

(2) Periodically verify compliance with either contract requirements or agency policy;

(3) Facilitate ongoing communication between program staff, family child care providers, and enrolled families; and,

(4) Provide recommendations for technical assistance and support the family child care provider in developing relationships with other child care professionals.

§ 1302.24 Locally-designed program option variations.

(a) *Waiver option*. Programs may request to operate a locally-designed program option, including a combination of program options, to better meet the unique needs of their communities or to demonstrate or test alternative approaches for providing program services. In order to operate a locally-designed program option, programs must seek a waiver as described in this section and must deliver the full range of services, consistent with § 1302.20(b), and demonstrate how any change to their program design is consistent with achieving program goals in subpart J of this part.

(b) *Request for approval*. A program's request to operate a locally-designed variation may be approved by the responsible HHS official through the end of a program's current grant or, if the request is submitted through a grant application for an upcoming project period, for the project period of the new award. Such approval may be revoked based on progress toward program goals as described in § 1302.102 and monitoring as described in § 1304.2.

(c) *Waiver requirements*. (1) The responsible HHS official may waive one or more of the requirements contained in § 1302.21(b), (c)(1)(i), and (c)(2)(iii) and (iv); § 1302.22(a) through (c); and § 1302.23(b) and (c), but may not waive ratios or group size for children under 24 months. Center-based locally-designed options must meet the minimums described in section 640(k)(1) of the Act for center-based programs.

(2) If the responsible HHS official determines a waiver of group size for center-based services would better meet

the needs of children and families in a community, the group size may not exceed the limits below:

(i) A group that serves children 24 to 36 months of age must have no more than ten children; and,

(ii) A group that serves predominantly three-year-old children must have no more than twenty children; and,

(iii) A group that serves predominantly four-year-old children must have no more than twenty-four children.

(3) If the responsible HHS official approves a waiver to allow a program to operate below the minimums described in § 1302.21(c)(2)(iii) or (iv), a program must meet the requirements described in § 1302.21(c)(2)(i), or in the case of a double session variation, a program must meet the requirements described in § 1302.21(c)(2)(ii).

(4) In order to receive a waiver under this section, a program must provide supporting evidence that demonstrates the locally-designed variation effectively supports appropriate development and progress in children's early learning outcomes.

(5) In order to receive a waiver of service duration, a program must meet the requirement in paragraph (c)(4) of this section, provide supporting evidence that it better meets the needs of parents than the applicable service duration minimums described in § 1302.21(c)(1) and (c)(2)(iii) and (iv), § 1302.22(c), or § 1302.23(c), and assess the effectiveness of the variation in supporting appropriate development and progress in children's early learning outcomes.

(d) *Transition from previously approved program options.* If, before November 7, 2016, a program was approved to operate a program option that is no longer allowable under §§ 1302.21 through 1302.23, a program may continue to operate that model until July 31, 2018.

Subpart C—Education and Child Development Program Services

§ 1302.30 Purpose.

All programs must provide high-quality early education and child development services, including for children with disabilities, that promote children's cognitive, social, and emotional growth for later success in school. A center-based or family child care program must embed responsive and effective teacher-child interactions. A home-based program must promote secure parent-child relationships and help parents provide high-quality early learning experiences. All programs must implement a research-based curriculum,

and screening and assessment procedures that support individualization and growth in the areas of development described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and support family engagement in children's learning and development. A program must deliver developmentally, culturally, and linguistically appropriate learning experiences in language, literacy, mathematics, social and emotional functioning, approaches to learning, science, physical skills, and creative arts. To deliver such high-quality early education and child development services, a center-based or family child care program must implement, at a minimum, the elements contained in §§ 1302.31 through 1302.34, and a home-based program must implement, at a minimum, the elements in §§ 1302.33 and 1302.35.

§ 1302.31 Teaching and the learning environment.

(a) *Teaching and the learning environment.* A center-based and family child care program must ensure teachers and other relevant staff provide responsive care, effective teaching, and an organized learning environment that promotes healthy development and children's skill growth aligned with the *Head Start Early Learning Outcomes Framework: Ages Birth to Five*, including for children with disabilities. A program must also support implementation of such environment with integration of regular and ongoing supervision and a system of individualized and ongoing professional development, as appropriate. This includes, at a minimum, the practices described in paragraphs (b) through (e) of this section.

(b) *Effective teaching practices.* (1) Teaching practices must:

(i) Emphasize nurturing and responsive practices, interactions, and environments that foster trust and emotional security; are communication and language rich; promote critical thinking and problem-solving; social, emotional, behavioral, and language development; provide supportive feedback for learning; motivate continued effort; and support all children's engagement in learning experiences and activities;

(ii) Focus on promoting growth in the developmental progressions described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* by aligning with and using the Framework and the curricula as described in § 1302.32 to direct planning of organized activities, schedules, lesson plans, and the

implementation of high-quality early learning experiences that are responsive to and build upon each child's individual pattern of development and learning;

(iii) Integrate child assessment data in individual and group planning; and,

(iv) Include developmentally appropriate learning experiences in language, literacy, social and emotional development, math, science, social studies, creative arts, and physical development that are focused toward achieving progress outlined in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five*.

(2) For dual language learners, a program must recognize bilingualism and biliteracy as strengths and implement research-based teaching practices that support their development. These practices must:

(i) For an infant or toddler dual language learner, include teaching practices that focus on the development of the home language, when there is a teacher with appropriate language competency, and experiences that expose the child to English;

(ii) For a preschool age dual language learner, include teaching practices that focus on both English language acquisition and the continued development of the home language; or,

(iii) If staff do not speak the home language of all children in the learning environment, include steps to support the development of the home language for dual language learners such as having culturally and linguistically appropriate materials available and other evidence-based strategies. Programs must work to identify volunteers who speak children's home language/s who could be trained to work in the classroom to support children's continued development of the home language.

(c) *Learning environment.* A program must ensure teachers implement well-organized learning environments with developmentally appropriate schedules, lesson plans, and indoor and outdoor learning experiences that provide adequate opportunities for choice, play, exploration, and experimentation among a variety of learning, sensory, and motor experiences and:

(1) For infants and toddlers, promote relational learning and include individualized and small group activities that integrate appropriate daily routines into a flexible schedule of learning experiences; and,

(2) For preschool age children, include teacher-directed and child-initiated activities, active and quiet learning activities, and opportunities for

individual, small group, and large group learning activities.

(d) *Materials and space for learning.* To support implementation of the curriculum and the requirements described in paragraphs (a), (b), (c), and (e) of this section a program must provide age-appropriate equipment, materials, supplies and physical space for indoor and outdoor learning environments, including functional space. The equipment, materials and supplies must include any necessary accommodations and the space must be accessible to children with disabilities. Programs must change materials intentionally and periodically to support children's interests, development, and learning.

(e) *Promoting learning through approaches to rest, meals, routines, and physical activity.* (1) A program must implement an intentional, age appropriate approach to accommodate children's need to nap or rest, and that, for preschool age children in a program that operates for 6 hours or longer per day provides a regular time every day at which preschool age children are encouraged but not forced to rest or nap. A program must provide alternative quiet learning activities for children who do not need or want to rest or nap.

(2) A program must implement snack and meal times in ways that support development and learning. For bottle-fed infants, this approach must include holding infants during feeding to support socialization. Snack and meal times must be structured and used as learning opportunities that support teaching staff-child interactions and foster communication and conversations that contribute to a child's learning, development, and socialization. Programs are encouraged to meet this requirement with family style meals when developmentally appropriate. A program must also provide sufficient time for children to eat, not use food as reward or punishment, and not force children to finish their food.

(3) A program must approach routines, such as hand washing and diapering, and transitions between activities, as opportunities for strengthening development, learning, and skill growth.

(4) A program must recognize physical activity as important to learning and integrate intentional movement and physical activity into curricular activities and daily routines in ways that support health and learning. A program must not use physical activity as reward or punishment.

§ 1302.32 Curricula.

(a) *Curricula.* (1) Center-based and family child care programs must implement developmentally appropriate research-based early childhood curricula, including additional curricular enhancements, as appropriate that:

(i) Are based on scientifically valid research and have standardized training procedures and curriculum materials to support implementation;

(ii) Are aligned with the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and, as appropriate, state early learning and development standards; and are sufficiently content-rich to promote measurable progress toward development and learning outlined in the Framework; and,

(iii) Have an organized developmental scope and sequence that include plans and materials for learning experiences based on developmental progressions and how children learn.

(2) A program must support staff to effectively implement curricula and at a minimum monitor curriculum implementation and fidelity, and provide support, feedback, and supervision for continuous improvement of its implementation through the system of training and professional development.

(b) *Adaptation.* A program that chooses to make significant adaptations to a curriculum or a curriculum enhancement described in paragraph (a)(1) of this section to better meet the needs of one or more specific populations must use an external early childhood education curriculum or content area expert to develop such significant adaptations. A program must assess whether the adaptation adequately facilitates progress toward meeting school readiness goals, consistent with the process described in § 1302.102(b) and (c). Programs are encouraged to partner with outside evaluators in assessing such adaptations.

§ 1302.33 Child screenings and assessments.

(a) *Screening.* (1) In collaboration with each child's parent and with parental consent, a program must complete or obtain a current developmental screening to identify concerns regarding a child's developmental, behavioral, motor, language, social, cognitive, and emotional skills within 45 calendar days of when the child first attends the program or, for the home-based program option, receives a home visit. A program that operates for 90 days or less must complete or obtain a current

developmental screening within 30 calendar days of when the child first attends the program.

(2) A program must use one or more research-based developmental standardized screening tools to complete the screening. A program must use as part of the screening additional information from family members, teachers, and relevant staff familiar with the child's typical behavior.

(3) If warranted through screening and additional relevant information and with direct guidance from a mental health or child development professional a program must, with the parent's consent, promptly and appropriately address any needs identified through:

(i) Referral to the local agency responsible for implementing IDEA for a formal evaluation to assess the child's eligibility for services under IDEA as soon as possible, and not to exceed timelines required under IDEA; and,

(ii) Partnership with the child's parents and the relevant local agency to support families through the formal evaluation process.

(4) If a child is determined to be eligible for services under IDEA, the program must partner with parents and the local agency responsible for implementing IDEA, as appropriate, and deliver the services in subpart F of this part.

(5) If, after the formal evaluation described in paragraph (a)(3)(i) of this section, the local agency responsible for implementing IDEA determines the child is not eligible for early intervention or special education and related services under IDEA, the program must:

(i) Seek guidance from a mental health or child development professional to determine if the formal evaluation shows the child has a significant delay in one or more areas of development that is likely to interfere with the child's development and school readiness; and,

(ii) If the child has a significant delay, partner with parents to help the family access services and supports to help address the child's identified needs.

(A) Such additional services and supports may be available through a child's health insurance or it may be appropriate for the program to provide needed services and supports under section 504 of the Rehabilitation Act if the child satisfies the definition of disability in 29 U.S.C. 705(9)(b) of the Rehabilitation Act, to ensure that the child who satisfies the definition of disability in 29 U.S.C. 705(9)(b) of the Rehabilitation Act is not excluded from the program on the basis of disability.

(B) A program may use program funds for such services and supports when no other sources of funding are available.

(b) *Assessment for individualization.*

(1) A program must conduct standardized and structured assessments, which may be observation-based or direct, for each child that provide ongoing information to evaluate the child's developmental level and progress in outcomes aligned to the goals described in the *Head Start Early Learning Child Outcomes Framework: Ages Birth to Five*. Such assessments must result in usable information for teachers, home visitors, and parents and be conducted with sufficient frequency to allow for individualization within the program year.

(2) A program must regularly use information from paragraph (b)(1) of this section along with informal teacher observations and additional information from family and staff, as relevant, to determine a child's strengths and needs, inform and adjust strategies to better support individualized learning and improve teaching practices in center-based and family child care settings, and improve home visit strategies in home-based models.

(3) If warranted from the information gathered from paragraphs (b)(1) and (2) of this section and with direct guidance from a mental health or child development professional and a parent's consent, a program must refer the child to the local agency responsible for implementing IDEA for a formal evaluation to assess a child's eligibility for services under IDEA.

(c) *Characteristics of screenings and assessments.* (1) Screenings and assessments must be valid and reliable for the population and purpose for which they will be used, including by being conducted by qualified and trained personnel, and being age, developmentally, culturally and linguistically appropriate, and appropriate for children with disabilities, as needed.

(2) If a program serves a child who speaks a language other than English, a program must use qualified bilingual staff, contractor, or consultant to:

(i) Assess language skills in English and in the child's home language, to assess both the child's progress in the home language and in English language acquisition;

(ii) Conduct screenings and assessments for domains other than language skills in the language or languages that best capture the child's development and skills in the specific domain; and,

(iii) Ensure those conducting the screening or assessment know and

understand the child's language and culture and have sufficient skill level in the child's home language to accurately administer the screening or assessment and to record and understand the child's responses, interactions, and communications.

(3) If a program serves a child who speaks a language other than English and qualified bilingual staff, contractors, or consultants are not able to conduct screenings and assessments, a program must use an interpreter in conjunction with a qualified staff person to conduct screenings and assessments as described in paragraphs (c)(2)(i) through (iii) of this section.

(4) If a program serves a child who speaks a language other than English and can demonstrate that there is not a qualified bilingual staff person or interpreter, then screenings and assessments may be conducted in English. In such a case, a program must also gather and use other information, including structured observations over time and information gathered in a child's home language from the family, for use in evaluating the child's development and progress.

(d) *Prohibitions on use of screening and assessment data.* The use of screening and assessment items and data on any screening or assessment authorized under this subchapter by any agent of the federal government is prohibited for the purposes of ranking, comparing, or otherwise evaluating individual children for purposes other than research, training, or technical assistance, and is prohibited for the purposes of providing rewards or sanctions for individual children or staff. A program must not use screening or assessments to exclude children from enrollment or participation.

§ 1302.34 Parent and family engagement in education and child development services.

(a) *Purpose.* Center-based and family child care programs must structure education and child development services to recognize parents' roles as children's lifelong educators, and to encourage parents to engage in their child's education.

(b) *Engaging parents and family members.* A program must offer opportunities for parents and family members to be involved in the program's education services and implement policies to ensure:

(1) The program's settings are open to parents during all program hours;

(2) Teachers regularly communicate with parents to ensure they are well-informed about their child's routines, activities, and behavior;

(3) Teachers hold parent conferences, as needed, but no less than two times per program year, to enhance the knowledge and understanding of both staff and parents of the child's education and developmental progress and activities in the program;

(4) Parents have the opportunity to learn about and to provide feedback on selected curricula and instructional materials used in the program;

(5) Parents and family members have opportunities to volunteer in the class and during group activities;

(6) Teachers inform parents, about the purposes of and the results from screenings and assessments and discuss their child's progress;

(7) Teachers, except those described in paragraph (b)(8) of this section, conduct at least two home visits per program year for each family, including one before the program year begins, if feasible, to engage the parents in the child's learning and development, except that such visits may take place at a program site or another safe location that affords privacy at the parent's request, or if a visit to the home presents significant safety hazards for staff; and,

(8) Teachers that serve migrant or seasonal families make every effort to conduct home visits to engage the family in the child's learning and development.

§ 1302.35 Education in home-based programs.

(a) *Purpose.* A home-based program must provide home visits and group socialization activities that promote secure parent-child relationships and help parents provide high-quality early learning experiences in language, literacy, mathematics, social and emotional functioning, approaches to learning, science, physical skills, and creative arts. A program must implement a research-based curriculum that delivers developmentally, linguistically, and culturally appropriate home visits and group socialization activities that support children's cognitive, social, and emotional growth for later success in school.

(b) *Home-based program design.* A home-based program must ensure all home visits are:

(1) Planned jointly by the home visitor and parents, and reflect the critical role of parents in the early learning and development of their children, including that the home visitor is able to effectively communicate with the parent, directly or through an interpreter;

(2) Planned using information from ongoing assessments that individualize learning experiences;

(3) Scheduled with sufficient time to serve all enrolled children in the home and conducted with parents and are not conducted when only babysitters or other temporary caregivers are present;

(4) Scheduled with sufficient time and appropriate staff to ensure effective delivery of services described in subparts D, E, F, and G of this part through home visiting, to the extent possible.

(c) *Home visit experiences.* A program that operates the home-based option must ensure all home visits focus on promoting high-quality early learning experiences in the home and growth towards the goals described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and must use such goals and the curriculum to plan home visit activities that implement:

(1) Age and developmentally appropriate, structured child-focused learning experiences;

(2) Strategies and activities that promote parents' ability to support the child's cognitive, social, emotional, language, literacy, and physical development;

(3) Strategies and activities that promote the home as a learning environment that is safe, nurturing, responsive, and language- and communication- rich;

(4) Research-based strategies and activities for children who are dual language learners that recognize bilingualism and biliteracy as strengths, and:

(i) For infants and toddlers, focus on the development of the home language, while providing experiences that expose both parents and children to English; and,

(ii) For preschoolers, focus on both English language acquisition and the continued development of the home language; and,

(5) Follow-up with the families to discuss learning experiences provided in the home between each visit, address concerns, and inform strategies to promote progress toward school readiness goals.

(d) *Home-based curriculum.* A program that operates the home-based option must:

(1) Ensure home-visiting and group socializations implement a developmentally appropriate research-based early childhood home-based curriculum that:

(i) Promotes the parent's role as the child's teacher through experiences focused on the parent-child relationship

and, as appropriate, the family's traditions, culture, values, and beliefs;

(ii) Aligns with the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and, as appropriate, state early learning standards, and, is sufficiently content-rich within the Framework to promote measurable progress toward goals outlined in the Framework; and,

(iii) Has an organized developmental scope and sequence that includes plans and materials for learning experiences based on developmental progressions and how children learn.

(2) Support staff in the effective implementation of the curriculum and at a minimum monitor curriculum implementation and fidelity, and provide support, feedback, and supervision for continuous improvement of its implementation through the system of training and professional development.

(3) If a program chooses to make significant adaptations to a curriculum or curriculum enhancement to better meet the needs of one or more specific populations, a program must:

(i) Partner with early childhood education curriculum or content experts; and,

(ii) Assess whether the adaptation adequately facilitates progress toward meeting school readiness goals consistent with the process described in § 1302.102(b) and (c).

(4) Provide parents with an opportunity to review selected curricula and instructional materials used in the program.

(e) *Group socialization.* (1) A program that operates the home-based option must ensure group socializations are planned jointly with families, conducted with both child and parent participation, occur in a classroom, community facility, home or field trip setting, as appropriate.

(2) Group socializations must be structured to:

(i) Provide age appropriate activities for participating children that are intentionally aligned to school readiness goals, the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and the home-based curriculum; and,

(ii) Encourage parents to share experiences related to their children's development with other parents in order to strengthen parent-child relationships and to help promote parents understanding of child development;

(3) For parents with preschoolers, group socializations also must provide opportunities for parents to participate in activities that support parenting skill development or family partnership goals

identified in § 1302.52(c), as appropriate and must emphasize peer group interactions designed to promote children's social, emotional and language development, and progress towards school readiness goals, while encouraging parents to observe and actively participate in activities, as appropriate.

(f) *Screening and assessments.* A program that operates the home-based option must implement provisions in § 1302.33 and inform parents about the purposes of and the results from screenings and assessments and discuss their child's progress.

§ 1302.36 Tribal language preservation and revitalization.

A program that serves American Indian and Alaska Native children may integrate efforts to preserve, revitalize, restore, or maintain the tribal language for these children into program services. Such language preservation and revitalization efforts may include full immersion in the tribal language for the majority of the hours of planned class operations. If children's home language is English, exposure to English as described in § 1302.31(b)(2)(i) and (ii) is not required.

Subpart D—Health Program Services

§ 1302.40 Purpose.

(a) A program must provide high-quality health, oral health, mental health, and nutrition services that are developmentally, culturally, and linguistically appropriate and that will support each child's growth and school readiness.

(b) A program must establish and maintain a Health Services Advisory Committee that includes Head Start parents, professionals, and other volunteers from the community.

§ 1302.41 Collaboration and communication with parents.

(a) For all activities described in this part, programs must collaborate with parents as partners in the health and well-being of their children in a linguistically and culturally appropriate manner and communicate with parents about their child's health needs and development concerns in a timely and effective manner.

(b) At a minimum, a program must:

(1) Obtain advance authorization from the parent or other person with legal authority for all health and developmental procedures administered through the program or by contract or agreement, and, maintain written documentation if they refuse to give authorization for health services; and,

(2) Share with parents the policies for health emergencies that require rapid response on the part of staff or immediate medical attention.

§ 1302.42 Child health status and care.

(a) *Source of health care.* (1) A program, within 30 calendar days after the child first attends the program or, for the home-based program option, receives a home visit, must consult with parents to determine whether each child has ongoing sources of continuous, accessible health care—provided by a health care professional that maintains the child's ongoing health record and is not primarily a source of emergency or urgent care—and health insurance coverage.

(2) If the child does not have such a source of ongoing care and health insurance coverage or access to care through the Indian Health Service, the program must assist families in accessing a source of care and health insurance that will meet these criteria, as quickly as possible.

(b) *Ensuring up-to-date child health status.* (1) Within 90 calendar days after the child first attends the program or, for the home-based program option, receives a home visit, with the exceptions noted in paragraph (b)(3) of this section, a program must:

(i) Obtain determinations from health care and oral health care professionals as to whether or not the child is up-to-date on a schedule of age appropriate preventive and primary medical and oral health care, based on: The well-child visits and dental periodicity schedules as prescribed by the Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) program of the Medicaid agency of the state in which they operate, immunization recommendations issued by the Centers for Disease Control and Prevention, and any additional recommendations from the local Health Services Advisory Committee that are based on prevalent community health problems;

(ii) Assist parents with making arrangements to bring the child up-to-date as quickly as possible; and, if necessary, directly facilitate provision of health services to bring the child up-to-date with parent consent as described in § 1302.41(b)(1).

(2) Within 45 calendar days after the child first attends the program or, for the home-based program option, receives a home visit, a program must either obtain or perform evidence-based vision and hearing screenings.

(3) If a program operates for 90 days or less, it has 30 days from the date the child first attends the program to satisfy paragraphs (b)(1) and (2) of this section.

(4) A program must identify each child's nutritional health needs, taking into account available health information, including the child's health records, and family and staff concerns, including special dietary requirements, food allergies, and community nutrition issues as identified through the community assessment or by the Health Services Advisory Committee.

(c) *Ongoing care.* (1) A program must help parents continue to follow recommended schedules of well-child and oral health care.

(2) A program must implement periodic observations or other appropriate strategies for program staff and parents to identify any new or recurring developmental, medical, oral, or mental health concerns.

(3) A program must facilitate and monitor necessary oral health preventive care, treatment and follow-up, including topical fluoride treatments. In communities where there is a lack of adequate fluoride available through the water supply and for every child with moderate to severe tooth decay, a program must also facilitate fluoride supplements, and other necessary preventive measures, and further oral health treatment as recommended by the oral health professional.

(d) *Extended follow-up care.* (1) A program must facilitate further diagnostic testing, evaluation, treatment, and follow-up plan, as appropriate, by a licensed or certified professional for each child with a health problem or developmental delay, such as elevated lead levels or abnormal hearing or vision results that may affect child's development, learning, or behavior.

(2) A program must develop a system to track referrals and services provided and monitor the implementation of a follow-up plan to meet any treatment needs associated with a health, oral health, social and emotional, or developmental problem.

(3) A program must assist parents, as needed, in obtaining any prescribed medications, aids or equipment for medical and oral health conditions.

(e) *Use of funds.* (1) A program must use program funds for the provision of diapers and formula for enrolled children during the program day.

(2) A program may use program funds for professional medical and oral health services when no other source of funding is available. When program funds are used for such services, grantee and delegate agencies must have written documentation of their efforts to access other available sources of funding.

§ 1302.43 Oral health practices.

A program must promote effective oral health hygiene by ensuring all children with teeth are assisted by appropriate staff, or volunteers, if available, in brushing their teeth with toothpaste containing fluoride once daily.

§ 1302.44 Child nutrition.

(a) *Nutrition service requirements.* (1) A program must design and implement nutrition services that are culturally and developmentally appropriate, meet the nutritional needs of and accommodate the feeding requirements of each child, including children with special dietary needs and children with disabilities. Family style meals are encouraged as described in § 1302.31(e)(2).

(2) Specifically, a program must:

(i) Ensure each child in a program that operates for fewer than six hours per day receives meals and snacks that provide one third to one half of the child's daily nutritional needs;

(ii) Ensure each child in a program that operates for six hours or more per day receives meals and snacks that provide one half to two thirds of the child's daily nutritional needs, depending upon the length of the program day;

(iii) Serve three- to five-year-olds meals and snacks that conform to USDA requirements in 7 CFR parts 210, 220, and 226, and are high in nutrients and low in fat, sugar, and salt;

(iv) Feed infants and toddlers according to their individual developmental readiness and feeding skills as recommended in USDA requirements outlined in 7 CFR parts 210, 220, and 226, and ensure infants and young toddlers are fed on demand to the extent possible;

(v) Ensure bottle-fed infants are never laid down to sleep with a bottle;

(vi) Serve all children in morning center-based settings who have not received breakfast upon arrival at the program a nourishing breakfast;

(vii) Provide appropriate healthy snacks and meals to each child during group socialization activities in the home-based option;

(viii) Promote breastfeeding, including providing facilities to properly store and handle breast milk and make accommodations, as necessary, for mothers who wish to breastfeed during program hours, and if necessary, provide referrals to lactation consultants or counselors; and,

(ix) Make safe drinking water available to children during the program day.

(b) *Payment sources.* A program must use funds from USDA Food, Nutrition,

and Consumer Services child nutrition programs as the primary source of payment for meal services. Early Head Start and Head Start funds may be used to cover those allowable costs not covered by the USDA.

§ 1302.45 Child mental health and social and emotional well-being.

(a) *Wellness promotion.* To support a program-wide culture that promotes children's mental health, social and emotional well-being, and overall health, a program must:

- (1) Provide supports for effective classroom management and positive learning environments; supportive teacher practices; and, strategies for supporting children with challenging behaviors and other social, emotional, and mental health concerns;
 - (2) Secure mental health consultation services on a schedule of sufficient and consistent frequency to ensure a mental health consultant is available to partner with staff and families in a timely and effective manner;
 - (3) Obtain parental consent for mental health consultation services at enrollment; and,
 - (4) Build community partnerships to facilitate access to additional mental health resources and services, as needed.
- (b) *Mental health consultants.* A program must ensure mental health consultants assist:
- (1) The program to implement strategies to identify and support children with mental health and social and emotional concerns;
 - (2) Teachers, including family child care providers, to improve classroom management and teacher practices through strategies that include using classroom observations and consultations to address teacher and individual child needs and creating physical and cultural environments that promote positive mental health and social and emotional functioning;
 - (3) Other staff, including home visitors, to meet children's mental health and social and emotional needs through strategies that include observation and consultation;
 - (4) Staff to address prevalent child mental health concerns, including internalizing problems such as appearing withdrawn and externalizing problems such as challenging behaviors; and,
 - (5) In helping both parents and staff to understand mental health and access mental health interventions, if needed.
 - (6) In the implementation of the policies to limit suspension and prohibit expulsion as described in § 1302.17.

§ 1302.46 Family support services for health, nutrition, and mental health.

(a) *Parent collaboration.* Programs must collaborate with parents to promote children's health and well-being by providing medical, oral, nutrition and mental health education support services that are understandable to individuals, including individuals with low health literacy.

(b) *Opportunities.* (1) Such collaboration must include opportunities for parents to:

- (i) Learn about preventive medical and oral health care, emergency first aid, environmental hazards, and health and safety practices for the home including health and developmental consequences of tobacco products use and exposure to lead, and safe sleep;
 - (ii) Discuss their child's nutritional status with staff, including the importance of physical activity, healthy eating, and the negative health consequences of sugar-sweetened beverages, and how to select and prepare nutritious foods that meet the family's nutrition and food budget needs;
 - (iii) Learn about healthy pregnancy and postpartum care, as appropriate, including breastfeeding support and treatment options for parental mental health or substance abuse problems, including perinatal depression;
 - (iv) Discuss with staff and identify issues related to child mental health and social and emotional well-being, including observations and any concerns about their child's mental health, typical and atypical behavior and development, and how to appropriately respond to their child and promote their child's social and emotional development; and,
 - (v) Learn about appropriate vehicle and pedestrian safety for keeping children safe.
- (2) A program must provide ongoing support to assist parents' navigation through health systems to meet the general health and specifically identified needs of their children and must assist parents:
- (i) In understanding how to access health insurance for themselves and their families, including information about private and public health insurance and designated enrollment periods;
 - (ii) In understanding the results of diagnostic and treatment procedures as well as plans for ongoing care; and,
 - (iii) In familiarizing their children with services they will receive while enrolled in the program and to enroll and participate in a system of ongoing family health care.

§ 1302.47 Safety practices.

(a) A program must establish, train staff on, implement, and enforce a system of health and safety practices that ensure children are kept safe at all times. A program should consult *Caring for our Children Basics*, available at http://www.acf.hhs.gov/sites/default/files/ecd/caring_for_our_children_basics.pdf, for additional information to develop and implement adequate safety policies and practices described in this part.

(b) A program must develop and implement a system of management, including ongoing training, oversight, correction and continuous improvement in accordance with § 1302.102, that includes policies and practices to ensure all facilities, equipment and materials, background checks, safety training, safety and hygiene practices and administrative safety procedures are adequate to ensure child safety. This system must ensure:

- (1) *Facilities.* All facilities where children are served, including areas for learning, playing, sleeping, toileting, and eating are, at a minimum:
 - (i) Meet licensing requirements in accordance with §§ 1302.21(d)(1) and 1302.23(d);
 - (ii) Clean and free from pests;
 - (iii) Free from pollutants, hazards and toxins that are accessible to children and could endanger children's safety;
 - (iv) Designed to prevent child injury and free from hazards, including choking, strangulation, electrical, and drowning hazards, hazards posed by appliances and all other safety hazards;
 - (v) Well lit, including emergency lighting;
 - (vi) Equipped with safety supplies that are readily accessible to staff, including, at a minimum, fully-equipped and up-to-date first aid kits and appropriate fire safety supplies;
 - (vii) Free from firearms or other weapons that are accessible to children;
 - (viii) Designed to separate toileting and diapering areas from areas for preparing food, cooking, eating, or children's activities; and,
 - (ix) Kept safe through an ongoing system of preventative maintenance.
- (2) *Equipment and materials.* Indoor and outdoor play equipment, cribs, cots, feeding chairs, strollers, and other equipment used in the care of enrolled children, and as applicable, other equipment and materials meet standards set by the Consumer Product Safety Commission (CPSC) or the American Society for Testing and Materials, International (ASTM). All equipment and materials must at a minimum:
 - (i) Be clean and safe for children's use and are appropriately disinfected;

(ii) Be accessible only to children for whom they are age appropriate;

(iii) Be designed to ensure appropriate supervision of children at all times;

(iv) Allow for the separation of infants and toddlers from preschoolers during play in center-based programs; and,

(v) Be kept safe through an ongoing system of preventative maintenance.

(3) *Background checks.* All staff have complete background checks in accordance with § 1302.90(b).

(4) *Safety training*—(i) *Staff with regular child contact.* All staff with regular child contact have initial orientation training within three months of hire and ongoing training in all state, local, tribal, federal and program-developed health, safety and child care requirements to ensure the safety of children in their care; including, at a minimum, and as appropriate based on staff roles and ages of children they work with, training in:

(A) The prevention and control of infectious diseases;

(B) Prevention of sudden infant death syndrome and use of safe sleeping practices;

(C) Administration of medication, consistent with standards for parental consent;

(D) Prevention and response to emergencies due to food and allergic reactions;

(E) Building and physical premises safety, including identification of and protection from hazards, bodies of water, and vehicular traffic;

(F) Prevention of shaken baby syndrome, abusive head trauma, and child maltreatment;

(G) Emergency preparedness and response planning for emergencies;

(H) Handling and storage of hazardous materials and the appropriate disposal of biocontaminants;

(I) Appropriate precautions in transporting children, if applicable;

(J) First aid and cardiopulmonary resuscitation; and,

(K) Recognition and reporting of child abuse and neglect, in accordance with the requirement at paragraph (b)(5) of this section.

(ii) *Staff without regular child contact.* All staff with no regular responsibility for or contact with children have initial orientation training within three months of hire; ongoing training in all state, local, tribal, federal and program-developed health and safety requirements applicable to their work; and training in the program's emergency and disaster preparedness procedures.

(5) *Safety practices.* All staff and consultants follow appropriate practices to keep children safe during all activities, including, at a minimum:

(i) Reporting of suspected or known child abuse and neglect, including that staff comply with applicable federal, state, local, and tribal laws;

(ii) Safe sleep practices, including ensuring that all sleeping arrangements for children under 18 months of age use firm mattresses or cots, as appropriate, and for children under 12 months, soft bedding materials or toys must not be used;

(iii) Appropriate indoor and outdoor supervision of children at all times;

(iv) Only releasing children to an authorized adult, and;

(v) All standards of conduct described in § 1302.90(c).

(6) *Hygiene practices.* All staff systematically and routinely implement hygiene practices that at a minimum ensure:

(i) Appropriate toileting, hand washing, and diapering procedures are followed;

(ii) Safe food preparation; and,

(iii) Exposure to blood and body fluids are handled consistent with standards of the Occupational Safety Health Administration.

(7) *Administrative safety procedures.* Programs establish, follow, and practice, as appropriate, procedures for, at a minimum:

(i) Emergencies;

(ii) Fire prevention and response;

(iii) Protection from contagious disease, including appropriate inclusion and exclusion policies for when a child is ill, and from an infectious disease outbreak, including appropriate notifications of any reportable illness;

(iv) The handling, storage, administration, and record of administration of medication;

(v) Maintaining procedures and systems to ensure children are only released to an authorized adult; and,

(vi) Child specific health care needs and food allergies that include accessible plans of action for emergencies. For food allergies, a program must also post individual child food allergies prominently where staff can view wherever food is served.

(8) *Disaster preparedness plan.* The program has all-hazards emergency management/disaster preparedness and response plans for more and less likely events including natural and manmade disasters and emergencies, and violence in or near programs.

(c) A program must report any safety incidents in accordance with § 1302.102(d)(1)(ii).

Subpart E—Family and Community Engagement Program Services

§ 1302.50 Family engagement.

(a) *Purpose.* A program must integrate parent and family engagement strategies into all systems and program services to support family well-being and promote children's learning and development. Programs are encouraged to develop innovative two-generation approaches that address prevalent needs of families across their program that may leverage community partnerships or other funding sources.

(b) *Family engagement approach.* A program must:

- (1) Recognize parents as their children's primary teachers and nurturers and implement intentional strategies to engage parents in their children's learning and development and support parent-child relationships, including specific strategies for father engagement;
- (2) Develop relationships with parents and structure services to encourage trust and respectful, ongoing two-way communication between staff and parents to create welcoming program environments that incorporate the unique cultural, ethnic, and linguistic backgrounds of families in the program and community;
- (3) Collaborate with families in a family partnership process that identifies needs, interests, strengths, goals, and services and resources that support family well-being, including family safety, health, and economic stability;
- (4) Provide parents with opportunities to participate in the program as employees or volunteers;
- (5) Conduct family engagement services in the family's preferred language, or through an interpreter, to the extent possible, and ensure families have the opportunity to share personal information in an environment in which they feel safe; and,
- (6) Implement procedures for teachers, home visitors, and family support staff to share information with each other, as appropriate and consistent with the requirements in part 1303, subpart C, of this chapter; FERPA; or IDEA, to ensure coordinated family engagement strategies with children and families in the classroom, home, and community.

§ 1302.51 Parent activities to promote child learning and development.

(a) A program must promote shared responsibility with parents for children's early learning and development, and implement family engagement strategies that are designed

to foster parental confidence and skills in promoting children's learning and development. These strategies must include:

(1) Offering activities that support parent-child relationships and child development including language, dual language, literacy, and bi-literacy development as appropriate;

(2) Providing parents with information about the importance of their child's regular attendance, and partner with them, as necessary, to promote consistent attendance; and,

(3) For dual language learners, information and resources for parents about the benefits of bilingualism and biliteracy.

(b) A program must, at a minimum, offer opportunities for parents to participate in a research-based parenting curriculum that builds on parents' knowledge and offers parents the opportunity to practice parenting skills to promote children's learning and development. A program that chooses to make significant adaptations to the parenting curriculum to better meet the needs of one or more specific populations must work with an expert or experts to develop such adaptations.

§ 1302.52 Family partnership services.

(a) *Family partnership process.* A program must implement a family partnership process that includes a family partnership agreement and the activities described in this section to support family well-being, including family safety, health, and economic stability, to support child learning and development, to provide, if applicable, services and supports for children with disabilities, and to foster parental confidence and skills that promote the early learning and development of their children. The process must be initiated as early in the program year as possible and continue for as long as the family participates in the program, based on parent interest and need.

(b) *Identification of family strengths and needs.* A program must implement intake and family assessment procedures to identify family strengths and needs related to the family engagement outcomes as described in the Head Start Parent Family and Community Engagement Framework, including family well-being, parent-child relationships, families as lifelong educators, families as learners, family engagement in transitions, family connections to peers and the local community, and families as advocates and leaders.

(c) *Individualized family partnership services.* A program must offer

individualized family partnership services that:

(1) Collaborate with families to identify interests, needs, and aspirations related to the family engagement outcomes described in paragraph (b) of this section;

(2) Help families achieve identified individualized family engagement outcomes;

(3) Establish and implement a family partnership agreement process that is jointly developed and shared with parents in which staff and families review individual progress, revise goals, evaluate and track whether identified needs and goals are met, and adjust strategies on an ongoing basis, as necessary, and;

(4) Assign staff and resources based on the urgency and intensity of identified family needs and goals.

(d) *Existing plans and community resources.* In implementing this section, a program must take into consideration any existing plans for the family made with other community agencies and availability of other community resources to address family needs, strengths, and goals, in order to avoid duplication of effort.

§ 1302.53 Community partnerships and coordination with other early childhood and education programs.

(a) *Community partnerships.* (1) A program must establish ongoing collaborative relationships and partnerships with community organizations such as establishing joint agreements, procedures, or contracts and arranging for onsite delivery of services as appropriate, to facilitate access to community services that are responsive to children's and families' needs and family partnership goals, and community needs and resources, as determined by the community assessment.

