Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply. This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

IX. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 21, 2022.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1396 to subpart D to read as follows:

§ 180.1396 Extract of *Caesalpinia spinosa;* exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for extract of *Caesalpinia spinosa* in or on all food commodities when used in accordance with good agricultural practices.

[FR Doc. 2023–00017 Filed 1–5–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1302

RIN 0970–AC90

Mitigating 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: Final rule.

SUMMARY: This final rule removes the requirement for universal masking for all individuals ages 2 and older. This final rule requires that Head Start programs have an evidence-based COVID–19 mitigation policy, developed in consultation with their Health Services Advisory Committee. This final rule does not address the vaccination and testing requirement, which is still under review. The vaccine requirement remains in effect.

DATES: *Effective date:* This final rule is effective January 6, 2023.

Compliance date: The compliance date for the evidence-based COVID–19 mitigation policy specified at § 1302.47(b)(9) is, March 7, 2023. For more information, *see* Implementation Timeframe.

FOR FURTHER INFORMATION CONTACT: Kate Troy, 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:

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I. Executive Summary

(1) Purpose of the Regulatory Action

(a) *The need for the regulatory action and how the action will meet that need:* The purpose of this regulatory action is to finalize, with modification, the Interim Final Rule with Comment Period (IFC), *Vaccine and Mask Requirements to Mitigate the Spread of COVID–19 in Head Start Programs,* which ACF issued on November 30, 2021 (86 FR 68052). This final rule takes into consideration the more than 1,700 public comments received on masking during the comment period, the most up to date data available on COVID–19, and knowledge gained through research on the transmission and effects of SARS–CoV–2 to establish a policy that prioritizes the health and safety of children served by the federal Head Start program, their families, and the program's staff while also adapting to the realities of evolving COVID–19 conditions. In brief, this final rule:

(1) removes the requirement of universal masking for all individuals 2 years of age and older when they are with 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.

(2) requires Head Start programs to have an evidence-based COVID–19 mitigation policy developed in consultation with their Health Services Advisory Committee (HSAC).

During this rulemaking process alone, there have been considerable gains in what the scientific, medical, and public health communities know and understand about SARS–CoV–2. More tools are available to protect against SARS–CoV2 than when the IFC was issued, and the conditions around COVID–19 have changed. These new tools include improved accessibility to vaccines for adults and children over age 6 months, treatments, tests, and improved information about other tools like ventilation to maximize protection and minimize transmission. For these reasons, and those further outlined in the preamble, ACF has removed the specific universal masking requirement and replaced it with a requirement that programs establish an evidence based COVID–19 mitigation policy in consultation with their HSAC.

Throughout the development of the IFC and this final rule, ACF has considered the guidance of the U.S. Centers for Disease Control and Prevention (CDC) as our lead public health agency to ensure the latest science guides our policies. After consideration and review of the latest CDC guidance, ACF has concluded that the universal masking requirement established in the IFC no longer is warranted.

The IFC was published at a point in time when the CDC recommended universal masking for individuals 2 years and older. At that time, vaccines were not yet available for children between the ages of two and five. Additionally, citing CDC data, ACF noted that ''although COVID–19 cases had begun to decline in parts of the country,'' ''data indicate[d] cases are beginning to rise in other parts,'' and ''the future trajectory of the pandemic [was] unclear.'' 86 FR 68053. ACF also highlighted the acute risks of the highly transmissible Delta variant, which at the time was ''the predominant variant in the United States and ha[d] resulted in greater rates of cases and hospitalizations among children than from other variants.'' *Ibid.* At this stage of the COVID–19 response, CDC recommends universal masking based on COVID–19 Community Level.

This final rule instead requires Head Start programs to have an evidence-based COVID–19 mitigation policy developed in consultation with their HSAC. The HSAC is an advisory group usually composed of local health providers; they may include pediatricians, nurses, nurse practitioners, dentists, nutritionists, and mental health providers. Head Start staff and parents also serve on the HSAC. All Head Start and Early Head Start programs are required to establish and maintain a HSAC (45 CFR 1302.40(b)).

Removing the universal mask requirement and replacing it with the requirement of an evidence-based COVID–19 mitigation policy allows Head Start programs to adapt to changing circumstances, to consider the unique challenges and needs faced by individual programs, and still supports the safest environments for the workforce, and the children and families Head Start serves.

(b) *Legal authority for the final rule:* ACF publishes this 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), (D) and (E), as amended by the Improving Head Start for School Readiness Act of 2007 (Pub. L. 110–134). Specifically, section 641A of the Head Start Act allows the Secretary to ''modify, as necessary, program performance standards by regulation applicable to Head Start agencies and programs.'' In developing this modification, the Secretary included relevant considerations pursuant to section 641A(a)(2) of the Head Start Act, 42 U.S.C. 9836a(a)(2). The Secretary finds it necessary and appropriate to set health and safety standards for Head Start programs to ensure they respond to the evolving COVID–19 pandemic to keep the environment where Head Start services are provided safe.

(2) Summary of the Major Provisions of the Regulatory Action

Head Start Program Performance Standards

Masking

This final rule removes the universal masking requirement for all individuals 2 years of age and older, which had applied universally subject to some exceptions.[1] While this final rule removes the universal masking requirement, programs may opt to include such requirements in their COVID–19 mitigation policy.

The universal masking requirement in the IFC mirrored CDC's recommendations in fall 2021 and was predicated on then-current data about COVID–19 and expectations about the future trajectory of the disease. The CDC has moved away from a recommendation for universal indoor masking in schools and early care and education facilities. On February 25, 2022, the CDC issued new COVID–19 mitigation recommendations to help individuals and communities make choices on what precautions to take, based on the level of disease burden in their community and the capacity of their nearby hospitals. CDC calls these ''COVID–19 Community Levels,'' which include low, medium, and high Community Level classifications. At present, CDC only recommends universal masking indoors at the high COVID–19 Community Level. As a result, Head Start programs may be operating with a more stringent masking requirement than the CDC indicates is warranted currently, and specifically, a requirement that reflects a different stage of the COVID–19 response when the CDC recommended universal masking for individuals ages 2 and older.

To clarify, programs may still promote, encourage, and even require universal masking as part of their COVID–19 evidence-based policy given the proven benefits of masking as an effective layered mitigation strategy against COVID–19, particularly when communities are experiencing a high level of disease burden or are serving high-risk populations (*e.g.,* when COVID–19 Community Levels are high).[2] The effectiveness of masking is discussed further in Section III and programs may find the responses helpful when developing their COVID–19 mitigation policies.

The removal of the universal masking requirement and replacement with the evidence-based COVID–19 mitigation policy gives Head Start programs more flexibility to adapt to the changing circumstances of COVID–19 while still protecting the health of children and consequently will reduce burden on programs.

Evidence-Based COVID–19 Mitigation Strategy

This final rule requires Head Start programs to have an evidence-based COVID–19 mitigation policy developed in consultation with the program's HSAC. This modification allows the rule to continue to be relevant and up to date as the level of COVID–19 impact in communities changes.

The evidence-based COVID–19 mitigation policy should consider multiple mitigation strategies such as access to vaccination, masking, ventilation, and testing. Per the CDC, Head Start programs should consider local conditions, including transmission levels as well as program characteristics such as the population of children and families served, when selecting mitigation strategies to prioritize for implementation.