(2) A program must establish necessary collaborative relationships and partnerships, with community organizations that may include:

(i) Health care providers, including child and adult mental health professionals, Medicaid managed care networks, dentists, other health professionals, nutritional service providers, providers of prenatal and postnatal support, and substance abuse treatment providers;

(ii) Individuals and agencies that provide services to children with disabilities and their families, elementary schools, state preschool providers, and providers of child care services;

(iii) Family preservation and support services and child protective services

and any other agency to which child abuse must be reported under state or tribal law;

(iv) Educational and cultural institutions, such as libraries and museums, for both children and families;

(v) Temporary Assistance for Needy Families, nutrition assistance agencies, workforce development and training programs, adult or family literacy, adult education, and post-secondary education institutions, and agencies or financial institutions that provide asset-building education, products and services to enhance family financial stability and savings;

(vi) Housing assistance agencies and providers of support for children and families experiencing homelessness, including the local educational agency liaison designated under section 722(g)(1)(J)(ii) of the McKinney-Vento Homeless Assistance Act (42 U.S.C. 11431 *et seq.*);

(vii) Domestic violence prevention and support providers; and,

(viii) Other organizations or businesses that may provide support and resources to families.

(b) *Coordination with other programs and systems.* A program must take an active role in promoting coordinated systems of comprehensive early childhood services to low-income children and families in their community through communication, cooperation, and the sharing of information among agencies and their community partners, while protecting the privacy of child records in accordance with subpart C of part 1303 of this chapter and applicable federal, state, local, and tribal laws.

(1) *Memorandum of understanding.* To support coordination between Head Start and publicly funded preschool programs, a program must enter into a memorandum of understanding with the appropriate local entity responsible for managing publicly funded preschool programs in the service area of the program, as described in section 642(e)(5) of the Act.

(2) *Quality Rating and Improvement Systems.* A program, with the exception of American Indian and Alaska Native programs, must participate in its state or local Quality Rating and Improvement System (QRIS) if:

(i) Its state or local QRIS accepts Head Start monitoring data to document quality indicators included in the state's tiered system;

(ii) Participation would not impact a program's ability to comply with the Head Start Program Performance Standards; and,

(iii) The program has not provided the Office of Head Start with a compelling reason not to comply with this requirement.

(3) *Data systems.* A program, with the exception of American Indian and Alaska Native programs unless they would like to and to the extent practicable, should integrate and share relevant data with state education data systems, to the extent practicable, if the program can receive similar support and benefits as other participating early childhood programs.

(4) *American Indian and Alaska Native programs.* An American Indian and Alaska Native program should determine whether or not it will participate in the systems described in paragraphs (b)(2) and (3) of this section.

Subpart F—Additional Services for Children With Disabilities

§ 1302.60 Full participation in program services and activities.

A program must ensure enrolled children with disabilities, including but not limited to those who are eligible for services under IDEA, and their families receive all applicable program services delivered in the least restrictive possible environment and that they fully participate in all program activities.

§ 1302.61 Additional services for children.

(a) *Additional services for children with disabilities.* Programs must ensure the individualized needs of children with disabilities, including but not limited to those eligible for services under IDEA, are being met and all children have access to and can fully participate in the full range of activities and services. Programs must provide any necessary modifications to the environment, multiple and varied formats for instruction, and individualized accommodations and supports as necessary to support the full participation of children with disabilities. Programs must ensure all individuals with disabilities are protected from discrimination under and provided with all services and program modifications required by section 504 of the Rehabilitation Act (29 U.S.C. 794), the Americans with Disabilities Act (42 U.S.C. 12101 *et seq.*), and their implementing regulations.

(b) *Services during IDEA eligibility determination.* While the local agency responsible for implementing IDEA determines a child's eligibility, a program must provide individualized services and supports, to the maximum extent possible, to meet the child's needs. Such additional supports may be

available through a child's health insurance or it may be appropriate or required to provide the needed services and supports under section 504 of the Rehabilitation Act if the child satisfies the definition of disability in section 705(9)(b) of the Rehabilitation Act. When such supports are not available through alternate means, pending the evaluation results and eligibility determination, a program must individualize program services based on available information such as parent input and child observation and assessment data and may use program funds for these purposes.

(c) *Additional services for children with an IFSP or IEP.* To ensure the individual needs of children eligible for services under IDEA are met, a program must:

(1) Work closely with the local agency responsible for implementing IDEA, the family, and other service partners, as appropriate, to ensure:

(i) Services for a child with disabilities will be planned and delivered as required by their IFSP or IEP, as appropriate;

(ii) Children are working towards the goals in their IFSP or IEP;

(iii) Elements of the IFSP or IEP that the program cannot implement are implemented by other appropriate agencies, related service providers and specialists;

(iv) IFSPs and IEPs are being reviewed and revised, as required by IDEA; and,

(v) Services are provided in a child's regular Early Head Start or Head Start classroom or family child care home to the greatest extent possible.

(2) Plan and implement the transition services described in subpart G of this part, including at a minimum:

(i) For children with an IFSP who are transitioning out of Early Head Start, collaborate with the parents, and the local agency responsible for implementing IDEA, to ensure appropriate steps are undertaken in a timely and appropriate manner to determine the child's eligibility for services under Part B of IDEA; and,

(ii) For children with an IEP who are transitioning out of Head Start to kindergarten, collaborate with the parents, and the local agency responsible for implementing IDEA, to ensure steps are undertaken in a timely and appropriate manner to support the child and family as they transition to a new setting.

§ 1302.62 Additional services for parents.

(a) *Parents of all children with disabilities.* (1) A program must collaborate with parents of children with disabilities, including but not

limited to children eligible for services under IDEA, to ensure the needs of their children are being met, including support to help parents become advocates for services that meet their children's needs and information and skills to help parents understand their child's disability and how to best support the child's development;

(2) A program must assist parents to access services and resources for their family, including securing adaptive equipment and devices and supports available through a child's health insurance or other entities, creating linkages to family support programs, and helping parents establish eligibility for additional support programs, as needed and practicable.

(b) *Parents of children eligible for services under IDEA.* For parents of children eligible for services under IDEA, a program must also help parents:

(1) Understand the referral, evaluation, and service timelines required under IDEA;

(2) Actively participate in the eligibility process and IFSP or IEP development process with the local agency responsible for implementing IDEA, including by informing parents of their right to invite the program to participate in all meetings;

(3) Understand the purposes and results of evaluations and services provided under an IFSP or IEP; and,

(4) Ensure their children's needs are accurately identified in, and addressed through, the IFSP or IEP.

§ 1302.63 Coordination and collaboration with the local agency responsible for implementing IDEA.

(a) A program must coordinate with the local agency responsible for implementing IDEA to identify children enrolled or who intend to enroll in a program that may be eligible for services under IDEA, including through the process described in § 1302.33(a)(3) and through participation in the local agency Child Find efforts.

(b) A program must work to develop interagency agreements with the local agency responsible for implementing IDEA to improve service delivery to children eligible for services under IDEA, including the referral and evaluation process, service coordination, promotion of service provision in the least restrictive appropriate community-based setting and reduction in dual enrollment which causes reduced time in a less restrictive setting, and transition services as children move from services provided under Part C of IDEA to services provided under Part B of IDEA and from preschool to kindergarten.

(c) A program must participate in the development of the IFSP or IEP if requested by the child's parents, and the implementation of the IFSP or IEP. At a minimum, the program must offer:

(1) To provide relevant information from its screenings, assessments, and observations to the team developing a child's IFSP or IEP; and,

(2) To participate in meetings with the local agency responsible for implementing IDEA to develop or review an IEP or IFSP for a child being considered for Head Start enrollment, a currently enrolled child, or a child transitioning from a program.

(d) A program must retain a copy of the IEP or IFSP for any child enrolled in Head Start for the time the child is in the program, consistent with the IDEA requirements in 34 CFR parts 300 and 303.

Subpart G—Transition Services

§ 1302.70 Transitions from Early Head Start.

(a) *Implementing transition strategies and practices.* An Early Head Start program must implement strategies and practices to support successful transitions for children and their families transitioning out of Early Head Start.

(b) *Timing for transitions.* To ensure the most appropriate placement and service following participation in Early Head Start, such programs must, at least six months prior to each child's third birthday, implement transition planning for each child and family that:

(1) Takes into account the child's developmental level and health and disability status, progress made by the child and family while in Early Head Start, current and changing family circumstances and, the availability of Head Start, other public pre-kindergarten, and other early education and child development services in the community that will meet the needs of the child and family; and,

(2) Transitions the child into Head Start or another program as soon as possible after the child's third birthday but permits the child to remain in Early Head Start for a limited number of additional months following the child's third birthday if necessary for an appropriate transition.

(c) *Family collaborations.* A program must collaborate with parents of Early Head Start children to implement strategies and activities that support successful transitions from Early Head Start and, at a minimum, provide information about the child's progress during the program year and provide strategies for parents to continue their

involvement in and advocacy for the education and development of their child.

(d) *Early Head Start and Head Start collaboration.* Early Head Start and Head Start programs must work together to maximize enrollment transitions from Early Head Start to Head Start, consistent with the eligibility provisions in subpart A, and promote successful transitions through collaboration and communication.

(e) *Transition services for children with an IFSP.* A program must provide additional transition services for children with an IFSP, at a minimum, as described in subpart F of this part.

§ 1302.71 Transitions from Head Start to kindergarten.

(a) *Implementing transition strategies and practices.* A program that serves children who will enter kindergarten in the following year must implement transition strategies to support a successful transition to kindergarten.

(b) *Family collaborations for transitions.* (1) A program must collaborate with parents of enrolled children to implement strategies and activities that will help parents advocate for and promote successful transitions to kindergarten for their children, including their continued involvement in the education and development of their child.

(2) At a minimum, such strategies and activities must:

(i) Help parents understand their child's progress during Head Start;

(ii) Help parents understand practices they use to effectively provide academic and social support for their children during their transition to kindergarten and foster their continued involvement in the education of their child;

(iii) Prepare parents to exercise their rights and responsibilities concerning the education of their children in the elementary school setting, including services and supports available to children with disabilities and various options for their child to participate in language instruction educational programs; and,

(iv) Assist parents in the ongoing communication with teachers and other school personnel so that parents can participate in decisions related to their children's education.

(c) *Community collaborations for transitions.* (1) A program must collaborate with local education agencies to support family engagement under section 642(b)(13) of the Act and state departments of education, as appropriate, and kindergarten teachers to implement strategies and activities that promote successful transitions to

kindergarten for children, their families, and the elementary school.

(2) At a minimum, such strategies and activities must include:

(i) Coordination with schools or other appropriate agencies to ensure children's relevant records are transferred to the school or next placement in which a child will enroll, consistent with privacy requirements in subpart C of part 1303 of this chapter;

(ii) Communication between appropriate staff and their counterparts in the schools to facilitate continuity of learning and development, consistent with privacy requirements in subpart C of part 1303 of this chapter; and,

(iii) Participation, as possible, for joint training and professional development activities for Head Start and kindergarten teachers and staff.

(3) A program that does not operate during the summer must collaborate with school districts to determine the availability of summer school programming for children who will be entering kindergarten and work with parents and school districts to enroll children in such programs, as appropriate.

(d) *Learning environment activities.* A program must implement strategies and activities in the learning environment that promote successful transitions to kindergarten for enrolled children, and at a minimum, include approaches that familiarize children with the transition to kindergarten and foster confidence about such transition.

(e) *Transition services for children with an IEP.* A program must provide additional transition services for children with an IEP, at a minimum, as described in subpart F of this part.

§ 1302.72 Transitions between programs.

(a) For families and children who move out of the community in which they are currently served, including homeless families and foster children, a program must undertake efforts to support effective transitions to other Early Head Start or Head Start programs. If Early Head Start or Head Start is not available, the program should assist the family to identify another early childhood program that meets their needs.

(b) A program that serves children whose families have decided to transition them to other early education programs, including public pre-kindergarten, in the year prior to kindergarten entry must undertake strategies and activities described in § 1302.71(b) and (c)(1) and (2), as practicable and appropriate.

(c) A migrant or seasonal Head Start program must undertake efforts to

support effective transitions to other migrant or seasonal Head Start or, if appropriate, Early Head Start or Head Start programs for families and children moving out of the community in which they are currently served.

Subpart H—Services to Enrolled Pregnant Women

§ 1302.80 Enrolled pregnant women.

(a) Within 30 days of enrollment, a program must determine whether each enrolled pregnant woman has an ongoing source of continuous, accessible health care—provided by a health care professional that maintains her ongoing health record and is not primarily a source of emergency or urgent care—and, as appropriate, health insurance coverage.

(b) If an enrolled pregnant woman does not have a source of ongoing care as described in paragraph (a) of this section and, as appropriate, health insurance coverage, a program must, as quickly as possible, facilitate her access to such a source of care that will meet her needs.

(c) A program must facilitate the ability of all enrolled pregnant women to access comprehensive services through referrals that, at a minimum, include nutritional counseling, food assistance, oral health care, mental health services, substance abuse prevention and treatment, and emergency shelter or transitional housing in cases of domestic violence.

(d) A program must provide a newborn visit with each mother and baby to offer support and identify family needs. A program must schedule the newborn visit within two weeks after the infant's birth.

§ 1302.81 Prenatal and postpartum information, education, and services.

(a) A program must provide enrolled pregnant women, fathers, and partners or other relevant family members the prenatal and postpartum information, education and services that address, as appropriate, fetal development, the importance of nutrition, the risks of alcohol, drugs, and smoking, labor and delivery, postpartum recovery, parental depression, infant care and safe sleep practices, and the benefits of breastfeeding.

(b) A program must also address needs for appropriate supports for emotional well-being, nurturing and responsive caregiving, and father engagement during pregnancy and early childhood.

§ 1302.82 Family partnership services for enrolled pregnant women.

(a) A program must engage enrolled pregnant women and other relevant family members, such as fathers, in the family partnership services as described in § 1302.52 and include a specific focus on factors that influence prenatal and postpartum maternal and infant health.

(b) A program must engage enrolled pregnant women and other relevant family members, such as fathers, in discussions about program options, plan for the infant's transition to program enrollment, and support the family during the transition process, where appropriate.

Subpart I—Human Resources Management

§ 1302.90 Personnel policies.

(a) *Establishing personnel policies and procedures.* A program must establish written personnel policies and procedures that are approved by the governing body and policy council or policy committee and that are available to all staff.

(b) *Background checks and selection procedures.* (1) Before a person is hired, directly or through contract, including transportation staff and contractors, a program must conduct an interview, verify references, conduct a sex offender registry check and obtain one of the following:

(i) State or tribal criminal history records, including fingerprint checks; or,

(ii) Federal Bureau of Investigation criminal history records, including fingerprint checks.

(2) A program has 90 days after an employee is hired to complete the background check process by obtaining:

(i) Whichever check listed in paragraph (b)(1) of this section was not obtained prior to the date of hire; and,

(ii) Child abuse and neglect state registry check, if available.

(3) A program must review the information found in each employment application and complete background check to assess the relevancy of any issue uncovered by the complete background check including any arrest, pending criminal charge, or conviction and must use Child Care and Development Fund (CCDF) disqualification factors described in 42 U.S.C. 9858f(c)(1)(D) and 42 U.S.C. 9858f(h)(1) or tribal disqualifications factors to determine whether the prospective employee can be hired or the current employee must be terminated.

(4) A program must ensure a newly hired employee, consultant, or

contractor does not have unsupervised access to children until the complete background check process described in paragraphs (b)(1) through (3) of this section is complete.

(5) A program must conduct the complete background check for each employee, consultant, or contractor at least once every five years which must include each of the four checks listed in paragraphs (b)(1) and (2) of this section, and review and make employment decisions based on the information as described in paragraph (b)(3) of this section, unless the program can demonstrate to the responsible HHS official that it has a more stringent system in place that will ensure child safety.

(6) A program must consider current and former program parents for employment vacancies for which such parents apply and are qualified.

(c) *Standards of conduct.* (1) A program must ensure all staff, consultants, contractors, and volunteers abide by the program's standards of conduct that:

(i) Ensure staff, consultants, contractors, and volunteers implement positive strategies to support children's well-being and prevent and address challenging behavior;

(ii) Ensure staff, consultants, contractors, and volunteers do not maltreat or endanger the health or safety of children, including, at a minimum, that staff must not:

(A) Use corporal punishment;

(B) Use isolation to discipline a child;

(C) Bind or tie a child to restrict movement or tape a child's mouth;

(D) Use or withhold food as a punishment or reward;

(E) Use toilet learning/training methods that punish, demean, or humiliate a child;

(F) Use any form of emotional abuse, including public or private humiliation, rejecting, terrorizing, extended ignoring, or corrupting a child;

(G) Physically abuse a child;

(H) Use any form of verbal abuse, including profane, sarcastic language, threats, or derogatory remarks about the child or child's family; or,

(I) Use physical activity or outdoor time as a punishment or reward;

(iii) Ensure staff, consultants, contractors, and volunteers respect and promote the unique identity of each child and family and do not stereotype on any basis, including gender, race, ethnicity, culture, religion, disability, sexual orientation, or family composition;

(iv) Require staff, consultants, contractors, and volunteers to comply with program confidentiality policies

concerning personally identifiable information about children, families, and other staff members in accordance with subpart C of part 1303 of this chapter and applicable federal, state, local, and tribal laws; and,

(v) Ensure no child is left alone or unsupervised by staff, consultants, contractors, or volunteers while under their care.

(2) Personnel policies and procedures must include appropriate penalties for staff, consultants, and volunteers who violate the standards of conduct.

(d) *Communication with dual language learners and their families.* (1) A program must ensure staff and program consultants or contractors are familiar with the ethnic backgrounds and heritages of families in the program and are able to serve and effectively communicate, either directly or through interpretation and translation, with children who are dual language learners and to the extent feasible, with families with limited English proficiency.

(2) If a majority of children in a class or home-based program speak the same language, at least one class staff member or home visitor must speak such language.

§ 1302.91 Staff qualifications and competency requirements.

(a) *Purpose.* A program must ensure all staff, consultants, and contractors engaged in the delivery of program services have sufficient knowledge, training and experience, and competencies to fulfill the roles and responsibilities of their positions and to ensure high-quality service delivery in accordance with the program performance standards. A program must provide ongoing training and professional development to support staff in fulfilling their roles and responsibilities.

(b) *Early Head Start or Head Start director.* A program must ensure an Early Head Start or Head Start director hired after November 7, 2016, has, at a minimum, a baccalaureate degree and experience in supervision of staff, fiscal management, and administration.

(c) *Fiscal officer.* A program must assess staffing needs in consideration of the fiscal complexity of the organization and applicable financial management requirements and secure the regularly scheduled or ongoing services of a fiscal officer with sufficient education and experience to meet their needs. A program must ensure a fiscal officer hired after November 7, 2016, is a certified public accountant or has, at a minimum, a baccalaureate degree in accounting, business, fiscal management, or a related field.

(d) *Child and family services management staff qualification requirements—(1) Family, health, and disabilities management.* A program must ensure staff responsible for management and oversight of family services, health services, and services to children with disabilities hired after November 7, 2016, have, at a minimum, a baccalaureate degree, preferably related to one or more of the disciplines they oversee.

(2) *Education management.* As prescribed in section 648A(a)(2)(B)(i) of the Act, a program must ensure staff and consultants that serve as education managers or coordinators, including those that serve as curriculum specialists, have a baccalaureate or advanced degree in early childhood education or a baccalaureate or advanced degree and equivalent coursework in early childhood education with early education teaching experience.

(e) *Child and family services staff—(1) Early Head Start center-based teacher qualification requirements.* As prescribed in section 645A(h) of the Act, a program must ensure center-based teachers that provide direct services to infants and toddlers in Early Head Start centers have a minimum of a Child Development Associate (CDA) credential or comparable credential, and have been trained or have equivalent coursework in early childhood development with a focus on infant and toddler development.

(2) *Head Start center-based teacher qualification requirements.* (i) The Secretary must ensure no less than fifty percent of all Head Start teachers, nationwide, have a baccalaureate degree in child development, early childhood education, or equivalent coursework.

(ii) As prescribed in section 648A(a)(3)(B) of the Act, a program must ensure all center-based teachers have at least an associate's or bachelor's degree in child development or early childhood education, equivalent coursework, or otherwise meet the requirements of section 648A(a)(3)(B) of the Act.

(3) *Head Start assistant teacher qualification requirements.* As prescribed in section 648A(a)(2)(B)(ii) of the Act, a program must ensure Head Start assistant teachers, at a minimum, have a CDA credential or a state-awarded certificate that meets or exceeds the requirements for a CDA credential, are enrolled in a program that will lead to an associate or baccalaureate degree or, are enrolled in a CDA credential program to be completed within two years of the time of hire.

(4) *Family child care provider qualification requirements.* (i) A program must ensure family child care providers have previous early child care experience and, at a minimum, are enrolled in a Family Child Care CDA program or state equivalent, or an associate's or baccalaureate degree program in child development or early childhood education prior to beginning service provision, and for the credential acquire it within eighteen months of beginning to provide services.

(ii) By August 1, 2018, a child development specialist, as required for family child care in § 1302.23(e), must have, at a minimum, a baccalaureate degree in child development, early childhood education, or a related field.

(5) *Center-based teachers, assistant teachers, and family child care provider competencies.* A program must ensure center-based teachers, assistant teachers, and family child care providers demonstrate competency to provide effective and nurturing teacher-child interactions, plan and implement learning experiences that ensure effective curriculum implementation and use of assessment and promote children's progress across the standards described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five* and applicable state early learning and development standards, including for children with disabilities and dual language learners, as appropriate.

(6) *Home visitors.* A program must ensure home visitors providing home-based education services:

(i) Have a minimum of a home-based CDA credential or comparable credential, or equivalent coursework as part of an associate's or bachelor's degree; and,

(ii) Demonstrate competency to plan and implement home-based learning experiences that ensure effective implementation of the home visiting curriculum and promote children's progress across the standards described in the *Head Start Early Learning Outcomes Framework: Ages Birth to Five*, including for children with disabilities and dual language learners, as appropriate, and to build respectful, culturally responsive, and trusting relationships with families.

(7) *Family services staff qualification requirements.* A program must ensure staff who work directly with families on the family partnership process hired after November 7, 2016, have within eighteen months of hire, at a minimum, a credential or certification in social work, human services, family services, counseling or a related field.

(8) *Health professional qualification requirements.* (i) A program must ensure health procedures are performed only by a licensed or certified health professional.

(ii) A program must ensure all mental health consultants are licensed or certified mental health professionals. A program must use mental health consultants with knowledge of and experience in serving young children and their families, if available in the community.

(iii) A program must use staff or consultants to support nutrition services who are registered dietitians or nutritionists with appropriate qualifications.

(f) *Coaches.* A program must ensure coaches providing the services described in § 1302.92(c) have a minimum of a baccalaureate degree in early childhood education or a related field.

§ 1302.92 Training and professional development.

(a) A program must provide to all new staff, consultants, and volunteers an orientation that focuses on, at a minimum, the goals and underlying philosophy of the program and on the ways they are implemented.

(b) A program must establish and implement a systematic approach to staff training and professional development designed to assist staff in acquiring or increasing the knowledge and skills needed to provide high-quality, comprehensive services within the scope of their job responsibilities, and attached to academic credit as appropriate. At a minimum, the system must include:

(1) Staff completing a minimum of 15 clock hours of professional development per year. For teaching staff, such professional development must meet the requirements described in section 648A(a)(5) of the Act.

(2) Training on methods to handle suspected or known child abuse and neglect cases, that comply with applicable federal, state, local, and tribal laws;

(3) Training for child and family services staff on best practices for implementing family engagement strategies in a systemic way, as described throughout this part;

(4) Training for child and family services staff, including staff that work on family services, health, and disabilities, that builds their knowledge, experience, and competencies to improve child and family outcomes; and,

(5) Research-based approaches to professional development for education

staff, that are focused on effective curricula implementation, knowledge of the content in *Head Start Early Learning Outcomes Framework: Ages Birth to Five*, partnering with families, supporting children with disabilities and their families, providing effective and nurturing adult-child interactions, supporting dual language learners as appropriate, addressing challenging behaviors, preparing children and families for transitions (as described in subpart G of this part), and use of data to individualize learning experiences to improve outcomes for all children.

(c) A program must implement a research-based, coordinated coaching strategy for education staff that:

(1) Assesses all education staff to identify strengths, areas of needed support, and which staff would benefit most from intensive coaching;

(2) At a minimum, provides opportunities for intensive coaching to those education staff identified through the process in paragraph (c)(1) of this section, including opportunities to be observed and receive feedback and modeling of effective teacher practices directly related to program performance goals;

(3) At a minimum, provides opportunities for education staff not identified for intensive coaching through the process in paragraph (c)(1) of this section to receive other forms of research-based professional development aligned with program performance goals;

(4) Ensures intensive coaching opportunities for the staff identified through the process in paragraph (c)(1) of this section that:

(i) Align with the program's school readiness goals, curricula, and other approaches to professional development;

(ii) Utilize a coach with adequate training and experience in adult learning and in using assessment data to drive coaching strategies aligned with program performance goals;

(iii) Provide ongoing communication between the coach, program director, education director, and any other relevant staff; and,

(iv) Include clearly articulated goals informed by the program's goals, as described in § 1302.102, and a process for achieving those goals; and,

(5) Establishes policies that ensure assessment results are not used to solely determine punitive actions for staff identified as needing support, without providing time and resources for staff to improve.

(d) If a program needs to develop or significantly adapt their approach to research-based professional

development to better meet the training needs of education staff, such that it does not include the requirements in paragraph (c) of this section, the program must partner with external early childhood education professional development experts. A program must assess whether the adaptation adequately supports staff professional development, consistent with the process laid out in subpart J of this part.

§ 1302.93 Staff health and wellness.

(a) A program must ensure each staff member has an initial health examination and a periodic re-examination as recommended by their health care provider in accordance with state, tribal, or local requirements, that include screeners or tests for communicable diseases, as appropriate. 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.

(b) A program must make mental health and wellness information available to staff regarding health issues that may affect their job performance, and must provide regularly scheduled opportunities to learn about mental health, wellness, and health education.

§ 1302.94 Volunteers.

(a) A program must ensure regular volunteers have been screened for appropriate communicable diseases in accordance with state, tribal or local laws. In the absence of state, tribal or local law, the Health Services Advisory Committee must be consulted regarding the need for such screenings.

(b) A program must ensure children are never left alone with volunteers.

Subpart J—Program Management and Quality Improvement

§ 1302.100 Purpose.

A program must provide management and a process of ongoing monitoring and continuous improvement for achieving program goals that ensures child safety and the delivery of effective, high-quality program services.

§ 1302.101 Management system.

(a) *Implementation.* A program must implement a management system that:

(1) Ensures a program, fiscal, and human resource management structure that provides effective management and oversight of all program areas and fiduciary responsibilities to enable delivery of high-quality services in all of

the program services described in subparts C, D, E, F, G, and H of this part;

(2) Provides regular and ongoing supervision to support individual staff professional development and continuous program quality improvement;

(3) Ensures budget and staffing patterns that promote continuity of care for all children enrolled, allow sufficient time for staff to participate in appropriate training and professional development, and allow for provision of the full range of services described in subparts C, D, E, F, G, and H of this part; and,

(4) Maintains an automated accounting and record keeping system adequate for effective oversight.

(b) *Coordinated approaches.* At the beginning of each program year, and on an ongoing basis throughout the year, a program must design and implement program-wide coordinated approaches that ensure:

(1) The training and professional development system, as described in § 1302.92, effectively supports the delivery and continuous improvement of high-quality services;

(2) The full and effective participation of children who are dual language learners and their families, by:

(i) Utilizing information from the program's community assessment about the languages spoken throughout the program service area to anticipate child and family needs;

(ii) Identifying community resources and establishing ongoing collaborative relationships and partnerships with community organizations consistent with the requirements in § 1302.53(a); and,

(iii) Systematically and comprehensively addressing child and family needs by facilitating meaningful access to program services, including, at a minimum, curriculum, instruction, staffing, supervision, and family partnerships with bilingual staff, oral language assistance and interpretation, or translation of essential program materials, as appropriate.

(3) The full and effective participation of all children with disabilities, including but not limited to children eligible for services under IDEA, by providing services with appropriate facilities, program materials, curriculum, instruction, staffing, supervision, and partnerships, at a minimum, consistent with section 504 of the Rehabilitation Act and the Americans with Disabilities Act; and,

(4) The management of program data to effectively support the availability, usability, integrity, and security of data. A program must establish procedures on

data management, and have them approved by the governing body and policy council, in areas such as quality of data and effective use and sharing of data, while protecting the privacy of child records in accordance with subpart C of part 1303 of this chapter and applicable federal, state, local, and tribal laws.

§ 1302.102 Achieving program goals.

(a) *Establishing program goals.* A program, in collaboration with the governing body and policy council, must establish goals and measurable objectives that include:

(1) Strategic long-term goals for ensuring programs are and remain responsive to community needs as identified in their community assessment as described in subpart A of this part;

(2) Goals for the provision of educational, health, nutritional, and family and community engagement program services as described in the program performance standards to further promote the school readiness of enrolled children;

(3) School readiness goals that are aligned with the *Head Start Early Learning Outcomes Framework: Ages Birth to Five*, state and tribal early learning standards, as appropriate, and requirements and expectations of schools Head Start children will attend, per the requirements of subpart B of part 1304 of this part; and,

(4) Effective health and safety practices to ensure children are safe at all times, per the requirements in §§ 1302.47, 1302.90(b) and (c), 1302.92(c)(1), and 1302.94 and part 1303, subpart F, of this chapter.

(b) *Monitoring program performance—(1) Ongoing compliance oversight and correction.* In order to ensure effective ongoing oversight and correction, a program must establish and implement a system of ongoing oversight that ensures effective implementation of the program performance standards, including ensuring child safety, and other applicable federal regulations as described in this part, and must:

(i) Collect and use data to inform this process;

(ii) Correct quality and compliance issues immediately, or as quickly as possible;

(iii) Work with the governing body and the policy council to address issues during the ongoing oversight and correction process and during federal oversight; and,

(iv) Implement procedures that prevent recurrence of previous quality and compliance issues, including

previously identified deficiencies, safety incidents, and audit findings.

(2) *Ongoing assessment of program goals.* A program must effectively oversee progress towards program goals on an ongoing basis and annually must:

(i) Conduct a self-assessment that uses program data including aggregated child assessment data, and professional development and parent and family engagement data as appropriate, to evaluate the program's progress towards meeting goals established under paragraph (a) of this section, compliance with program performance standards throughout the program year, and the effectiveness of the professional development and family engagement systems in promoting school readiness;

(ii) Communicate and collaborate with the governing body and policy council, program staff, and parents of enrolled children when conducting the annual self-assessment; and,

(iii) Submit findings of the self-assessment, including information listed in paragraph (b)(2)(i) of this section to the responsible HHS official.

(c) *Using data for continuous improvement.* (1) A program must implement a process for using data to identify program strengths and needs, develop and implement plans that address program needs, and continually evaluate compliance with program performance standards and progress towards achieving program goals described in paragraph (a) of this section.

(2) This process must:

(i) Ensure data is aggregated, analyzed and compared in such a way to assist agencies in identifying risks and informing strategies for continuous improvement in all program service areas;

(ii) Ensure child-level assessment data is aggregated and analyzed at least three times a year, including for sub-groups, such as dual language learners and children with disabilities, as appropriate, except in programs operating fewer than 90 days, and used with other program data described in paragraph (c)(2)(iv) of this section to direct continuous improvement related to curriculum choice and implementation, teaching practices, professional development, program design and other program decisions, including changing or targeting scope of services; and,

(iii) For programs operating fewer than 90 days, ensures child assessment data is aggregated and analyzed at least twice during the program operating period, including for subgroups, such as dual language learners and children with disabilities, as appropriate, and

used with other program data described in paragraph (c)(2)(iv) of this section to direct continuous improvement related to curriculum choice and implementation, teaching practices, professional development, program design and other program decisions, including changing or targeting scope of services;

(iv) Use information from ongoing monitoring and the annual self-assessment, and program data on teaching practice, staffing and professional development, child-level assessments, family needs assessments, and comprehensive services, to identify program needs, and develop and implement plans for program improvement; and,

(v) Use program improvement plans as needed to either strengthen or adjust content and strategies for professional development, change program scope and services, refine school readiness and other program goals, and adapt strategies to better address the needs of sub-groups.

(d) *Reporting.* (1) A program must submit:

(i) Status reports, determined by ongoing oversight data, to the governing body and policy council, at least semi-annually;

(ii) Reports, as appropriate, to the responsible HHS official immediately or as soon as practicable, related to any significant incidents affecting the health and safety of program participants, circumstances affecting the financial viability of the program, breaches of personally identifiable information, or program involvement in legal proceedings, any matter for which notification or a report to state, tribal, or local authorities is required by applicable law, including at a minimum:

(A) Any reports regarding agency staff or volunteer compliance with federal, state, tribal, or local laws addressing child abuse and neglect or laws governing sex offenders;

(B) Incidents that require classrooms or centers to be closed for any reason;

(C) Legal proceedings by any party that are directly related to program operations; and,

(D) All conditions required to be reported under § 1304.12, including disqualification from the Child and Adult Care Food Program (CACFP) and license revocation.

(2) Annually, a program must publish and disseminate a report that complies with section 644(a)(2) of the Act and includes a summary of a program's most recent community assessment, as described in § 1302.11(b), consistent

with privacy protections in subpart C of part 1303 of this chapter.

(3) If a program has had a deficiency identified, it must submit, to the responsible HHS official, a quality improvement plan as required in section 641A(e)(2) of the Act.

§ 1302.103 Implementation of program performance standards.

(a) A current program as of November 7, 2016, must implement a program-wide approach for the effective and timely implementation of the changes to the program performance standards, including the purchase of materials and allocation of staff time, as appropriate.

(b) A program's approach to implement the changes included in parts 1301 through 1304 of this chapter must ensure adequate preparation for effective and timely service delivery to children and their families including, at a minimum, review of community assessment data to determine the most appropriate strategy for implementing required program changes, including assessing any changes in the number of children who can be served, as necessary, the purchase of and training on any curriculum, assessment, or other materials, as needed, assessment of program-wide professional development needs, assessment of staffing patterns, the development of coordinated approaches described in § 1302.101(b), and the development of appropriate protections for data sharing; and children enrolled in the program on November 7, 2016 are not displaced during a program year and that children leaving Early Head Start or Head Start at the end of the program year following November 7, 2016 as a result of any slot reductions received services described in §§ 1302.70 and 1302.72 to facilitate successful transitions to other programs.

PART 1303—FINANCIAL AND ADMINISTRATIVE REQUIREMENTS

Sec.

1303.1 Overview.

Subpart A—Financial Requirements

1303.2 Purpose.

1303.3 Other requirements.

1303.4 Federal financial assistance, non-federal match, and waiver requirements.

1303.5 Limitations on development and administrative costs.

Subpart B—Administrative Requirements

1303.10 Purpose.

1303.11 Limitations and prohibitions.

1303.12 Insurance and bonding.

Subpart C—Protections for the Privacy of Child Records

1303.20 Establishing procedures.

1303.21 Program procedures—applicable confidentiality provisions.

1303.22 Disclosures with, and without, parental consent.

1303.23 Parental rights.

1303.24 Maintaining records.

Subpart D—Delegation of Program Operations

1303.30 Grantee responsibility and accountability.

1303.31 Determining and establishing delegate agencies.

1303.32 Evaluations and corrective actions for delegate agencies.

1303.33 Termination of delegate agencies.

Subpart E—Facilities

1303.40 Purpose.

1303.41 Approval of previously purchased facilities.

1303.42 Eligibility to purchase, construct, and renovate facilities.

1303.43 Use of grant funds to pay fees.

1303.44 Applications to purchase, construct, and renovate facilities.

1303.45 Cost-comparison to purchase, construct, and renovate facilities.

1303.46 Recording and posting notices of federal interest.

1303.47 Contents of notices of federal interest.

1303.48 Grantee limitations on federal interest.

1303.49 Protection of federal interest in mortgage agreements.

1303.50 Third party leases and occupancy arrangements.

1303.51 Subordination of the federal interest.

1303.52 Insurance, bonding, and maintenance.

1303.53 Copies of documents.

1303.54 Record retention.

1303.55 Procurement procedures.

1303.56 Inspection of work.

Subpart F—Transportation

1303.70 Purpose.

1303.71 Vehicles.

1303.72 Vehicle operation.

1303.73 Trip routing.

1303.74 Safety procedures.

1303.75 Children with disabilities.

Authority: 42 U.S.C. 9801 *et seq.*

§ 1303.1 Overview.

Section 641A of the Act requires that the Secretary modify as necessary program performance standards including administrative and financial management standards (section 641A(a)(1)(C)). This part specifies the financial and administrative requirements of agencies. Subpart A of this part outlines the financial requirements consistent with sections 640(b) and 644(b) and (c) of the Act. Subpart B of this part specifies the administrative requirements consistent with sections 644(a)(1), 644(e), 653, 654, 655, 656, and 657A of the Act. Subpart C of this part implements the statutory provision at section 641A(b)(4) of the Act that directs the Secretary to ensure the confidentiality of any personally

identifiable data, information, and records collected or maintained. Subpart D of this part prescribes regulations for the operation of delegate agencies consistent with Section 641(A)(d). Subpart E of this part implements the statutory requirements in Section 644(c), (f) and (g) related to

facilities. Subpart F prescribes regulations on transportation consistent with section 640(i) of the Act.

Subpart A—Financial Requirements

§ 1303.2 Purpose.

This subpart establishes regulations applicable to program administration

and grants management for all grants under the Act.

§ 1303.3 Other requirements.

The following chart includes HHS regulations that apply to all grants made under the Act:

Cite	Title
45 CFR part 16	Department grant appeals process.
45 CFR part 30	HHS Standards and Procedures for Claims collection.
45 CFR part 46	Protection of human subjects.
45 CFR part 75	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.
45 CFR part 80	Nondiscrimination under programs receiving federal assistance through the Department of Health and Human Services—Effectuation of title VI and VII of the Civil Rights Act of 1964.
45 CFR part 81	Practice and procedure for hearings under part 80.
45 CFR part 84	Nondiscrimination on the basis of handicap in federally assisted programs.
45 CFR part 87	Equal treatment for faith based organizations.
2 CFR part 170	FFATA Sub-award and executive compensation.
2 CFR 25.110	CCR/DUNS requirement.

§ 1303.4 Federal financial assistance, non-federal match, and waiver requirements.

In accordance with section 640(b) of the Act, federal financial assistance to a grantee will not exceed 80 percent of the approved total program costs. A grantee must contribute 20 percent as non-federal match each budget period. The responsible HHS official may approve a waiver of all or a portion of the non-federal match requirement on the basis of the grantee’s written application submitted for the budget period and any supporting evidence the responsible HHS official requires. In deciding whether to grant a waiver, the responsible HHS official will consider the circumstances specified at section 640(b) of the Act and whether the grantee has made a reasonable effort to comply with the non-federal match requirement.

§ 1303.5 Limitations on development and administrative costs.