Although the national vaccination requirement remains in place while the vaccination portion of the IFC is under review, Head Start programs may include additional considerations beyond the original IFC requirement to support vaccination efforts, including for example, requiring staff remain up to date on COVID–19 boosters, sharing information on COVID–19 vaccination with staff and families, and/or partnering with local agencies to increase vaccination access.

OHS will issue supplementary information at the time of publication of this rule to Head Start programs to provide information that may assist programs in developing an evidence-based policy. Specifically, this supplementary information will reference the latest research and science on layered mitigation strategies, including information from the CDC guidance for Early Childhood Education settings, CDC COVID–19 Community Levels guidance, and state and local guidance. OHS will update this guidance as appropriate.

This final rule requires programs to have established an evidence-based COVID–19 mitigation policy in consultation with their HSAC by March 7, 2023.

(3) Costs and Benefits

This final rule revises requirements established on November 30, 2021, through an Interim Final Rule with Comment (IFC), ''Vaccine and Mask Requirements To Mitigate the Spread of COVID–19 in Head Start Programs.'' [3] In our main analysis, we evaluate the likely impacts of the final rule in comparison to a baseline scenario of the IFC without modifications.

The final rule requires that Head Start programs have an evidence-based COVID–19 mitigation policy, developed in consultation with their HSAC. This requirement will result in a one-time cost for each program to develop its mitigation policy. Although the final rule is not prescriptive with respect to the elements of these mitigation policies, we identify and estimate ongoing costs to Head Start programs by modeling elements of a mitigation policy that are intended to be representative of a range of potential options.

This final rule also removes the requirement for universal masking for all individuals two years of age and older. While some programs may maintain masking for certain groups or under certain circumstances, removing this requirement will likely result in fewer masks worn. All else equal, if fewer masks are worn as a result of the rule, this may result in increased transmission risk of SARS–CoV–2; however, this could be offset by other elements of evidence based COVID–19 mitigation policies developed by Head Start programs.

Overall, we anticipate that the cost savings associated with removing the universal masking requirement will exceed the incremental costs of the mitigation policies. Thus, the final rule will result in net cost savings, which accrue primarily to Head Start programs. Over a 3-month time horizon, we estimate that the final rule may result in about $9.2 million in net benefits; in other words, this amount is our estimate of the net cost savings attributable to the final rule.

II. 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 (HSPPS) require programs to comply with state immunization enrollment and attendance requirements and to work with families to ensure children who are behind on immunizations or other care get on a schedule to catch up (45 CFR 1302.15(e) and1302.42(b)(1)). 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.

All Head Start and Early Head Start programs are required to establish and maintain a HSAC (45 CFR 1302.40(b)). The HSAC is an advisory group usually composed of local health providers; they may include pediatricians, nurses, nurse practitioners, dentists, nutritionists, and mental health providers, among others. Head Start staff and parents also serve on the HSAC. As HSACs are usually comprised of local health care providers, they provide an existing framework that supports Head Start programs in accessing and leveraging expertise to promote child health. The HSPPS specifically requires the HSAC to provide expertise in determining whether children are up to date on age-appropriate preventive and primary medical and oral health care; support the program in identifying children's nutritional health needs; and consult on appropriate screenings for communicable diseases for regular volunteers in cases where there is an absence of state, tribal or local laws.

It is vitally important that the Head Start program itself is safe for all children, families, and staff. For this reason, the HSPPS specify that the program must ensure Head Start 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 ACF's highest priority. While this is always important, COVID–19 has highlighted the need to ensure staff and young children are also protected.

ACF published an IFC in the **Federal Register** on November 30, 2021 (86 FR 68052). ACF issued the IFC on the basis of its authority in Section 641A of the Head Start Act, which allows 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(a)(1)(C)), (D), and (E). In developing these modifications, the Secretary included relevant considerations pursuant to section 641A(a)(2) of the Head Start Act, 42 U.S.C. 9836a(a)(2).[4] The Secretary consulted with experts in child health, including pediatricians, a pediatric infectious disease specialist, and the recommendations of the CDC and the U.S. Food and Drug Administration (FDA).[5] [6] [7] [8] The Secretary considered OHS's past experience with the longstanding health and safety requirements of the HSPPS 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. Challenges considered included 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. Based on all these factors, the Secretary found it necessary and appropriate to set health and safety standards for the condition of Head Start facilities that address the transmission of the SARS–CoV–2 and avoid severe illness, hospitalization, and death among program participants.

As of January 1, 2022,[9] [10] following decisions by the United States District Courts for the Northern District of Texas and the Western District of Louisiana, implementation and enforcement of the IFC was enjoined in the following 25 States: Alabama, Alaska, Arizona, Arkansas, Florida, Georgia, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, West Virginia, and Wyoming. Head Start, Early Head Start, and Early Head Start-Child Care Partnership grant recipients in those 25 states were not required to comply with the IFC pending future developments in the litigation. The IFC remained in effect in all other states, the District of Columbia, and U.S. territories. In this final rule, discussion of the states not implementing the requirement relative to states that are implementing the requirements is in reference to these injunctions.

As of the date of publication of the IFC, children under the age of 5 were not eligible for the COVID–19 vaccine. On June 17, 2022, the FDA authorized the emergency use of the Moderna and Pfizer-BioNTech COVID–19 vaccines to include children 6 months through 5 years of age. Due to the extension of this mitigation strategy to this age cohort, Head Start children who are vaccinated are now less vulnerable to the effects of COVID–19. COVID–19 vaccines continue to provide crucial protections against severe disease, hospitalization, and death in children and adolescents.

The IFC generated many comments. We analyze and discuss those comments in Part IV, Public Comments Analysis.

III. Overview of Public Comments on the Interim Final Rule With Comment Period

The comment period for the IFC was open for 30 days and closed on December 30, 2021. OHS received more than 1,700 comments that expressed concerns with masking generally, and most of those comments focused on masking children. As noted, this final rule does not address the vaccination or testing requirements in the IFC and, therefore, does not include a summary of the comments that pertain to that requirement.

Most comments came from individuals, including Head Start directors, other Head Start staff members, Members of Congress, and parents. A smaller subset of comments came from associations on behalf of their membership.

The comments expressing concerns with masking, and particularly the masking policy for children, include, but are not limited to, concerns regarding the physical health of children, the potential impact on their social-emotional and speech development, the safety and efficacy of masks, and the violation of parental rights. Other areas of concern included: difficulties sustaining partnerships, mostly related to conflicting requirements with school districts; the requirements being a violation of individual rights and an overreach of the federal government; and the sentiment that a national versus local approach to COVID–19 results in what commenters often referred to as a ''one-size-fits-all'' approach. Other comments cited disagreement with the mask requirement due to factually inaccurate information, such as the masking of children leading to carbon dioxide poisoning. A small minority of the submissions expressed support for the IFC. Supportive commenters commended ACF for its efforts to ensure the safety of Head Start children, families, and staff, noted that the mandate made them feel safer about Head Start services and viewed the requirements as a prioritization of the needs of children and staff, using evidence-based practices. Many of the supportive commenters acknowledged the challenges associated with the mask requirement but agreed that the dynamic nature of SARS–CoV–2 warranted this requirement.