(a) *Limitations.* (1) Costs to develop and administer a program cannot be excessive or exceed 15 percent of the total approved program costs. Allowable costs to develop and administer a Head Start program cannot exceed 15 percent of the total approved program costs, which includes both federal costs and non-federal match, unless the responsible HHS official grants a waiver under paragraph (b) of this section that approves a higher percentage in order to carry out the purposes of the Act.

(2) To assess total program costs and determine whether a grantee meets this requirement, the grantee must:

(i) Determine the costs to develop and administer its program, including the local costs of necessary resources;

(ii) Categorize total costs as development and administrative or program costs;

(iii) Identify and allocate the portion of dual benefits costs that are for development and administration;

(iv) Identify and allocate the portion of indirect costs that are for development and administration versus program costs; and,

(v) Delineate all development and administrative costs in the grant application and calculate the percentage of total approved costs allocated to development and administration.

(b) *Waivers.* (1) The responsible HHS official may grant a waiver for each budget period if a delay or disruption to program services is caused by circumstances beyond the agency’s control, or if an agency is unable to administer the program within the 15 percent limitation and if the agency can demonstrate efforts to reduce its development and administrative costs.

(2) If at any time within the grant funding cycle, a grantee estimates development and administration costs will exceed 15 percent of total approved costs, it must submit a waiver request to the responsible HHS official that explains why costs exceed the limit, that indicates the time period the waiver will cover, and that describes what the grantee will do to reduce its development and administrative costs to comply with the 15 percent limit after the waiver period.

Subpart B—Administrative Requirements

§ 1303.10 Purpose.

A grantee must observe standards of organization, management, and administration that will ensure, so far as

reasonably possible, that all program activities are conducted in a manner consistent with the purposes of the Act and the objective of providing assistance effectively, efficiently, and free of any taint of partisan political bias or personal or family favoritism.

§ 1303.11 Limitations and prohibitions.

An agency must adhere to sections 644(e), 644(g)(3), 653, 654, 655, 656, and 657A of the Act. These sections pertain to union organizing, the Davis-Bacon Act, limitations on compensation, nondiscrimination, unlawful activities, political activities, and obtaining parental consent.

§ 1303.12 Insurance and bonding.

An agency must have an ongoing process to identify risks and have cost-effective insurance for those identified risks; a grantee must require the same for its delegates. The agency must specifically consider the risk of accidental injury to children while participating in the program. The grantee must submit proof of appropriate coverage in its initial application for funding. The process of identifying risks must also consider the risk of losses resulting from fraudulent acts by individuals authorized to disburse Head Start funds. Consistent with 45 CFR part 75, if the agency lacks sufficient coverage to protect the federal government’s interest, the agency must maintain adequate fidelity bond coverage.

Subpart C—Protections for the Privacy of Child Records

§ 1303.20 Establishing procedures.

A program must establish procedures to protect the confidentiality of any

personally identifiable information (PII) in child records.

§ 1303.21 Program procedures—applicable confidentiality provisions.

(a) If a program is an educational agency or institution that receives funds under a program administered by the Department of Education and therefore is subject to the confidentiality provisions under the Family Educational Rights and Privacy Act (FERPA), then it must comply with those confidentiality provisions of FERPA instead of the provisions in this subpart.

(b) If a program serves a child who is referred to, or found eligible for services under, IDEA, then a program must comply with the applicable confidentiality provisions in Part B or Part C of IDEA to protect the PII in records of those children, and, therefore, the provisions in this subpart do not apply to those children.

§ 1303.22 Disclosures with, and without, parental consent.

(a) *Disclosure with parental consent.*

(1) Subject to the exceptions in paragraphs (b) and (c) of this section, the procedures to protect PII must require the program to obtain a parent's written consent before the program may disclose such PII from child records.

(2) The procedures to protect PII must require the program to ensure the parent's written consent specifies what child records may be disclosed, explains why the records will be disclosed, and identifies the party or class of parties to whom the records may be disclosed. The written consent must be signed and dated.

(3) "Signed and dated written consent" under this part may include a record and signature in electronic form that:

(i) Identifies and authenticates a particular person as the source of the electronic consent; and,

(ii) Indicates such person's approval of the information.

(4) The program must explain to the parent that the granting of consent is voluntary on the part of the parent and may be revoked at any time. If a parent revokes consent, that revocation is not retroactive and therefore it does not apply to an action that occurred before the consent was revoked.

(b) *Disclosure without parental consent but with parental notice and opportunity to refuse.* The procedures to protect PII must allow the program to disclose such PII from child records without parental consent if the program notifies the parent about the disclosure, provides the parent, upon the parent's

request, a copy of the PII from child records to be disclosed in advance, and gives the parent an opportunity to challenge and refuse disclosure of the information in the records, before the program forwards the records to officials at a program, school, or school district in which the child seeks or intends to enroll or where the child is already enrolled so long as the disclosure is related to the child's enrollment or transfer.

(c) *Disclosure without parental consent.* The procedures to protect PII must allow the program to disclose such PII from child records without parental consent to:

(1) Officials within the program or acting for the program, such as contractors and subrecipients, if the official provides services for which the program would otherwise use employees, the program determines it is necessary for Head Start services, and the program maintains oversight with respect to the use, further disclosure, and maintenance of child records, such as through a written agreement;

(2) Officials within the program, acting for the program, or from a federal or state entity, in connection with an audit or evaluation of education or child development programs, or for enforcement of or compliance with federal legal requirements of the program; provided the program maintains oversight with respect to the use, further disclosure, and maintenance of child records, such as through a written agreement, including the destruction of the PII when no longer needed for the purpose of the disclosure, except when the disclosure is specifically authorized by federal law or by the responsible HHS official;

(3) Officials within the program, acting for the program, or from a federal or state entity, to conduct a study to improve child and family outcomes, including improving the quality of programs, for, or on behalf of, the program, provided the program maintains oversight with respect to the use, further disclosure, and maintenance of child records, such as through a written agreement, including the destruction of the PII when no longer needed for the purpose of the disclosure;

(4) Appropriate parties in order to address a disaster, health or safety emergency during the period of the emergency, or a serious health and safety risk such as a serious food allergy, if the program determines that disclosing the PII from child records is necessary to protect the health or safety of children or other persons;

(5) Comply with a judicial order or lawfully issued subpoena, provided the program makes a reasonable effort to notify the parent about all such subpoenas and court orders in advance of the compliance therewith, unless:

(i) A court has ordered that neither the subpoena, its contents, nor the information provided in response be disclosed;

(ii) The disclosure is in compliance with an ex parte court order obtained by the United States Attorney General (or designee not lower than an Assistant Attorney General) concerning investigations or prosecutions of an offense listed in 18 U.S.C. 2332b(g)(5)(B) or an act of domestic or international terrorism as defined in 18 U.S.C. 2331.

(iii) A parent is a party to a court proceeding directly involving child abuse and neglect (as defined in section 3 of the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101)) or dependency matters, and the order is issued in the context of that proceeding, additional notice to the parent by the program is not required; or,

(iv) A program initiates legal action against a parent or a parent initiates legal action against a program, then a program may disclose to the court, also without a court order or subpoena, the child records relevant for the program to act as plaintiff or defendant.

(6) The Secretary of Agriculture or an authorized representative from the Food and Nutrition Service to conduct program monitoring, evaluations, and performance measurements for the Child and Adult Care Food Program under the Richard B. Russell National School Lunch Act or the Child Nutrition Act of 1966, if the results will be reported in an aggregate form that does not identify any individual: Provided, that any data collected must be protected in a manner that will not permit the personal identification of students and their parents by other than the authorized representatives of the Secretary of Agriculture and any PII must be destroyed when the data are no longer needed for program monitoring, evaluations, and performance measurements;

(7) A caseworker or other representative from a state, local, or tribal child welfare agency, who has the right to access a case plan for a child who is in foster care placement, when such agency is legally responsible for the child's care and protection, under state or tribal law, if the agency agrees in writing to protect PII, to use information from the child's case plan for specific purposes intended of addressing the child's needs, and to

destroy information that is no longer needed for those purposes; and,

(8) Appropriate parties in order to address suspected or known child maltreatment and is consistent with applicable federal, state, local, and tribal laws on reporting child abuse and neglect.

(d) *Written agreements.* When a program establishes a written agreement with a third party, the procedures to protect such PII must require the program to annually review and, if necessary, update the agreement. If the third party violates the agreement, then the program may:

(1) Provide the third party an opportunity to self-correct; or,

(2) Prohibit the third party from access to records for a set period of time as established by the programs governing body and policy council.

(e) *Annual notice.* The procedures to protect PII must require the program to annually notify parents of their rights in writing described in this subpart and applicable definitions in part 1305 of this chapter, and include in that notice a description of the types of PII that may be disclosed, to whom the PII may be disclosed, and what may constitute a necessary reason for the disclosure without parental consent as described in paragraph (c) of this section.

(f) *Limit on disclosing PII.* A program must only disclose the information that is deemed necessary for the purpose of the disclosure.

§ 1303.23 Parental rights.

(a) *Inspect record.* (1) A parent has the right to inspect child records.

(2) If the parent requests to inspect child records, the program must make the child records available within a reasonable time, but no more than 45 days after receipt of request.

(3) If a program maintains child records that contain information on more than one child, the program must ensure the parent only inspects information that pertains to the parent's child.

(4) The program shall not destroy a child record with an outstanding request to inspect and review the record under this section.

(b) *Amend record.* (1) A parent has the right to ask the program to amend information in the child record that the parent believes is inaccurate, misleading, or violates the child's privacy.

(2) The program must consider the parent's request and, if the request is denied, render a written decision to the parent within a reasonable time that informs the parent of the right to a hearing.

(c) *Hearing.* (1) If the parent requests a hearing to challenge information in the child record, the program must schedule a hearing within a reasonable time, notify the parent, in advance, about the hearing, and ensure the person who conducts the hearing does not have a direct interest in its outcome.

(2) The program must ensure the hearing affords the parent a full and fair opportunity to present evidence relevant to the issues.

(3) If the program determines from evidence presented at the hearing that the information in the child records is inaccurate, misleading, or violates the child's privacy, the program must either amend or remove the information and notify the parent in writing.

(4) If the program determines from evidence presented at the hearing that information in the child records is accurate, does not mislead, or otherwise does not violate the child's privacy, the program must inform the parent of the right to place a statement in the child records that either comments on the contested information or that states why the parent disagrees with the program's decision, or both.

(d) *Right to copy of record.* The program must provide a parent, free of charge, an initial copy of child records disclosed to third parties with parental consent and, upon parent request, an initial copy of child records disclosed to third parties, unless the disclosure was for a court that ordered neither the subpoena, its contents, nor the information furnished in response be disclosed.

(e) *Right to inspect written agreements.* A parent has the right to review any written agreements with third parties.

§ 1303.24 Maintaining records.

(a) A program must maintain child records in a manner that ensures only parents, and officials within the program or acting on behalf of the program have access, and such records must be destroyed within a reasonable timeframe after such records are no longer needed or required to be maintained.

(b) A program must maintain, with the child records, for as long as the records are maintained, information on all individuals, agencies, or organizations to whom a disclosure of PII from the child records was made (except for program officials and parents) and why the disclosure was made. If a program uses a web-based data system to maintain child records, the program must ensure such child records are adequately protected and

maintained according to current industry security standards.

(c) If a parent places a statement in the child record, the program must maintain the statement with the contested part of the child record for as long as the program maintains the record and, disclose the statement whenever it discloses the portion of the child record to which the statement relates.

Subpart D—Delegation of Program Operations

§ 1303.30 Grantee responsibility and accountability.

A grantee is accountable for the services its delegate agencies provide. The grantee supports, oversees and ensures delegate agencies provide high-quality services to children and families and meet all applicable Head Start requirements. The grantee can only terminate a delegate agency if the grantee shows cause why termination is necessary and provides a process for delegate agencies to appeal termination decisions. The grantee retains legal responsibility and authority and bears financial accountability for the program when services are provided by delegate agencies.

§ 1303.31 Determining and establishing delegate agencies.

(a) If a grantee enters into an agreement with another entity to serve children, the grantee must determine whether the agreement meets the definition of "delegate agency" in section 637(3) of the Act.

(b) A grantee must not award a delegate agency federal financial assistance unless there is a written agreement and the responsible HHS official approves the agreement before the grantee delegates program operations.

§ 1303.32 Evaluations and corrective actions for delegate agencies.

A grantee must evaluate and ensure corrective action for delegate agencies according to section 641A(d) of the Act.

§ 1303.33 Termination of delegate agencies.

(a) If a grantee shows cause why termination is appropriate or demonstrates cost effectiveness, the grantee may terminate a delegate agency's contract.

(b) The grantee's decision to terminate must not be arbitrary or capricious.

(c) The grantee must establish a process for defunding a delegate agency, including an appeal of a defunding decision and must ensure the process is fair and timely.

(d) The grantee must notify the responsible HHS official about the appeal and its decision.

Subpart E—Facilities

§ 1303.40 Purpose.

This subpart prescribes what a grantee must establish to show it is eligible to purchase, construct and renovate facilities as outlined in section 644(c), (f) and (g) of the Act. It explains how a grantee may apply for funds, details what measures a grantee must take to protect federal interest in facilities purchased, constructed or renovated with grant funds, and concludes with other administrative provisions. This subpart applies to major renovations. It only applies to minor renovations and repairs, when they are included with a purchase application and are part of purchase costs.

§ 1303.41 Approval of previously purchased facilities.

If a grantee purchased a facility after December 31, 1986, and seeks to use grant funds to continue to pay purchase costs for the facility or to refinance current indebtedness and use grant funds to service the resulting debt, the grantee may apply for funds to meet those costs. The grantee must submit an application that conforms to requirements in this part and in the Act to the responsible HHS official. If the responsible HHS official approves the grantee's application, Head Start funds may be used to pay ongoing purchase costs, which include principal and interest on approved loans.

§ 1303.42 Eligibility to purchase, construct, and renovate facilities.

(a) *Preliminary eligibility.* (1) Before a grantee can apply for funds to purchase, construct, or renovate a facility under § 1303.44, it must establish that:

(i) The facility will be available to Indian tribes, or rural or other low-income communities;

(ii) The proposed purchase, construction or major renovation is within the grantee's designated service area; and,

(iii) The proposed purchase, construction or major renovation is necessary because the lack of suitable facilities in the grantee's service area will inhibit the operation of the program.

(2) If a program applies to construct a facility, that the construction of such facilities is more cost-effective than the purchase of available facilities or renovation.

(b) *Proving a lack of suitable facilities.* To satisfy paragraph (a)(1)(iii) of this section, the grantee must have a written

statement from an independent real estate professional familiar with the commercial real estate market in the grantee's service area, that includes factors considered and supports how the real estate professional determined there are no other suitable facilities in the area.

§ 1303.43 Use of grant funds to pay fees.

A grantee may submit a written request to the responsible HHS official for reasonable fees and costs necessary to determine preliminary eligibility under § 1303.42 before it submits an application under § 1303.44. If the responsible HHS official approves the grantee's application, the grantee may use federal funds to pay fees and costs.

§ 1303.44 Applications to purchase, construct, and renovate facilities.

(a) *Application requirements.* If a grantee is preliminarily eligible under § 1303.42 to apply for funds to purchase, construct, or renovate a facility, it must submit to the responsible HHS official:

(1) A statement that explains the anticipated effect the proposed purchase, construction or renovation has had or will have on program enrollment, activities and services, and how it determined what the anticipated effect would be;

(2) A deed or other document showing legal ownership of the real property where facilities activity is proposed, legal description of the facility site, and an explanation why the location is appropriate for the grantee's service area;

(3) Plans and specifications for the facility, including square footage, structure type, the number of rooms the facility will have or has, how the rooms will be used, where the structure will be positioned or located on the building site, and whether there is space available for outdoor play and for parking;

(4) Certification by a licensed engineer or architect that the facility is, or will be upon completion, structurally sound and safe for use as a Head Start facility and that the facility complies, or will comply upon completion, with local building codes, applicable child care licensing requirements, the accessibility requirements of the Americans with Disabilities Act, section 504 of the Rehabilitation Act of 1973, the Flood Disaster Protection Act of 1973, and the National Historic Preservation Act of 1966;

(5) A description of proposed renovations or repairs to make the facility suitable for program activities, and plans and specification that

describe the facility after renovation or repair;

(6) A proposed schedule that details when the grantee will acquire, renovate, repair and occupy the facility;

(7) An estimate by a licensed independent certified appraiser of the facility's fair market value after proposed purchase and associated repairs and renovations construction, or major renovation is completed is required for all facilities activities except for major renovations to leased property;

(8) The cost comparison described in § 1303.45;

(9) A statement that shows what share of the purchase, construction, or major renovation will be paid with grant funds and what the grantee proposes to contribute as a nonfederal match to the purchase, construction or major renovation;

(10) A statement from a lender, if a grantee applies to use Head Start funds to continue purchase on a facility or refinance existing debt on a facility that indicates the lender is willing to comply with § 1303.49;

(11) The terms of any proposed or existing loan(s) related to purchase, construction or major renovation of the facility, including copies of any funding commitment letters, mortgages, promissory notes, potential security agreements to be entered into, information on all other sources of funding, construction or major renovation, and any restrictions or conditions imposed by other funding sources;

(12) A Phase I environmental site assessment that describes the environmental condition of the proposed facility site and any structures on the site;

(13) A description of the efforts by the grantee to coordinate or collaborate with other providers in the community to seek assistance, including financial assistance, prior to the use of funds under this section; and,

(14) Any additional information the responsible HHS official may require.

(b) *Additional requirements for leased properties.* (1) If a grantee applies to renovate leased property, it must submit to the responsible HHS official information described in paragraph (a) of this section, a copy of the existing or proposed lease agreement, and the landlord or lessor's consent.

(2) If a grantee applies to purchase a modular unit it intends to site on leased property or on other property the grantee does not own, the grantee must submit to the responsible HHS official information described in paragraph (a) of this section and a copy of the

proposed lease or other occupancy agreement that will allow the grantee access to the modular unit for at least 15 years.

(c) *Non-federal match.* Any non-federal match associated with facilities activities becomes part of the federal share of the facility.

§ 1303.45 Cost-comparison to purchase, construct, and renovate facilities.

(a) *Cost comparison.* (1) If a grantee proposes to purchase, construct, or renovate a facility, it must submit a detailed cost estimate of the proposed activity, compare the costs associated with the proposed activity to other available alternatives in the service area, and provide any additional information the responsible HHS official requests. The grantee must demonstrate that the proposed activity will result in savings when compared to the costs that would be incurred to acquire the use of an alternative facility to carry out program.

(2) In addition to requirements in paragraph (a)(1) of this section, the grantee must:

- (i) Identify who owns the property;
- (ii) List all costs related to the purchase, construction, or renovation;
- (iii) Identify costs over the structure's useful life, which is at least 20 years for a facility that the grantee purchased or constructed and at least 15 years for a modular unit the grantee renovated, and deferred costs, including mortgage balloon payments, as costs with associated due dates; and,
- (iv) Demonstrate how the proposed purchase, construction, or major renovation is consistent with program management and fiscal goals, community needs, enrollment and program options and how the proposed facility will support the grantee as it provides quality services to children and families.

(b) *Continue purchase or refinance.* To use funds to continue purchase on a facility or to refinance an existing indebtedness, the grantee must compare the costs of continued purchase against the cost of purchasing a comparable facility in the service area over the remaining years of the facility's useful life. The grantee must demonstrate that the proposed activity will result in savings when compared to the cost that would be incurred to acquire the use of an alternative facility to carry out the program.

(c) *Multi-purpose use.* If the grantee intends to use a facility to operate a Head Start program and for another purpose, it must disclose what percentage of the facility will be used for non-Head Start activities, along with costs associated with those activities, in

accordance with applicable cost principles.

§ 1303.46 Recording and posting notices of federal interest.

(a) *Survival of federal interest.* A grantee that receives funds under this subpart must file notices of federal interest as set forth in paragraph (b) of this section. Federal interest cannot be defeated by a grantee's failure to file a notice of federal interest.

(b) *Recording notices of federal interest.* (1) If a grantee uses federal funds to purchase real property or a facility, excluding modular units, appurtenant to real property, it must record a notice of federal interest in the official real property records for the jurisdiction where the facility is or will be located. The grantee must file the notice of federal interest as soon as it uses Head Start funds to either fully or partially purchase a facility or real property where a facility will be constructed or as soon as it receives permission from the responsible HHS official to use Head Start funds to continue purchase on a facility.

(2) If a grantee uses federal funds in whole or in part to construct a facility, it must record the notice of federal interest in the official real property records for the jurisdiction in which the facility is located as soon as it receives the notice of award to construct the facility.

(3) If a grantee uses federal funds to renovate a facility that it, or a third party owns, the grantee must record the notice of federal interest in the official real property records for the jurisdiction in which the facility is located as soon as it receives the notice of award to renovate the facility.

(4) If a grantee uses federal funds in whole or in part to purchase a modular unit or to renovate a modular unit, the grantee must post the notice of federal interest, in clearly visible locations, on the exterior of the modular unit and inside the modular unit.

§ 1303.47 Contents of notices of federal interest.

(a) *Facility and real property a grantee owns.* A notice of federal interest for a facility, other than a modular unit, and real property the grantee owns or will own, must include:

- (1) The grantee's correct legal name and current mailing address;
- (2) A legal description of the real property;
- (3) Grant award number, amount and date of initial facilities funding award or initial use of base grant funds for ongoing purchase or mortgage payments;

(4) A statement that the notice of federal interest includes funds awarded in grant award(s) and any Head Start funds subsequently used to purchase, construct or to make major renovations to the real property;

(5) A statement that the facility and real property will only be used for purposes consistent with the Act and applicable Head Start regulations;

(6) A statement that the facility and real property will not be mortgaged or used as collateral, sold or otherwise transferred to another party, without the responsible HHS official's written permission;

(7) A statement that the federal interest cannot be subordinated, diminished, nullified or released through encumbrance of the property, transfer of the property to another party or any other action the grantee takes without the responsible HHS official's written permission;

(8) A statement that confirms that the agency's governing body received a copy of the notice of federal interest prior to filing and the date the governing body was provided with a copy; and,

(9) The name, title, and signature of the person who drafted the notice.

(b) *Facility leased by a grantee.* (1) A notice of federal interest for a leased facility, excluding a modular unit, on land the grantee does not own, must be recorded in the official real property records for the jurisdiction where the facility is located and must include:

- (i) The grantee's correct legal name and current mailing address;
- (ii) A legal description of affected real property;
- (iii) The grant award number, amount and date of initial funding award or initial use of base grant funds for major renovation;
- (iv) Acknowledgement that the notice of federal interest includes any Head Start funds subsequently used to make major renovations on the affected real property;
- (v) A statement the facility and real property will only be used for purposes consistent with the Act and applicable Head Start regulations; and,
- (vi) A lease or occupancy agreement that includes the required information from paragraphs (b)(1)(i) through (v) of this section may be recorded in the official real property records for the jurisdiction where the facility is located to serve as a notice of federal interest.

(2) If a grantee cannot file the lease or occupancy agreement described in paragraph (b)(1)(vi) of this section in the official real property records for the jurisdiction where the facility is located, it may file an abstract. The abstract must include the names and addresses of

parties to the lease or occupancy agreement, terms of the lease or occupancy agreement, and information described in paragraphs (a)(1) through (9) of this section.

(c) *Modular units.* A notice of federal interest on a modular unit the grantee purchased or renovated must be visible and clearly posted on the exterior of the modular and inside the modular and must include:

(1) The grantee's correct legal name and current mailing address;

(2) The grant award number, amount and date of initial funding award or initial use of base grant funds to purchase or renovate;

(3) A statement that the notice of federal interest includes any Head Start funds subsequently used for major renovations to the modular unit;

(4) A statement that the facility and real property will only be used for purposes consistent with the Act and applicable Head Start regulations;

(5) A statement that the modular unit will not be mortgaged or used as collateral, sold or otherwise transferred to another party, without the responsible HHS official's written permission;

(6) A statement that the federal interest cannot be subordinated, diminished, nullified or released through encumbrance of the property, transfer to another party, or any other action the grantee takes without the responsible HHS official's written permission;

(7) A statement that the modular unit cannot be moved to another location without the responsible HHS official's written permission;

(8) A statement that confirms that the agency's governing body has received a copy of the filed notice of federal interest and the date the governing body was provided with a copy; and,

(9) The name, title, and signature of the person who completed the notice for the grantee agency.

§ 1303.48 Grantee limitations on federal interest.

(a) A grantee cannot mortgage, use as collateral for a credit line or for other loan obligations, or, sell or transfer to another party, a facility, real property, or a modular unit it has purchased, constructed or renovated with Head Start funds, without the responsible HHS official's written permission.

(b) A grantee must have the responsible HHS official's written permission before it can use real property, a facility, or a modular unit subject to federal interest for a purpose other than that for which the grantee's application was approved.

§ 1303.49 Protection of federal interest in mortgage agreements.

(a) Any mortgage agreement or other security instrument that is secured by real property or a modular unit constructed or purchased in whole or in part with federal funds or subject to renovation with federal funds must:

(1) Specify that the responsible HHS official can intervene in case the grantee defaults on, terminates or withdraws from the agreement;

(2) Designate the responsible HHS official to receive a copy of any notice of default given to the grantee under the terms of the agreement and include the regional grants management officer's current address;

(3) Include a clause that requires any action to foreclose the mortgage agreement or security agreement be suspended for 60 days after the responsible HHS official receives the default notice to allow the responsible HHS official reasonable time to respond;

(4) Include a clause that preserves the notice of federal interest and the grantee's obligation for its federal share if the responsible HHS official fails to respond to any notice of default provided under this section;

(5) Include a statement that requires the responsible HHS official to be paid the federal interest before foreclosure proceeds are paid to the lender, unless the official's rights under the notice of federal interest have been subordinated by a written agreement in conformance with § 1303.51;

(6) Include a clause that gives the responsible HHS official the right to cure any default under the agreement within the designated period to cure the default; and,

(7) Include a clause that gives the responsible HHS official the right to assign or transfer the agreement to another interim or permanent grantee.

(b) A grantee must immediately notify the responsible HHS official of any default under an agreement described in paragraph (a) of this section.

§ 1303.50 Third party leases and occupancy arrangements.

(a) After November 7, 2016, if a grantee receives federal funds to purchase, construct or renovate a facility on real property the grantee does not own or to purchase or renovate a modular unit on real property the grantee does not own, the grantee must have a lease or other occupancy agreement of at least 30 years for purchase or construction of a facility and at least 15 years for a major renovation or placement of a modular unit.

(b) The lease or occupancy agreement must:

(1) Provide for the grantee's right of continued use and occupancy of the leased or occupied premises during the entire term of the lease;

(2) Designate the regional grants management officer to receive a copy of any notice of default given to the grantee under the terms of the agreement and include the regional grants management officer's current address;

(3) Specify that the responsible HHS official has the right to cure any default under the lease or occupancy agreement within the designated period to cure default; and,

(4) Specify that the responsible HHS official has the right to transfer the lease to another interim or replacement grantee.

§ 1303.51 Subordination of the federal interest.

Only the responsible HHS official can subordinate federal interest to the rights of a lender or other third party. Subordination agreements must be in writing and the mortgage agreement or security agreement for which subordination is requested must comply with § 1303.49. When the amount of federal funds already contributed to the facility exceeds the amount to be provided by the lender seeking subordination, the federal interest may only be subordinated if the grantee can show that funding is not available without subordination of the federal interest.

§ 1303.52 Insurance, bonding, and maintenance.

(a) *Purpose.* If a grantee uses federal funds to purchase or continue purchase on a facility, excluding modular units, the grantee must obtain a title insurance policy for the purchase price that names the responsible HHS official as an additional loss payee.

(b) *Insurance coverage.* (1) If a grantee uses federal funds to purchase or continue purchase on a facility or modular unit the grantee must maintain physical damage or destruction insurance at the full replacement value of the facility, for as long as the grantee owns or occupies the facility.

(2) If a facility is located in an area the National Flood Insurance Program defines as high risk, the grantee must maintain flood insurance for as long as the grantee owns or occupies the facility.

(3) A grantee must submit to the responsible HHS official, within 10 days after coverage begins, proof of insurance coverage required under paragraphs (a) and (b) of this section.

(c) *Maintenance.* A grantee must keep all facilities purchased or constructed in whole or in part with Head Start funds in good repair in accordance with all applicable federal, state, and local laws, rules and regulations, including Head Start requirements, zoning requirements, building codes, health and safety regulations and child care licensing standards.

§ 1303.53 Copies of documents.

A grantee must submit to the responsible HHS official, within 10 days after filing or execution, copies of deeds, leases, loan instruments, mortgage agreements, notices of federal interest, and other legal documents related to the use of Head Start funds for purchase, construction, major renovation, or the discharge of any debt secured by the facility.

§ 1303.54 Record retention.

A grantee must retain records pertinent to the lease, purchase, construction or renovation of a facility funded in whole or in part with Head Start funds, for as long as the grantee owns or occupies the facility, plus three years.

§ 1303.55 Procurement procedures.

(a) A grantee must comply with all grants management regulations, including specific regulations applicable to transactions in excess of the current simplified acquisition threshold, cost principles, and its own procurement procedures, and must provide, to the maximum extent practical, open and full competition.

(b) A grantee must obtain the responsible HHS official's written approval before it uses Head Start funds, in whole or in part, to contract construction or renovation services. The grantee must ensure these contracts are paid on a lump sum fixed-price basis.

(c) A grantee must obtain prior written approval from the responsible HHS official for contract modifications that would change the scope or objective of a project or would materially alter the costs, by increasing the amount of grant funds needed to complete the project.

(d) A grantee must ensure all construction and renovation contracts paid, in whole or in part with Head Start funds contain a clause that gives the responsible HHS official or his or her designee access to the facility, at all reasonable times, during construction and inspection.

§ 1303.56 Inspection of work.

The grantee must submit to the responsible HHS official a final facility

inspection report by a licensed engineer or architect within 30 calendar days after the project is completed. The inspection report must certify that the facility complies with local building codes, applicable child care licensing requirements, is structurally sound and safe for use as a Head Start facility, complies with the access requirements of the Americans with Disabilities Act, section 504 of the Rehabilitation Act, and the Flood Disaster Protection Act of 1973, and complies with National Historic Preservation Act of 1966.

Subpart F—Transportation

§ 1303.70 Purpose.

(a) *Applicability.* This rule applies to all agencies, including those that provide transportation services, with the exceptions and exclusions provided in this section, regardless of whether such transportation is provided directly on agency owned or leased vehicles or through arrangement with a private or public transportation provider.

(b) *Providing transportation services.*

(1) If a program does not provide transportation services, either for all or a portion of the children, it must provide reasonable assistance, such as information about public transit availability, to the families of such children to arrange transportation to and from its activities, and provide information about these transportation options in recruitment announcements.

(2) A program that provides transportation services must make reasonable efforts to coordinate transportation resources with other human services agencies in its community in order to control costs and to improve the quality and the availability of transportation services.

(3) A program that provides transportation services must ensure all accidents involving vehicles that transport children are reported in accordance with applicable state requirements.

(c) *Waiver.* (1) A program that provides transportation services must comply with all provisions in this subpart. A Head Start program may request to waive a specific requirement in this part, in writing, to the responsible HHS official, as part of an agency's annual application for financial assistance or amendment and must submit any required documentation the responsible HHS official deems necessary to support the waiver. The responsible HHS official is not authorized to waive any requirements with regard to children enrolled in an Early Head Start program. A program may request a waiver when:

(i) Adherence to a requirement in this part would create a safety hazard in the circumstances faced by the agency; and,

(ii) For preschool children, compliance with requirements related to child restraint systems at §§ 1303.71(d) and 1303.72(a)(1) or bus monitors at § 1303.72(a)(4) will result in a significant disruption to the program and the agency demonstrates that waiving such requirements is in the best interest of the children involved.

(2) The responsible HHS official is not authorized to waive any requirements of the Federal Motor Vehicle Safety Standards (FMVSS) made applicable to any class of vehicle under 49 CFR part 571.

§ 1303.71 Vehicles.

(a) *Required use of schools buses or allowable alternative vehicles.* A program, with the exception of transportation services to children served under a home-based option, must ensure all vehicles used or purchased with grant funds to provide transportation services to enrolled children are school buses or allowable alternate vehicles that are equipped for use of height- and weight-appropriate child restraint systems, and that have reverse beepers.

(b) *Emergency equipment.* A program must ensure each vehicle used in providing such services is equipped with an emergency communication system clearly labeled and appropriate emergency safety equipment, including a seat belt cutter, charged fire extinguisher, and first aid kit.

(c) *Auxiliary seating.* A program must ensure any auxiliary seating, such as temporary or folding jump seats, used in vehicles of any type providing such services are built into the vehicle by the manufacturer as part of its standard design, are maintained in proper working order, and are inspected as part of the annual inspection required under paragraph (e)(2)(i) of this section.

(d) *Child restraint systems.* A program must ensure each vehicle used to transport children receiving such services is equipped for use of age-, height- and weight-appropriate child safety restraint systems as defined in part 1305 of this chapter.

(e) *Vehicle maintenance.* (1) A program must ensure vehicles used to provide such services are in safe operating condition at all times.

(2) The program must:

(i) At a minimum, conduct an annual thorough safety inspection of each vehicle through an inspection program licensed or operated by the state;

(ii) Carry out systematic preventive maintenance on vehicles; and,

(iii) Ensure each driver implements daily pre-trip vehicle inspections.

(f) *New vehicle inspection.* A program must ensure bid announcements for school buses and allowable alternate vehicles to transport children in its program include correct specifications and a clear statement of the vehicle's intended use. The program must ensure vehicles are examined at delivery to ensure they are equipped in accordance with the bid specifications and that the manufacturer's certification of compliance with the applicable FMVSS is included with the vehicle.

§ 1303.72 Vehicle operation.

(a) *Safety.* A program must ensure:

(1) Each child is seated in a child restraint system appropriate to the child's age, height, and weight;

(2) Baggage and other items transported in the passenger compartment are properly stored and secured, and the aisles remain clear and the doors and emergency exits remain unobstructed at all times;

(3) Up-to-date child rosters and lists of the adults each child is authorized to be released to, including alternates in case of emergency, are maintained and no child is left behind, either at the classroom or on the vehicle at the end of the route; and,

(4) With the exception of transportation services to children served under a home-based option, there is at least one bus monitor on board at all times, with additional bus monitors provided as necessary.

(b) *Driver qualifications.* A program, with the exception of transportation services to children served under a home-based option, must ensure drivers, at a minimum:

(1) In states where such licenses are granted, have a valid Commercial Driver's License (CDL) for vehicles in the same class as the vehicle the driver will operating; and,

(2) Meet any physical, mental, and other requirements as necessary to perform job-related functions with any necessary reasonable accommodations.

(c) *Driver application review.* In addition to the applicant review process prescribed § 1302.90(b) of this chapter, a program, with the exception of transportation services to children served under a home-based option, must ensure the applicant review process for drivers includes, at minimum:

(1) Disclosure by the applicant of all moving traffic violations, regardless of penalty;

(2) A check of the applicant's driving record through the appropriate state agency, including a check of the

applicant's record through the National Driver Register, if available;

(3) A check that drivers qualify under the applicable driver training requirements in the state or tribal jurisdiction; and,

(4) After a conditional employment offer to the applicant and before the applicant begins work as a driver, a medical examination, performed by a licensed doctor of medicine or osteopathy, establishing that the individual possesses the physical ability to perform any job-related functions with any necessary accommodations.

(d) *Driver training.* (1) A program must ensure any person employed as a driver receives training prior to transporting any enrolled child and receives refresher training each year.

(2) Training must include:

(i) Classroom instruction and behind-the-wheel instruction sufficient to enable the driver to operate the vehicle in a safe and efficient manner, to safely run a fixed route, to administer basic first aid in case of injury, and to handle emergency situations, including vehicle evacuation, operate any special equipment, such as wheelchair lifts, assistance devices or special occupant restraints, conduct routine maintenance and safety checks of the vehicle, and maintain accurate records as necessary; and,

(ii) Instruction on the topics listed in § 1303.75 related to transportation services for children with disabilities.

(3) A program must ensure the annual evaluation of each driver of a vehicle used to provide such services includes an on-board observation of road performance.

(e) *Bus monitor training.* A program must train each bus monitor before the monitor begins work, on child boarding and exiting procedures, how to use child restraint systems, completing any required paperwork, how to respond to emergencies and emergency evacuation procedures, how to use special equipment, child pick-up and release procedures, how to conduct and pre- and post-trip vehicle checks. Bus monitors are also subject to staff safety training requirements in § 1302.47(b)(4) of this chapter including Cardio Pulmonary Resuscitation (CPR) and first aid.

§ 1303.73 Trip routing.

(a) A program must consider safety of the children it transports when it plans fixed routes.

(b) A program must also ensure:

(1) The time a child is in transit to and from the program must not exceed one hour unless there is no shorter route

available or any alternative shorter route is either unsafe or impractical;

(2) Vehicles are not loaded beyond maximum passenger capacity at any time;

(3) Drivers do not back up or make U-turns, except when necessary for safety reasons or because of physical barriers;

(4) Stops are located to minimize traffic disruptions and to afford the driver a good field of view in front of and behind the vehicle;

(5) When possible, stops are located to eliminate the need for children to cross the street or highway to board or leave the vehicle;

(6) Either a bus monitor or another adult escorts children across the street to board or leave the vehicle if curbside pick-up or drop off is impossible; and,

(7) Drivers use alternate routes in the case of hazardous conditions that could affect the safety of the children who are being transported, such as ice or water build up, natural gas line breaks, or emergency road closing.

§ 1303.74 Safety procedures.

(a) A program must ensure children who receive transportation services are taught safe riding practices, safety procedures for boarding and leaving the vehicle and for crossing the street to and from the vehicle at stops, recognition of the danger zones around the vehicle, and emergency evacuation procedures, including participating in an emergency evacuation drill conducted on the vehicle the child will be riding.

(b) A program that provides transportation services must ensure at least two bus evacuation drills in addition to the one required under paragraph (a) of this section are conducted during the program year.

§ 1303.75 Children with disabilities.

(a) A program must ensure there are school buses or allowable alternate vehicles adapted or designed for transportation of children with disabilities available as necessary to transport such children enrolled in the program. This requirement does not apply to the transportation of children receiving home-based services unless school buses or allowable alternate vehicles are used to transport the other children served under the home-based option by the grantee. Whenever possible, children with disabilities must be transported in the same vehicles used to transport other children enrolled in the Head Start or Early Head Start program.

(b) A program must ensure special transportation requirements in a child's IEP or IFSP are followed, including special pick-up and drop-off

requirements, seating requirements, equipment needs, any assistance that may be required, and any necessary training for bus drivers and monitors.