IV. Public Comments Analysis

We respond to the comments we received on masking in response to the IFC in this section-by-section discussion. We also address public comments in more detail in Section V where we discuss how we have made changes to the IFC. Before discussing the requirements in the final rule, we respond to the general comments we received in response to the IFC related to the burden of the masking requirement, challenges around full enrollment, the implementation timeline, and the lack of a termination date of the masking requirement. Many comments we received reiterated the same or similar information that fell into these broad categories, and we believe it is clearer for us to respond to similarly grouped comments in this way.

Burden of Requirements

Comment: Commenters shared concerns that it is too burdensome to implement and enforce the new policies and procedures related to the mask requirement given the day-to-day complexities that come with navigating the ongoing pandemic. A majority of commenters raised concerns about the increased burden and stress imposed on staff and families due to the mask mandate.

Response: ACF is aware that programs have universally experienced increased burden related to operating amidst SARS–CoV–2 transmission. The masking requirement outlined in the IFC necessitated additional effort to implement, and these efforts were warranted at an earlier time to address COVID–19, given the age of children served and the disproportionate impact of the pandemic on children and staff in Head Start programs. Thus, while the requirement required increased effort, it was a critical part of a layered mitigation strategy to provide the maximum possible protection against COVID–19 infection to Head Start children, staff, and families.

Head Start programs implementing this requirement were able to do so successfully while continuing to operate their programs. That said, the requirement in this final rule of a COVID–19 mitigation policy gives Head Start programs more flexibility to adapt to the changing circumstances of COVID–19 and to benefit from prevailing public health recommendations concerning the most effective COVID–19 mitigation strategies while still protecting the health of children and being responsive to the needs of their communities.

Challenges to Enrollment

Comment: Comments highlighted that many programs are already struggling to meet full enrollment and suggested that the mask requirement is further hindering their efforts to enroll families, especially when the requirement contradicts local school district policies. Commenters discussed the consequence of families removing their children from the program due to the mask requirement because they disagree with the requirement, believed it should be the decision of parents, or are concerned about inappropriate developmental consequences.

Response: ACF recognizes that enrollment has been challenging for some Head Start programs, particularly as they work to reach more families and be fully enrolled. However, ACF has no evidence that the mask requirement specifically hindered enrollment efforts nationally. OHS center status data suggests that enrollment of children increased in the months following the publication of the IFC, and the ability to provide children with in-person services remained steady after the issuance of the IFC. In the 4 months after the rule was implemented (February 2022–May 2022 [11]), programs reported a percent change increase of 7 percent in the total average actual enrollment, as compared to the 4 months leading up to effective date of the final rule (September–December 2021). Additionally, in the 4 months leading up to the effective date of the IFC, programs reported an average of 91.25 percent of enrolled children who received full in-person services. Again 4 months after the rule was implemented, programs reported an average of 92.6 percent of enrolled children were receiving full in-person services. Notably, in May 2022, the data show our highest percentage of reported enrolled children receiving full in-person services since the start of the pandemic (93.4 percent). If we examine the 25 states not implementing the requirements, as compared to the states and territories that were implementing the requirements, both groups increased their reported percentage of children served fully in-person after publication of the IFC. From November 2021 to March 2022, both groups of states increased their reported percentage of children served fully in-person by 2 percent.

In sum, the data does not show an indication that the requirement hindered programs' ability to operate in-person services.[12] While center status data has limitations and cannot be used to prove causation from any provisions in the IFC, based on the data available, OHS has not seen significant impact on slot-level operating status at the regional or national level. OHS has not seen a decrease in actual enrollment levels in the months following the publication of the IFC. Despite many commenters' speculation that these requirements would result in families removing their children from Head Start programs on a large scale, and ultimately, leading to extensive classroom closures, there has been no indication that these predictions occurred.

While some individual families may have removed their children from Head Start, we have not seen a large-scale exodus from Head Start programs.

Compared to the provisions in the IFC, ACF anticipates the shift to an evidence based COVID–19 mitigation policy will result in families being less inclined to disenroll their children.

Implementation Timeline

Comment: Commenters reported various concerns broadly related to the timeline for the implementation of this requirement. Commenters raised concerns about the immediate effective date of the masking requirement, stating they did not have enough notice to properly inform their staff and families and set up policies and procedures. Commenters also raised concerns about the IFC's publication relative to the pandemic. Comments included doubt that a required mitigation strategy for masking is necessary and effective if it was put into place almost two years into the pandemic.

Response: ACF understands that the effective date for the masking requirement was challenging. We value this input and have taken these comments into consideration in the development of the implementation timeline for this final rule. IFCs, or provisions within IFCs, are used when an agency has good cause to issue a final rule without first publishing a proposed rule. ACF issued an IFC to protect Head Start staff, children, and families in response to alarming trends in the data and inadequate vaccination coverage. The lengthier process associated with a notice of proposed rulemaking (NPRM) process would have impeded ACF's ability to put the necessary mitigation strategies in place to create the safest possible environment for staff, children, and families based on the information available at the time. The Secretary found it necessary and appropriate to set health and safety standards for the condition of Head Start facilities to ensure the reduction in transmission of the SARS–CoV–2, based on the science at the time, and to avoid severe illness, hospitalization, and death among program participants.

In this final rule, in consideration of public comment concerns relative to the implementation timeline, the requirement to have established an evidence-based COVID–19 mitigation policy in consultation with their HSAC is effective 60 days following publication of the final rule, March 7, 2023. This compliance date will allow programs to develop and implement the required policy.

Indefinite Requirements

Comment: Commenters raised concerns with the lack of the termination date for the universal mask requirement. ACF invited comment on the decision to leave an undetermined end date or set a finite end date, such as 6 months from the effective date of the rule. Programs reported concerns that the indefinite nature of the requirement impedes their ability to update their internal policies, inform staff of expectations, update parents and families, budget for next year and outline expectations for prospective staff and families.

Response: ACF's final rule addresses these concerns in two respects:

(1) ACF has removed the universal masking requirement in this final rule, which means that all individuals ages 2 and older no longer need to wear a mask indoors, when there are two or more individuals on transportation, and, if unvaccinated, when outside in crowded spaces and during activities that involve sustained close contact with others, unless their program opts to include such requirements under its COVID mitigation policy.

(2) ACF is now requiring Head Start programs to have an evidence-based COVID–19 mitigation policy developed in consultation with the HSAC. ACF believes this change will address concerns with the lack of a termination date that existed in the IFC for the universal masking requirement. A fuller discussion of this change is included in Section VI.

Comments About Section 1302.47(b)(5)(vi) Masking

The majority of commenters expressed concerns regarding the universal mask requirement for children 2 years of age and older in Head Start programs. There were several topics raised within this broader area of concern.

Comment: Some commenters raised the concern that having staff masked might be particularly difficult for young children who lip-read. There was also concern that staff will have difficulty hearing children who are masked. More prevalent, many commenters raised concerns regarding the potential for children to experience delays due to mask use, including social and emotional delays and developmental delays. Specifically, commenters expressed concern that the prolonged use of masks among young children would result in social and emotional delays due to the lack of facial recognition of emotional cues. Other commenters feared masks may hinder

children's acquisition of speech and language and consequently children will experience developmental delays.