PART 1304—FEDERAL ADMINISTRATIVE PROCEDURES

Subpart A—Monitoring, Suspension, Termination, Denial of Refunding, Reduction in Funding, and Their Appeals

Sec.

- 1304.1 Purpose.
- 1304.2 Monitoring.
- 1304.3 Suspension with notice.
- 1304.4 Emergency suspension without advance notice.
- 1304.5 Termination and denial of refunding.
- 1304.6 Appeal for prospective delegate agencies.
- 1304.7 Legal fees.

Subpart B—Designation Renewal

- 1304.10 Purpose and scope.
- 1304.11 Basis for determining whether a Head Start agency will be subject to an open competition.
- 1304.12 Grantee reporting requirements concerning certain conditions.
- 1304.13 Requirements to be considered for designation for a five-year period when the existing grantee in a community is not determined to be delivering a high-quality and comprehensive Head Start program and is not automatically renewed.
- 1304.14 Tribal government consultation under the Designation Renewal System for when an Indian Head Start grant is being considered for competition.
- 1304.15 Designation request, review and notification process.
- 1304.16 Use of CLASS: Pre-K instrument in the Designation Renewal System.

Subpart C—Selection of Grantees Through Competition

- 1304.20 Selection among applicants.

Subpart D—Replacement of American Indian and Alaska Native Grantees

- 1304.30 Procedure for identification of alternative agency.
- 1304.31 Requirements of alternative agency.
- 1304.32 Alternative agency—prohibition.

Subpart E—Head Start Fellows Program

- 1304.40 Purpose.
- 1304.41 Fellows Program.

Authority: 42 U.S.C. 9801 *et seq.*

Subpart A—Monitoring, Suspension, Termination, Denial of Refunding, Reduction in Funding, and Their Appeals

§ 1304.1 Purpose.

(a) Section 641A(c) of the Act requires the Secretary to monitor whether a grantee meets program governance, program operations, and financial and administrative standards described in this regulation and to identify areas for improvements and areas of strength as

part of the grantee's ongoing self-assessment process. This subpart focuses on the monitoring process. It discusses areas of noncompliance, deficiencies, and corrective action through quality improvement plans.

(b) Section 646(a) of the Act requires the Secretary to prescribe procedures for notice and appeal for certain adverse actions. This subpart establishes rules and procedures to suspend financial assistance to a grantee, deny a grantee's application for refunding, terminate, or reduce a grantee's assistance under the Act when the grantee improperly uses federal funds or fails to comply with applicable laws, regulations, policies, instructions, assurances, terms and conditions or, if the grantee loses its legal status or financial viability. This subpart does not apply to reductions to a grantee's financial assistance based on chronic under-enrollment procedures at section 641A(h) of the Act or to matters described in subpart B. This subpart does not apply to any administrative action based upon any violation, or alleged violation, of title VI of the Civil Rights Act of 1964. Except as otherwise provided for in this subpart, the appeals and processes in this subpart will be governed by the Departmental Appeals Board regulations at 45 CFR part 16.

§ 1304.2 Monitoring.

(a) *Areas of noncompliance.* If a responsible HHS official determines through monitoring, pursuant to section 641(A)(c)(1) and (2) of the Act, that a grantee fails to comply with any of the standards described in parts 1301, 1302, and 1303 of this chapter, the official will notify the grantee promptly in writing, identify the area of noncompliance, and specify when the grantee must correct the area of noncompliance.

(b) *Deficiencies.* If the Secretary determines that a grantee meets one of the criteria for a deficiency, as defined in section 637(2)(C) of the Act, the Secretary shall inform the grantee of the deficiency. The grantee must correct the deficiency pursuant to section 641A(e)(1)(B) of the Act, as the responsible HHS official determines.

(c) *Quality improvement plans.* If the responsible HHS official does not require the grantee to correct a deficiency immediately as prescribed under section 641A(e)(1)(B)(i) of the Act, the grantee must submit to the official, for approval, a quality improvement plan that adheres to section 641A(e)(2)(A) of the Act.

§ 1304.3 Suspension with notice.

(a) *Grounds to suspend financial assistance with notice.* If a grantee

breaches or threatens to breach any requirement stated in §§ 1304.3 through 1304.5, the responsible HHS official may suspend the grantee's financial assistance, in whole or in part, after it has given the grantee notice and an opportunity to show cause why assistance should not be suspended.

(b) *Notice requirements.* (1) The responsible HHS official must notify the grantee in writing that ACF intends to suspend financial assistance, in whole or in part. The notice must:

- (i) Specify grounds for the suspension;
- (ii) Include the date suspension will become effective;
- (iii) Inform the grantee that it has the opportunity to submit to the responsible HHS official, at least seven days before suspension becomes effective, any written material it would like the official to consider, and to inform the grantee that it may request, in writing, no later than seven days after the suspension notice was mailed, to have an informal meeting with the responsible HHS official;
- (iv) Invite the grantee to voluntarily correct the deficiency; and,
- (v) Include a copy of this subpart.

(2) The responsible HHS official must promptly transmit the suspension notice to the grantee. The notice becomes effective when the grantee receives the notice, when the grantee refuses delivery, or when the suspension notice is returned to sender unclaimed.

(3) The responsible HHS official must send a copy of the suspension notice to any delegate agency whose actions or whose failures to act substantially caused or contributed to the proposed suspension. The responsible HHS official will inform the delegate agency that it is entitled to submit written material to oppose the suspension and to participate in the informal meeting, if one is held. In addition, the responsible HHS official may give notice to the grantee's other delegate agencies.

(4) After the grantee receives the suspension notice, it has three days to send a copy of the notice to delegate agencies that would be financially affected by a suspension.

(c) *Opportunity to show cause.* The grantee may submit to the responsible HHS official any written material to show why financial assistance should not be suspended. The grantee may also request, in writing, to have an informal meeting with the responsible HHS official. If the grantee requests an informal meeting, the responsible HHS official must schedule the meeting within seven days after the grantee receives the suspension notice.

(d) *Extensions.* If the responsible HHS official extends the time or the date by which a grantee has to make requests or to submit material, it must notify the grantee in writing.

(e) *Decision.* (1) The responsible HHS official will consider any written material presented before or during the informal meeting, as well as any proof the grantee has adequately corrected what led to suspension, and will render a decision within five days after the informal meeting. If no informal meeting is held, the responsible HHS official will render a decision within five days after it receives written material from all concerned parties.

(2) If the responsible HHS official finds the grantee failed to show cause why ACF should not suspend financial assistance, the official may suspend financial assistance, in whole or in part, and under terms and conditions as he or she deems appropriate.

(3) A suspension must not exceed 30 days, unless the conditions under section 646(a)(5)(B) are applicable or the grantee requests the suspension continue for an additional period of time and the responsible HHS official agrees.

(4) The responsible HHS official may appoint an agency to serve as an interim grantee to operate the program until the grantee's suspension is lifted, or as otherwise provided under section 646(a)(5)(B) of the Act.

(f) *Obligations incurred during suspension.* New obligations the grantee incurs while under suspension are not allowed unless the responsible HHS official expressly authorizes them in the suspension notice or in an amendment to the suspension notice. Necessary and otherwise allowable costs which the grantee could not reasonably avoid during the suspension period will be allowed if they result from obligations the grantee properly incurred before suspension and not in anticipation of suspension or termination. The responsible HHS official may allow third-party in-kind contributions applicable to the suspension period to satisfy cost sharing or matching requirements.

(g) *Modify or rescind suspension.* The responsible HHS official may modify or rescind suspension at any time, if the grantee can satisfactorily show that it has adequately corrected what led to suspension and that it will not repeat such actions or inactions. Nothing in this section precludes the HHS official from imposing suspension again for additional 30 day periods if the cause of the suspension has not been corrected.

§ 1304.4 Emergency suspension without advance notice.

(a) *Grounds to suspend financial assistance without advance notice.* The responsible HHS official may suspend financial assistance, in whole or in part, without prior notice and an opportunity to show cause if there is an emergency situation, such as a serious risk for substantial injury to property or loss of project funds, a federal, state, or local criminal statute violation, or harm to staff or participants' health and safety.

(b) *Emergency suspension notification requirements.* (1) The emergency suspension notification must:

(i) Specify the grounds for the suspension;

(ii) Include terms and conditions of any full or partial suspension;

(iii) Inform that grantee it cannot make or incur any new expenditures or obligations under suspended portion of the program; and,

(iv) Advise that within five days after the emergency suspension becomes effective, the grantee may request, in writing, an informal meeting with the responsible HHS official to show why the basis for the suspension was not valid and should be rescinded and that the grantee has corrected any deficiencies.

(2) The responsible HHS official must promptly transmit the emergency suspension notification to the grantee that shows the date of receipt. The emergency suspension becomes effective upon delivery of the notification or upon the date the grantee refuses delivery, or upon return of the notification unclaimed.

(3) Within two workdays after the grantee receives the emergency suspension notification, the grantee must send a copy of the notice to delegate agencies affected by the suspension.

(4) The responsible HHS official must inform affected delegate agencies that they have the right to participate in the informal meeting.

(c) *Opportunity to show cause.* If the grantee requests an informal meeting, the responsible HHS official must schedule a meeting within five workdays after it receives the grantee's request. The suspension will continue until the grantee has been afforded such opportunity and until the responsible HHS official renders a decision.

Notwithstanding provisions in this section, the responsible HHS official may proceed to deny refunding or to initiate termination proceedings at any time even though the grantee's financial assistance has been suspended in whole or in part.

(d) *Decision.* (1) The responsible HHS official will consider any written material presented before or during the informal meeting, as well as any proof the grantee has adequately corrected what led to suspension, and render a decision within five work days after the informal meeting.

(2) If the responsible HHS official finds the grantee failed to show cause why suspension should be rescinded, the responsible HHS official may continue the suspension, in whole or in part, and under the terms and conditions specified in the emergency suspension notification.

(3) A suspension must not exceed 30 days, unless the conditions under section 646(a)(5)(B) are applicable or the grantee requests the suspension to continue for an additional period of time and the responsible HHS official agrees.

(4) The responsible HHS official may appoint an agency to serve as an interim grantee to operate the program until either the grantee's emergency suspension is lifted or a new grantee is selected.

(e) *Obligations incurred during suspension.* Any new obligations the grantee incurs during the suspension period will not be allowed unless the responsible HHS official expressly authorizes them in the suspension notice or in an amendment to the suspension notice. Necessary and otherwise allowable costs which the grantee could not reasonably avoid during the suspension period will be allowed if those costs result from obligations properly incurred before suspension and not in anticipation of suspension, denial of refunding or termination. The responsible HHS official may allow third-party in-kind contributions applicable to the suspension period to satisfy cost sharing or matching requirements.

(f) *Modify or rescind suspension.* The responsible HHS official may modify or rescind suspension at any time, if the grantee can satisfactorily show that it has adequately corrected what led to the suspension and that it will not repeat such actions or inactions. Nothing in this section precludes the HHS official from imposing suspension again for additional 30 day periods if the cause of the suspension has not been corrected.

§ 1304.5 Termination and denial of refunding.

(a) *Grounds to terminate financial assistance or deny a grantee's application for refunding.* (1) A responsible HHS official may terminate financial assistance in whole or in part

to a grantee or deny a grantee's application for refunding.

(2) The responsible HHS official may terminate financial assistance in whole or in part, or deny refunding to a grantee for any one or for all of the following reasons:

(i) The grantee is no longer financially viable;

(ii) The grantee has lost the requisite legal status or permits;

(iii) The grantee has failed to timely correct one or more deficiencies as defined in the Act;

(iv) The grantee has failed to comply with eligibility requirements;

(v) The grantee has failed to comply with the Head Start grants administration or fiscal requirements set forth in 45 CFR part 1303;

(vi) The grantee has failed to comply with requirements in the Act;

(vii) The grantee is debarred from receiving federal grants or contracts; or

(viii) The grantee has failed to abide by any other terms and conditions of its award of financial assistance, or any other applicable laws, regulations, or other applicable federal or state requirements or policies.

(b) *Notice requirements.* (1) The responsible HHS official will notify the grantee and such notice will:

(i) Include the legal basis for termination or adverse action as described in paragraph (a) of this section;

(ii) Include factual findings on which the action is based or reference specific findings in another document that form the basis for termination or denial of refunding;

(iii) Cite to any statutory provisions, regulations, or policy issuances on which ACF relies for its determination;

(iv) Inform the grantee that it may appeal the denial or termination within 30 days to the Departmental Appeals Board, that the appeal will be governed by 45 CFR part 16, except as otherwise provided in the Head Start appeals regulations, that a copy of the appeal must sent to the responsible HHS official, and that it has the right to request and receive a hearing, as mandated under section 646 of the Act;

(v) Inform the grantee that only its board of directors, or an official acting on the board's behalf can appeal the decision;

(vi) Name the delegate agency, if the actions of that delegate are the basis, in whole or in part, for the proposed action; and,

(vii) Inform the grantee that the appeal must meet requirements in paragraph (c) of this section; and, that if the responsible HHS official fails to meet requirements in this paragraph, the

pending action may be dismissed without prejudice or remanded to reissue it with corrections.

(2) The responsible HHS official must provide the grantee as much notice as possible, but must notify the grantee no later than 30 days after ACF receives the annual application for refunding, that it has the opportunity for a full and fair hearing on whether refunding should be denied.

(c) *Grantee's appeal.* (1) The grantee must adhere to procedures and requirements for appeals in 45 CFR part 16, file the appeal with the Departmental Appeals Board, and serve a copy of the appeal on the responsible HHS official who issued the termination or denial of refunding notice. The grantees must also serve a copy of its appeal on any affected delegate.

(2) Unless funding has been suspended, funding will continue while a grantee appeals a termination decision, unless the responsible HHS official renders an adverse decision, or unless the current budget period is expired. If the responsible HHS official has not rendered a decision by the end of the current budget period, the official will award the grantee interim funding until a decision is made or the project period ends.

(d) *Funding during suspension.* If a grantee's funding is suspended, the grantee will not receive funding during the termination proceedings, or at any other time, unless the action is rescinded or the grantee's appeal is successful.

(e) *Interim and replacement grantees.* The responsible HHS official may appoint an interim or replacement grantee as soon as a termination action is affirmed by the Departmental Appeals Board.

(f) *Opportunity to show cause.* (1) If the Departmental Appeals Board sets a hearing for a proposed termination or denial of refunding action, the grantee has five workdays to send a copy of the notice it receives from the Departmental Appeals Board, to all delegate agencies that would be financially affected by termination and to each delegate agency identified in the notice.

(2) The grantee must send to the Departmental Appeals Board and to the responsible HHS official a list of the delegate agencies it notified and the dates when it notified them.

(3) If the responsible HHS official initiated proceedings because of a delegate agency's activities, the official must inform the delegate agency that it may participate in the hearing. If the delegate agency chooses to participate in the hearing, it must notify the responsible HHS official in writing

within 30 days of the grantee's appeal. If any other delegate agency, person, agency or organization wishes to participate in the hearing, it may request permission to do so from the Departmental Appeals Board.

(4) If the grantee fails to appear at the hearing, without good cause, the grantee will be deemed to have waived its right to a hearing and consented to have the Departmental Appeals Board make a decision based on the parties' written information and argument.

(5) A grantee may waive the hearing and submit written information and argument for the record, within a reasonable period of time to be fixed by the Departmental Appeals Board.

(6) The responsible HHS official may attempt, either personally or through a representative, to resolve the issues in dispute by informal means prior to the hearing.

(g) *Decision.* The Departmental Appeals Board's decision and any measure the responsible HHS official takes after the decision is fully binding upon the grantee and its delegate agencies, whether or not they actually participated in the hearing.

§ 1304.6 Appeal for prospective delegate agencies.

(a) *Appeal.* If a grantee denies, or fails to act on, a prospective delegate agency's funding application, the prospective delegate may appeal the grantee's decision or inaction.

(b) *Process for prospective delegates.* To appeal, a prospective delegate must:

(1) Submits the appeal, including a copy of the funding application, to the responsible HHS official within 30 days after it receives the grantee's decision; or within 30 days after the grantee has had 120 days to review but has not notified the applicant of a decision; and,

(2) Provide the grantee with a copy of the appeal at the same time the appeal is filed with the responsible HHS official.

(c) *Process for grantees.* When an appeal is filed with the responsible HHS official, the grantee must respond to the appeal and submit a copy of its response to the responsible HHS official and to the prospective delegate agency within 30 work days.

(d) *Decision.* (1) The responsible HHS official will sustain the grantee's decision, if the official determines the grantee did not act arbitrarily, capriciously, or otherwise contrary to law, regulation, or other applicable requirements.

(2) The responsible HHS official will render a written decision to each party within a reasonable timeframe. The

official's decision is final and not subject to further appeal.

(3) If the responsible HHS official finds the grantee did act arbitrarily, capriciously, or otherwise contrary to law, regulation, or other applicable requirements, the grantee will be directed to reevaluate their applications.

§ 1304.7 Legal fees.

(a) An agency is not authorized to charge to its grant legal fees or other costs incurred to appeal terminations, reductions of funding, or denials of applications of refunding decisions.

(b) If a program prevails in a termination, reduction, or denial of refunding decision, the responsible HHS official may reimburse the agency for reasonable and customary legal fees, incurred during the appeal, if:

(1) The Departmental Appeals Board overturns the responsible HHS official's decision;

(2) The agency can prove it incurred fees during the appeal; and,

(3) The agency can prove the fees incurred are reasonable and customary.

Subpart B—Designation Renewal

§ 1304.10 Purpose and scope.

The purpose of this subpart is to set forth policies and procedures for the designation renewal of Head Start and Early Head Start programs. It is intended that these programs be administered effectively and responsibly; that applicants to administer programs receive fair and equitable consideration; and that the legal rights of current Head Start and Early Head Start grantees be fully protected. The Designation Renewal System is established in this part to determine whether Head Start and Early Head Start agencies deliver high-quality services to meet the educational, health, nutritional, and social needs of the children and families they serve; meet the program and financial requirements and standards described in section 641A(a)(1) of the Head Start Act; and qualify to be designated for funding for five years without competing for such funding as required under section 641(c) of the Head Start Act with respect to Head Start agencies and pursuant to section 645A(b)(12) and (d) with respect to Early Head Start agencies. A competition to select a new Head Start or Early Head Start agency to replace a Head Start or Early Head Start agency that has been terminated voluntarily or involuntarily is not part of the Designation Renewal System established in this Part, and is subject instead to the requirements of § 1304.20.

§ 1304.11 Basis for determining whether a Head Start agency will be subject to an open competition.

A Head Start or Early Head Start agency shall be required to compete for its next five years of funding whenever the responsible HHS official determines that one or more of the following seven conditions existed during the relevant time period covered by the responsible HHS official's review under § 1304.15:

(a) An agency has been determined by the responsible HHS official to have one or more deficiencies on a single review conducted under section 641A(c)(1)(A), (C), or (D) of the Act in the relevant time period covered by the responsible HHS official's review under § 1304.15.

(b) An agency has been determined by the responsible HHS official based on a review conducted under section 641A(c)(1)(A), (C), or (D) of the Act during the relevant time period covered by the responsible HHS official's review under § 1304.15 not to have:

(1) After December 9, 2011, established program goals for improving the school readiness of children participating in its program in accordance with the requirements of section 641A(g)(2) of the Act and demonstrated that such goals:

(i) Appropriately reflect the ages of children, birth to five, participating in the program;

(ii) Align with the Birth to Five Head Start Child Outcomes Framework, state early learning guidelines, and the requirements and expectations of the schools, to the extent that they apply to the ages of children, birth to five, participating in the program and at a minimum address the domains of language and literacy development, cognition and general knowledge, approaches toward learning, physical well-being and motor development, and social and emotional development;

(iii) Were established in consultation with the parents of children participating in the program.

(2) After December 9, 2011, taken steps to achieve the school readiness goals described under paragraph (b)(1) of this section demonstrated by:

(i) Aggregating and analyzing aggregate child-level assessment data at least three times per year (except for programs operating less than 90 days, which will be required to do so at least twice within their operating program period) and using that data in combination with other program data to determine grantees' progress toward meeting its goals, to inform parents and the community of results, and to direct continuous improvement related to curriculum, instruction, professional

development, program design and other program decisions; and,

(ii) Analyzing individual ongoing, child-level assessment data for all children birth to age five participating in the program and using that data in combination with input from parents and families to determine each child's status and progress with regard to, at a minimum, language and literacy development, cognition and general knowledge, approaches toward learning, physical well-being and motor development, and social and emotional development and to individualize the experiences, instructional strategies, and services to best support each child.

(c) An agency has been determined during the relevant time period covered by the responsible HHS official's review under § 1304.15:

(1) After December 9, 2011, to have an average score across all classrooms observed below the following minimum thresholds on any of the three CLASS: Pre-K domains from the most recent CLASS: Pre-K observation:

(i) For the Emotional Support domain the minimum threshold is 4;

(ii) For the Classroom Organization domain, the minimum threshold is 3;

(iii) For the Instructional Support domain, the minimum threshold is 2;

(2) After December 9, 2011, to have an average score across all classrooms observed that is in the lowest 10 percent on any of the three CLASS: Pre-K domains from the most recent CLASS: Pre-K observation among those currently being reviewed unless the average score across all classrooms observed for that CLASS: Pre-K domain is equal to or above the standard of excellence that demonstrates that the classroom interactions are above an exceptional level of quality. For all three domains, the "standard of excellence" is a 6.

(d) An agency has had a revocation of its license to operate a Head Start or Early Head Start center or program by a state or local licensing agency during the relevant time period covered by the responsible HHS official's review under § 1304.15, and the revocation has not been overturned or withdrawn before a competition for funding for the next five-year period is announced. A pending challenge to the license revocation or restoration of the license after correction of the violation shall not affect application of this requirement after the competition for funding for the next five-year period has been announced.

(e) An agency has been suspended from the Head Start or Early Head Start program by ACF during the relevant time period covered by the responsible

HHS official's review under § 1304.16 and the suspension has not been overturned or withdrawn. If there is a pending appeal and the agency did not have an opportunity to show cause as to why the suspension should not have been imposed or why the suspension should have been lifted if it had already been imposed under this part, the agency will not be required to compete based on this condition. If an agency has received an opportunity to show cause, the condition will be implemented regardless of appeal status.

(f) An agency has been debarred from receiving federal or state funds from any federal or state department or agency or has been disqualified from the Child and Adult Care Food Program (CACFP) any time during the relevant time period covered by the responsible HHS official's review under § 1304.15 but has not yet been terminated or denied refunding by ACF. (A debarred agency will only be eligible to compete for Head Start funding if it receives a waiver described in 2 CFR 180.135.)

(g) An agency has been determined within the twelve months preceding the responsible HHS official's review under § 1304.15 to be at risk of failing to continue functioning as a going concern. The final determination is made by the responsible HHS official based on a review of the findings and opinions of an audit conducted in accordance with section 647 of the Act; an audit, review or investigation by a state agency; a review by the National External Audit Review (NEAR) Center; or an audit, investigation or inspection by the Department of Health and Human Services Office of Inspector General.

§ 1304.12 Grantee reporting requirements concerning certain conditions.

(a) Head Start agencies must report in writing to the responsible HHS official within 30 working days of December 9, 2011, if the agency has had a revocation of a license to operate a center by a state or local licensing entity during the period between June 12, 2009, and December 9, 2011.

(b) Head Start agencies must report in writing to the responsible HHS official within 10 working days of occurrence any of the following events following December 9, 2011:

(1) The agency has had a revocation of a license to operate a center by a state or local licensing entity.

(2) The agency has filed for bankruptcy or agreed to a reorganization plan as part of a bankruptcy settlement.

(3) The agency has been debarred from receiving federal or state funds from any federal or state department or agency or has been disqualified from the

Child and Adult Care Food Program (CACFP).

(4) The agency has received an audit, audit review, investigation or inspection report from the agency's auditor, a state agency, or the cognizant federal audit agency containing a determination that the agency is at risk for ceasing to be a going concern.

§ 1304.13 Requirements to be considered for designation for a five-year period when the existing grantee in a community is not determined to be delivering a high-quality and comprehensive Head Start program and is not automatically renewed.

In order to compete for the opportunity to be awarded a five-year grant, an agency must submit an application to the responsible HHS official that demonstrates that it is the most qualified entity to deliver a high-quality and comprehensive Head Start or Early Head Start program. The application must address the criteria for selection listed at section 641(d)(2) of the Act for Head Start. Any agency that has had its Head Start or Early Head Start grant terminated for cause in the preceding five years is excluded from competing in such competition for the next five years. A Head Start or Early Head Start agency that has had a denial of refunding, as defined in 45 CFR part 1305, in the preceding five years is also excluded from competing.

§ 1304.14 Tribal government consultation under the Designation Renewal System for when an Indian Head Start grant is being considered for competition.

(a) In the case of an Indian Head Start or Early Head Start agency determined not to be delivering a high-quality and comprehensive Head Start or Early Head Start program, the responsible HHS official will engage in government-to-government consultation with the appropriate tribal government or governments for the purpose of establishing a plan to improve the quality of the Head Start program or Early Head Start program operated by the Indian Head Start or Indian Early Head Start agency.

(1) The plan will be established and implemented within six months after the responsible HHS official's determination.

(2) Not more than six months after the implementation of that plan, the responsible HHS official will reevaluate the performance of the Indian Head Start or Early Head Start agency.

(3) If the Indian Head Start or Early Head Start agency is still not delivering a high-quality and comprehensive Head Start or Early Head Start program, the responsible HHS official will conduct an open competition to select a grantee

to provide services for the community currently being served by the Indian Head Start or Early Head Start agency.

(b) A non-Indian Head Start or Early Head Start agency will not be eligible to receive a grant to carry out an Indian Head Start program, unless there is no Indian Head Start or Early Head Start agency available for designation to carry out an Indian Head Start or Indian Early Head Start program.

(c) A non-Indian Head Start or Early Head Start agency may receive a grant to carry out an Indian Head Start program only until such time as an Indian Head Start or Indian Early Head Start agency in such community becomes available and is designated pursuant to this part.

§ 1304.15 Designation request, review and notification process.

(a) Grantees must apply to be considered for Designation Renewal.

(1) For the transition period, each Head Start or Early Head Start agency wishing to be considered to have their designation as a Head Start or Early Head Start agency renewed for a five year period without competition shall request that status from ACF within six months of December 9, 2011.

(2) After the transition period, each Head Start or Early Head Start agency wishing to be considered to have their designation as a Head Start or Early Head Start agency renewed for another five year period without competition shall request that status from ACF at least 12 months before the end of their five year grant period or by such time as required by the Secretary.

(b) ACF will review the relevant data to determine if one or more of the conditions under § 1304.11 were met by the Head Start and Early Head Start agency's program:

(1) During the first year of the transition period, ACF shall review the data on each Head Start and Early Head Start agency to determine if any of the conditions under § 1304.11(a) or (d) through (g) were met by the agency's program since June 12, 2009.

(2) During the remainder of the transition period, ACF shall review the data on each Head Start and Early Head Start agency still under grants with indefinite project periods and for whom ACF has relevant data on all of the conditions in § 1304.11(a) through (g) to determine if any of the conditions under § 1304.11(a) or (d) through (g) were met by the agency's program since June 12, 2009, or if the conditions under § 1304.11(b) or (c) existed in the agency's program since December 9, 2011.

(3) Following the transition period, ACF shall review the data on each Head Start and Early Head Start agency in the fourth year of the grant to determine if any of the conditions under § 1304.11 existed in the agency's program during the period of that grant.

(c) ACF will give notice to grantees on Designation Renewal System status, except as provided in § 1304.14:

(1) During the first year of the transition period, ACF shall give written notice to all grantees meeting any of the conditions under § 1304.11(a) or (d) through (g) since June 12, 2009, by certified mail return receipt requested or other system that establishes the date of receipt of the notice by the addressee, stating that the Head Start or Early Head Start agency will be required to compete for funding for an additional five-year period, identifying the conditions ACF found, and summarizing the basis for the finding. All grantees that do not meet any of the conditions under § 1304.11(a) or (d) through (g) will remain under indefinite project periods until the time period described under paragraph (b)(2) of this section.

(2) During the remainder of the transition period, ACF shall give written notice to all grantees still under grants with indefinite project periods and on the conditions in § 1304.11(a) through (g) by certified mail return receipt requested or other system that establishes the date of receipt of the notice by the addressee stating either:

(i) The Head Start or Early Head Start agency will be required to compete for funding for an additional five-year period because ACF finds that one or more conditions under § 1304.11(a) through (g) has been met during the relevant time period described in paragraph (b) of this section, identifying the conditions ACF found, and summarizing the basis for the finding; or

(ii) That such agency has been determined on a preliminary basis to be eligible for renewed funding for five years without competition because ACF finds that none of the conditions under § 1304.11 have been met during the relevant time period described in paragraph (b) of this section. If prior to the award of that grant, ACF determines that the grantee has met one of the conditions under § 1304.11 during the relevant time period described in paragraph (b) of this section, this determination will change and the grantee will receive notice under paragraph (c)(2)(i) of this section that it will be required to compete for funding for an additional five-year period.

(3) Following the transition period, ACF shall give written notice to all grantees at least 12 months before the

expiration date of a Head Start or Early Head Start agency's then current grant by certified mail return receipt requested or other system that establishes the date of receipt of the notice by the addressee, stating:

(i) The Head Start or Early Head Start agency will be required to compete for funding for an additional five-year period because ACF finds that one or more conditions under § 1304.11 were met by the agency's program during the relevant time period described in paragraph (b) of this section, identifying the conditions ACF found, and summarizing the basis for the finding; or,

(ii) That such agency has been determined on a preliminary basis to be eligible for renewed funding for five years without competition because ACF finds that none of the conditions under § 1304.11 have been met during the relevant time period described in paragraph (b) of this section. If prior to the award of that grant, ACF determines that the grantee has met one of the conditions under § 1304.11 during the relevant time period described in paragraph (b) of this section, this determination will change and the grantee will receive notice under paragraph (c)(3)(i) of this section that it will be required to compete for funding for an additional five-year period.

§ 1304.16 Use of CLASS: Pre-K instrument in the Designation Renewal System.

Except when all children are served in a single classroom, ACF will conduct observations of multiple classes operated by the grantee based on a random sample of all classes and rate the conduct of the classes observed using the CLASS: Pre-K instrument. When the grantee serves children in its program in a single class, that class will be observed and rated using the CLASS: Pre-K instrument. The domain scores for that class will be the domain scores for the grantee for that observation. After the observations are completed, ACF will report to the grantee the scores of the classes observed during the CLASS: Pre-K observations in each of the domains covered by the CLASS: Pre-K instrument. ACF will average CLASS: Pre-K instrument scores in each domain for the classes operated by the agency that ACF observed to determine the agency's score in each domain.

Subpart C—Selection of Grantees Through Competition

§ 1304.20 Selection among applicants.

(a) In selecting an agency to be designated to provide Head Start, Early Head Start, Migrant or Seasonal Head

Start or tribal Head Start or Early Head Start services, the responsible HHS official will consider the applicable criteria at Section 641(d) of the Head Start Act and any other criteria outlined in the funding opportunity announcement.

(b) In competitions to replace or potentially replace a grantee the responsible HHS official will also consider the extent to which the applicant supports continuity for participating children, the community and the continued employment of effective, well qualified personnel.

(c) In competitions to replace or potentially replace a current grantee, the responsible HHS official will give priority to applicants that have demonstrated capacity in providing effective, comprehensive, and well-coordinated early childhood education and development services and programs to children and their families.

Subpart D—Replacement of American Indian and Alaska Native Grantees

§ 1304.30 Procedure for identification of alternative agency.

(a) An Indian tribe whose Head Start grant has been terminated, relinquished, designated for competition or which has been denied refunding as a Head Start agency, may identify an alternate agency and request the responsible HHS official to designate such agency as an alternative agency to provide Head Start services to the tribe if:

(1) The tribe was the only agency that was receiving federal financial assistance to provide Head Start services to members of the tribe; and,

(2) The tribe would be otherwise precluded from providing such services to its members because of the termination or denial of refunding.

(b)(1) The responsible HHS official, when notifying a tribal grantee of the intent to terminate financial assistance or deny its application for refunding, or its designation for competition must notify the grantee that it may identify an agency and request that the agency serve as the alternative agency in the event that the grant is terminated or refunding denied, or the grant is not renewed without competition.

(2) The tribe must identify the alternate agency to the responsible HHS official in writing.

(3) The responsible HHS official will notify the tribe, in writing, whether the alternative agency proposed by the tribe is found to be eligible for Head Start funding and capable of operating a Head Start program. If the alternative agency identified by the tribe is not an eligible agency capable of operating a Head Start

program, the tribe will have 15 days from the date of the sending of the notification to that effect from the responsible HHS official to identify another agency and request that the agency be designated. The responsible HHS official will notify the tribe in writing whether the second proposed alternate agency is found to be an eligible agency capable of operating the Head Start program.

(4) If the tribe does not identify an eligible, suitable alternative agency, a grantee will be designated under these regulations.

(c) If the tribe appeals a termination of financial assistance or a denial of refunding, it will, consistent with the terms of § 1304.5, continue to be funded pending resolution of the appeal. However, the responsible HHS official and the grantee will proceed with the steps outlined in this regulation during the appeal process.

(d) If the tribe does not identify an agency and request that the agency be appointed as the alternative agency, the responsible HHS official will seek a permanent replacement grantee under these regulations.

§ 1304.31 Requirements of alternative agency.

The agency identified by the Indian tribe must establish that it meets all requirements established by the Head Start Act and these requirements for designation as a Head Start grantee and that it is capable of conducting a Head Start program. The responsible HHS official, in deciding whether to designate the proposed agency, will analyze the capacity and experience of the agency according to the criteria found in section 641(d) of the Head Start Act and § 1304.20.

§ 1304.32 Alternative agency—prohibition.

(a) No agency will be designated as the alternative agency pursuant to this subpart if the agency includes an employee who:

(1) Served on the administrative or program staff of the Indian tribal grantee described under section 646(e)(1)(A) of the Act; and

(2) Was responsible for a deficiency that:

(i) Relates to the performance standards or financial management standards described in section 641A(a)(1) of the Act; and,

(ii) Was the basis for the termination of assistance under section 646(e)(1)(A) of the Act or denial of refunding described in § 1304.4.

(b) The responsible HHS official shall determine whether an employee was responsible for a deficiency within the meaning and context of this section.

Subpart E—Head Start Fellows Program

§ 1304.40 Purpose.

As provided in section 648A(d) of the Act, the Head Start Fellows Program is designed to enhance the ability of Head Start Fellows to make significant contributions to Head Start and to other child development and family services programs.

§ 1304.41 Fellows Program.

(a) *Selection.* An applicant must be working on the date of application in a local Head Start program or otherwise working in the field of child development and family services. The qualifications of the applicants for Head Start Fellowship positions will be competitively reviewed.

(b) *Placement.* Head Start Fellows may be placed in the Head Start national and regional offices; local Head Start agencies and programs; institutions of higher education; public or private entities and organizations concerned with services to children and families; and other appropriate settings.

(c) *Restrictions.* A Head Start Fellow who is not an employee of a local Head Start agency or program may only be placed in the national or regional offices within the Department of Health and Human Services that administer Head Start or local Head Start agencies. Head Start Fellows shall not be placed in any agency whose primary purpose, or one of whose major purposes is to influence federal, state or local legislation.

(d) *Duration.* Head Start Fellowships will be for terms of one year, and may be renewed for a term of one additional year.

(e) *Status.* For the purposes of compensation for injuries under chapter 81 of title 5, United States Code, Head Start Fellows shall be considered to be employees, or otherwise in the service or employment, of the federal government. Head Start Fellows assigned to the national or regional offices within the Department of Health and Human Services shall be considered employees in the Executive Branch of the federal government for the purposes of chapter 11 of title 18, United States Code, and for the purposes of any administrative standards of conduct applicable to the employees of the agency to which they are assigned.

PART 1305—DEFINITIONS

Sec.

1305.1 Purpose.

1305.2 Terms.

Authority: 42 U.S.C. 9801 *et seq.*

§ 1305.1 Purpose.

The purpose of this part is to define terms for the purposes of this subchapter.

§ 1305.2 Terms.

For the purposes of this subchapter, the following definitions apply:

ACF means the Administration for Children and Families in the Department of Health and Human Services.

Act means the Head Start Act, Sec. 635 *et seq.*, Public Law 97-35, 95 Stat. 499-511 (codified as amended at 42 U.S.C. Section 9801, *et seq.*).

Agency means the body that receives the Head Start grant.

Aggregate child-level assessment data means the data collected by an agency on the status and progress of the children it serves that have been combined to provide summary information about groups of children enrolled in specific classes, centers, home-based or other options, groups or settings, or other groups of children such as dual language learners, or to provide summary information by specific domains of development.

Allowable alternate vehicle means a vehicle designed for carrying eleven or more people, including the driver, that meets all the Federal Motor Vehicle Safety Standards applicable to school buses, except 49 CFR 571.108 and 571.131.

Budget period means the interval of time, into which a multi-year period of assistance (project period) is divided for budgetary and funding purposes.

Case plan is defined as presented in 42 U.S.C. 675(1) which, in summary, is a written document that must include a number of specified items including, but is not limited to, a plan for safe and proper care of the child in foster care placement, health records, and a plan for ensuring the educational stability of the child in foster care.

Child-level assessment data means the data collected by an agency on an individual child from one or more valid and reliable assessments of a child's status and progress, including but not limited to direct assessment, structured observations, checklists, staff or parent report measures, and portfolio records or work samples.

Child records means records that:

(1) Are directly related to the child;

(2) Are maintained by the program, or by a party acting for the program; and

(3) Include information recorded in any way, such as print, electronic, or digital means, including media, video, image, or audio format.

Child restraint system means any device designed to restrain, seat, or position children that meets the current requirements of Federal Motor Vehicle Safety Standard No. 213, Child Restraint Systems, 49 CFR 571.213, for children in the weight category established under the regulation, or any device designed to restrain, seat, or position children, other than a Type I seat belt as defined at 49 CFR 571.209, for children not in the weight category currently established by 49 CFR 571.213.

Child with a disability is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

CLASS: Pre-K means The Classroom Assessment Scoring System (CLASS). The CLASS is an observational instrument that assesses classroom quality in preschool through third grade classrooms. This tool meets the requirements described in 641(c)(1)(D) and 641A(c)(2)(F) of the Head Start Act (42 U.S.C. 9836(c)(1)(D) and 9836a(c)(2)(F)). The CLASS assesses three domains of classroom experience: Emotional Support, Classroom Organization, and Instructional Support.

(1) Emotional Support measures children's social and emotional functioning in the classroom, and includes four dimensions: Positive Climate, Negative Climate, Teacher Sensitivity and Regard for Student Perspectives. Positive Climate addresses the emotional connection, respect, and enjoyment demonstrated between teachers and children and among children. Negative Climate addresses the level of expressed negativity such as anger, hostility, or aggression exhibited by teachers and/or children in the classroom. Teacher Sensitivity addresses teachers' awareness of and responsiveness to children's academic and emotional concerns. Regard for Student Perspectives addresses the degree to which teachers' interactions with children and classroom activities place an emphasis on children's interests, motivations, and points of view.

(2) Classroom Organization measures a broad array of classroom processes related to the organization and management of children's behavior, time, and attention in the classroom. It includes three dimensions: Behavior Management, Productivity, and Instructional Learning Formats. Behavior Management addresses how effectively teachers monitor, prevent, and redirect behavior. Productivity addresses how well the classroom runs with respect to routines and the degree to which teachers organize activities and directions so that maximum time can be spent on learning activities. Instructional Learning Formats addresses how teachers facilitate activities and provide interesting materials so that children are engaged and learning opportunities are maximized.

(3) Instructional Support measures the ways in which teachers implement curriculum to effectively support cognitive and language development. It includes three dimensions: Concept Development, Quality of Feedback, and Language Modeling. Concept Development addresses how teachers use instructional discussions and activities to promote children's higher order thinking skills in contrast to a focus on rote instruction. Quality of Feedback addresses how teachers extend children's learning through their responses to children's ideas, comments, and work. Language Modeling addresses the extent to which teachers facilitate and encourage children's language.

(4) Assessments with the CLASS involve observation-based measurement of each dimension on a seven point scale. A score ranging from 1 (minimally characteristic) to 7 (highly characteristic) is given for each

dimension and represents the extent to which that dimension is characteristic of that classroom. Relevant dimension scores are used to calculate each domain score.

Commercial Driver's License (CDL) means a license issued by a state or other jurisdiction, in accordance with the standards contained in 49 CFR part 383, to an individual which authorizes the individual to operate a class of commercial motor vehicles.

Construction means new buildings, and excludes renovations, alterations, additions, or work of any kind to existing buildings.

Continuity of care means Head Start or Early Head Start services provided to children in a manner that promotes primary caregiving and minimizes the number of transitions in teachers and teacher assistants that children experience over the course of the day, week, program year, and to the extent possible, during the course of their participation from birth to age three in Early Head Start and in Head Start.

Deficiency is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

Delegate agency is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

Development and administrative costs mean costs incurred in accordance with an approved Head Start budget which do not directly relate to the provision of program component services, including services to children with disabilities, as set forth and described in the Head Start program performance standards (45 CFR part 1304).

Disclosure means to permit access to or the release, transfer, or other communication of PII contained in child records by any means, including oral, written, or electronic means, to any party except the party identified as the party that provided or created the record.

Double session variation means a center-based option that employs a single teacher to work with one group of children in the morning and a different group of children in the afternoon.

Dual benefit costs mean costs incurred in accordance with an approved Head Start budget which directly relate to both development and administrative functions and to the program component services, including services to children with disabilities, as set forth and described in the Head Start program performance standards (45 CFR part 1304).

Dual language learner means a child who is acquiring two or more languages at the same time, or a child who is learning a second language while continuing to develop their first language. The term "dual language learner" may encompass or overlap substantially with other terms frequently used, such as bilingual, English language learner (ELL), Limited English Proficient (LEP), English learner, and children who speak a Language Other Than English (LOTE).

Early Head Start agency means a public or private non-profit or for-profit entity designated by ACF to operate an Early Head Start program to serve pregnant women and children from birth to age three, pursuant to Section 645A(e) of the Head Start Act.

Enrolled (or any variation of) means a child has been accepted and attended at least one class for center-based or family child care option or at least one home visit for the home-based option.

Enrollment year means the period of time, not to exceed twelve months, during which a Head Start program provides center or home-based services to a group of children and their families.

Facility means a structure, such as a building or modular unit, appropriate for use in carrying out a Head Start program and used primarily to provide Head Start services, including services to children and their families, or for administrative purposes or other activities necessary to carry out a Head Start program.

Family means all persons living in the same household who are supported by the child's parent(s) or guardian(s)' income; and are related to the child's parent(s) or guardian(s) by blood, marriage, or adoption; or are the child's authorized caregiver or legally responsible party.

Federal interest is a property right which secures the right of the federal awarding agency to recover the current fair market value of its percentage of participation in the cost of the facility in the event the facility is no longer used for Head Start purposes by the grantee or upon the disposition of the property. When a grantee uses Head Start funds to purchase, construct or renovate a facility, or make mortgage payments, it creates a federal interest. The federal interest includes any portion of the cost of purchase, construction, or renovation contributed by or for the entity, or a related donor organization, to satisfy a matching requirement.

Federal Motor Vehicle Safety Standards (FMVSS) means the National Highway and Traffic Safety Administration's standards for motor vehicles and motor vehicle equipment (49 CFR part 571) established under section 30111 of Title 49, United States Code.

Financial viability means that an organization is able to meet its financial obligations, balance funding and expenses and maintain sufficient funding to achieve organizational goals and objectives.

Fixed route means the established routes to be traveled on a regular basis by vehicles that transport children to and from Head Start or Early Head Start program activities, and which include specifically designated stops where children board or exit the vehicle.

Foster care means 24-hour substitute care for children placed away from their parents or guardians and for whom the state agency has placement and care responsibility. This includes, but is not limited to, placements in foster family homes, foster homes of relatives, group homes, emergency shelters, residential facilities, child-care institutions, and pre-adoptive homes. A child is in foster care in accordance with this definition regardless of whether the foster care facility is licensed and payments are made by the state or local agency for the care of the child, whether adoption subsidy payments are being made prior to the finalization of an adoption, or whether there is federal matching of any payments that are made.

Full-working-day means not less than 10 hours of Head Start or Early Head Start services per day.

Funded enrollment means the number of participants which the Head Start grantee is to serve, as indicated on the grant award.

Going concern means an organization that operates *without* the threat of liquidation for the foreseeable future, a period of at least 12 months.

Grantee means the local public or private non-profit agency or for-profit agency which has been designated as a Head Start agency under 42 U.S.C. 9836 and which has been granted financial assistance by the responsible HHS official to operate a Head Start program.

Head Start agency means a local public or private non-profit or for-profit entity designated by ACF to operate a Head Start program to serve children age three to compulsory school age, pursuant to section 641(b) and (d) of the Head Start Act.

Head Start Early Learning Outcomes Framework: Ages Birth to Five means the *Head Start Early Learning Outcomes Framework: Ages Birth to Five*, which describes the skills, behaviors, and knowledge that programs must foster in all children. It includes five central domains: Approaches to Learning; Social and Emotional Development; Language and Literacy; Cognition; and Perceptual, Motor, and Physical Development. These central domains are broken into five domains for infants and toddlers and seven domains for preschoolers. Infant and Toddler domains are Approaches to Learning; Social and Emotional Development; Language and Communication; Cognition; and Perceptual, Motor, and Physical Development. Preschool domains are Approaches to Learning; Social and Emotional Development; Language and Communication; Literacy; Mathematics Development; Scientific Reasoning; and Perceptual, Motor, and Physical Development. Domains are divided into sub-domains with goals that describe broad skills, behaviors, and concepts that are important for school success. Developmental progressions describe the skills, behaviors and concepts that children may demonstrate as they progress. As described in the Head Start Act, the Framework is central to program operations that promote high-quality early learning environments (42 U.S.C. 9832(21)(G)(iv)(II)(aa), 42 U.S.C. 9835(o), 42 U.S.C. 9836(d)(2)(C), 42 U.S.C. 9836a(g)(2)(A), 42 U.S.C. 9837(f)(3)(E), 42 U.S.C. 9837a(a)(3), 42 U.S.C. 9837a(a)(14), 42 U.S.C. 9837b(a)(2)(B)(iii), 42 U.S.C. 9837b(a)(4)(A)(i), and 42 U.S.C. 9837b(a)(4)(B)(iii)).

Homeless children means the same as *homeless children and youths* in Section 725(2) of the McKinney-Vento Homeless Assistance Act at 42 U.S.C. 11434a(2).

Home visitor means the staff member in the home-based program option assigned to work with parents to provide comprehensive services to children and their families through home visits and group socialization activities.

Hours of planned class operations means hours when children are scheduled to attend. Professional development, training, orientation, teacher planning, data analysis, parent-teacher conferences, home visits, classroom sanitation, and transportation do

not count toward the hours of planned class operations.

Income means gross cash income and includes earned income, military income (including pay and allowances, except those described in Section 645(a)(3)(B) of the Act), veteran's benefits, Social Security benefits, unemployment compensation, and public assistance benefits. Additional examples of gross cash income are listed in the definition of "income" which appears in U.S. Bureau of the Census, Current Population Reports, Series P-60-185 (available at <https://www2.census.gov/prod2/popscon/p60-185.pdf>).

Indian Head Start agency means a program operated by an Indian tribe (as defined by the Act) or designated by an Indian tribe to operate on its behalf.

Indian tribe is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

Individualized Education Program is defined in the same manner as presented in the Individuals with Disabilities Education Act (20 U.S.C. 1400 *et seq.*).

Individualized Family Service Plan is defined in the same manner as presented in the Individuals with Disabilities Education Act (20 U.S.C. 1400 *et seq.*).

Legal status means the existence of an applicant or grantee as a public agency or organization under the law of the state in which it is located, or existence as a private nonprofit or for-profit agency or organization as a legal entity recognized under the law of the state in which it is located. Existence as a private non-profit agency or organization may be established under applicable state or federal law.

Local agency responsible for implementing IDEA means the early intervention service provider under Part C of IDEA and the local educational agency under Part B of IDEA.

Major renovation means any individual or collection renovation that has a cost equal to or exceeding \$250,000. It excludes minor renovations and repairs except when they are included in a purchase application.

Migrant family means, for purposes of Head Start eligibility, a family with children under the age of compulsory school attendance who changed their residence by moving from one geographic location to another, either intrastate or interstate, within the preceding two years for the purpose of engaging in agricultural work and whose family income comes primarily from this activity.

Migrant or Seasonal Head Start Program means:

(1) With respect to services for migrant farm workers, a Head Start program that serves families who are engaged in agricultural labor and who have changed their residence from one geographic location to another in the preceding 2-year period; and,

(2) With respect to services for seasonal farmworkers, a Head Start program that serves families who are engaged primarily in seasonal agricultural labor and who have not changed their residence to another geographic location in the preceding 2-year period.

Minor renovation means improvements to facilities, which do not meet the definition of major renovation.

Modular unit means a portable prefabricated structure made at another location and moved to a site for use by a Head Start grantee to carry out a Head Start program, regardless of the manner or extent to which the modular unit is attached to underlying real property.

National Driver Register means the National Highway Traffic Safety Administration's automated system for assisting state driver license officials in obtaining information regarding the driving records of individuals who have been denied licenses for cause; had their licenses denied for cause, had their licenses canceled, revoked, or suspended for cause, or have been convicted of certain serious driving offenses.

Parent means a Head Start child's mother or father, other family member who is a primary caregiver, foster parent or authorized caregiver, guardian or the person with whom the child has been placed for purposes of adoption pending a final adoption decree.

Participant means a pregnant woman or child who is enrolled in and receives services from a Head Start, an Early Head Start, a Migrant or Seasonal Head Start, or an American Indian and Alaska Native Head Start program.

Personally identifiable information (PII) means any information that could identify a specific individual, including but not limited to a child's name, name of a child's family member, street address of the child, social security number, or other information that is linked or linkable to the child.

Program means a Head Start, Early Head Start, migrant, seasonal, or tribal program, funded under the Act and carried out by an agency, or delegate agency, to provide ongoing comprehensive child development services.

Program costs mean costs incurred in accordance with an approved Head Start budget which directly relate to the provision of program component services, including services to children with disabilities, as set forth and described in the Head Start Program Performance Standards (45 CFR part 1304).

Purchase means to buy an existing facility, including outright purchase, down payment or through payments made in satisfaction of a mortgage or other loan agreement, whether principal, interest or an allocated portion principal and/or interest. The use of grant funds to make a payment under a capital lease agreement, as defined in the cost principles, is a purchase subject to these provisions. Purchase also refers to an approved use of Head Start funds to continue paying the cost of purchasing facilities or refinancing an existing loan or mortgage beginning in 1987.

Real property means land, including land improvements, buildings, structures and all appurtenances thereto, excluding movable machinery and equipment.

Recruitment area means that geographic locality within which a Head Start program seeks to enroll Head Start children and families. The recruitment area can be the

same as the service area or it can be a smaller area or areas within the service area.

Relevant time period means:

(1) The 12 months preceding the month in which the application is submitted; or

(2) During the calendar year preceding the calendar year in which the application is submitted, whichever more accurately reflects the needs of the family at the time of application.

Repair means maintenance that is necessary to keep a Head Start facility in working condition. Repairs do not add significant value to the property or extend its useful life.

Responsible HHS official means the official of the Department of Health and Human Services who has authority to make grants under the Act.

School readiness goals mean the expectations of children's status and progress across domains of language and literacy development, cognition and general knowledge, approaches to learning, physical well-being and motor development, and social and emotional development that will improve their readiness for kindergarten.

School bus means a motor vehicle designed for carrying 11 or more persons (including the driver) and which complies with the Federal Motor Vehicle Safety Standards applicable to school buses.

Service area means the geographic area identified in an approved grant application within which a grantee may provide Head Start services.

Staff means paid adults who have responsibilities related to children and their families who are enrolled in programs.

State is defined in the same manner as presented in the Head Start Act, 42 U.S.C. 9801.

Termination of a grant or delegate agency agreement means permanent withdrawal of the grantee's or delegate agency's authority to obligate previously awarded grant funds before that authority would otherwise expire. It also means the voluntary relinquishment of that authority by the grantee or delegate agency. Termination does not include:

(1) Withdrawal of funds awarded on the basis of the grantee's or delegate agency's underestimate of the unobligated balance in a prior period;

(2) Refusal by the funding agency to extend a grant or award additional funds (such as refusal to make a competing or noncompeting continuation renewal, extension or supplemental award);

(3) Withdrawal of the unobligated balance as of the expiration of a grant; and

(4) Annulment, *i.e.*, voiding of a grant upon determination that the award was obtained fraudulently or was otherwise illegal or invalid from its inception.

Total approved costs mean the sum of all costs of the Head Start program approved for a given budget period by the Administration for Children and Families, as indicated on the Financial Assistance Award. Total approved costs consist of the federal share plus any approved non-federal match,

including non-federal match above the statutory minimum.

Transition period means the three-year time period after December 9, 2011, on the Designation Renewal System during which ACF will convert all of the current continuous Head Start and Early Head Start grants into five-year grants after reviewing each grantee to determine if it meets any of the conditions under § 1304.12 of this chapter that require recompetition or if the grantee will receive its first five-year grant non-competitively.

Transportation services means the planned transporting of children to and from sites where an agency provides services funded under the Head Start Act. Transportation services can involve the pick-up and discharge of children at regularly scheduled times and pre-arranged sites, including trips between children's homes and program settings. The term includes services provided directly by the Head Start and Early Head Start grantee or delegate agency and services which such agencies arrange to be provided by another organization or an individual. Incidental trips, such as transporting a sick child home before the end of the day, or such as might be required to transport small groups of children to and from necessary services, are not included under the term.

Verify or any variance of the word means to check or determine the correctness or truth by investigation or by reference.

[FR Doc. 2016-19748 Filed 9-1-16; 11:15 am]

BILLING CODE 4184-01-P

Exhibit 3



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1302

RIN 0970-AC90

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 for COVID-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 contractors 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.

Table of Contents

I. Tribal Consultation Statement
II. Statutory Authority
III. Executive Summary
A. Purpose of the Interim Final Rule
B. Interim Final Rule Justification
C. Waiver of Proposed Rulemaking
IV. Background
V. Provisions of the Interim Final Rule
VI. Regulatory Process Matters
Treasury and General Government
Appropriations Act of 1999
Federalism Assessment Executive Order
13132
Congressional Review
Paperwork Reduction Act of 1995
VII. Economic Analysis of Impacts
VIII. Alternatives Considered

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 (E), 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 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

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.

⁶ <https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status> MMWR Morb Mortal Wkly Rep 2021;70:1255–1260. DOI: <https://dx.doi.org/10.15585/mmwr.mm7036e2>.

⁷ <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination>.

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, 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

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>

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*

Greater understanding about the spread of SARS-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 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.

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>.

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 of SARS-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 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

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.>

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>.

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 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

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

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, 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 2021²⁴ 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,

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

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 infection²⁷ but that "vaccination 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

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, Anjana 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](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext).

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.

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 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

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 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

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., Aharoni, 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.

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>.

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: <https://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*

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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 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

National Academy of Sciences of the United States of America, 118(5), e2014746118. <https://doi.org/10.1073/pnas.2014746118>.

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>.

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 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

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>.

percent, though lower in home-based programs. That 73 percent is a nationwide 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 Head Start were

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>.

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 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.

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.

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 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

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>.

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>.

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, 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

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.

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>.

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 data⁶⁵). 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 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

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-1504#:~:text=Staff%20who%20need%20help%20identifying,800%2D422%2D4453\).&text=All%20Head%20Start%20programs%20must,of%20child%20abuse%20and%20neglect](https://eclkc.ohs.acf.hhs.gov/policy/im/acf-im-hs-1504#:~: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>.

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.

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

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>.

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/COVID-15Oct21.aspx>.

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 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

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.

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 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 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 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

⁷¹ <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>.

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>.

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>.

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,

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>.

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

This IFC adds a new provision to part 1302, 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

⁸⁰ Office of Head Start. “FY 2021 American Rescue Plan Funding Increase for Head Start

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 (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

Programs.” May 4, 2021. Available at: <https://eclkc.ohs.acf.hhs.gov/policy/pi/acf-pi-hs-21-03>.

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.

medical necessity requires a delay in vaccination,⁸² 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 (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 to the COVID-19 vaccination requirement specified in § 1302.93 and § 1302.94.

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).

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).

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 U.S.C. 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](https://www.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.

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

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>.

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* Public Law 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.

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

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

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 to overly prescriptive about ventilation given the range of facilities and spaces used by center-based and family child care programs.

Second, as discussed in this IFC, being fully vaccinated for COVID-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.

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.

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>.

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>.

**Appendix to Section VII of
Supplementary Information: Economic
Analysis of Impacts**

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

**Administration for Children and
Families**

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

**Final Regulatory Impact Analysis;
Final Regulatory Flexibility Analysis;
Unfunded Mandates Reform Act
Analysis; Office of Head Start,
Administration for Children and
Families, Department of Health and
Human Services**

Prepared by

Office of Science and Data Policy

**Office of the Assistant Secretary for
Planning and Evaluation**

Office of the Secretary

**Department of Health and Human
Services**

I. Introduction and Summary

A. 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 has 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.

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small entities. These impacts are discussed in detail in the Final Small Entity Analysis.

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This interim final rule establishes vaccine, record keeping, and mask requirements to mitigate the spread of COVID-19 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 against 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.

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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.

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	Annualized Quantified					7%		
	Qualitative					3%		
Transfers	Federal Annualized Monetized \$millions/year					7%		
						3%		
	From/To	From:			To:			
	Other Annualized Monetized \$millions/year					7%		
					3%			
	From/To	From:			To:			
Effects	State, Local or Tribal Government:							
	Small Business: Wages: Growth:							

II. Economic Analysis of Impacts

A. Background

Since its inception in 1965, Head Start has been a leader in helping children from low-income families reach 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, the Office of Head Start 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. 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 5 can access in person services, especially after so many children spent a year or more away from in-person Head Start services.

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 that cannot be eliminated or reduced by reasonable accommodation, in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act. Ensuring that children and families can benefit from program services as safely as possible is the Office of Head Start’s highest priority.

COVID–19 has resulted in substantial reductions in in-person Head Start services available to children and their families. As described in greater detail in the Baseline Section, a majority of Head Start centers have moved from fully in-person services to a virtual/remote or a hybrid operating status, while other centers remain closed as a result of a COVID–19 case or outbreak in a program. Without the vaccination and masking requirements of this regulatory action, there is a higher likelihood of transmission of SARS–COV–2 at in-person Head Start settings, which would result in more people at greater risk for COVID–19-related morbidity and mortality, including children returning home and exposing family members. This interim final rule is needed to address the health risks from COVID–19 and to increase the likelihood that Head Start centers are able to reopen or return to in-person services safely.

C. Purpose of the Rule

This regulatory action requires COVID–19 vaccination among all staff employed in Head Start programs, as well as for

volunteers that interact with children. The interim final rule also requires mask wearing for all adults and children aged 2 years and older in certain in-person Head Start settings. This regulation also requires recordkeeping of vaccination status for both volunteers and staff. This regulation is necessary to ensure healthy, safe conditions for in-person early care and education services to children and their families enrolled in Head Start programs nationwide. Being fully vaccinated against COVID–19, combined with wearing a mask, are the safest and most effective ways for Head Start programs to mitigate the spread of COVID–19 among the children and families they serve, as well as among staff and volunteers. This action will help more early childhood centers safely remain open and provide needed services to Head Start children and families.

D. Baseline Conditions

This section describes the baseline scenario of no new regulatory action from which the incremental changes to these outcomes from the policy options considered are measured. The scope of this economic analysis is limited to the impacts that are attributable to this regulatory action, which covers more than 20,000 Head Start Centers. The requirements of this interim final rule will cover about 273,000 staff, and a share of the 1 million Head Start volunteers who interact with children in certain in-person Head Start settings. It will also impact a share

of the 864,000 children in certain in-person Head Start settings.

On September 9, 2021, President Biden announced the “Path Out of the Pandemic” COVID-19 Action Plan,⁸⁸ which announced the development of a Head Start vaccination requirement, and other elements of a national strategy to combat COVID-19. In our primary analysis, we exclude impacts attributable to other elements of this comprehensive national strategy. For example, the COVID-19 Action Plan announced the development of the Emergency Temporary Standard (ETS) recently issued by the Department of Labor’s Occupational Safety and Health Administration (OSHA). Among other provisions, the OSHA ETS 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 COVID-19 testing and wear a face covering. Centers for Medicare & Medicaid Services (CMS) also recently issued an interim final rule with comment period that requires COVID-19 vaccinations for workers in most health care settings that receive Medicare or Medicaid reimbursement.⁸⁹ The OSHA action covers over 80 million workers, while the CMS action will apply to approximately 76,000 providers and cover more than 17 million health care workers across the country. Additionally, through Executive Orders 14042, “Ensuring Adequate COVID Safety Protocols for Federal Contractors”⁹⁰ and 14043, “Requiring Coronavirus Disease 2019 Vaccination for Federal Employees,”⁹¹ and other actions, all federal executive branch employees, including the military, and all federal contractors will be required to be fully vaccinated. In total, the vaccination requirements associated with the Action Plan apply to about 100 million Americans.

These actions (if implemented, despite ongoing litigation) would likely have significant impacts on the measured outcomes described in this baseline scenario. For example, a recent White House report⁹² discusses existing vaccination requirements and summarizes several potential impacts of widespread adoption of such requirements, such as those envisioned in the Action Plan: “[V]accination requirements have repeatedly been shown to increase vaccination rates among workers by 20 to 25 percentage points, and in some cases by significantly more. More than three out of four (75.5%) working-aged adult Americans are currently in the labor force, so increasing the share of workers who are fully vaccinated by 20 to 25

percentage points could vaccinate an additional 30 to 38 million working-age Americans, cutting the total share of unvaccinated Americans roughly in half. This could have a major effect on case rates, hospitalization rates, and death rates—preventing future waves of the virus from having as significant an effect as occurred during the spread of the Delta variant. At an individual level, unvaccinated people are more than five times as likely to get a symptomatic case of COVID-19 and more than 10 times as likely to be hospitalized or to die from COVID-19.”

There are challenges in extrapolating from private-sector or smaller jurisdiction mandates to broader action by the federal government, especially in regards to the effectiveness of the mandates; however, the estimates contained in the White House Report are broadly consistent with DOL’s estimate “that approximately 75.3 million (89.4 percent) of covered employees will be vaccinated when the ETS is in full effect.”⁹³ We exclude these potential spill-over impacts in characterizing our baseline, adopting a regulatory scenario that does not account for other elements of the COVID-19 Action Plan.

The scope of the COVID-19 vaccine requirement is limited to staff at Head Start programs and volunteers that interact with children at Head Start programs. To characterize the baseline scenario, we present forecasts that are specific to the 273,000 staff employed or contracted by Head Start programs,⁹⁴ and discuss volunteers separately. We provide quantitative projections of COVID-19 vaccine coverage, and for each of the COVID-19 outcomes described above. Our forecasts are based on COVID-19 Projections maintained by the Institute for Health Metrics and Evaluation (IHME).⁹⁵ IHME summarizes its projections in a Data Release Information Sheet:

“IHME has developed projections for total and daily deaths, daily infections and testing, hospital resource use, and social distancing due to COVID-19 for a number of countries. Forecasts at the subnational level are included for select countries. The projections for total deaths, daily deaths, and daily infections and testing each include a reference scenario: Current projection, which assumes social distancing mandates are re-imposed for 6 weeks whenever daily deaths reach 8 per million (0.8 per 100k). They also include two additional scenarios: Mandates easing, which reflects continued easing of social distancing mandates, and mandates are not re-imposed; and Universal Masks, which reflects 95% mask usage in public in every location. Hospital resource use forecasts are based on the Current projection scenario.

Social distancing forecasts are based on the Mandates easing scenario. These projections are produced with a model that incorporates data on observed COVID-19 deaths, hospitalizations, and cases, information about social distancing and other protective measures, mobility, and other factors. They include uncertainty intervals and are being updated daily with new data. These forecasts were developed in order to provide hospitals, policy makers, and the public with crucial information about how expected need aligns with existing resources, so that cities and countries can best prepare.”

We adopt the IHME reference scenario as the source of our baseline forecasts. Since the IHME estimates are “produced with a model that incorporates data on observed COVID-19 deaths, hospitalizations, and cases, information about social distancing and other protective measures, mobility, and other factors,” this significantly narrows the wide range of analytic choices that would otherwise be necessary to characterize the baseline scenario. Since the IHME projections cover the entire United States population, we adjust these projections to align with data specific to Head Start. We discuss the specific adjustments in the following narrative.

Vaccine Coverage

A recent study measured “COVID-19 Vaccine Uptake Among U.S. Child Care Providers,” with 21,663 respondents, including 1,456 individuals providing services through Head Start or Early Head Start. Among Head Start survey respondents, 73.0% reported receiving a COVID-19 vaccine. We interpret this to mean that respondents had received at least one dose. This interpretation is consistent with the study’s comparison to the general adult population. The authors note that “[t]he survey was active between May 26, 2021 and June 23, 2021,” and compare the overall findings to vaccine uptake for the U.S. general adult population of 65%.⁹⁶ Since Head Start staff are more likely to be vaccinated than the general adult population, our baseline forecast will reflect this difference. Specifically, we extend this point-in-time estimate to the vaccine coverage forecasts by adopting an assumption that Head Start staff are about 12% more likely to be vaccinated than the general adult population,⁹⁷ and that this relationship will persist under the time horizon of the baseline scenario of this analysis. As a sample calculation, if the general adult population vaccine coverage rate increases to 67.1%, we would infer a corresponding increase in the Head Start vaccine coverage rate to 74.6%.⁹⁸

The Center for Disease Control and Prevention (CDC) maintains a COVID Data

⁸⁸ <https://www.whitehouse.gov/covidplan/>.

⁸⁹ <https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination>.

⁹⁰ <https://www.federalregister.gov/documents/2021/09/14/2021-19924/ensuring-adequate-covid-safety-protocols-for-federal-contractors>.

⁹¹ <https://www.federalregister.gov/documents/2021/09/14/2021-19927/requiring-coronavirus-disease-2019-vaccination-for-federal-employees>.

⁹² <https://www.whitehouse.gov/wp-content/uploads/2021/10/Vaccination-Requirements-Report.pdf>.

⁹³ <https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23643.pdf>.

⁹⁴ <https://eclkc.ohs.acf.hhs.gov/about-us/article/head-start-program-facts-fiscal-year-2019>.

⁹⁵ Institute for Health Metrics and Evaluation (IHME). COVID-19 Mortality, Infection, Testing, Hospital Resource Use, and Social Distancing Projections. Seattle, United States of America: Institute for Health Metrics and Evaluation (IHME), University of Washington, 2020. <http://www.healthdata.org/covid/data-downloads>. Accessed on November 10, 2022.

⁹⁶ Patel KM, Malik AA, Lee A, et al. (2021). “COVID-19 vaccine uptake among US child care providers.” *Pediatrics*; doi: 10.1542/peds.2021-053813.

⁹⁷ $0.73/0.65 = 1.12$. We perform calculations in the model based on the share of individuals who are unvaccinated. The comparable calculation is $1 - [(1 - 0.73)/(1 - 0.65)] = 0.23$, which indicates that Head Start staff are about 23% less likely to be unvaccinated than the general adult population.

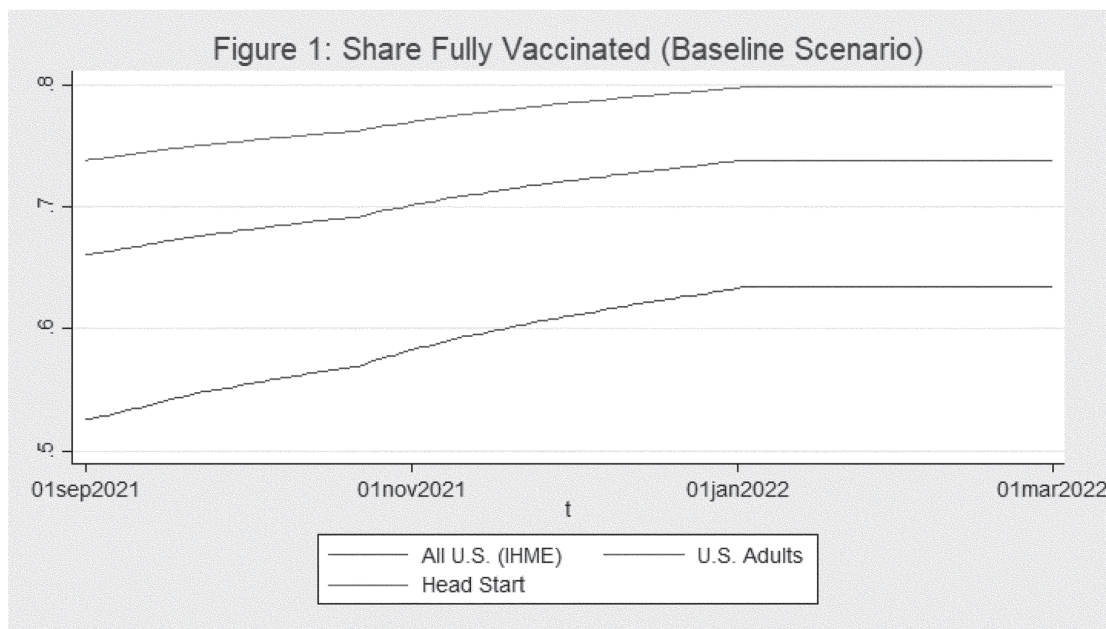
⁹⁸ $1 - [(1 - 0.671) * (1 - 0.23)] = 0.75$.

Tracker on its website, which includes a summary of COVID-19 vaccinations in the United States. On November 10, 2021, CDC reports that 58.5% of the total U.S. population are fully vaccinated, and reports 70.3% for a subset of the population that are 18 years of age or older (hereafter, “adults”).⁹⁹ The IHME COVID-19 projections are reported at a population level, and do not contain separate projections that are limited to the adult population. Therefore, generating a baseline forecast of vaccine coverage among Head Start staff from the IHME projections first requires an intermediate step of estimating vaccine coverage for the adult population. We follow the same approach for this adjustment as we discussed to translate adult vaccine coverage estimates to Head

Start staff vaccine coverage estimates. Specifically, we calculate a point-in-time relationship using November 10, 2021 CDC data, and assume that this relationship will persist over the time horizon of the analysis. We assume that adults are about 20.1% more likely to be vaccinated than the total population.¹⁰⁰ Combining the adjustments, a population vaccine coverage rate on November 10, 2021 for the total U.S. population of 58.5% would correspond to a 77.1% Head Start vaccine coverage rate.¹⁰¹

We assume that vaccination coverage will continue to increase over time and incorporate this into our baseline. For example, the IHME projections indicate U.S. vaccine coverage of 60.0% on November 18, 2021. This estimate increases to 63.4% on

March 1, 2022, the last date covered in the most recent IHME projections available at the time of the analysis. We assume that vaccine coverage for Head Start will follow a similar trajectory, after accounting for the adjustments described above, and incorporate this into our baseline. Figure 1 presents forecasts of vaccine uptake under the baseline scenario. These forecasts include the unadjusted IHME projections for the total population, our adjustments to project adult vaccination coverage, and adult vaccination coverage specific to Head Start staff. For Head Start, we anticipate the vaccine coverage rate will increase from 77.9% on November 18, 2021 to 79.8% on March 1, 2022 under the baseline scenario of no further regulatory action.



COVID-19 Cases, Deaths, and Hospitalizations Among U.S. Adults

The IHME projections include estimates for infections, new hospital admissions, and deaths at a population level. Several adjustments are necessary to convert these population-level estimates to estimates appropriate for the Head Start staff population characteristics. Specifically, we adjust for the age distribution and vaccine coverage rates of Head Start staff. We discuss these adjustments in the narrative contained in the next two sections.

We generate projections of daily cases by multiplying IHME’s projections of daily infections with its daily estimates of the infection detection ratio.¹⁰² Over the period covering November 19, 2021 to March 1,

2022, the estimated infection detection ratio varies between 0.4693 and 0.4993, suggesting that, on any particular day, measured COVID-19 cases likely represent between 47% and 49% of the total COVID-19 infections. We assume that this measure is consistent with the CDC’s case definition.¹⁰³ We acknowledge the importance of these additional infections that are not confirmed cases but focus on the metric of confirmed COVID-19 cases, which is more comparable with other sources of data used in this analysis.

We make several initial adjustments of the IHME projections, which cover the entire U.S. population, to generate forecasts that are limited to the adult population. Using CDC COVID-19 line-level case surveillance data

that cover July 1–September 30, 2021, we estimate that 21% of COVID-19 cases were individuals aged <18 years.¹⁰⁴ We adjust the total population case projections by this percentage to capture only adult cases. We follow the same procedure for mortality: CDC case surveillance data indicate that 0.1% of COVID-19 deaths were individuals aged <18 years. We adjust the total population death projections by this percentage to capture only adult deaths.¹⁰⁵ We follow the same procedure for hospitalizations: CDC COVID-NET data on laboratory-confirmed COVID-19 associated hospitalizations indicate that 1.9% of COVID-19 hospitalizations were

⁹⁹ https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

¹⁰⁰ $0.703/0.585 \approx 1.20$. Calculated in the model as $1 - [(1 - 0.703)/(1 - 0.585)] \approx 0.284$, with the interpretation is adults are about 28.4% less likely to be unvaccinated than the total population.

¹⁰¹ $1 - [(1 - .585) * (1 - 0.284) * (1 - 0.23)] \approx 0.771$.

¹⁰² <http://www.healthdata.org/special-analysis/covid-19-estimating-historical-infections-time-series>.

¹⁰³ <https://ndc.services.cdc.gov/case-definitions/coronavirus-disease-2019-2021/>.

¹⁰⁴ Calculation based on CDC COVID-19 Line level case surveillance data, HHS Protect. $1,414,206/6,589,127 \approx 0.21$. This share is somewhat

higher in recent months than in earlier periods. For all documented COVID-19 cases through September 30, 2021, the share is 14% ($4,461,790/31,537,748 \approx 0.14$). Accessed October 8, 2021.

¹⁰⁵ Calculation based on data extracted from <https://covid.cdc.gov/covid-data-tracker/#demographics.637/567,704> ≈ 0.001 . Accessed October 3, 2021.

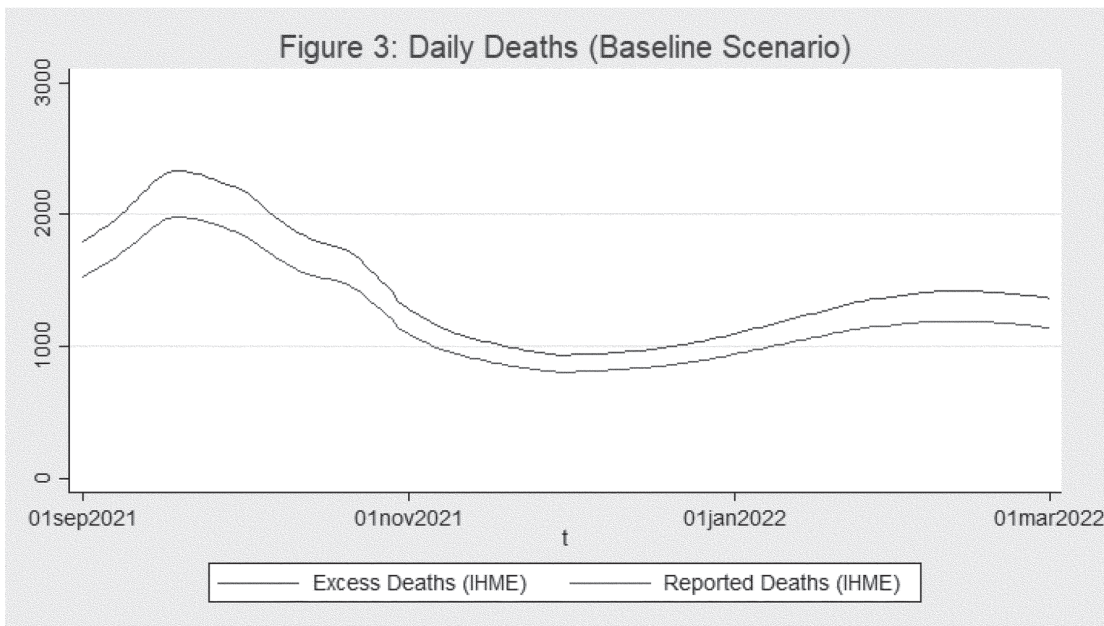
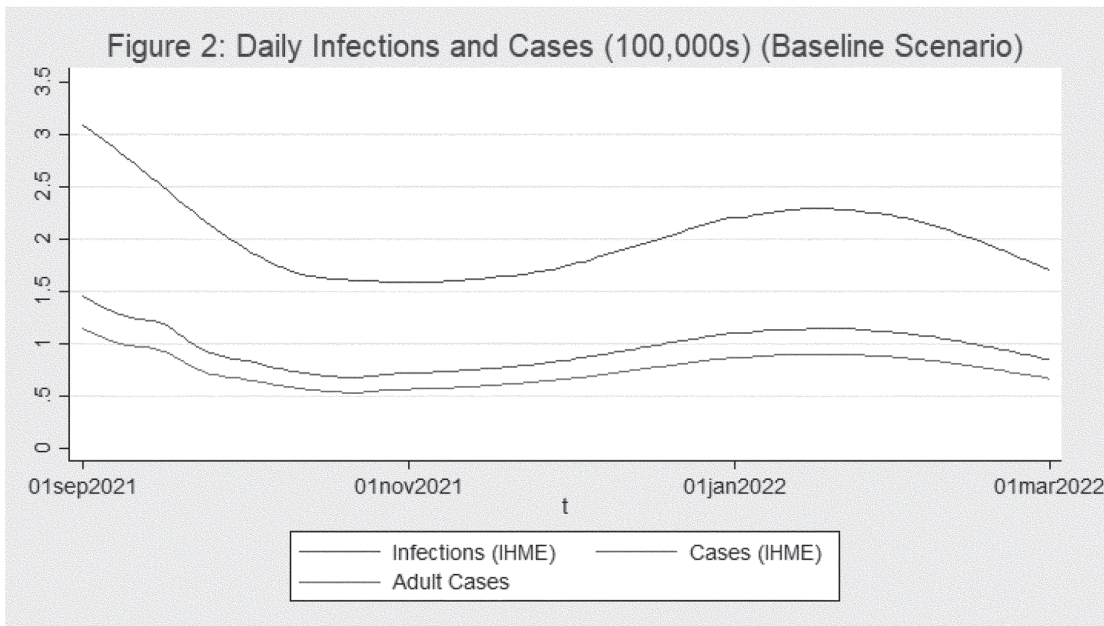
individuals aged <18 years.¹⁰⁶ We adjust the total population hospital admission projections by this percentage to capture only adult hospital admissions. We note that the hospitalization data provide more limited coverage than data on cases and deaths. This adjustment assumes that the distribution of hospitalizations by age nationally are similar

to the underlying data. We believe this assumption is more justified, in the context of this analysis, than not performing an adjustment.