Response: While studies show masks may reduce decibels, attenuate frequencies, and remove visual cues which is a risk for young children who are developing speech, language, and pre-reading/reading skills, no serious adverse events have been reported.[13] [14] Guidance from the American Academy of Pediatrics notes that teachers and staff may need to use clear paneled masks to adequately serve students who are deaf or hard of hearing, students receiving speech/language services, young students in early education programs, and English language learners.[15] Further, staff use of clear paneled masks when communicating with students who are deaf or hard of hearing may also be required by federal disability rights laws, which mandate that such students have equal opportunity to participate in the program.

With respect to the more prevalent concern about social-emotional or developmental delays due to mask use, although there have been numerous opinion pieces, there are few scientific studies published on the risk/benefit of adults wearing masks on young children's social-emotional and language development. While some of the comments will not be applicable to the final rule, given the revised requirements, programs may find the responses helpful as they consider the appropriateness of various alternatives to the universal masking requirement for their COVID–19 mitigation policies.

ACF identified relevant studies, and in sum, there is not sufficient evidence of an impact on social-emotional development when adults are wearing masks.[16] [17] [18] [19] [20]

There is only one study that suggests that wearing a mask impairs children's ability to read emotions, but there are more studies, as noted above, that show no impact. There are no published studies on the long-term effects of young children's development when adults wear masks. The CDC currently recommends universal mask use when the COVID–19 Community Level [21] is high and ACF recommends that Head Start programs develop a policy on masking that aligns with state, local, and national public health guidance.

Comment: Many of the same commenters were worried about the safety of children wearing masks and their efficacy in mitigating the spread of COVID–19, some of whom cited conflicting guidance on mask use among young children in World Health Organization (WHO) and United Nations International Children's Emergency Fund (UNICEF) reports. Commenters reported concerns that face masks can reduce oxygen intake, leading to carbon dioxide poisoning from re-breathing the air we normally breathe out. Some commenters were concerned specifically about the impact of mask wearing for children with special health care needs. Other concerns included: that masks quickly become unhygienic with young children and themselves spread germs, that wearing a face mask weakens one's immune system, or that mask use increases one's chances of getting sick if exposed to the COVID–19 virus.

Response: To be clear, there has been no evidence to substantiate the claim that mask use leads to reduced oxygen intake or carbon dioxide poisoning, weakens one's immune system, or increases one's chances of getting sick. The CDC Science Brief: *Community Use of Masks to Control the Spread of SARS–CoV–2* (last updated December 2021 at the time of this publication) provides clear information on SARS–CoV–2 transmission and the efficacy of masks. SARS–CoV–2 infection is transmitted predominantly by inhalation of respiratory droplets generated when people cough, sneeze, sing, talk, or breathe. Well-fitting masks are primarily intended to reduce the emission of virus-laden droplets by the wearer (''source control''), which is especially relevant for asymptomatic or pre-symptomatic infected wearers who feel well and may be unaware of their infectiousness to others.[22] [23] Studies demonstrate that wearing well-fitting masks also provides protection to the wearer by reducing wearers' exposure to infectious droplets through filtration, including filtration of fine droplets and particles less than 10 microns.[24] Improving fit and filtration—for example, through strategies such as using mask fitters or layering a cloth mask over a medical procedure mask—can improve wearer protection. The community benefit of wearing well-fitting masks for SARS–CoV–2 control is due to the combination of source control and filtration protection for the wearer; the individual prevention benefit of wearing masks increases with increasing numbers of people using masks consistently and correctly in a given setting.[25]

With respect to the safety of children wearing masks and their efficacy in mitigating the spread of COVID–19, ACF points to several studies. First, in terms of safety, there is no evidence to suggest that wearing a mask makes it harder for individuals to breathe, impacts their lung development, or traps carbon dioxide.[26] [27] [28]

Second, in terms of the efficacy of children wearing masks as a mitigation strategy, there have been a few studies about mask use in K–12 settings since 2020, as well as one study conducted in early childhood settings. In sum, the available research suggests that the required use of masks for children in schools and early childhood education settings results in lower incidence of SARS–CoV–2 transmission and fewer school closures.[29] [30] [31] [32]

Additionally, commenters have cited a joint UNICEF and WHO report [33] that recommended children aged up to 5 years should not wear masks as a general preventive strategy. This recommendation conflicts with the most current CDC guidance and ACF is choosing to rely on the lead U.S. public health agency over other organizations. The report also acknowledges that evidence is limited around the use of masks in children for COVID–19 and countries may ultimately choose to recommend a lower age cut-off for mask use. Having access to the same data, countries have come to different conclusions on the benefits and harms of children wearing masks, with the U.S. and Canada recommending masking for children ages 2 and up.

Additionally, ACF acknowledges that commenters had valid concerns regarding the hygienics of masking children and agree that children may need extra masks should theirs become soiled. ACF encourages programs to consider the use of COVID–19 response funds and ongoing operational funds to purchase extra masks for children in response to this concern.

In sum, consistent with the CDC recommendations and available research, masking children is an appropriate policy option and is recommended as one layered mitigation strategy against COVID–19 when local conditions necessitate. Despite commenters' concerns, ACF has not received reports following the publication of the IFC indicating that masks caused Head Start children significant health and safety consequences.

Comment: Parents and stakeholders reported concern that the mask requirement for children does not respect parental choice. They expressed an overarching concern that the universal mask requirement for young children is contrary to the belief that parents know what is best for their child—a pillar of the philosophy of Head Start. Comments suggested that some parents have elected to remove

their child from Head Start because of this requirement.

Response Much like the HSPPS requirement that children remain up to date on age-appropriate immunizations, there are public health issues that warrant prioritizing the health of the broader Head Start community—particularly as early childhood education occurs in congregate settings—and ACF believes the mask requirement is one such example. However, the CDC's recommendations have changed as the circumstances of COVID–19 have evolved and the local context and disease burden in the local community are key considerations for the use of masks and other mitigation strategies, ACF's final rule reflects this change.

Comment: There was also a concern among commenters that the requirement for children to mask outdoors is unnecessary, especially in rural areas and/or settings where playgrounds are often used just by one classroom. Commenters were also concerned that masks are too difficult for young children to wear, and staff will have a challenging time continuously reminding children to wear them correctly. Commenters expressed concern that the time spent reminding children to wear masks would ultimately come at the expense of teaching and supporting children in other ways.

Response: ACF has modified the requirement in response to the evolving circumstances of COVID–19 and to points raised during the public comment period. We discuss the changes to this requirement fully in Section V, but in summary, the requirement that Head Start programs have an evidence-based COVID–19 mitigation policy supports programs in scaling up or down mask use in response to the prevalence of COVID–19 epidemiology in their community and determining, in consultation with the program's HSAC, what circumstances necessitate mask use.

We think this change will, in part, address concerns related to outdoor masking, as programs will have the ability to create their own individual evidence-based COVID–19 mitigation policy, including with respect to outdoor masking.

Comment: Many comments raised the issue of workforce attrition and loss of volunteers due to unwillingness to comply with the masking requirements. Commenters explained that the impact of staff attrition in the classroom will lead to classroom closure and the loss of services to children and families. Commenters reported that this requirement imposes yet another barrier to already difficult hiring conditions and exacerbates staff shortages. They also noted that this requirement will ultimately lead potential staff to choose to work at other local child care centers that do not have such COVID-related requirements.