Figure 2 presents the IHME projections of daily infections, cases, and our estimates of adult cases. Figure 3 presents the IHME projection of daily excess deaths and

reported deaths. This analysis focuses on the projections of reported deaths, which are more comparable with other data sources used in this analysis. Figure 4 presents the IHME projections of daily new hospital admissions and adjusted estimates for adult cases.

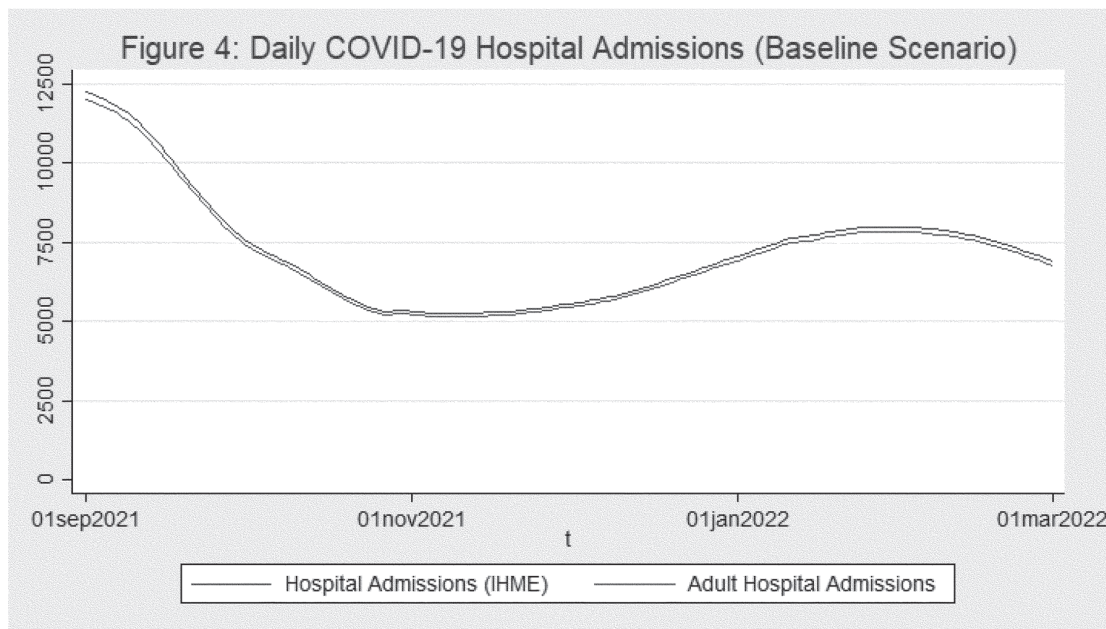
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¹⁰⁶ Calculation based on COVID-19-Associated Hospitalization Surveillance Network, Centers for

Disease Control and Prevention. <https://gis.cdc.gov/>

[grasp/covidnet/COVID19_5.html](https://gis.cdc.gov/grasp/covidnet/COVID19_5.html). 4,228/220,539 ≈ 0.019. Accessed on October 3, 2021.

**BILLING CODE 4184-01-C****COVID-19 Cases, Deaths, and Hospital Admissions Among Head Start Staff**

Head Start staff differ from the general U.S. adult population level in several ways. First, the size of the population is much smaller. Using the IHME total population estimate of about 328 million, and a Census estimate of the population share of adults of about 78%,¹⁰⁷ we compute a total of 255 million adults. The 273,000 Head Start staff represent about 0.1% of total adults. As an initial adjustment, we adjust the baseline scenario estimates of daily cases, deaths, and hospital admissions downward to reflect the population under the scope of the interim final rule.

If Head Start staff had a COVID-19 risk profile that matched the adult population, no further adjustments would be necessary; however, as described above, a higher share of Head Start staff are fully vaccinated than the adult population as a whole, and we expect this trend to continue through the time horizon of the baseline scenario of this analysis. To properly account for the risk reductions to Head Start staff attributable to higher vaccination rates, we perform an adjustment based on published estimates of the incidence rate ratios (IRRs) that compare outcomes for unvaccinated and vaccinated persons at a population level, which provide a measure of vaccine effectiveness.¹⁰⁸

This CDC study reports averaged weekly, age-standardized IRRs for cases, hospitalizations, and deaths, among persons who were not fully vaccinated (simplified

later by describing these as “unvaccinated”) compared with those among fully vaccinated persons. The IRRs suggest that vaccinated individuals experienced a significantly reduced risk of infection, hospitalization, and death, including during a period when Delta became the most common variant. For the June 20–July 17, 2021 period, the point estimates of the average weekly IRRs for all ages were 4.6 for cases, 10.4 for hospitalizations, and 11.3 for deaths. For individuals between ages 18 and 49 years, these estimates are 4.5 for cases, 15.2 for hospitalizations, and 17.2 for deaths. For individuals between ages 50 and 64 years, these estimates are 4.9 for cases, 10.9 for hospitalizations, and 17.9 for deaths. For individuals aged ≥65 years, these estimates are 4.6 for cases, 7.6 for hospitalizations, and 9.6 for deaths.

The IRR of 4.6 for cases means that vaccination offers strong protection against COVID-19 and that fully vaccinated people had about a five-fold reduction in risk of infection compared with people not fully vaccinated. These IRR estimates cover adults and are standardized to match the U.S. adult population. They are calculated by dividing average weekly incidence on a per capita basis among unvaccinated individuals by the incidence among fully vaccinated individuals. For example, the study calculates the IRR for cases by dividing 89.1 cases per 100,000 unvaccinated individuals by 19.4 cases per 100,000 vaccinated individuals.¹⁰⁹

For comparison, the CDC study underlying these estimates also reports higher measurements of the IRR during an earlier time period, covering April 4–June 19, 2021. Specifically, the comparable IRR estimates were 11.1 for cases, 13.3 for hospitalizations, and 16.6 for deaths. The study does not disentangle the changes in the IRR measurements across these time periods that

that are attributable to the highly transmissible Delta variant or other factors, such as the potential decline in vaccine effectiveness as the time since vaccination increases. Although the IRRs are unlikely to remain constant over time, the estimates corresponding to the June 20–July 17, 2021 period represent the best available estimates of the IRR for the time horizon of this analysis.

We also generate IRR estimates specific to the Head Start teacher population. These estimates reflect differences in the age distribution of Head Start teachers rather than observational data on COVID-19 cases, since ACF does not collect this information. To generate these estimates, we pair the age-specific IRR estimates with the corresponding age range for Head Start teachers. ACF data indicates that 10.4% of Head Start teachers are ages 18–29 years; ages 30–39 years, 29.6%; ages 40–49 years, 26.7%; ages 50–59 years, 21.7%; and ages >60 years, 11.6%.¹¹⁰ For the purposes of this analysis, we assume that half of Head Start teachers 60 years and older are ages 60–64 years, and half are ages >65 years. Table 2 presents the central estimates of the age-standardized IRRs for cases, hospitalizations and deaths for the adult population, as reported in the CDC study, and IRRs for the same outcomes, but standardized for the age profile of Head Start teachers. We later apply these estimates, which reflect the Head Start teacher age

¹⁰⁷ <https://www.census.gov/popclock/data-tables.php?component=pyramid>.

¹⁰⁸ Scobie HM, Johnson AG, Suthar AB, et al. (2021). “Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4–July 17, 2021.” *Morbidity and Mortality Weekly Report* 2021;70:12841290. DOI: <http://dx.doi.org/10.15585/mmwr.mm7037e1>.

¹⁰⁹ $89.1/19.4 \approx 4.6$.

¹¹⁰ Doran, Elizabeth, Natalie Reid, Sara Bernstein, Tutrang Nguyen, Myley Dang, Ann Li, Ashley Kopack Klein, Sharika Rakibullah, Myah Scott, Judy Cannon, Jeff Harrington, Addison Larson, Louisa Tarullo, and Lizabeth Malone (2021). *A Portrait of Head Start Classrooms and Programs in Spring 2020: FACES 2019 Descriptive Data Tables and Study Design*. OPRE Report #2021–215, Washington, DC: Office of Planning, Research, and Evaluation, Administration for Children and Families, U.S. Department of Health and Human Services. Pending Publication.

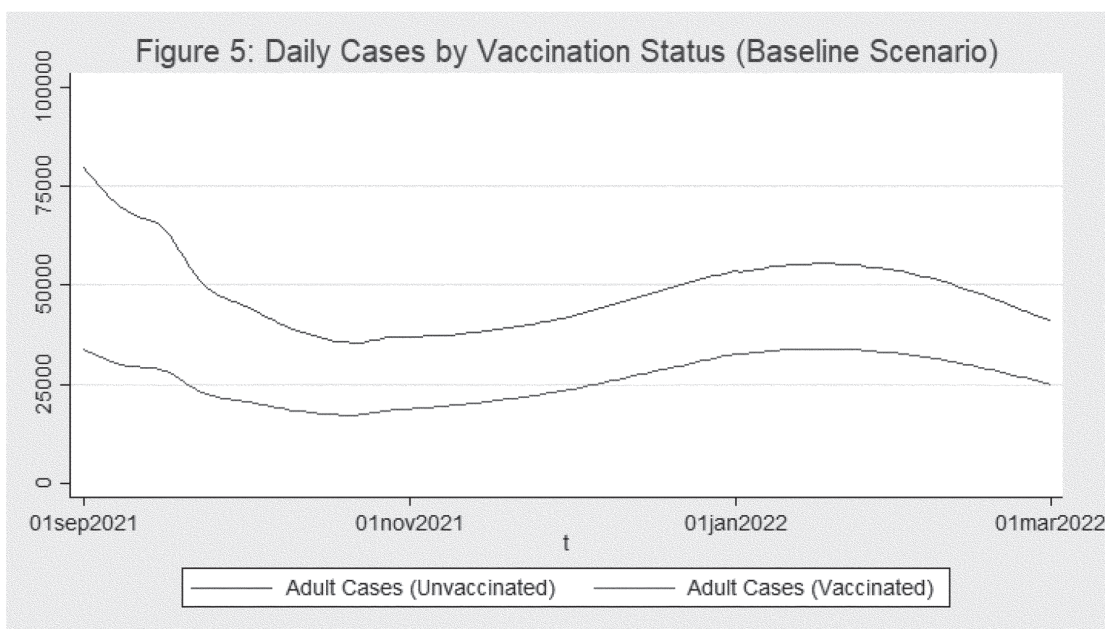
profile, for a broader population of Head Start staff.

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Table 2. Incidence Rate Ratios for Adults and Head Start Teachers

Age Range (years)	Share of Teachers	Case IRR	Hospitalization IRR	Death IRR
18-29	10.4%	4.5	15.2	17.2
30-39	29.6%	4.5	15.2	17.2
40-49	26.7%	4.5	15.2	17.2
50-59	21.7%	4.9	10.9	17.9
60-64	5.8%	4.9	10.9	17.9
65+	5.8%	4.6	7.6	9.6
Adults		4.6	10.4	11.3
Head Start		4.6	13.6	17.0

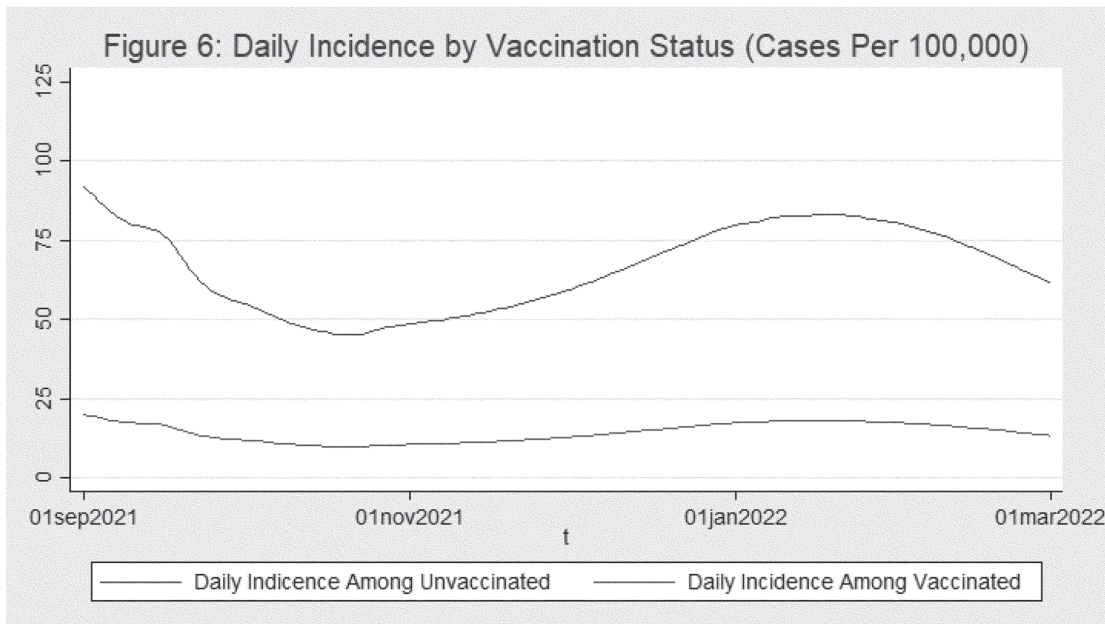
By adopting the adult age-standardized IRR estimates, we are able to disaggregate COVID-19 cases among unvaccinated individuals from cases among vaccinated individuals. Figure 5 presents these estimates for the adult population.



We combine estimates of the daily adult cases among unvaccinated individuals and daily estimates of the unvaccinated adult population to generate daily incidence rates among unvaccinated individuals on a per capita basis. We perform similar calculations to generate daily incidence rates among vaccinated individuals on a per capita basis.

Figure 6 reports the daily incidence over time and by vaccination status. These estimates are reported as cases per 100,000 individuals. For the last week in our projections, covering February 23, 2022 to March 1, 2022, the weekly incidence rate for unvaccinated adults is about 446 cases per 100,000, while the weekly incidence rate for vaccinated

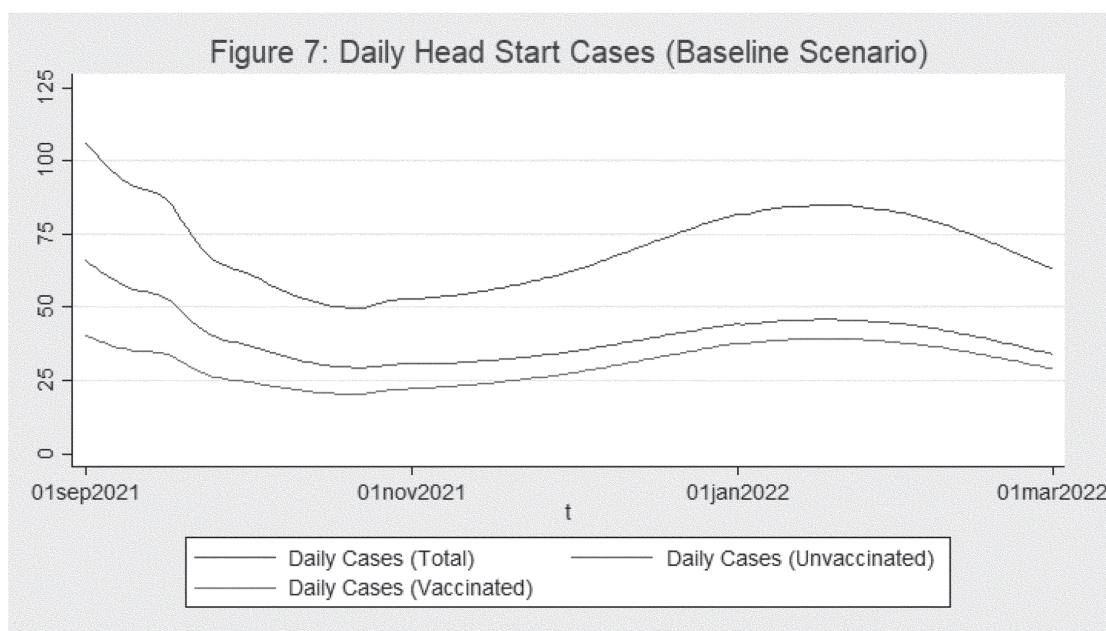
adults is about 97 cases per 100,000, which is consistent with a 4.6 IRR. This time period corresponds to an adult vaccination rate of 73.8%, for a total adult weekly incidence rate of about 188 cases per 100,000, and a total weekly adult case count of 480,523.



To generate estimates of cases among Head Start staff, we combine the estimates of vaccine uptake from Figure 1, estimates of the daily incidence by vaccination status, applying the IRR measure specific to Head Start staff, with outcomes scaled by the number of Head Start staff. This approach assumes, for the purpose of developing quantitative projections, that daily exposure to COVID-19 among Head Start staff is largely driven by interactions with the public as a whole and that Head Start staff face similar exposure to these risks as other

adults. If Head Start staff face greater exposure to these risks than the adult population, such as through routine contact with children who are generally not eligible for a COVID-19 vaccination, this will cause our baseline estimates of cases, hospitalizations, and deaths among Head Start staff to be downward biased. This would similarly result in our estimates of the health benefits from increases in vaccine coverage to be downward biased. We project that Head Start staff will experience lower per-capita case counts than the general adult

population due to higher rates of vaccination, and a higher IRR rate consistent with the age profile of Head Start staff compared to all adults. Figure 7 presents daily Head Start cases. For the last week in our projections, covering February 23, 2022 to March 1, 2022, we estimate about 457 total cases, with 246 cases from unvaccinated, and 211 cases from vaccinated Head Start staff. These cases translate to a baseline Head Start weekly incidence rate of about 167 cases per 100,000.



We generate estimates of the Head Start deaths and hospital admissions using the same approach as we describe for cases. We adopt IRR estimates specific to the Head Start staff population of 17.0 for deaths and an IRR of 13.6 for hospitalizations. These IRRs indicate that the COVID-19 vaccines provide even stronger protection against COVID-19 associated hospitalization and death than against infections. We perform adjustments to the adult incidence rates that are intended to control for deaths and hospital admissions that are concentrated in older age groups than we observe among Head Start staff.

Using CDC surveillance data through October 3, 2021, we observe that, among the 567,704 COVID-19 deaths in the United States for which age data are available, 319,311 deaths are among individuals ≥ 75 years. While the Head Start workforce includes a number of older individuals, very few are ≥ 75 years. Head Start data indicate that 11.6% of teachers are age 60 years or

older, compared to the general population share of 22.7%. We anticipate that almost all of the Head Start teachers age 60 years or older are between age 60 and 74 years, and assume this is also true for the broader Head Start staff population. Therefore, we adjust the adult death incidence rate to exclude deaths among individuals ≥ 75 years. This adjustment reduces the baseline forecast for Head Start deaths downwards by about 56%.¹¹¹ Older individuals are also hospitalized at higher rates than younger peers, but this difference is less pronounced than for deaths. Among laboratory-confirmed COVID-19-associated hospitalizations for which age data are available, about 43% are individuals ≥ 65 years,¹¹² an age subgroup representing about 16.5% of the total population. Since only 5.8% of Head Start staff are individuals ≥ 65 years, we reduce the total population baseline forecasts for hospitalizations by about two thirds¹¹³ of 43%, or about 28%,¹¹⁴ since we expect a

significant share of these hospitalizations to be among individuals older than most Head Start staff.

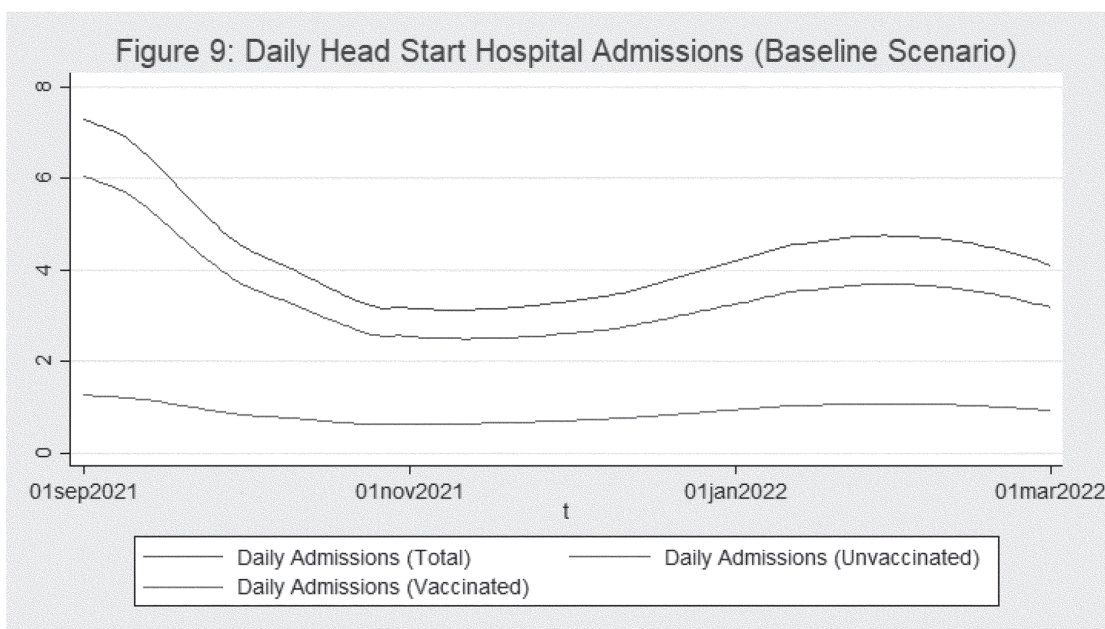
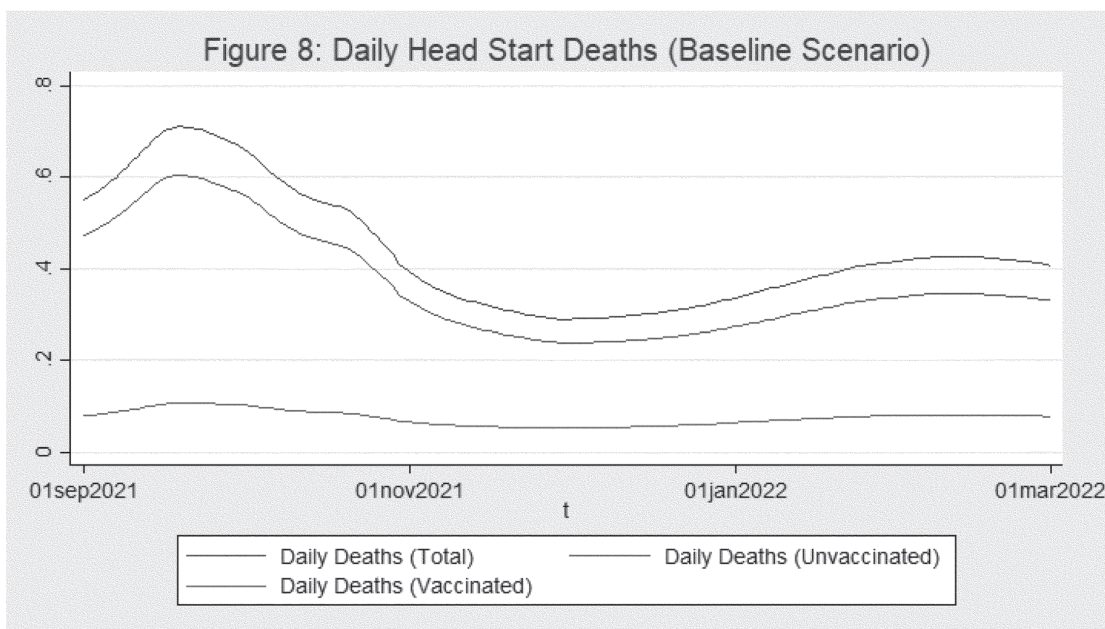
Figure 8 reports daily Head Start deaths attributable to COVID-19 under the baseline scenario. For the entire period of the baseline scenario, we anticipate fewer than one COVID-19 related death per day among Head Start staff. For the last week in our projections, covering February 23, 2022 to March 1, 2022, we estimate 2.9 weekly deaths out of the total Head Start staff population of 273,000. To provide additional context, this is a weekly incidence rate of 1.06 deaths per 100,000 individuals. The comparable adult weekly incidence rate is about 3.18 deaths per 100,000 individuals. Figure 9 reports daily Head Start hospital admissions. For the last week in our projections, we estimate 29 hospital admissions for a weekly incidence rate of 10.8 per 100,000.

¹¹¹ $319,311 / (567,704 - 637) \approx 0.56$.

¹¹² $92,960 / (220,539 - 4,228) \approx 0.43$.

¹¹³ $0.058 / 0.165 \approx 0.35$, $1 - 0.35 = 0.65$.

¹¹⁴ $0.43 * 0.65 \approx 0.28$.



Head Start Program Operating Status and Staffing

The Office of Head Start has tracked the operating status of programs since the onset of the pandemic. In March and April of 2020, more than 90% of programs closed all in-person operations. By August of 2020, 21% of programs had reopened for in-person services, 26% remained closed for in-person services due to COVID-19, and the remainder of programs were closed for summer months as regularly scheduled. In December 2020, data show the highest combined percentage (67%) of Head Start centers operating as solely virtual/remote or as hybrid, with an additional 5% of centers closed. Together, these centers account for over 13,500 centers

nationwide. This represents many working parents for whom unpredictable closures and transitions to virtual learning come at a cost, present difficult decisions between employment and child care responsibilities, and major financial impacts on their household.

Most recently, July 2021 data show that 2% of centers were closed due to COVID-19, 14% of centers were operating virtual/remote, and 44% of centers were operating in a hybrid status, which includes programs that are alternating between in-person services, virtual or remote services, or some combination of the two. Only 35% of centers were operating fully in-person. We do not have comparable data for about 5% of

centers.¹¹⁵ While closures have declined, the majority of Head Start centers are still operating in virtual/remote or a hybrid status. We adopt these estimates as providing a reasonable representation of the operating status of Head Start centers under the baseline scenario of no regulatory action. These estimates are intended to represent a steady state of overall operating status under the baseline scenario rather than indicating that any particular center will remain in its current status without regulatory action. Table 3 presents the in-person days per week

¹¹⁵ We are missing data on about 5% of centers. For the purposes of this analysis, we assign an operating status to these centers in proportion with the centers for which we have complete data.

by center status. For these estimates, we adopt several assumptions: (1) The average number of staff and children served by each center does not vary by center status; (2) that centers in hybrid operating status meet in person 2.5 days per week, on average; and (3) that centers in fully in-person status meet in

person 5.0 days per week, on average. For the purpose of this analysis, we also assume that the centers with unknown operating status are distributed evenly across each center status category. For our estimate of the total number of children, we use “funded enrollment,” which refers to the number of

children and pregnant people that are supported by federal Head Start funds in a program at any one time during the program year, but reduce this estimate by 1% to account for pregnant people enrolled in Early Head Start.¹¹⁶

Table 3. In-Person Days Per Week by Center Status

Center Status	Centers	Staff	Children	In-Person Days Per Week	In-Person Days Per Week	
					Staff	Children
Closed	414	5,453	17,264	0.0	0	0
Virtual/Remote	3,013	39,698	125,679	0.0	0	0
Hybrid	9,667	127,391	403,305	2.5	318,477	1,008,264
Fully In-Person	7,623	100,458	318,041	5.0	502,292	1,590,204
Total	20,717	273,000	864,289	N/A	820,769	2,598,467

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Early care and education providers, including Head Start programs, are currently experiencing significant challenges in recruiting and retaining staff that are attributable to the COVID-19 pandemic and general trends in early care and education labor markets. These ongoing challenges, which represent the baseline scenario and are not attributable to the interim final rule, are difficult to quantify; however, the section on Costs expands on this discussion. This discussion includes a range of estimates to inform how the requirements in this rule could exacerbate this issue for certain programs, which could include programs not being able to fully staff their classrooms.

E. Impact on Vaccine Coverage

The key parameter underlying the estimated benefits and costs of the interim final rule is the incremental impact on vaccine uptake, which is the difference between the share of individuals who are unvaccinated under the baseline scenario and who are induced to get fully vaccinated under the interim final rule. As we discuss further in the Benefits and Costs sections, higher rates of incremental vaccine uptake are associated with higher benefit estimates, but also lower overall costs. Given the importance of this parameter and its uncertain nature, we perform an analysis of

several scenarios for vaccine uptake, and present estimates of the benefits and costs of the interim final rule for each scenario. Each of the scenarios adopt the following timing and simplifying assumptions:

(1) For the purposes of this analysis, we adopt November 22, 2021 as the public announcement date of the interim final rule.

(2) The effective date of the vaccination requirement is January 31, 2022. We anticipate that some Head Start staff will wait until January 31, 2022 to receive their final vaccination dose.

(3) We do not attribute any impact on the rate of fully vaccinated Head Start staff until at least December 6, 2021. The earliest impacts would be among Head Start staff who have received one COVID-19 dose as part of a two-dose series at the time of the public announcement of the interim final rule to complete their two-dose series. The latest impacts would be among Head Start staff who receive their final dose on January 31, 2022, who will be considered fully vaccinated two weeks later, on February 14, 2022.

(4) The interim final rule describes exemptions from the vaccination requirement. For the purposes of this analysis, we assume that 5% of total Head Start staff will seek and be granted an exemption from the vaccination

requirement.¹¹⁷ These individuals will not be induced to get fully vaccinated under the interim final rule. This assumption translates to least 13,650¹¹⁸ Head Start staff who will remain unvaccinated under all vaccine coverage scenarios.

Our upper-bound scenario is based on an observation contained in the HHS *Guidelines for Regulatory Impact Analysis*, which notes that “[i]n most cases, the analysis focuses on estimating the incremental compliance costs incurred by the regulated entities, assuming full compliance with the regulation, and government costs.”¹¹⁹ For the purpose of this analysis, we maintain the assumption that 5% of Head Start staff will seek and be granted an exemption, while the remaining 95% will be fully vaccinated. These represent two of the routes that Head Start staff can demonstrate full compliance with the interim final rule. We note that the HHS *Guidelines for Regulatory Impact Analysis* further recommend that “[a]nalytists should consider the uncertainty associated with an assumption of full compliance and provide analysis of alternative assumptions, as appropriate.”

Our lower-bound scenario adopts an estimate drawn from an Issue Brief published by the HHS’s Office of the Assistant Secretary for Planning and Evaluation (ASPE), which finds that “[a]s of August 2021, approximately 30% of U.S. adults are

¹¹⁶ <https://eclkc.ohs.acf.hhs.gov/sites/default/files/pdf/no-search/hs-program-fact-sheet-2019.pdf>.

¹¹⁷ This estimate is consistent with an assumption discussed in the Preamble of the Emergency Temporary Standard recently issued by the Department of Labor’s Occupational Safety and

Health Administration. “OSHA estimates that some 5% of employees may have a medical contraindication or request an accommodation from the rule’s requirements for disability or sincerely held religious belief reasons.” <https://www.federalregister.gov/documents/2021/11/05/>

2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard.

¹¹⁸ $0.05 * 273,000 = 13,650$.

¹¹⁹ <https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis>.

unvaccinated; among these, approximately 44% may be willing to get vaccinated against COVID-19.”¹²⁰ This published finding is based on an analysis using survey data for Week 33 of the Household Pulse Survey (June 23–July 5, 2021). We perform an identical calculation using Week 39 (September 29–October 11) survey responses, which results in a lower estimate of 33.4%. We assume that 33.4% of the unvaccinated individuals will be induced to get fully vaccinated by this time under the policy scenario. Under this scenario, about 86.6% of Head Start staff are fully vaccinated by February 14, 2022.

These estimates are from a nationally representative survey of households, but are broadly consistent with responses from another survey specific to U.S. child care providers.¹²¹ In this survey, which informs our baseline forecast of Head Start staff vaccine coverage, overall vaccine uptake among U.S. child care providers was 78.2%. Among unvaccinated survey respondents,

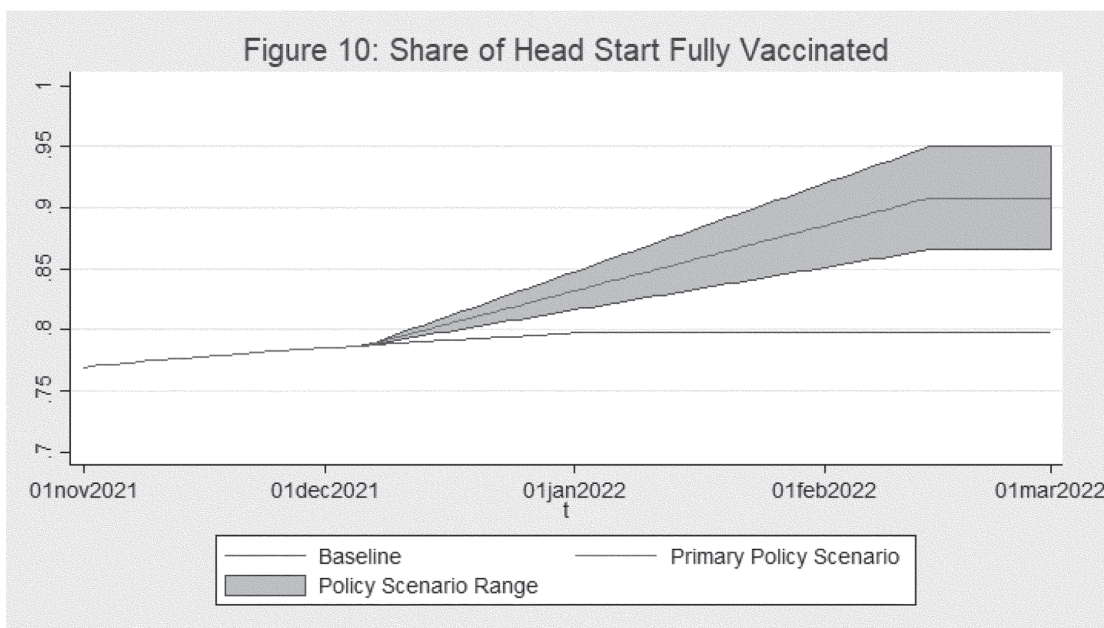
including child care providers not affiliated with Head Start, the authors note that “only 5.0% were ‘absolutely certain’ that they would get vaccinated in the future, 6.9% were ‘very likely,’ 28.2% were ‘somewhat likely.’” These percentages, which sum to 40.1%, suggest substantial room for additional vaccine uptake among child care providers, even though rates significantly exceeded the general population at the time of the survey. As a sample calculation, if 40.1% of the 21.8% of unvaccinated survey respondents get vaccinated, this would increase the overall vaccine uptake among U.S. child care providers from 78.2% to 86.9%. This estimate is slightly above our lower-bound estimate of vaccine coverage for Head Start staff under the interim final rule.

We anticipate that the vaccination requirement will induce more unvaccinated Head Start staff to get fully vaccinated than the lower-bound vaccine-uptake estimates suggest. For our primary scenario, we adopt the midpoint vaccine coverage rate between

our lower- and upper-bound scenarios, and project overall vaccine coverage of 90.8% among Head Start staff by February 14, 2022.

Figure 10 presents our forecasts of the share of Head Start staff who are fully vaccinated under the baseline scenario, and our range of policy scenarios. For our baseline scenario, we estimate the share who are fully vaccinated of 79.8%, or 217,879 fully vaccinated Head Start staff out of 273,000 total staff. We estimate a range of estimates under of our policy scenario between 86.6% and 95.0%, for an incremental vaccine uptake of between 6.8% and 15.2%. For our primary policy scenario, we estimate overall vaccine coverage of 90.8%, for an incremental vaccine uptake of 11.0%. Under the primary scenario, we estimate 247,833 fully vaccinated Head Start staff, and an incremental 29,953 staff fully vaccinated attributable to the interim final rule.

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E. Benefits of the Rule

We follow identical procedures outlined in the baseline section to generate forecasts of COVID-19 cases, deaths, and hospitalizations that are consistent with a range of vaccine coverage estimates under the policy scenarios. We estimate the likely impacts of the interim final rule by calculating the difference between the measurable COVID-

19 outcomes under the policy scenarios against the baseline scenario described in the previous section.