Response: ACF acknowledges programs are facing unprecedented challenges recruiting and retaining qualified staff that existed before the onset of the pandemic. We also acknowledge that some commenters were concerned that the mask requirement in the IFC may exacerbate these challenges. At the same time, it is difficult to determine what share of recruitment and retainment challenges are attributable to this requirement as compared to other causes. ACF is aware that compensation has significantly affected the early childhood workforce shortage and is the number one reason for Head Start staff attrition. Research with the broader early care and education (ECE) field indicates higher compensation for ECE professionals can improve employment stability and reduce turnover (and vice versa, with lower wages linked to higher turnover).'' [34]

Additionally, while there are workforce challenges nationally that exist both in those states implementing the requirements and in those that are not, we have no evidence that the workforce challenges among Head Start programs are more pervasive in those states implementing the mask requirement.

As noted in the Background of this final rule in Section II, Head Start regulations have always prioritized the health and safety of the children and families we enroll. At the time of the IFC's publication the evidence of the efficacy of the use of masks in reducing transmission of SARS–CoV–2 was substantial. Masks are effective at reducing transmission of SARS–CoV–2, the virus that causes COVID–19, when worn consistently and correctly. ACF affirms in this final rule the importance of mask use as a key mitigation strategy and believes requiring programs to have an evidence-based COVID–19 policy that includes mask use in appropriate circumstances will support the safest environment possible for Head Start staff, children, and families.

OHS continues to support Head Start programs and provide training and technical assistance as programs navigate this workforce shortage.

V. Implementation Timeframe

For adoption of the COVID–19 mitigation policy, the compliance date is March 7, 2023, 60 days following the publication of the final rule. This means that Head Start programs must have established an evidence-based COVID–19 mitigation policy developed in consultation with their HSAC 60 days after the publication of the final rule. This requirement applies to all Head Start grant recipients, including those that have been under a court injunction and not subject to the vaccination and masking requirements in the IFC issued on November 30, 2021. The removal of the universal masking requirement occurs immediately upon publication.

VI. Section-by-Section Discussion of Changes in This Final Rule

In this section, we discuss two changes made in this final rule. The two changes include:

(1) removing the requirement of universal masking for all individuals 2 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.

(2) requiring Head Start programs to have an evidence-based COVID–19 mitigation policy developed in consultation with their HSAC.

The modifications are based on current public health data and best practices, input from numerous stakeholders, and the continually evolving landscape of COVID–19 conditions. We specifically relied on the guidance from and consultation with the country's leading public health agency, the CDC. Additionally, ACF received letters from state and national Head Start associations, outlining their feedback and perspectives on the implications on these requirements. We also received input from the grant recipient community, some of whom contributed their feedback as part of the nearly 2,700 comments we received during the public comment period. OHS also hosted two webinars following the publication of the IFC, which provided another opportunity for grant recipients to provide input and raise questions from their respective vantage points as executive directors, program directors, fiscal officers, staff members, and parents. Finally, OHS regularly consulted experts internal to OHS, ACF, HHS, and OHS's National Center advisers, all of whom bring expertise in diverse areas of program operations, including administrative and fiscal, health and safety, infectious disease management, and child development.

As such, the Secretary satisfied the relevant considerations pursuant to section 641A(a)(2)(A) of the Head Start Act, 42 U.S.C. 9836a(a)(2)(A). We believe the changes we make below ensure these sections are clear, updated, streamlined, and transparent to the public.

1. Masking Requirement

The masking requirement in the IFC mirrored the CDC's recommendations issued in the fall of 2021 that all individuals ages 2 and older wear a mask indoors, wear a mask when there are two or more individuals on transportation, and, if unvaccinated, wear a mask when outside in crowded spaces and during activities that involve sustained close contact with others. In this final rule, ACF is removing the masking requirement and requiring Head Start programs to have an evidence-based COVID–19 mitigation policy developed in consultation with their HSAC.

The rationale for this change is twofold. First, the CDC's guidance, and the science and data that established the basis for that guidance, has changed as the conditions surrounding COVID–19 have evolved. The IFC was published at a point in time when the CDC recommended universal masking for individuals 2 years and older. At that time, citing CDC data, ACF noted that ''although COVID–19 cases had begun to decline in parts of the country,'' ''data indicate[d] cases are beginning to rise in other parts,'' and ''the future trajectory of the pandemic [was] unclear.'' 86 FR 68053. ACF also highlighted the acute risks of the highly transmissible Delta variant, which at the time was ''the predominant variant in the United States and ha[d] resulted in greater rates of cases and hospitalizations among children than from other variants.'' *Ibid.* At this stage of COVID–19 response, the science and data point to an approach that takes into account the impact of COVID–19 in the community, as demonstrated by the CDC's COVID–19 Community Levels. On February 25, 2022, the CDC issued these new recommendations to help individuals and communities make choices on what precautions to take, based on the level of disease burden in their community. As a result, Head Start programs may be operating with a more stringent masking requirement than the CDC indicates is warranted currently, and specifically a requirement that reflects a different stage of the response to COVID–19 when the CDC recommended universal masking for individuals ages 2 and older.

Second, the public comments on the IFC emphasized that the masking requirement prescribed a ''one-size-fits-all'' approach and did not consider the variation in locations and local conditions. Many cited low transmission rates within their communities, mainly in rural parts of the country that are particularly struggling with other issues which were only compounded by the circumstances of COVID–19. The shift away from universal masking for individuals 2 years and older allows programs to adapt more quickly to changing circumstances. The focus on a COVID–19 mitigation policy, is consistent with the comments and more reflective of the CDC's emphasis on layered prevention strategies—like staying up to date on vaccines, staying home when sick, ventilation, wearing masks, and hand washing—all of which have a key role in minimizing the spread of COVID–19.

As mentioned, throughout the development of the IFC and the final rule, ACF has leaned on the CDC as our lead public health agency to guide our policies. The CDC's new recommendations shift their focus to mask use depending upon the COVID–19 Community Levels. For that reason, and those further outlined in the preamble, ACF has removed the universal masking requirement.

2. Evidence-Based COVID–19 Mitigation Policy Requirement

In place of the universal masking requirement, ACF is requiring Head Start programs to have an evidence-based COVID–19 mitigation policy developed in consultation with their HSAC. Evidence-based is an umbrella term that refers to using the best research evidence (*e.g.,* found in health sciences literature) and clinical expertise (*e.g.,* what health care providers know) in content development.[35] Integrating the best available science with the knowledge and considered judgements from stakeholders and experts benefits Head Start children, families, and staff. [36] In the context of COVID–19, mitigation refers to measures taken to reduce or lower SARS–CoV–2 transmission, infection, or disease severity. Other terms used for this same concept are ''risk reduction strategies'' or ''prevention strategies.''

The evidence-based COVID–19 mitigation policy should consider multiple mitigation strategies such as vaccination, masking, ventilation, and testing. Note, the national vaccination requirement remains in place while under review for those Head Start programs in states that are not subject to the court injunctions. However, Head Start programs may include additional considerations beyond the original IFC requirement in their approach to vaccination as part of their COVID–19 mitigation policy, including for example, requiring staff remain up to date on COVID–19 boosters, sharing information on COVID–19 vaccination with staff and families, and/or partnering with local agencies to increase vaccination uptake. Where appropriate, policies should acknowledge that staff may request reasonable accommodations based on Federal law because of a disability, medical condition, or sincerely-held religious belief, practice, or observance regarding elements of the mitigation policy. When developing an COVID–19 mitigation policy Head Start programs should consider the risk factors for their staff and the families served, the available strategies, or combination of strategies, to be used when the impact of COVID–19 changes in the community (such as testing, improving indoor air quality, staying home when sick, etc.);.); and how the risk of exposure could change depending on the Head Start services provided. Head Start programs may also want to consider additional precautions regardless of the prevalence of impact from COVID–19 at that time. As noted in the CDC's guidance to K–12 schools and ECE settings, ECE program administrators should work with local health officials to consider other local conditions and factors when deciding to implement prevention measures. For example, ECE-specific indicators—such as vaccination rates among children, pediatric-specific healthcare capacity, pediatric hospitalizations, and pediatric emergency visits—can help with decision-making. Head Start programs may consider the extent to which children or staff are at increased risk for severe disease from COVID–19 or have family members at increased risk for severe disease. ECE programs may choose to implement universal indoor mask use to meet the needs of the families they serve, which could include people at risk for getting very sick with COVID–19.[37]

Note that the universal masking requirement was included at § 1302.47(b)(5)(vi) in the IFC. The requirement that Head Start programs have a COVID–19 mitigation policy is included in this final rule at § 1302.47(b)(9).

3. Severability

To the extent a court may stay or enjoin any part of this final rule or the IFC, ACF intends that other provisions

or parts of provisions of this final rule and the IFC should remain in effect. In particular, ACF intends this final rule to take effect notwithstanding any stay or injunction of the separate vaccine requirement imposed by the IFC, which remains under agency review, and vice versa. Any provision 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 and shall not affect the remainder thereof or the application of the provision to other persons or circumstances.

VII. 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 final rule will not have any impact on the autonomy or integrity of the family as an institution.

Federalism Assessment Executive Order 13132

Executive Order 13132 requires federal agencies to consult with state and local government officials if they develop regulatory policies with federalism implications. Federalism is rooted in the belief that issues that are not national in scope or significance are most appropriately addressed by the level of government close to the people. This rule will not have substantial direct impact on the states, on the relationship between the federal government and the states, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this action does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

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). Based on our estimates of the impact of this rule, the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has designated this rule as ''not major'' under the CRA.

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.

The IFC established new recordkeeping requirements and as required under the PRA, ACF submitted a request for approval of these recordkeeping requirements. The initial request was approved through an emergency clearance process, allowing for 6 months of approval under the PRA. This was followed by a full request, including two public comment periods, to extend approval of the recordkeeping requirements without changes. The OMB Control Number for this information collection request (ICR) is 0970–0583.

Under this final rule, Head Start grant recipients are required to update their program policies and procedures to include an evidence-based COVID–19 mitigation policy developed in consultation with their Health Services Advisory Committee. ACF will request a revision to OMB number 0970–0583 to add this recordkeeping requirement through an emergency clearance process. This will allow for 6 months of approval under the PRA to support the requirement going into effect 60 days following the publication of this rule. We will follow the initial emergency approval with a full request to extend approval of the recordkeeping requirement. The full request will include two public comment periods inviting comments on this new recordkeeping requirement and related burden. These public comment periods will be announced through separate notices published in the **Federal Register**. The first notice will invite comments within 60-days of publication and is expected to publish soon after the publication of this final rule. The second notice will publish when ACF submits the full extension request to OMB and will invite comments to be submitted to OMB within 30-days of publication.

The burden of updating program policies and procedures is estimated at a total of 8 hours per grant recipient. To promote flexibility for local programs, there is no standardized instrument associated with the recordkeeping requirement under this final rule. See the Regulatory Impact Analysis section for related cost estimations.

Information collection	Number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Grant Recipient Updating Program Policies and Procedures	1,604	1	8	12,832
Total Burden Hours				12,832

VIII. Regulatory Impact Analysis

I. Introduction and Summary

A. Introduction

We have examined the impacts of this 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 final rule is a 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 final rule are cost savings, this analysis concludes, and we certify that the 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.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in expenditures in any year that meet or exceed this amount.

B. Summary of Benefits and Costs

This final rule revises requirements established on November 30, 2021, through an Interim Final Rule with Comment (IFC), ''Vaccine and Mask Requirements To Mitigate the Spread of COVID–19 in Head Start Programs.'' [38] In our main analysis, we evaluate the likely impacts of the final rule in comparison to a baseline scenario of the IFC without modifications.

The final rule requires that Head Start programs have an evidence-based COVID–19 mitigation policy, developed in consultation with their Health Services Advisory Committee. This requirement will result in a one-time cost for each program to develop its policy. Although the final rule is not prescriptive with respect to the elements of these mitigation policies, we identify and estimate ongoing costs to Head Start programs by modeling elements of a policy that are intended to be representative of a range of potential options. We address uncertainty in the representativeness of this mitigation policy in a scenario analysis that considers a range of more stringent and less stringent approaches to mitigation in the main analysis; and we address uncertainty in projecting COVID–19 over the time horizon of the analysis by considering a range of observed historic COVID–19 metrics in Section E. Uncertainty and Sensitivity Analyses. For our primary analysis, we adopt a baseline scenario of the IFC, and perform a sensitivity analysis to consider an alternative baseline that incorporates the impact of federal court injunctions affecting the IFC and a second alternative baseline of no IFC requirements.

This final rule also removes the requirement for universal masking for all individuals two years of age and older. Removing this requirement will likely result in fewer masks worn. All else equal, if fewer masks are worn as a result of the rule, this may result in increased transmission risk of SARS-CoV–2; however, this could be offset by other elements of evidence-based COVID–19 mitigation policies developed by Head Start programs.

Overall, we anticipate that the cost savings associated with removing the universal masking requirement will exceed the incremental costs of the mitigation policies. Thus, the final rule will result in net cost savings, which accrue primarily to Head Start programs. Over a 3-month time horizon, we estimate that the final rule may result in about $9.2 million in net benefits, which matches our estimate of the quantified net cost savings attributable to the final rule. Table 1 reports a range of estimates of the incremental impacts of the final rule that account for uncertainty in projecting COVID–19 over the time horizon of the analysis.

ACF considered many policy alternatives beyond the regulatory option of the final rule. In addition to assessing the impact of the final rule, this RIA analyzes and quantifies the impacts of several alternatives related to the masking requirement.

TABLE 1—SUMMARY OF COST SAVINGS, COSTS, AND NET BENEFITS, 2021 DOLLARS, 3-MONTH TIME HORIZON

Category	Primary estimate	Low estimate	High estimate
Cost Savings	$11,516,589	$10,820,796	$12,212,383
Costs	2,271,134	2,271,134	2,271,134
Quantified Net Benefits	9,245,455	8,549,662	9,941,249

Note: Estimates do not depend on the choice of 3% or 7% discount rate.