Reduction in Cases Among Head Start Staff

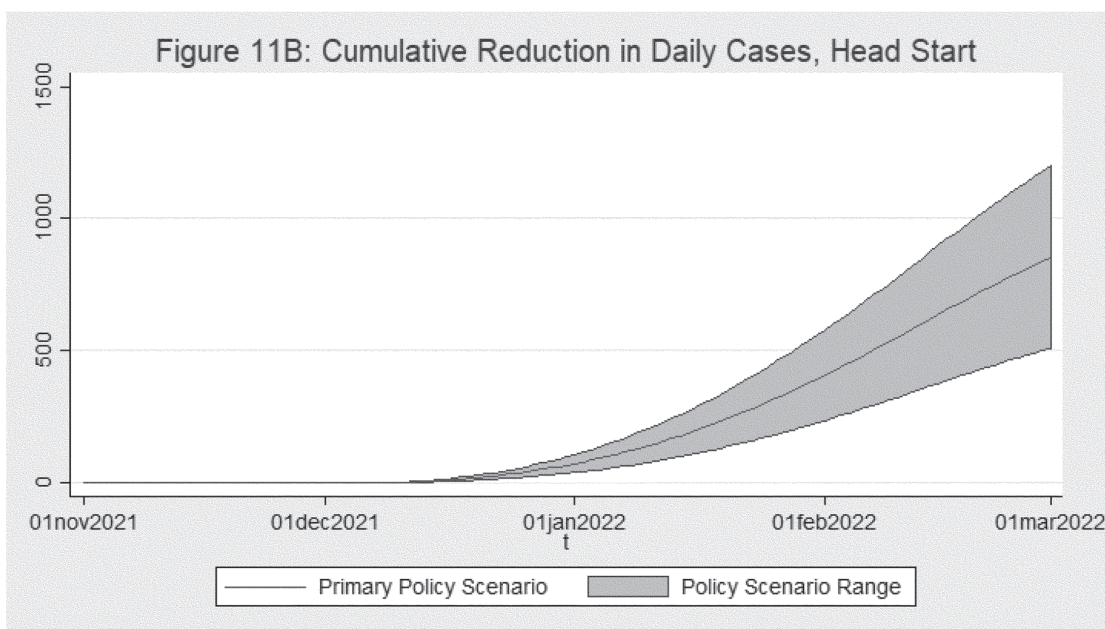
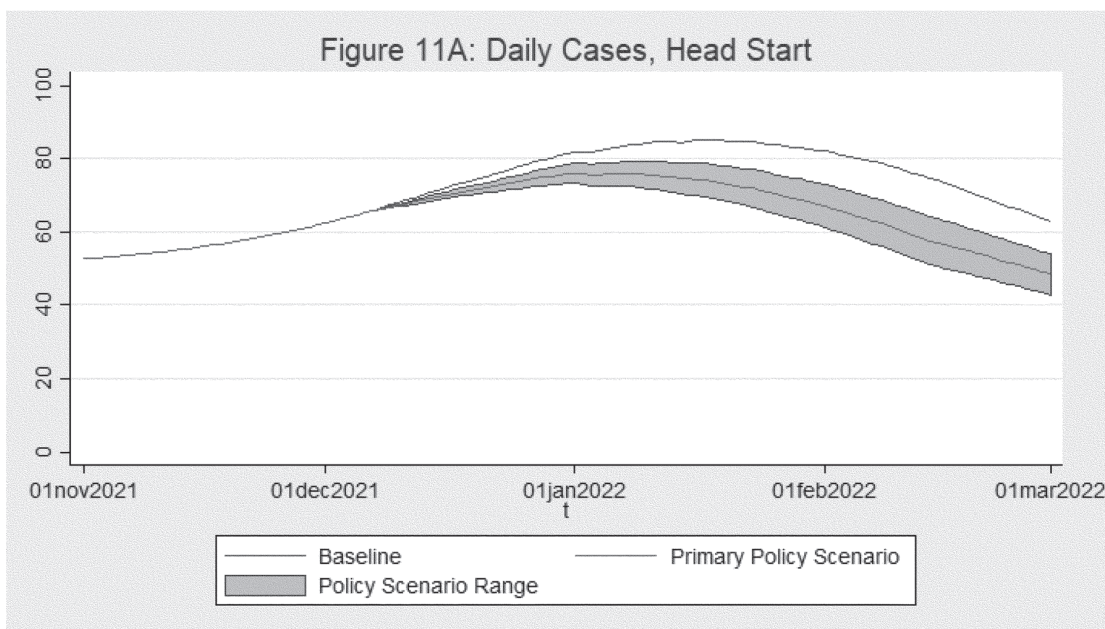
Figure 11A presents our estimates of the daily COVID-19 cases among Head Start Staff under each scenario. The baseline scenario corresponds to the estimates presented in

Figure 7 in the previous section. Figure 11B presents the cumulative reduction in cases over time that are attributable to the interim final rule under the vaccine coverage scenarios. Through March 1, 2022, the impact of the interim final rule is cumulative COVID-19 case reductions between 510 and 1,198, which correspond to the range of vaccine coverage scenarios.

¹²⁰ <https://aspe.hhs.gov/reports/unvaccinated-willing-ib>.

¹²¹ Patel KM, Malik AA, Lee A, et al. (2021). “COVID-19 vaccine uptake among US child care

providers.” *Pediatrics*; doi: 10.1542/peds.2021-053813.

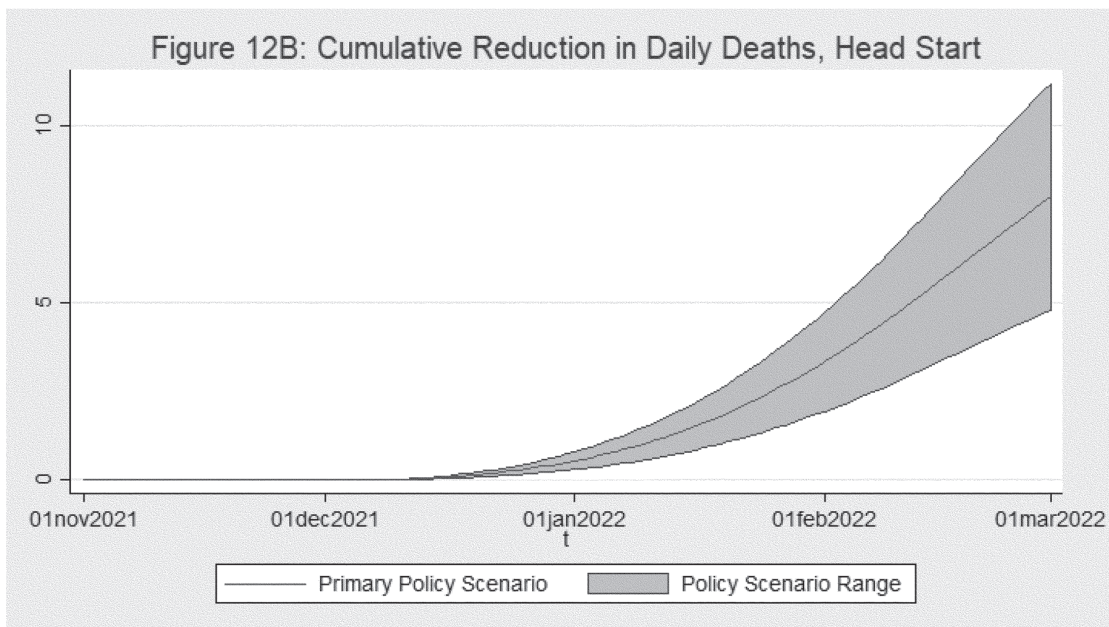
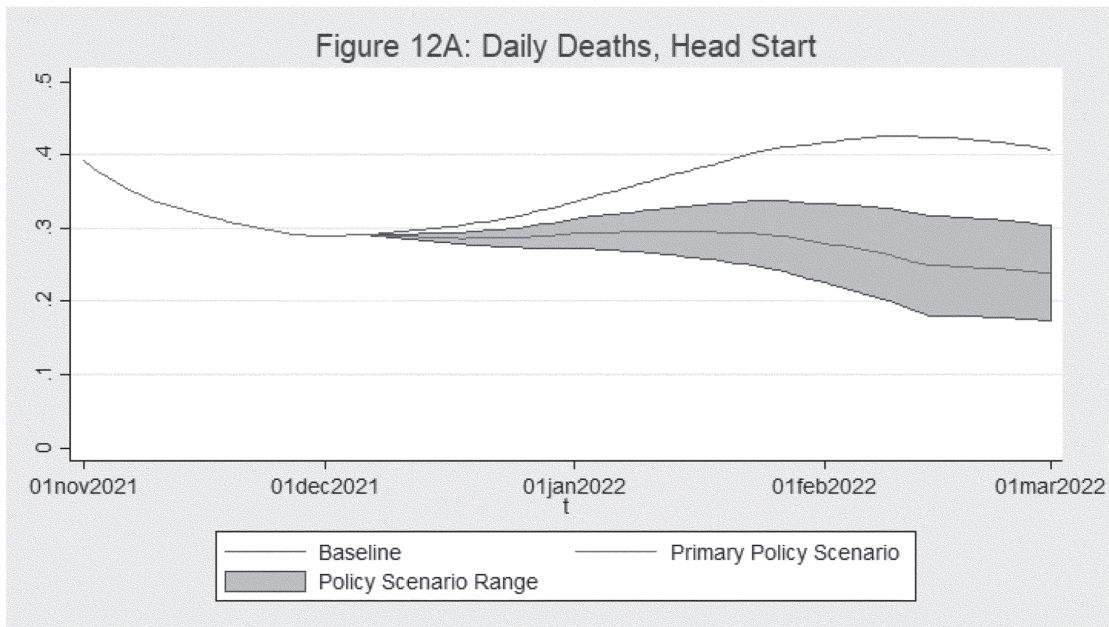


Reduction in Deaths Among Head Start Staff

Figure 12A presents our estimates of the daily COVID-19 deaths among Head Start Staff under each scenario. The baseline

scenario corresponds to the estimates presented in Figure 8 in the previous section. Figure 12B presents the cumulative reduction in deaths over time that are attributable to the interim final rule under the vaccine coverage

scenarios. Through March 1, 2022, the impact of the interim final rule is cumulative COVID-19 mortality reductions between 4.8 and 11.2, which correspond to the range of vaccine coverage scenarios.

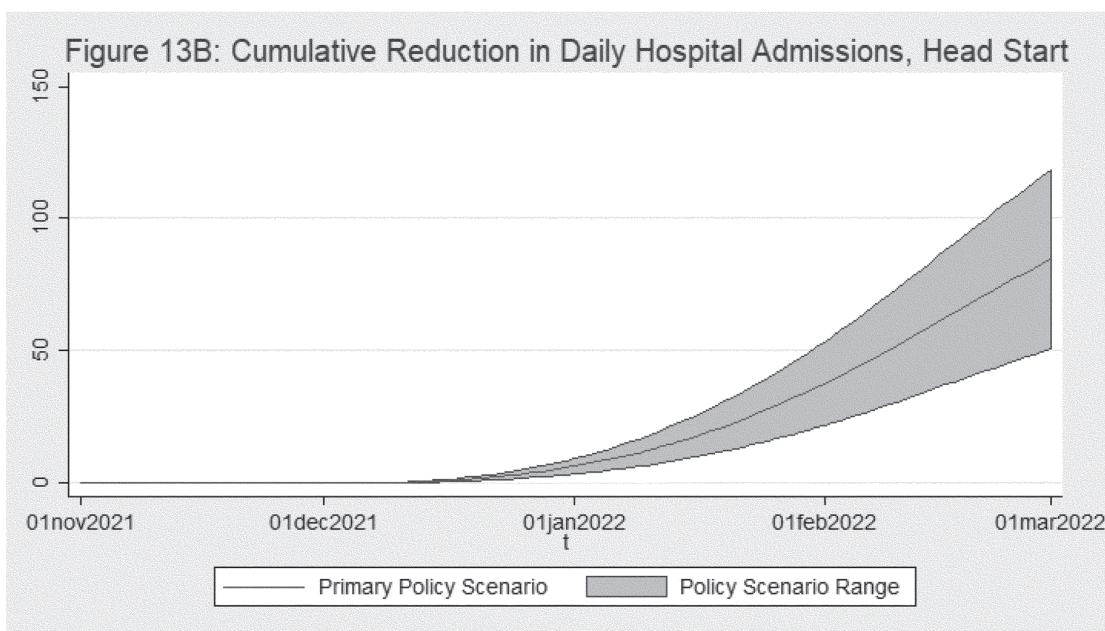
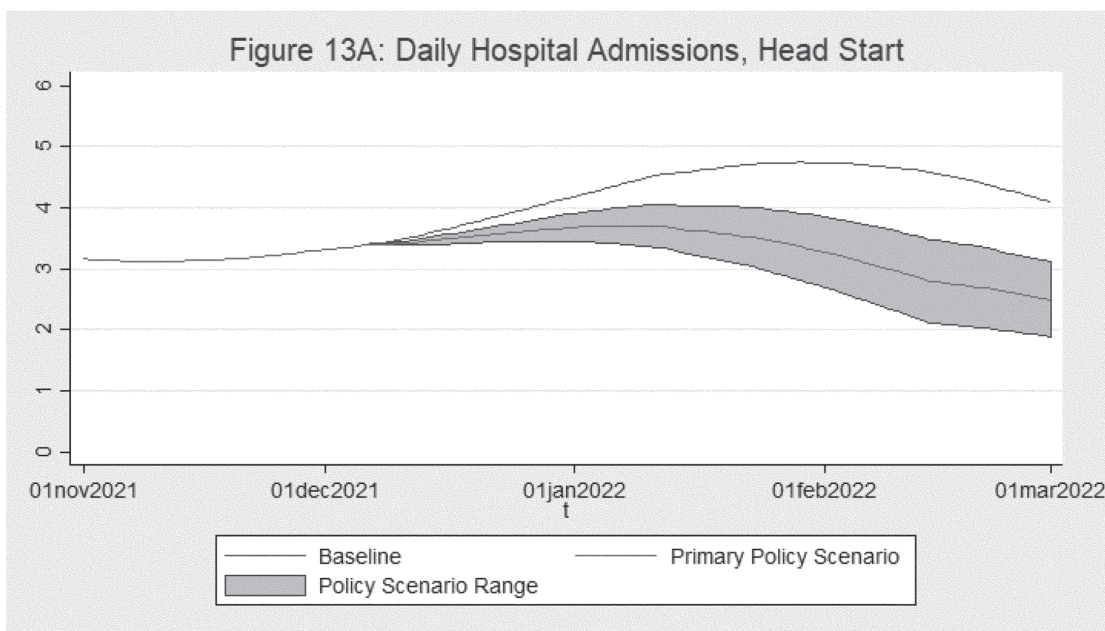


Reduction in Hospital Admissions Among Head Start Staff

Figure 13A presents our estimates of the daily COVID-19 hospital admissions among Head Start Staff under each scenario. The

baseline scenario corresponds to the estimates presented in Figure 9 in the previous section. Figure 13B presents the cumulative reduction in hospital admissions over time that are attributable to the interim final rule under the vaccine coverage

scenarios. Through March 1, 2022, the impact of the interim final rule is cumulative COVID-19 hospital admission reductions between 51 and 118, which correspond to the range of vaccine coverage scenarios.



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Valuing Health Benefits Among Head Start Staff

Table 3 summarizes several measurable improvements in COVID-19 outcomes for Head Start staff that are attributable to the interim final rule. For the baseline scenario of no new regulatory action, and for each of the vaccine coverage scenarios, we report the share of Head Start staff that are fully vaccinated by March 1, 2022, and the corresponding cumulative cases, deaths, and hospital admissions averted over the time horizon of the analysis.

IHME’s daily projections for U.S. hospital admissions include about 35% that result in intensive care unit (ICU) admissions. Head Start hospital admissions estimates are adjusted downwards to reflect a lower rate of hospitalization among younger individuals. We similarly expect the share of hospitalizations that include an ICU admission to be lower for Head Start staff compared to the general adult population; however, we are not aware of an estimate that is directly transferable, and adjust this estimate of the share of hospital admissions that result in an ICU admission down by half.

We believe this assumption is more justified, in the context of this analysis, than not performing an adjustment. Assuming about 17.5% of the cumulative hospital admissions result in an ICU admission, we estimate 76 ICU admissions under the baseline scenario, and between 55 and 67 ICU admissions under the interim final rule, depending on the vaccine coverage scenario. Therefore, we measure a reduction of between 9 and 21 ICU admissions under the interim final rule. We follow the same approach to calculate non-ICU hospital admissions for the remaining 82.5% of total hospital admissions.

Table 4. Cumulative Impacts Among Staff by Vaccine Coverage Scenario

Outcome	Baseline Scenario	Vaccine Coverage Scenario			Difference		
		Low	Primary	High	Low	Primary	High
		Fully Vaccinated Rate	79.8%	86.6%	90.8%	95.0%	6.8%
Cases	7,724	7,214	6,870	6,526	-510	-854	-1,198
Deaths	37.3	32.4	29.3	26.1	-4.8	-8.0	-11.2
Hospital Admissions	428	377	343	309	-51	-84	-118
Non-ICU	352	310	282	255	-42	-69	-97
ICU	76	67	61	55	-9	-15	-21

Valuing risk reductions associated with regulations that address the COVID-19 presents major challenges. We adopt an approach to monetize the cumulative cases, deaths, and hospitalizations averted under the interim final rule by closely following the methodology described in an ASPE report on “Valuing COVID-19 Mortality and Morbidity Risk Reductions in U.S. Department of Health and Human Services Regulatory Impact Analyses.”¹²² This paper addresses these challenges by summarizing the impacts of COVID-19 on health and longevity, describing the conceptual framework for valuation, investigating some of the available valuation research (as of March, 2021), and discussing the implications.¹²³ We note that the impact of the virus is rapidly evolving, and new data are continually emerging. We have reviewed the assumptions and evidence contained in this report and conclude that the quantitative estimates remain useful for assessing the impacts of this interim final rule.

Valuing these risk reductions using the estimates contained in the ASPE report requires assumptions that map the non-fatal risk reductions quantified in Table 4 into “mild,” “severe,” and “critical” case-severity categories. These categories are characterized by common symptoms experienced for an acute phase and post-acute phase. Below, we reference the description of each case-severity category from Table 3.2 Common

¹²² <https://aspe.hhs.gov/reports/valuing-covid-19-risk-reductions-hhs-rias>.

¹²³ Additional relevant citations not contained in the report include Viscusi, W.K. Pricing the global health risks of the COVID-19 pandemic. *J Risk Uncertain* 61, 101–128 (2020). <https://doi.org/10.1007/s11166-020-09337-2> and Viscusi W.K. Economic lessons for COVID-19 pandemic policies [published online ahead of print, 2021 Mar 4]. *South Econ J.* 2021;10.1002/soej.12492. doi:10.1002/soej.12492.

Symptoms of Nonfatal COVID-19 Cases by Severity Level of the ASPE Report.¹²⁴

For the acute phase of a critical case, “[i]ndividuals will have early symptoms similar to those of mild and severe disease. Individuals may quickly progress to respiratory failure and may also have septic shock, encephalopathy (brain disease), heart disease or failure, coagulation dysfunction (inability of blood to clot normally), and acute kidney injury. Organ dysfunction can be life-threatening. Individuals with critical disease often receive prolonged mechanical ventilation.” For the post-acute phase, “[i]ndividuals are likely to have long-term physical and cognitive impairment similar to other critical illnesses.” We initially assign the 9 to 21 averted ICU admissions to the critical case category, but we reduce these estimates by the number of deaths averted. This approach avoids the potential for double counting, since the underlying VSL estimates likely include the willingness-to-pay to avoid some morbidity prior to death.

The ASPE Report discusses these considerations in greater detail, noting that “COVID-19 deaths are generally preceded by about two weeks of symptoms, including fever, shortness of breath, high respiratory rate, and cough. They may also involve being placed on mechanical ventilation in a medically induced coma.” This is in contrast to “[t]he studies that underlie the HHS VSL estimates, [which] focus largely on occupational risks that lead to relatively immediate death from injury.” Therefore, we explore the sensitivity of the overall results to this approach. Including the value of a critical case to the value of the mortality reductions for these individuals prior to death would increase the total monetized

¹²⁴ <https://aspe.hhs.gov/reports/valuing-covid-19-risk-reductions-hhs-rias>. Table 3.2 appears on page 35.

health benefits by between \$8.7 million and \$20.3 million, depending on the vaccine coverage scenario. We do not include these estimates in the summary of monetized benefits.

For the acute phase of a severe case, “[i]ndividuals will have early symptoms similar to those of mild disease, such as fever and cough, which may be accompanied by gastrointestinal symptoms, such as diarrhea. The disease continues to progress for over a week. Dyspnea (shortness of breath), high respiratory rate, and/or blood oxygen saturation of ≤ 93 percent occur. Individuals typically have pneumonia and require supplementary oxygen. Individuals with severe disease should be hospitalized.” For the post-acute phase, “[i]ndividuals may have post-acute symptoms, such as cough, shortness of breath, fatigue, and pain.” We assign the 42 to 97 non-ICU hospital admissions averted to the severe case category.

For the acute phase of a mild case, “[i]ndividuals will have symptoms of acute upper respiratory tract infection, which may include fever, fatigue, myalgia (muscle aches), cough, and sore throat. Some cases may have digestive symptoms, such as nausea, abdominal pain, and diarrhea. Loss of taste and smell are common symptoms. Individuals may have mild pneumonia (infection of the lungs), and some may have wheezing or dyspnea (shortness of breath) but blood oxygen saturation remains above 93 percent.” For the post-acute phase, “[i]ndividuals may have post-acute symptoms, such as cough, shortness of breath, fatigue, and pain.” We initially assign the 510 to 1,198 cumulative cases averted to the mild case category, but we reduce these estimates by the corresponding estimates of critical and severe cases to avoid double counting. This yields an estimate of between 460 to 1,080 mild cases averted.

We considered a further adjustment to the estimate range for mild cases to account for the share of cases that are asymptomatic. As noted above, these estimates are derived from projections of *measured COVID-19 cases, rather than total COVID-19 infections*. Over the period of the analysis, these represent slightly less than half of the total projected infections, including those not confirmed through testing. This means that, while our measure of mild cases likely includes some confirmed cases that are asymptomatic, it does not include some symptomatic COVID-19 infections that are not confirmed through testing. The ASPE report also discusses the potential for “cases that are initially asymptomatic or mildly symptomatic may ultimately lead to impaired health over the longer run,” suggesting that the VSC estimates for mild cases may underestimate the full long-run health-related quality of life consequences of an infection. Given the multiple sources and potential direction of the bias, we have determined that it is appropriate to not make an explicit adjustment. However, we have incorporated

uncertainty into the main analysis, which includes a range of total cases averted. We also perform a sensitivity analysis for all health benefits monetized in this analysis by applying a range of VSC and VSL estimates.

The mortality and morbidity risk reductions we identify in this regulatory impact analysis accrue to a working-age Head Start staff population. We have taken care to ensure that our estimates of the cumulative cases, deaths, and hospital admissions averted would not be biased upwards due to an overrepresentation of deaths and hospital admissions among individuals older than the typical Head Start staff. Thus, we adopt the population-average VSL and VSC estimates contained in the ASPE report, with a minor adjustment of 0.8% to account for real income growth, since the mortality and morbidity risk reductions occur in 2021 and the underlying estimates are from a 2020 base year.

Table 5A reports the mortality risk reductions attributable to the interim final rule, and the morbidity risk reductions, categorized by case-severity category. We

monetize these impacts using a VSL of about \$11.5 million, and VSC estimates that vary by case severity. We multiply the risk reductions by the appropriate VSL or VSC estimate to generate estimates of the value of these risk reductions. We sum these to generate a monetized benefit of the health benefits to Head Start staff attributable to the interim final rule under the vaccine coverage scenarios. Using a 3% discount rate, which affects the underlying value per quality-adjusted life year estimate used in the ASPE report to generate the VSC estimates, we report a total value of risk reduction of between \$66.0 million and \$154.1 million. Table 5B reports the same estimates using a 7% discount rate. Under this discount rate, we report a total value of risk reduction of between \$68.2 million and \$159.2 million. All estimates are reported using 2020 dollars. These impacts cover the period between the publication date of the interim final rule and March 1, 2022, the last day reported in the IHME projections.

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Table 5A. Value of COVID-19 Risk Reductions Among Staff, 3% Discount Rate

Risk Reduction	Vaccine Coverage			VSL or VSC	Value of Risk Reduction (\$ millions)		
	Scenario				Low	Primary	High
	Low	Primary	High				
Mortality Reductions	4.8	8.0	11.2	\$11,501,365	\$55.2	\$92.0	\$128.8
Morbidity Reductions							
Mild Cases	459.8	769.8	1,079.7	\$5,846	\$2.7	\$4.5	\$6.3
Severe Cases	41.6	69.4	97.2	\$13,104	\$0.5	\$0.9	\$1.3
Critical Cases	4.2	7.0	9.8	\$1,814,400	\$7.6	\$12.7	\$17.7
Total Value of Risk Reductions					\$66.0	\$110.1	\$154.1

Table 5B. Value of COVID-19 Risk Reductions Among Staff, 7% Discount Rate

Risk Reduction	Vaccine Coverage Scenario			VSL or VSC	Value of Risk Reduction (\$ millions)		
	Low	Primary	High		Low	Primary	High
	Mortality Reductions	4.8	8.0		11.2	\$11,501,365	\$55.2
Morbidity Reductions							
Mild Cases	459.8	769.8	1,079.7	\$9,778	\$4.5	\$7.5	\$10.6
Severe Cases	41.6	69.4	97.2	\$22,176	\$0.9	\$1.5	\$2.2
Critical Cases	4.2	7.0	9.8	\$1,814,400	\$7.6	\$12.7	\$17.7
Total Value of Risk Reductions					\$68.2	\$113.7	\$159.2

BILLING CODE 4184-01-C**Valuing Time Savings for Head Start Families From Reductions in Absenteeism**

We also anticipate reductions in time spent by parents or other caretakers providing needed support for children due to COVID-19 infections among Head Start staff. Several assumptions are necessary to quantify this impact. Since 273,000 Head Start staff provide services for 864,289 children, a 1:3.2 ratio, we assume that each staff missing work due to a COVID-19 infection means that an average of 3.2 children will need support from parents or other caretakers during this absence. We assume that a typical COVID-19 case results in two weeks of missed work, which corresponds to an average of 5 days a week, with 6 hours per day of providing Head Start services. Combining these assumptions, we estimate that cases of COVID-19 among Head Start staff results in an average of 190 hours of support for children that will be provided by a parent or other caretaker. *As discussed earlier, the interim final rule is anticipated to reduce COVID-19 cases among Head Start staff by a cumulative 510 to 1,198 cases over the time horizon of the analysis. Each of these cases averted corresponds to 190 hours of time saved by parents or other caregivers.*

We also anticipate that a COVID-19 case at a center operating fully in-person can result in missed work for other Head Start staff who were in close contact and potentially exposed. This impact is limited to unvaccinated staff, since CDC guidance indicates that “[p]eople who are fully vaccinated do not need to quarantine if they come into close contact with someone diagnosed with COVID-19.”¹²⁵ We assume that all unvaccinated staff will be considered close contacts and need to quarantine. For simplicity, we adopt 20.2% as the share of Head Start staff unvaccinated on the last day of our baseline projections. We anticipate that Head Start staff at fully in-person centers represent 37% of the total staff cases, which is in line with the share of centers that are operating fully in-person, and that each center has about 13 staff, which is in line with the average number of staff per center. Among these 13 staff, about 3 are unvaccinated. To avoid double counting, we reduce this estimate by 1 to account for the initial COVID-19 case.

¹²⁵ <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-contact-tracing/about-quarantine.html>.

To monetize these impacts, we adopt a value of time based on after-tax wages. Our approach matches the default assumptions for valuing changes in time use for individuals undertaking administrative and other tasks on their own time, which are outlined in an ASPE report on “Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices.”¹²⁶ We start with a measurement of the usual weekly earnings of wage and salary workers of \$990.¹²⁷ We divide this weekly rate by 40 hours to calculate an hourly pre-tax wage rate of \$24.75. We adjust this hourly rate downwards by an effective tax rate of about 17%, resulting in a post-tax hourly wage rate of \$20.55. We report a range for the total value of time saved of between \$3.3 million and \$7.5 million, depending on the vaccine coverage scenario.

¹²⁶ <https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework>.

¹²⁷ <https://www.bls.gov/news.release/pdf/wkyeng.pdf>, second quarter of 2021.

Table 6. Value of Time Savings from Reduced Absenteeism

Impact	Low	Primary	High
Cases Averted	510	854	1,198
Cases Averted at In-Person Centers	188	314	441
Unvaccinated Close Contacts	1.7	1.7	1.7
Additional Quarantines Averted	312	522	732
Total Absences Averted	822	1,376	1,930
Hours Saved Per Absentee	190	190	190
Total Hours Saved	156,198	261,406	366,614
Value of Time in Hours	\$20.55	\$20.55	\$20.55
Value of Reduced Absenteeism	\$3,210,121	\$5,372,304	\$7,534,486

As a sensitivity analysis, we augmented the post-tax wage rate to account for non-wage benefits. To capture non-wage benefits, we apply an estimate of the share of compensation from employer supplements to wages and salaries of about 18%, or \$4.55 per hour using a pre-tax hourly wage as the base.¹²⁸ This results in a value of time of \$25.10 per hour. Using this alternative value of time, the value of time savings from reduced absenteeism would range from \$3.9 million to \$9.2 million, with a primary estimate of \$6.6 million.

Benefits Related to Head Start Program Operating Status

We consider it probable that the substantial reduction in COVID-19 cases per day among Head Start staff and volunteers will result in fewer center closures due to COVID-19. For a number of reasons, the interim final rule will not eliminate the risk of COVID-19 among Head Start staff, volunteers, and children. Among these reasons, we do not expect that all staff and volunteers will be fully vaccinated under the interim final rule. We also do not expect many children to be fully vaccinated under either the baseline or any of the vaccine coverage scenarios under the policy for the time horizon of the analysis. As described in our discussion of the baseline scenario, being fully vaccinated is associated with a substantial reduction in the risk of a COVID-19 infection; however, it does not eliminate this risk. Thus, since the interim final rule will not eliminate the risk of COVID-19, we cannot reasonably conclude that all currently closed Head Start

centers will reopen and remain open for the time horizon of the analysis. We do not estimate the reduction in closures anticipated due to the interim final rule; however, we present a calculation of how we would value this impact on a per-center basis.

As discussed in the Baseline section, the most recent data available at the time of this analysis indicates that 393 Head Start centers were closed due to COVID-19, representing about 2% of centers. We also presented an estimate of 17,264 children potentially unable to access Head Start services due to these closures, which is about 42 children per center. We restate the assumption that each child not served by these centers requires 30 hours of support per week from family and caregivers that would normally be provided by Head Start staff and volunteers. This means each center closure results in 1,318 hours of support needed per week that would typically be provided by Head Start staff. Combined with the approach to valuing time described earlier, this means each center closure averted by the interim final rule could result in time saved for parents and caregivers valued at \$25,722 per week. If 1% of total Head Start centers reopen as a result of the interim final rule, we would monetize these benefits at \$5.3 million per week.

We also anticipate that the reduction in COVID-19 infection risks among Head Start staff, paired with the mask requirement, will result in a larger share of centers operating fully in person. As discussed in the Baseline section, 3,013 centers are operating in a virtual/remote status and 9,667 centers are operating in a hybrid status. We estimate that 125,679 children are receiving services in centers operating in a virtual/remote status

and that 403,305 children are receiving services in centers operating in a hybrid status. We anticipate that centers transitioning from virtual/remote status to hybrid status, or from hybrid status to fully in-person status could result in time saved for parents and caregivers. We do not provide an estimate, but we expect the value of time saved for these impacts would be less than the value of time saved from reopening closed centers.

The value of time saved for families due to Head Start centers reopening, centers transitioning from virtual/remote status to hybrid status, and centers transitioning from hybrid status to fully in-person status are likely to be substantial. However, these time savings are only part of the anticipated benefits to children and families as the result of fewer closures, and more in-person services. *Head Start* promotes school readiness for children in low-income families by offering educational, nutritional, health, social, and other services. We expect that Head Start centers that are able to reopen or move towards more in-person services under the interim final rule will be more effective in meeting these goals and the needs of Head Start families.

Valuing Health Benefits Among Head Start Volunteers

The interim final rule requires volunteers that interact with children at Head Start programs to be fully vaccinated. In 2019, approximately 1,061,000 adults volunteered in their local Head Start program. Of these, 749,000 were parents of Head Start

¹²⁸ <https://fredblog.stlouisfed.org/2018/10/employer-contributions/>.

children.¹²⁹ We have less information about these adults than for Head Start staff. For the purposes of providing estimates under the baseline and interim final rule, we make the following assumptions:

1. The baseline vaccine coverage rate for Head Start volunteers matches the overall adult vaccine coverage rate.
2. The mortality and morbidity risks for adult Head Start volunteers match the risks for Head Start staff, except through differences in vaccine coverage.
3. The requirement under the interim final rule will be less salient to unvaccinated volunteers than for staff since it is not linked to employment. We start with the lower-bound incremental vaccine-uptake estimate that, among unvaccinated adults, approximately 33.4% will be induced to get fully vaccinated. As discussed earlier, this

estimate is based on an analysis of the Household Pulse Survey. We reduce this estimate by half, which is similar to excluding adults who are “unsure about getting a vaccine,” and results in an incremental vaccine-uptake estimate of about 16.7%.

4. The volunteers most likely to be impacted by the policy are the volunteers associated with centers operating under a hybrid or fully in-person status. For volunteers at centers that are closed or in a virtual/remote operating status, we adopt an incremental vaccine-uptake of 0%.

5. We assume that the requirement will be even less salient for volunteers associated with centers operating in hybrid status. For these volunteers, we further reduce the incremental vaccine-uptake estimate by half, which is similar to excluding adults who

“will probably get a vaccine.” This results in an incremental-vaccine uptake of about 8.4%.

6. We do not estimate a second incremental vaccine-uptake scenario, such as the upper-bound full-compliance scenario for staff, since volunteers can comply with the requirement by choosing to not interact with children in an in-person Head Start setting. We also note that some of these volunteers may be induced to get vaccinated due to another COVID-19 vaccination requirement.

7. For the purposes of this analysis, we assume that volunteers are distributed evenly across Head Start centers, regardless of operating status.

Table 7 summarizes these assumptions for the number of volunteers, and the incremental vaccine-uptake assumptions that vary by center operating status.

Table 7. Vaccine Uptake Among Head Start Volunteers by Center Status

Center Status	Centers	Volunteers	Vaccine-Uptake Assumption
Closed	414	21,193	0.0%
Virtual/Remote	3,013	154,283	0.0%
Hybrid	9,667	495,097	8.4%
Fully In-Person	7,623	390,426	16.7%
Total	20,717	1,061,000	N/A

We follow identical steps for estimating the baseline scenario and policy scenario for Head Start staff, except to substitute the number of volunteers and vaccine-uptake assumptions for each center operating status category. As noted above, we also assume that the baseline vaccination coverage among volunteers matches the adult vaccination coverage, rather than the higher Head Start staff vaccination coverage.

Table 8 summarizes several measurable improvements in COVID-19 outcomes for Head Start volunteers at centers operating fully-in person that we attribute to the interim final rule. We estimate a total increase of 28,163 volunteers who are fully vaccinated, or about 2.7% of the total volunteers. To put this into the context of other vaccine requirements and to continue the discussion of attribution of impacts, we

consider the Head Start volunteers under the baseline scenario who are also covered by the DOL ETS as employees of covered employers. DOL recently estimated 27.0% of covered employees would be vaccinated under the ETS, not including the 62.4% of covered employees vaccinated in the baseline, pre-ETS.¹³⁰ If every Head Start volunteer was covered by this interim final rule, the DOL ETS as an employee of a covered employer, and no other vaccine requirements, our 2.6% estimate would attribute about 10% of the incremental vaccine coverage to this interim final rule and about 90% to the DOL ETS. As a sensitivity analysis on the appropriate attribution of impacts, we also report the net benefits of the interim final rule, excluding all benefits and costs associated with volunteers. These estimates are identical to

the policy alternative of not including volunteers in the scope of the policy, which appears in Table 26.

For the baseline scenario of no new regulatory action, and for interim final rule scenario, we report the share of these volunteers that are fully vaccinated by March 1, 2022, and the corresponding cumulative cases, deaths, and hospital admissions averted over the time horizon of the analysis. Table 9 presents the same estimates for Head Start volunteers associated with centers in hybrid operating status. Table 10 presents the same estimates that combine Head Start volunteers associated with centers in virtual/remote and closed operating statuses. Table 11 presents the estimates for all Head Start volunteers.

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¹²⁹ <https://eclkc.ohs.acf.hhs.gov/sites/default/files/pdf/no-search/hs-program-fact-sheet-2019.pdf>.

¹³⁰ <https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23643.pdf>. Table IV.B.8.

Table 8. Impacts Among Volunteers at In-Person Centers

Outcome	Baseline	Interim Final Rule	Difference
Fully Vaccinated Rate	73.8%	78.2%	4.4%
Cumulative Cases	10,368	10,035	-333
Cumulative Deaths	130.1	122.9	-7.2
Cumulative Hospital Admissions			
Non-ICU	731	693	-37
ICU	158	150	-8
Total	888	843	-45

Table 9. Impacts Among Volunteers at Hybrid Centers

Outcome	Baseline	Interim Final Rule	Difference
Fully Vaccinated Rate	73.8%	76.0%	2.2%
Cumulative Cases	13,421	13,273	-148
Cumulative Deaths	170.6	167.2	-3.4
Cumulative Hospital Admissions			
Non-ICU	957	940	-17
ICU	206	203	-4
Total	1,163	1,142	-21

Table 10. Impacts Among Volunteers at Virtual/Remote and Closed Centers

Outcome	Baseline	Interim Final Rule	Difference
Fully Vaccinated Rate	73.8%	73.8%	0.0%
Cumulative Cases	5,599	5,599	0
Cumulative Deaths	71.9	71.9	0
Cumulative Hospital Admissions			
Non-ICU	400	400	0
ICU	86	86	0
Total	486	486	0

Table 11. Impacts Among All Head Start Volunteers

Outcome	Baseline	Interim Final Rule	Difference
Cumulative Cases	29,388	28,907	-481
Cumulative Deaths	372.6	362.1	-10.6
Cumulative Hospital Admissions			
Non-ICU	2,087	2,033	-55
ICU	450	438	-12
Total	2,538	2,471	-66

We value the mortality and morbidity risk reductions experienced by Head Start volunteers following an identical methodology described above for Head Start staff. This includes the process for categorizing morbidity reductions by case-

severity category, and the adjustments to prevent double counting. Table 12 presents the total value of COVID-19 mortality and morbidity risk reductions for Head Start volunteers across all centers, for a 3% discount rate, which affects the value per

quality-adjusted life year estimates underlying the VSC estimates. Table 13 presents the same estimates for a 7% discount rate.