C. Comments on the Final Regulatory Impact Analysis and Our Responses

On November 30, 2021, we published a regulatory impact analysis of the IFC.[39] In the following paragraphs, we describe and respond to comments we received on our analysis of the impacts of the IFC (hereafter, ''IFC RIA''). We have numbered each comment to help distinguish between the different comment themes. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, or the order in which it was discussed by the commenter(s). We received additional comments on the IFC that are discussed elsewhere in the Preamble. Note that this section does not address comments received on the vaccination requirement since it is under review and not part of this final rule.

(Comment 1) We received several comments related to the IFC RIA assumptions related to masking. At least one commenter noted that many children require more than one mask per day, indicating that we underestimated the number of masks required. At least one commenter suggested that the total costs associated with masking that are attributable to the IFC are overstated because many parents would provide masks for their children without the masking requirement.

(Response 1) We agree with the comment that the assumption of one mask per day per child may underestimate the number of masks needed. In this RIA, we double this estimate to two masks per day per child in Head Start settings. This revised assumption is intended to represent the average number of masks per day across all children masking at Head Start programs under the final rule, recognizing that some children only require 1 mask per day and some children require more than 2 masks per day. We agree with the comment that the total cost of masking should account for masks that would be worn without the IFC; however, we disagree that the IFC RIA made no adjustment for this. Specifically, the IFC RIA included the following explicit adjustment for mask usage under the Baseline Scenario of no regulatory action: ''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.'' [40] In this RIA, we adopt a higher estimate of the share of masking costs attributable to the final rule, which reflects lower levels of voluntary masking and less masking attributable to state and local mask requirements.

(Comment 2) At least one commenter suggested our assumption that the average price per mask of $0.14 was lower than their experience.

(Response 2) We acknowledge that the price per mask varies over time, by region, and by retail channel. We also acknowledge that the average price will vary by the type of mask, as well as the quantity of masks purchased at one time. In developing the RIA of the final rule, we further explored this assumption by performing additional market research to identify current prices for disposable masks. Through this process, we identified an online vendor selling 100 disposable masks for $6.99,[41] and another vendor selling 100 disposable children's sized masks for $7.99,[42] which correspond to about $0.07 per mask and $0.08 per mask, respectively. We note that the per-mask prices may be higher for some customers after accounting for shipping costs. Ultimately, we disagree with the commenter that the RIA's assumption of average price per mask of $0.14 is too low and maintain this cost-per-mask assumption in this RIA. In addition to variation in the price per disposable masks, we know that some individuals comply with the masking requirements through the use of other face coverings, including reusable cloth masks. Accounting for reusable cloth masks would likely lower our estimate of the total cost associated with masking.

(Comment 3) We received many comments related to the potential staff turnover attributable to the IFC. Most of these comments indicated their opposition to the policy based on the potential staff turnover, which included some comments that were specific to a particular program or individual. Several comments expressed a view that the IFC RIA's estimates of the potential staff turnover were too low; however, these comments generally did not include alternative estimates and did not include recommendations for alternative analytic approach that would produce different estimates. One commenter, however, estimated that the IFC ''could lead to Head Start programs losing between 46,614 and 72,422 employees, or 18% to 26% of all staff,'' [43] deriving these results from a survey fielded after the IFC was published. We also received at least one comment that estimated one third of all Head Start staff would turnover. Several other comments gave turnover estimates that were specific to a particular program but did not provide comparable estimates of the turnover across all Head Start programs.

(Response 3) We note that the IFC RIA gave significant attention to the potential staff turnover attributable to the IFC. In that analysis, we analyzed a range of vaccine coverage scenarios and estimated the potential staff turnover for each of those scenarios. The IFC RIA reported a primary estimate of 11,517 Head Start staff potentially turning over as a result of the IFC and presented a range of turnover estimates between 0 staff to 23,035 staff, or between 0% and 8% of the total staff. In actuality, the turnover attributable to the IFC was much lower than the primary estimate in the IFC RIA. ACF currently believes the turnover attributable to the IFC was less than 1% of staff. The actual turnover was therefore also significantly below the turnover estimates of between 46,614 and 72,422 staff suggested in one comment, and less than the turnover estimate suggested by one commenter that one-third of staff turnover, which would amount to 91,000 staff.

(Comment 4) We received at least one comment that indicated the IFC RIA overestimated the number of Head Start volunteers.

(Response 4) We agree with the comment. The IFC RIA reported an estimate of the number of volunteers that predated the COVID–19 pandemic. In this analysis, we adopt a more recent estimate of 464,161 volunteers for the 2021–2022 program year, which covers Fall 2021 to Spring 2022.

II. Analysis of the Revisions to the Interim Final Rule

A. Baseline of the Interim Final Rule

For our primary analysis of the final rule, we adopt a baseline scenario of the requirements of the IFC in effect nationally over the time horizon of our analysis. The IFC added provisions to the Head Start Program Performance Standards to impose three requirements: [44]

(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, 2022.

(3) For those granted an exemption to the requirement specified in (2), at least

weekly testing for current SARS-CoV–2 infection.

The baseline scenario accounts for the ongoing impacts associated with the IFC, including the benefits and costs of each of these provisions. This final rule does not address the vaccination requirement, which is still under review. Thus, we focus our quantitative assessment of the baseline scenario on the ongoing costs of the masking requirements of the IFC. In our scenario analysis below, the baseline scenario corresponds to the Universal Scenario, indicating that, without further regulatory action, the masking requirements will always be in effect for all Head Start programs in all counties.

We also considered two alternative baseline scenarios. The first alternative baseline scenario incorporates the impact of federal court injunctions affecting the IFC. The second alternative baseline scenario assumes no IFC requirements are in effect. This analysis appears in Section E. Uncertainty and Sensitivity Analyses.

B. Scenario Analysis Approach

The final rule requires that Head Start programs have an evidence-based masking policy for COVID–19 mitigation, developed in consultation with their Health Services Advisory Committee. We are uncertain over the elements of the policies that Head Start programs will adopt under the final rule; however, we anticipate that elements of the policies will either be in effect at all times or closely tied to local COVID–19 conditions. As the first step in quantifying the impacts for a range of potential mitigation policies that could be adopted by Head Start programs, we consider five discrete scenarios:

- Scenario 1, ''Universal'': Requirement will always be in effect.
- Scenario 2, ''High Level'': Requirement will be in effect in counties with a High COVID–19 Community Level.
- Scenario 3, ''High or Medium Level'': Requirement will be in effect in counties with a High or Medium COVID–19 Community Level.
- Scenario 4, ''Community Transmission'': Requirement will be in effect in counties with a High or Substantial COVID–19 County Level of Community Transmission.
- Scenario 5, ''Voluntary'': Requirement will never be in effect.

We analyzed historic data at the county level on COVID–19 Community Level [45] covering the 37-week period ending on November 3, 2022 for which data are currently available, and COVID–19 County Level of Community Transmission [46] data covering 237 days (about 34 weeks) ending on October 18, 2022. For each observation in the historic data, we calculate the share of the U.S. population living in counties with a High Community Level, the share of the U.S. population living in counties with a High or Medium Community Level, and the share of the U.S. population living in counties with High or Substantial Community Transmission. As one example calculation, on September 29, 2022, 107 counties had a High Community Level, or about 3.3% of counties. 5,239,101 people live in those 107 counties, which is about 1.6% of the total U.S. population. If all Head Start programs had adopted a masking requirement at centers in counties with a High COVID–19 Community Level, the requirement would have covered 1.6% of all staff, children, and volunteers for that week. This metric has fluctuated over time, reaching a maximum share of 60.9% of the U.S. population living in a county with High COVID–19 Community Level on July 28, 2022.