Table 12. Value of COVID-19 Risk Reductions Among Volunteers, 3% Discount Rate

Risk Reduction	Impact	VSL or VSC (3%)	Value of Risk
			Reduction
Mortality Reductions	10.6	\$11,501,365	\$121,440,804
Morbidity Reductions			
Mild Cases	414	\$5,846	\$2,422,527
Severe Cases)	54.5	\$13,104	\$714,294
Critical Cases	1.2	\$1,814,400	\$2,176,442
Total Value of Risk Reductions			\$126,754,066

Table 13. Value of COVID-19 Risk Reductions Among Volunteers, 7% Discount Rate

Risk Reduction	Impact	VSL or VSC (7%)	Value of Risk
			Reduction
Mortality Reductions	10.6	\$11,501,365	\$121,440,804
Morbidity Reductions			
Mild Cases	414	\$9,778	\$4,051,467
Severe Cases	54.5	\$22,176	\$1,208,805
Critical Cases	1.2	\$1,814,400	\$2,176,442
Total Value of Risk Reductions			\$128,877,518

Summary of Monetized Benefits

We identify several sources of monetized benefits that are attributable to the interim final rule. Table 14 reports the monetized benefits from mortality and morbidity risk

reductions to Head Start staff, mortality and morbidity risk reductions to Head Start volunteers, and time savings for parents and caregivers. These estimates cover both Head Start staff vaccination coverage scenarios, and correspond to VSC estimates using a 3%

discount rate. All estimates cover the time period between the publication of the interim final rule and March 1, 2022, and are reported in 2020 dollars. Table 15 reports the same estimates using a 7% discount rate.

Table 14. Monetized Benefits Attributable to the Interim Final Rule, 3% Discount Rate

Value of Impact	Low	Primary	High
COVID-19 Risk Reductions, Staff	\$66,021,974	\$110,059,221	\$154,096,444
COVID-19 Risk Reductions, Volunteers	\$126,754,066	\$126,754,066	\$126,754,066
Absenteeism Reductions	\$3,210,121	\$5,372,304	\$7,534,486
Total Monetized Benefits	\$195,986,161	\$242,185,591	\$288,384,996

Table 15. Monetized Benefits Attributable to the Interim Final Rule, 7% Discount Rate

Value of Impact	Low	Primary	High
COVID-19 Risk Reductions, Staff	\$68,206,983	\$113,715,169	\$159,223,331
COVID-19 Risk Reductions, Volunteers	\$128,877,518	\$128,877,518	\$128,877,518
Absenteeism Reductions	\$3,210,121	\$5,372,304	\$7,534,486
Total Monetized Benefits	\$200,294,622	\$247,964,991	\$295,635,335

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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. These impacts include reductions in secondary infections from vaccinated Head Start staff and volunteers to other staff and volunteers, children, and families. We anticipate that the masking requirement will also reduce transmission at in-person Head Start settings from individuals covered by the requirement. This impact includes a reduction in COVID-19 transmission from children to Head Start teachers, staff, and other children. The reductions in transmission attributable to the interim final rule will result in additional, unquantified reductions in mortality and morbidity risks to Head Start children and families, and to the general public.

We request comment on potential quantitative estimation of benefits for Head Start staff who receive exemptions (associated with ancillary provisions and reduced exposure when colleagues are vaccinated) using a study by Chen, Glymour, et al. (2021).¹³¹ In this paper, estimates of excess mortality among 18- to 65-year-olds in

California during the eight months from March to October, 2020, are summarized across various industry categories, including teacher assistants, for whom the estimated ratio is 1.28.¹³² The “unemployed or missing [employment data]” category has an excess mortality risk ratio of 1.23—which may yield a reasonable estimate of the new risk level in cases of rule-induced staff turnover. During most of the eight months covered by the Chen et al. study, California imposed stay-at-home requirements, but these policies were relaxed somewhat during the early and mid-summer, the result being an increase in COVID-19 mortality. Visual inspection of Chen et al.’s Figure 2 allows for estimation analogous to that described above, using the excess mortality risk ratios for August 1, and yielding a result that the scope for workplace safety improvements is lesser in the context of relatively free movement and activity, as compared with a situation of broader non-workplace mitigation measures. In other words, whatever the overall effectiveness of Cal/OSHA’s workplace health and safety requirements—presumably similar to this IFR’s ancillary provisions—it should be

¹³² The list of occupations with specific estimates differs, omitting teacher assistants, in a subsequent version of the paper. Chen, Yea-Hung, Maria Glymour, Alicia Riley, John Balmes, Kate Duchowny, Robert Harrison, Ellicott Matthay, Kirsten Bibbins-Domingo. “Excess mortality associated with the COVID-19 pandemic among Californians 18–65 years of age, by occupational sector and occupation: March through October 2020.” *medRxiv* 2021.01.21.21250266; doi: <https://doi.org/10.1101/2021.01.21.21250266>.

reduced substantially when extrapolated to a context without widespread stay-at-home policies. An additional tendency toward overstatement in the potential estimation approach exists because it does not incorporate a netting off of the impacts of other jurisdictions’—including California’s own—mitigation activities. (In other words, it would be necessary to use the correct baseline before attributing benefits to this IFR.) By contrast, this suggested quantification method has a tendency toward underestimation in that it does not account for reduction in exposure due to exemption-receiving Head Start staff being surrounded by colleagues who are more widely vaccinated. In addition to seeking comment on how to address these challenges in a potential quantitative estimate of benefits for exemption recipients, we request feedback on the potential to use literature such as Chen, Glymour et al. to proxy the new risk level for non-turnover cases.

F. Costs of the Rule

The most significant cost of the interim final rule stems from the potential for Head Start staff to decline COVID-19 vaccination. This would result in a number of potential consequences, each of which is likely to represent a substantial social cost. Table 16 presents the number of Head Start staff anticipated to be fully vaccinated under the vaccine coverage scenarios, under a shared assumption that 5% of Head Start staff will seek and receive an exemption from the vaccination requirement. Under the lower-bound vaccine coverage scenario, as many as

¹³¹ Chen, Yea-Hung, Maria Glymour, Alicia Riley, John Balmes, Kate Duchowny, Robert Harrison, Ellicott Matthay, Kirsten Bibbins-Domingo. “Excess mortality associated with the COVID-19 pandemic among Californians 18–65 years of age, by occupational sector and occupation: March through October 2020.” *medRxiv* 2021.01.21.21250266; doi: <https://doi.org/10.1101/2021.01.21.21250266>.

23,035 Head Start staff will not meet the vaccination requirement and also not receive an exemption. The upper-bound vaccine coverage scenario reflects all Head Start staff that do not meet the vaccination requirement receiving an exemption. Under our primary scenario, 11,517 Head Start Staff will not meet the vaccination requirement and also not receive an exemption from the vaccination requirement.

Table 16. Head Start Staff COVID-19 Vaccine Requirement Response

Possibilities

Outcome Under Policy Scenario	Low	Primary	High
Fully Vaccinated Rate	86.6%	90.8%	95.0%
Exemption Rate	5.0%	5.0%	5.0%
Compliance Rate, Pre-Turnover	91.6%	95.8%	100.0%
Head Start Staff in Compliance, Pre-Turnover	249,965	261,483	273,000
Potential Head Start Staff Turnover	23,035	11,517	0

We anticipate some staff employed by Head Start programs will choose to leave the program due to vaccination and mask mandates. There are already significant challenges in recruiting and retaining staff among early care and education providers including Head Start and the requirements in this rule could exacerbate this issue for certain programs, resulting in programs not being able to fully staff their classrooms. This could also result in costs to programs to recruit new qualified staff to replace those staff that leave the program and may result in interruption of services for children and families.

Costs Associated With Head Start Staff Vacancies

In this section, we describe our approach for valuing the costs associated with Head Start staff vacancies associated with quitters that are attributable to the interim final rule. We follow many of the assumptions contained in the Benefits section that outline the value of time savings for parents and caretakers of children attributable to the

interim final rule through vaccine coverage and reduced COVID-19 cases among Head Start teachers. For each COVID-19 case averted, parents and caretakers experienced 190 hours of time savings, assuming each COVID-19 case lasts two weeks. To value the countervailing risk of staff vacancies, we adopt an assumption that each Head Start staff that quits in response to the interim final rule will leave a vacancy that lasts an average of two weeks. This assumption is intended to reflect an average duration among vacancies that are filled faster and vacancies that are filled slower than two weeks. It is also intended to be inclusive of any efforts by Head Start centers that anticipate resignations on the effective date of the policy to identify replacements when the vaccine requirement takes effect. We also anticipate that Head Start centers will be able to prepare in advance for these vacancies and reduce the impact on families through increased caseloads per staff. This preparation would not be possible for absenteeism due to a COVID-19 case or outbreak. We reduce the average number of

families affected by half, which results in an overall estimate of about 95 hours of time costs for parents and caretakers of children receiving Head Start services per vacancy from resignations. We are not aware of another estimate of how long a typical vacancy of this nature lasts; however, given that we anticipate this to be a significant cost attributable to the interim final rule, we have determined that these assumptions are more justified, in the context of this analysis, than not monetizing this cost. We acknowledge significant uncertainty in several of these estimates and discuss the nature of and implications of each source.

We also include a cost of training the replacement Head Start staff. We assume that new-employee training takes an average of 40 hours, and we adopt a value of time based on the median wage rate of preschool and kindergarten teachers of \$14.36 per hour.¹³³ We double this wage to generate a fully loaded wage that accounts for benefits and other indirect costs. Table 17 reports the costs of vacancies and costs of training under the vaccine coverage scenarios.

¹³³ https://www.bls.gov/oes/current/naics4_624400.htm.

Table 17. Costs of Staff Vacancies

Impact	Low	Primary	High
Vacancies	23,035	11,517	0
Hours per Vacancy	95	95	95
Total Hours	2,187,747	1,093,873	0
Value of Time	\$20.55	\$20.55	\$20.55
Subtotal, Vacancy Costs	\$44,961,638	\$22,480,819	\$0
Hours Training			
Replacements	40	40	40
Value of Time	\$28.72	\$28.72	\$28.72
Subtotal, Training Costs	\$26,462,078	\$13,231,039	\$0
Total	\$71,423,717	\$35,711,858	\$0

Table 17 presents cost estimates that vary by the vaccine coverage scenarios, which directly impact the number of vacancies that we attribute to the interim final rule. For these calculations, we adopt a common estimate of two weeks for Head Start centers to fill these vacancies. As noted in the baseline section, early care and education providers are currently experiencing significant challenges in recruiting and retaining staff that are attributable to the COVID-19 pandemic and general trends in early care and education labor markets. The general trends in early care and education labor markets suggest that filling these vacancies could take longer than two weeks. However, the interim final rule directly addresses the risk of SARS-COV-2 transmission at Head Start centers. The vaccination and masking requirements might lead to new hiring of employees who would not feel safe working in these environments absent these rules. This effect would reduce the average time to fill each vacancy. Alternatively, this could represent an additional source of benefits not captured in the main analysis elsewhere.

These cost estimates reflect one approach to account for the cost of staff vacancies. Other approaches may be reasonable. For example, in the context of its interim final rule with comment period that requires COVID-19 vaccinations for workers in most

health care settings that receive Medicare and Medicaid reimbursement, CMS calculates the likely magnitude of hiring costs by applying an analysis of the direct hiring costs for workers in the long-term care sector.¹³⁴ After updating for inflation, CMS reports a direct hiring cost of \$4,000 per worker.¹³⁵ The total cost estimates in Table 17 amount to \$3,100 per worker. Substituting CMS's per-worker estimate would result in a range of total cost estimates from \$0 to \$92 million, with a central estimate of \$46 million.

The cost of staff vacancies estimates also reflect an estimate of the value of time of \$20.55 per hour, which we also use to estimate the benefits from reduced absenteeism. In a sensitivity analysis for those benefits, we applied a higher value of time of \$25.10. Performing an identical sensitivity analysis for these costs yield a higher central estimate of vacancy costs of \$27.5 million, which is a \$5.0 million increase compared to the estimate in Table 17. This value of time would also yield a higher estimate of vacancy costs under the low-coverage scenario of \$54.9 million, which is a \$10.0 million increase compared to the estimate in Table 17.

In addition to the costs we identify and monetize related to staff vacancies, we also note the potential costs associated with reduced support from volunteers. However, as with staff, it is also conceivable that some

individuals who do not currently feel safe volunteering at in-person Head Start settings will feel comfortable volunteering under the interim final rule. On net, this could increase the support Head Start centers receive from volunteers.

Cost to Head Start Staff and Volunteers to Get Fully Vaccinated

We identify a second cost related to Head Start staff and volunteers getting fully vaccinated. We adopt an estimate of 2 hours as the time necessary to receive one COVID-19 vaccine dose, and adopt a simplifying assumption that each individual induced to get fully vaccinated under the interim final rule will receive two vaccine doses. This estimate is intended to be inclusive of scheduling time; commuting time; time receiving a vaccine dose; waiting time, including after receiving a vaccine dose to watch for any reactions; and recovery time. We value the time spent to get fully vaccinated using a \$20.55 per hour value of time, described above, for a total value of time per person of about \$82. We also include costs associated with the vaccine doses and costs of administration. Using an estimated \$20 cost per dose of vaccine, \$20 as the cost per vaccine administration, we compute the cost of vaccine doses and administration of \$80 per person. Table 18 reports the total costs related to vaccination.

¹³⁴ Dorie Seavey, "The Cost of Frontline Turnover in Long-Term Care," Better Jobs Better Care Report, Washington, DC: Institute for the Future of Aging

Services, American Association of Homes and Services for the Aging, 2004

¹³⁵ <https://www.govinfo.gov/content/pkg/FR-2021-11-05/pdf/2021-23831.pdf>.

Table 18. Costs Related to Vaccination

Cost Element	Low	Primary	High
Additional Staff Vaccinated	18,436	29,953	41,470
Additional Volunteers Vaccinated	28,163	28,163	28,163
Hours to Receive One Dose	2	2	2
Doses per Person	2	2	2
Value of Time in Hours	\$20.55	\$20.55	\$20.55
Value of Time per Person	\$82	\$82	\$82
Subtotal, Value of Time for Staff	\$1,515,532	\$2,462,324	\$3,409,116
Subtotal, Value of Time for Volunteers	\$2,315,203	\$2,315,203	\$2,315,203
Cost per Dose of Vaccine	\$20	\$20	\$20
Cost per Vaccine Administration	\$20	\$20	\$20
Doses per Person	2	2	2
Cost of Vaccine Doses and Administration per Person	\$80	\$80	\$80
Subtotal, Vaccine Doses and Administration	\$3,727,923	\$4,649,305	\$5,570,686
Total Costs of Vaccination	\$7,558,658	\$9,426,831	\$11,295,005

The costs related to vaccination reflect an estimate of the value of time, \$20.55 per hour, used elsewhere in this analysis. In other cases where this value of time is applied, we have also performed a sensitivity analysis that applies a higher value of time of \$25.10. Performing an identical sensitivity analysis for these costs yields a value of time per person to get vaccinated of about \$100. This higher value of time results in total costs of between \$8.4 million and \$12.6 million, with a central estimate of \$10.5 million, which is an increase of between \$0.8 million and \$1.3 million. Regardless of the chosen value of time, the costs in Table 18 may be underestimated, since they do not include costs associated with adverse events reported after COVID-19 vaccination.¹³⁶

Cost of Masking

This regulation also requires mask wearing for all adults and children age 2 and older in certain in-person Head Start settings. As

an intermediate step, we estimate the total in-person days per week for staff, children, and volunteers. We replicate the in-person days per week for staff and children using the estimates reported in Table 3, but we reduce the estimate for children by 14% to account for children younger than age 2 that are not subject to the requirement. To estimate the in-person days per week for volunteers, we assume they are evenly distributed across center by operating status, such that 390,426 are associated with fully in-person centers, and 495,0975 are associated with centers in hybrid operating status. For purposes of this calculation, we assume that volunteers associated with in-person centers will volunteer in person an average of once per week, and that volunteers at centers in hybrid operating status will volunteer in person an average of once every other week. We expect that the 175,476 combined volunteers associated with closed or virtual/remote centers will not volunteer in-person.

These assumptions and data indicate that Head Start volunteers will average 637,975 in-person days per week.

We assume that each staff, child, and volunteer will use one mask per day, and adopt an estimate of the cost per surgical mask of \$0.14.¹³⁷ We anticipate that staff, children, and volunteers will combine for a total of 3,693,426 masks per week, with the total weekly cost of these masks of \$517,080. We anticipate that a substantial portion of these individuals would wear masks when in-person at Head Start programs without this requirement, and adopt an estimate of 25% for the share of these costs that are attributable to the interim final rule. Finally, we calculate that the masking requirement will be effective for the entire time horizon of this analysis. Table 19 reports the costs of masking that are attributable to the interim final rule.

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¹³⁶ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>

¹³⁷ <https://www.regulations.gov/document/OSHA-2020-0004-1033>, Table VI.B.14.

Table 19. Costs of Masking Attributable to the Interim Final Rule

Cost Element	Estimate
In-Person Days per Week, Staff	820,769
In-Person Days per Week, Children	2,598,467
In Person Days per Week, Children (2+)	2,234,682
In Person Days per Week, Volunteers	637,975
Masks per Person per Day	1
Total Masks per Week	3,693,426
Cost per Mask	\$0.14
Total Cost of Masks per Week	\$517,080
Attributable Share	25%
Weekly Attributable Costs	\$129,270
Weeks Effective	13
Total Masking Costs	\$1,680,509

Cost of Testing

We also identified a cost of testing Head Start staff and volunteers that receive an exemption from the vaccine requirement. Across all scenarios, we anticipate that 5% of Head Start Staff will receive an exemption, so 13,650 staff will be unvaccinated under the interim final rule. We further assume that 5% of Head Start volunteers, or about 53,050,

will also receive an exemption. We assume that only staff and volunteers associated with Head Start centers that are fully in-person or in hybrid status will be tested. We assume that Head Start staff and volunteers will be tested weekly, and that this requirement will be effective for about 4 weeks of the time horizon of the analysis, from January 31, to March 1, 2022. This effective period is

shorter than for the masking provision, which is effective immediately. We calculate that about 230,627 tests will be performed, and adopt an estimate of \$10 per test. Table 20 presents these estimates and the total cost estimate of about \$2.3 million. For the purpose of this analysis, we assume that the costs of testing are borne by the Head Start centers.

Table 20. Cost of Testing Unvaccinated Staff

Cost Element	Estimate
Exempted Staff	13,650
Exempted Volunteers	53,050
Total Exemptions	66,700
Share of Exemptions at In-Person/Hybrid Centers	83%
Head Start Staff and Volunteers Requiring Testing	55,669
Tests Per Week	1
Weeks Effective	4
Total Tests	230,627
Cost Per Test	\$10
Total Cost of Testing	\$2,306,273

Recordkeeping Costs

We anticipate that the interim final rule will result in recordkeeping activities. The Paperwork Reduction Act analysis estimates the total burden of 6,670 hours. To monetize this impact, we apply an estimate of the hourly wage of Education and Childcare Administrators, Preschool and Daycare, for individuals working in the Child Day Care Services industry. According to the U.S. Bureau of Labor Statistics, the hourly mean

wage for these individuals is \$24.78 per hour.¹³⁸ We adjust this hourly rate to account for benefits and other indirect costs by multiplying by two, for a fully loaded hourly wage rate of \$49.56. Multiplying the fully loaded wage rate by the number of hours results in a total cost of \$330,565.20.

Total Costs

We identify several sources of costs that are attributable to the interim final rule.

Table 21 reports the monetized costs related to staff vacancies, costs of vaccination, costs of masking, costs of testing, and costs of recordkeeping. These estimates cover the Head Start staff vaccination coverage scenarios, and do not differ by discount rate. All estimates cover the same time horizon and are reported in 2020 dollars.

¹³⁸ <https://www.bls.gov/oes/current/oes119031.htm>. Wage rate for job code 11-9031.

Table 21. Monetized Costs Attributable to the Interim Final Rule

Value of Impact	Low	Primary	High
Staff Vacancies	\$44,961,638	\$22,480,819	\$0
Training	\$26,462,078	\$13,231,039	\$0
Vaccination	\$7,558,658	\$9,426,831	\$11,295,005
Masking	\$1,680,509	\$1,680,509	\$1,680,509
Testing	\$2,306,273	\$2,306,273	\$2,306,273
Recordkeeping	\$330,565	\$330,565	\$330,565
Total Monetized Costs	\$83,299,721	\$49,456,037	\$15,612,352

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We consider it probable that the substantial reduction in COVID-19 cases per day among Head Start staff will result in fewer center closures due to COVID-19. We do not estimate the reduction in closures anticipated due to the interim final rule; however, we presented a calculation of how we would value the benefit of reopening on a per-center basis. For comparison, we also estimate the additional cost of masking, and additional cost of testing exempted staff and volunteers for centers that reopen.

If 1% of total Head Start centers reopen as a result of the interim final rule, this would result in 207 centers reopening. For the purposes of this cost analysis, we calculate the number of masks required under for a center operating fully in-person. This would result in 2,730 staff, 8,643 children, 10,610 volunteers wearing masks at in-person Head

Start settings. They would require 67,474 masks on a weekly basis, 16,869 of which we attribute to the interim final rule. The total cost of these additional masks would be \$2,362 per week. For testing, the same number of centers reopening would result in 667 additional exempted staff and volunteers requiring testing every week, which corresponds to \$6,670 in testing costs per week. These costs sum to \$9,031 per week. To continue the comparison, if 1% of closed centers reopen, we would monetize the benefits in time saved for parents and caregivers at \$5.3 million per week. This comparison only includes impacts we are able to monetize, and does not account for changes in COVID-19 risks associated with reopening. As discussed elsewhere, these risks will be reduced as a result of the vaccination and masking requirements.

G. Net Benefits

We have analyzed the major impacts of the interim final rule under several scenarios of incremental vaccine-uptake among Head Start staff that are unvaccinated in the baseline scenario of no new regulatory action. In previous sections, we have indicated that the benefits are higher and that the costs are lower under the high vaccine coverage scenario than the low vaccine coverage scenario. In this section, we demonstrate the magnitudes. Table 22 presents the total costs, benefits, and net benefits that are attributable to the interim final rule under a 3% discount rate. Table 23 presents these same estimates using a 7% discount rate. Both sets of estimates cover the same time horizon.

Table 22. Net Benefits, 3% Discount Rate, 2020 dollars

Total Impacts	Low	Primary	High
Benefits	\$195,986,161	\$242,185,591	\$288,384,996
Costs	\$83,299,721	\$49,456,037	\$15,612,352
Net Benefits	\$112,686,440	\$192,729,554	\$272,772,644

Table 23. Net Benefits, 7% Discount Rate, 2020 dollars

Total Impacts	Low	Primary	High
Benefits	\$200,294,622	\$247,964,991	\$295,635,335
Costs	\$83,299,721	\$49,456,037	\$15,612,352
Net Benefits	\$116,994,900	\$198,508,954	\$280,022,983

An analytic issue not addressed in the assessment underlying these results is the question of how to interpret individuals' hesitation or unwillingness, in the absence of regulation, to accept an intervention that achieves extensive health protection for themselves, with little or no out-of-pocket cost, and ever-lessening time or inconvenience cost; a simplistic revealed-preference monetization of the rule's effect would be that it yields minimal or negative benefits for such staff members, even the ones for whom it prevents or reduces severity of COVID-19 infection. Given the dynamic nature of the pandemic—including scientific innovations and other human responses—it may be that long-run equilibrium for COVID-19 vaccines has not been reached, in which case the above use of VSL-related estimates for staff-member risk valuation may be appropriate at this time. On the other hand,

other valuation approaches may also be worth exploring.

Toward that end, we use Herzog and Schlottmann (1990) to estimate a cap on how much the benefits of an employment-based health or safety regulation could exceed its costs.¹³⁹ Under this model, benefits accrue partially to workers in the form of health and longevity improvements (net of lost wage premiums) and partially to employers in the form of wage reductions, and the sum of worker and employer portions equals the monetized value of health and longevity improvements. Herzog and Schlottmann find that the wage reduction portion of total benefits is somewhere between 42.9% ($=\$4.29/\10.01) and 74.3% ($=\$3.67/\4.94). Put another way, the total benefits of a rule should be no more than 1.3 ($=\$4.94/\3.67) to 2.3 ($=\$10.01/\4.29) times the regulatory costs incurred by employers; otherwise, the wage reductions experienced by those employers

would make it profit-maximizing (or surplus-maximizing, for non-profit entities) for them to mandate vaccination or perform the other risk-abatement activities without a regulation forcing them to do so.

The first several rows of Table 24 show upper bounds on staff benefits estimated by applying the Herzog and Schlottmann ratios to the estimated costs of the IFR (assuming for simplicity, as elsewhere in this analysis, that employers incur the costs).¹⁴⁰ Unlike in Tables 22 and 23, and the analysis that feeds into them, the quantified staff benefits in Table 24 are not necessarily limited to individuals who are newly vaccinated. Another, even more fundamental difference, is that Table 24 demonstrates an approach in which low costs are correlated with low staff benefits and high costs with high staff benefits.

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¹³⁹ Herzog, Henry W. and Alan M. Schlottmann. "Valuing Risk in the Workplace: Market Price, Willingness to Pay, and the Optimal Provision of

Safety," *The Review of Economics and Statistics* 72(3): August 1990, pp. 463–470.

¹⁴⁰ Herzog and Schlottmann use an old data set (1965–1970) and focus on work settings quite

different from child care centers. We request comment on whether more recent or better-tailored inputs are available.

Table 24. Net Benefits Upper Bounds, Alternative Approach, 2020 dollars

Total Impacts *	Low	Middle	High
Costs	\$15,612,352	\$49,456,037	\$83,299,721
Upper Bound Staff Benefits, Using 1.3 Ratio	\$21,014,991	\$66,570,251	\$112,125,510
Upper Bound Staff Benefits, Using 2.3 Ratio	\$36,428,821	\$115,397,419	\$194,366,016
Upper Bound Total Benefits, Using 1.3 Ratio	\$157,426,995	\$200,820,072	\$244,213,149
Upper Bound Total Benefits, Using 2.3 Ratio	\$172,840,824	\$249,647,240	\$326,453,655
Upper Bound Net Benefits, Using 1.3 Ratio	\$141,814,643	\$151,364,036	\$160,913,428
Upper Bound Net Benefits, Using 2.3 Ratio	\$157,228,473	\$200,191,203	\$243,153,934

* Non-staff benefits per Table 15.

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H. Distributional Effects

Executive Order 13985 on *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government* includes consideration of agency policies and actions that create or exacerbate barriers to full and equal participation by all eligible individuals. As noted previously, a large share of children served by Head Start programs are from culturally and linguistically diverse families. And the majority of Head Start children are also from families experiencing poverty. In FY 2019, OHS administrative data indicate that 37% of

Head Start children were Hispanic or Latino and the remaining 63% were of non-Hispanic or Latino origin. Further, 44% were White, 30% were Black or African American, 10% were biracial or multi-racial, 4% were American Indian or Alaska Native, and 2% were Asian.¹⁴¹ As is evident with these data, the indirect beneficiaries of this IFR—the children and families served by Head Start programs—are disproportionately from diverse racial and ethnic groups, as well as from low-income families, and they will benefit greatly from reduced exposure to COVID-19 from teachers who are newly vaccinated.

I. Uncertainty and Sensitivity Analysis

In the main analysis, we report the value of COVID-19 mortality risk reductions using the central HHS estimate of the VSL of \$11.5 million, and value of morbidity risk reductions using estimates of the VSC that are derived from the central VSL. As a sensitivity analysis, we recalculate these benefits using the low and high estimates of the VSL, which range from \$5.3 million to \$17.5 million. Table 25 reports the value of these risk reductions using the full range of VSL estimates.

¹⁴¹ Source: Head Start Program Information Report; the remaining 10% of children were reported as “Other or Unspecified.”

Table 25. Value of COVID-19 Risk Reductions Using Range of VSL Estimates, 3% Discount Rate

Risk Reduction	VSL or VSC Estimate			Value of Risk Reduction (\$ millions)		
	Low	Central	High	Low	Central	High
Mortality Reductions	\$5,367,303	\$11,501,365	\$17,507,633	\$99.6	\$213.4	\$324.9
Morbidity Reductions						
Mild Cases	\$2,728	\$5,846	\$8,900	\$3.2	\$6.9	\$10.5
Severe Cases	\$6,115	\$13,104	\$19,947	\$0.8	\$1.6	\$2.5
Critical Cases	\$846,720	\$1,814,400	\$2,761,920	\$6.9	\$14.8	\$22.6
Total Value of Risk Reductions				\$110.5	\$236.8	\$360.5

In our main analysis, we assume that the vaccination, masking, and other requirements will be in effect for the entire time horizon of the analysis. We also considered a scenario that these requirements will end at an earlier point in time. Specifically, we evaluated a scenario that the requirements would be repealed through subsequent rulemaking or expire on January 16, 2022, which corresponds to the last day of the most recent renewal of the COVID-19 public health emergency.¹⁴² For this scenario, we assume that Head Start staff are surprised on January 16, 2022 by the announcement, and that unvaccinated staff discontinue efforts to get fully vaccinated. This results in a lower vaccine coverage rate of between 84.9% and

91.5%, compared to a vaccine coverage rate of between 86.6% and 95.0% under the scenario of the requirement in effect through at least January 31, 2022. This would result in smaller reductions in mortality and morbidity risks, and smaller reductions in absenteeism. It would also eliminate the costs from staff vacancies and training attributable to the interim final rule, substantially reduce the costs of masking and testing; and reduce the total costs of vaccinations.

J. Analysis of Regulatory Alternatives to the Rule

We evaluated several regulatory alternatives to the interim final rule. First, we

assessed the impact of not including volunteers in the scope of the vaccine requirement of the interim final rule. Under this regulatory alternative, the reductions in mortality and morbidity for volunteers induced to get fully vaccinated outlined in Tables 12 and 13 would not occur. We also anticipate a reduction in costs attributable to the rule related to the costs related to vaccination described in in Table 18. Table 26 reports the net benefits of this policy alternative, using a 3% discount rate. Compared to our analysis of the interim final rule, this option would result in lower net benefits under the vaccine coverage scenarios that we analyzed.

Table 26. Net Benefits of Policy Alternative, 3% Discount Rate, 2020 dollars

Total Impacts	Low	Primary	High
Benefits	\$69,232,095	\$115,431,524	\$161,630,929
Costs	\$78,731,453	\$44,887,768	\$11,044,084
Net Benefits	-\$9,499,358	\$70,543,756	\$150,586,846

We also considered two alternatives to the masking requirement. One alternative includes eliminating the masking requirement entirely. This policy alternative would reduce the cost estimates of the interim final rule by \$1.7 million in line with

the calculations presented in Table 19. A second alternative would limit the masking requirement to unvaccinated individuals. Under this policy alternative, the weekly masks needed for Head Start staff and volunteers would be reduced significantly, in

line with the vaccine coverage rates. When the vaccination requirement takes effect, only the 5% of Head Start staff and volunteers who receive an exemption would be expected to wear a mask. This reduces the weekly masks for Staff and volunteers

¹⁴² <https://www.phe.gov/emergency/news/healthactions/phe/Pages/COVID-15Oct21.aspx>.

attributable to the rule by about 95%. This policy alternative would also result in small reduction in the number of masks needed for children. About 1% of Head Start children are age 5 years and older, and some of these children may get vaccinated in response to CDC's "recommendation that children 5 to 11 years old be vaccinated against COVID-19 with the Pfizer-BioNTech pediatric vaccine."¹⁴³ We estimate that the cost of masking under this policy alternative would be about \$1.0 million, which is about \$0.6 million lower than the masking requirement under the interim final rule.

While we do not include a monetized benefit for the masking requirement, we anticipate that it will reduce transmission of SARS-COV-2 at in-person Head Start settings from individuals covered by the requirement. This impact includes a reduction in transmission from children to Head Start teachers, staff, and other children. The reductions in transmission attributable to the interim final rule will result in additional, unquantified reductions in mortality and morbidity risks to Head Start children and families, and to the general public. Compared to the analysis of the interim final rule, the two masking policy alternatives would result in fewer averted COVID-19 cases, hospitalizations, and deaths.

Finally, we considered a policy alternative of linking the vaccination, masking, and other requirements of the interim final rule to the COVID-19 public health emergency. Evaluating this policy alternative requires an additional assumption about the duration of the public health emergency. In the Uncertainty and Sensitivity Analysis, we

explore a scenario in which the requirements would be repealed through subsequent rulemaking or expire on January 16, 2022, which corresponds to the last day of the most recent renewal of the COVID-19 public health emergency. That sensitivity analysis represents one possible outcome for this policy alternative. The main analysis, which assumes that the requirements will remain in effect through the time horizon of this analysis, represents another possible outcome for this policy alternative.

III. Final Small Entity Analysis

We have examined the economic implications of this interim final rule as required by the Regulatory Flexibility Act. This analysis, as well as other sections in this Regulatory Impact Analysis, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

A. Description and Number of Affected Small Entities

The U.S. Small Business Administration (SBA) maintains a Table of Small Business Size Standards Matched to North American Industry Classification System Codes (NAICS).¹⁴⁴ We replicate the SBA's description of this table:

This table lists small business size standards matched to industries described in the North American Industry Classification System (NAICS), as modified by the Office of Management and Budget, effective January 1, 2017. The latest NAICS codes are referred to as NAICS 2017.

The size standards are for the most part expressed in either millions of dollars (those preceded by "\$") or number of employees (those without the "\$"). A size standard is the largest that a concern can be and still qualify as a small business for Federal Government programs. For the most part, size standards are the average annual receipts or the average employment of a firm.

This interim final rule will impact small entities in NAICS category 624410, Child Day Care Services, which has a size standard of \$8.0 million dollars. We assume that all 20,717 Head Start centers are below this threshold and are considered small entities.

B. Description of the Impacts of the Rule on Small Entities

We identify three categories of costs of the interim final rule that could impact small entities. Specifically, we expect that small entities will need to train Head Start staff to replace those who resign, and monetize these costs at about \$13.2 million. For the purposes of this calculation, we assume that Head Start centers will purchase masks sufficient to cover every in-person staff, child, and volunteer, at a cost of about \$1.7 million. We also assume that Head Start centers will incur the costs of testing for staff, at a cost of about \$2.3 million. Finally, we attribute the costs of recordkeeping to small entities, at a cost of about \$0.3 million. These combine for a total cost to small entities of \$17.5 million. Dividing by the 20,717 Head Start centers, these costs are about \$847 per small entity. As an alternative calculation, we estimate these costs are \$864 per small entity, excluding closed Head Start centers.

Table 27. Costs Per Small Entity

Impact	Costs to Small Entities	Cost Per Small Entity
Training	\$13,231,039	\$638.66
Masking	\$1,680,509	\$81.12
Testing	\$2,306,273	\$111.32
Recordkeeping	\$330,565	\$15.96
Total	\$17,548,386	\$847.05

The Department considers a rule to have a significant impact on a substantial number of small entities if it has at least a 3% impact on revenue on at least 5% of small entities. Therefore, we perform a threshold analysis to

determine whether these costs are likely to result in a significant impact on a substantial number of small entities. For \$847 to exceed the impact threshold, a small entity would need to have revenue below \$28,235 over the

time horizon of the analysis, or annual revenue of less than about \$113,000.

The Administration for Children and Families awards about \$10 billion in grants to Head Start programs, including Early Head

¹⁴³ <https://www.cdc.gov/media/releases/2021/s1102-PediatricCOVID-19Vaccine.html>.

¹⁴⁴ U.S. Small Business Administration (2019). "Table of Size Standards." August 19, 2019. <https://www.sba.gov/document/support-table-size-standards>.

Start-Child Care Partnerships.¹⁴⁵ Across 20,717 centers, this averages to \$466,192, which is well above the \$113,000 threshold. Thus, we conclude that the interim final rule is not likely to result in a significant impact on a substantial number of small entities.

List of Subjects in 45 CFR Part 1302

COVID–19, Education of disadvantaged, Grant programs—social programs, Head Start, Health care, Mask use, Monitoring, Safety, Vaccination.

JooYeun Chang,

Principal Deputy Assistant Secretary for Children and Families.

Approved:

Xavier Becerra,

Secretary.

For the reasons discussed in the preamble, we amend 45 CFR part 1302 as follows:

PART 1302—PROGRAM OPERATIONS

■ 1. The authority citation for part 1302 continues to read as:

Authority: 42 U.S.C. 9801 *et seq.*

■ 2. In § 1302.47, revise paragraphs (b)(5)(iv) and (v) and add paragraph (b)(5)(vi) to read as follows:

§ 1302.47 Safety practices.

* * * * *

(b) * * *

(5) * * *

(iv) Only releasing children to an authorized adult;

(v) All standards of conduct described in § 1302.90(c); and

(vi) Masking, using masks recommended by CDC, for all individuals 2 years of age or older when there are two or more individuals on 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, except:

(A) Children or adults when they are either eating or drinking;

(B) Children when they are napping;

(C) When a person cannot wear a mask, or cannot safely wear a mask, because of a disability as defined by the Americans with Disabilities Act; or

(D) When a child’s health care provider advises an alternative face covering to accommodate the child’s special health care needs.

* * * * *

■ 3. In § 1302.93, add paragraphs (a)(1) and (2) to read as follows:

Subpart I—Human Resources Management

§ 1302.93 Staff health and wellness.

(a) * * *

(1) All staff, and those contractors whose activities involve contact with or providing direct services to children and families, must be fully vaccinated for COVID–19, other than those employees:

(i) For whom a vaccine is medically contraindicated;

(ii) For whom medical necessity requires a delay in vaccination; or

(iii) Who are legally entitled to an accommodation with regard to the COVID–19 vaccination requirements based on an applicable Federal law.

(2) Those granted an accommodation outlined in paragraph (a)(1) of this section must undergo SARS–COV–2 testing for current infection at least weekly with those who have negative test results to remain in the classroom or working directly with children.

Those with positive test results must be immediately excluded from the facility, so they are away from children and staff until they are determined to no longer be infectious.

* * * * *

■ 4. In § 1302.94, revise paragraph (a) to read as follows:

§ 1302.94 Volunteers.

(a) A program must ensure volunteers have been screened for appropriate communicable diseases in accordance with state, tribal or local laws. In the absence of state, tribal, or local law, the Health Services Advisory Committee must be consulted regarding the need for such screenings.

(1) All volunteers in classrooms or working directly with children other than their own must be fully vaccinated for COVID–19, other than those volunteers:

(i) For whom a vaccine is medically contraindicated;

(ii) For whom medical necessity requires a delay in vaccination; or

(iii) Who are legally entitled to an accommodation with regard to the COVID–19 vaccination requirements based on an applicable Federal law.

(2) Those granted an accommodation outlined in paragraph (a)(1) of this section must undergo SARS–CoV–2 testing for current infection at least weekly with those who have negative test results to remain in the classroom or work directly with children. Those with positive test results must be immediately excluded from the facility, so they are away from children and staff until they are determined to no longer be infectious.

* * * * *

[FR Doc. 2021–25869 Filed 11–29–21; 8:45 am]

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¹⁴⁵ <https://eclkc.ohs.acf.hhs.gov/sites/default/files/pdf/no-search/hs-program-fact-sheet-2019.pdf>.