To quantify the impact of the final rule, we average these population shares over the time period of the historic data and adopt these as our primary estimates of the share of the population covered by the requirements for scenarios 2, 3, and 4 over the time horizon of the analysis. Table 2 presents estimates of the average population shares, which we multiply with the total number of Head Start staff, children, and volunteers for our primary estimates of the average number of staff and children covered by the requirements for each of the Scenarios. As one example calculation, under the ''High Level'' Scenario, we estimate that an average of 46,594 staff [= 17.1% × 273,000] would be required to mask each week over the time horizon of the analysis. Table 2 summarizes these estimates, which correspond to our primary estimates for each scenario. In Section E. Uncertainty and Sensitivity Analyses, we address uncertainty in our estimate of the average weekly population shares.

TABLE 2—ESTIMATES OF THE AVERAGE NUMBER OF HEAD START STAFF, CHILDREN, AND VOLUNTEERS IN COUNTIES WITH REQUIREMENT IN EFFECT

Scenario	Share (%)	Staff	Children	Volunteers
1: Universal	100.0	273,000	864,289	464,161
2: High Level	17.1	46,594	147,513	79,221
3: High or Medium Level	43.5	118,673	375,707	201,771
4: Community Transmission	86.3	235,504	745,582	400,410
5: Voluntary	0.0	0	0	0

C. Impacts of the Revisions to the Interim Final Rule

Masking

We estimate the number of masks required, and the costs of masking, under each of the five scenarios. As an intermediate step to calculating the number of masks required, we estimate the total in-person days per week for staff, children, and volunteers. Table 3 reports data on the operating status of Head Start Centers and presents estimates of the in-person days per week by center status. These figures come from May 2022 administrative data, the last month of data before summer break. 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; (3) that centers in fully in-person status meet in person 5.0 days per week, on average; (4) that staff and children attend 100% of in-person days; and (5) that volunteers attend 20% of in-person days. For the purposes 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.[47]

TABLE 3—HEAD START CENTER OPERATING STATUS AND IN-PERSON DAYS PER WEEK FOR STAFF AND CHILDREN

Center status	Centers	Count			In-person days per week		
		Staff	Children	Volunteers	Staff	Children	Volunteers
Closed	501	6,814	21,573	11,586	0	0	0
Virtual/Remote	424	5,758	18,229	9,790	0	0	0
Hybrid	2,474	33,622	106,444	57,165	84,056	266,111	28,583
Fully In-Person	16,686	226,806	718,042	385,620	1,134,028	3,590,211	385,620
Total	20,085	273,000	864,289	464,161	1,218,083	3,856,322	414,203

To calculate the costs of masking under each scenario, we replicate the in-person days per week for staff and children using the estimates reported in Table 3. We reduce the estimate for children by 14% to account for children younger than age 2 that were not subject to the requirement of the IFC. We assume that staff and volunteers will use an average of one mask per day, that children will use an average of two masks per day and adopt an estimate of the cost per disposable surgical mask of $0.14. Under the Universal Scenario, we anticipate that staff, children, and volunteers will combine for a total of about 8.3 million masks per week, with the total weekly cost of these masks of about $1.2 million. We anticipate that some individuals would wear masks when in-person at Head Start programs without this requirement and adopt an estimate of 92% for the share of these costs attributable to the revised masking requirement under this scenario.

This assumption is intended to be consistent with a current projection of the mask use of 8%, representing ''the percentage of the population who say they always wear a mask in public.'' [48] This parameter should be interpreted as the average share of staff, children, and volunteers at in-person Head Start settings who would mask over the time period of the analysis, covering a range of masking outcomes that will vary over time; however, the actual share of individuals wearing a mask on any particular day will likely vary on a number of factors, including local COVID–19 conditions. We analyze the total costs over a 3-month time horizon and report an estimate of the total masking costs attributable to the final rule under Scenario 1 of about $13.9 million. We replicate this analysis for each of the other scenarios and report total masking costs for each. Finally, we report cost savings of the final rule for each scenario compared to the IFC.

TABLE 4—COST ASSOCIATED WITH MASKING, AND COST SAVINGS COMPARED TO IFC, FOR EACH SCENARIO

Cost element	Universal	High level	High and medium level	Community transmission	Voluntary
In Person Days per Week:					
Staff	1,218,083	1,218,083	1,218,083	1,218,083	1,218,083
All Children	3,856,322	3,856,322	3,856,322	3,856,322	3,856,322
Children (2+)	3,316,437	3,316,437	3,316,437	3,316,437	3,316,437
Volunteers	414,203	414,203	414,203	414,203	414,203
Masks per Staff per Day	1	1	1	1	1
Masks per Child per Day	2	2	2	2	2
Masks per Volunteer per Day	1	1	1	1	1
Centers Requiring Masking	100%	17.1%	43.5%	86.3%	0.0%
Total Masks per Week	8,265,160	1,410,660	3,592,871	7,129,967	0
Cost per Mask	$0.14	$0.14	$0.14	$0.14	$0.14
Cost of Masks per Week	$1,157,122	$197,492	$503,002	$998,195	$0
Attributable Share	92%	92%	92%	92%	92%
Weekly Attributable Cost	$1,064,553	$181,693	$462,762	$918,340	$0
Weeks Included in This Analysis	13	13	13	13	13
Total Masking Costs	$13,886,709	$2,370,120	$6,036,562	$11,979,414	$0
Cost Savings	$0	$11,516,589	$7,850,147	$1,907,295	$13,886,709

We adopt the Universal Scenario as our baseline scenario, which corresponds to the IFC approach of requiring masking at 100% of centers. We assume that the representative mitigation policy will follow the current CDC Guidelines on masking, and therefore adopt the High Level Scenario for our primary estimate of the costs of masking under the final rule. Thus, we conclude that the final rule will result in about $11.5 million in cost savings from fewer masks.

Costs of Communicating and Learning Current Masking Requirements

While the modifications to the IFC result in overall cost savings, we anticipate an additional cost to Head Start centers to communicate the current masking requirements. For each of the 19,160 centers operating fully in-person or in a hybrid status, we assume that one supervisor will spend five minutes each week to learn and communicate the current county Community Level and communicate the current requirements. Across these centers, this is about 1,597 hours per week. To monetize this impact, we apply an estimate of the value of time for on-the-job activities of supervisors, described in the Appendix, of $45.50 per hour. Multiplying this hourly value of time by the number of hours results in $72,649 per week, or $947,674 over a 3-month time horizon.

We also identify a cost to other staff to receive this information. Each of the approximately 226,806 staff at fully in-person centers and 33,622 staff at centers in hybrid operating status will

need to be aware of the current requirements. Subtracting the 19,160 staff responsible for learning and communicating the current county Community Level, we assume that 241,268 staff will receive this information. We assume that receiving this information will take 30 seconds per week and calculate that it will take a total of 2,011 hours per week across all staff. To monetize this impact, we apply an estimate of the value of time for on-the-job activities for non-supervisory staff, described in the Appendix, of $28.20 per hour. Multiplying this hourly value of time by the number of hours results in $56,698 per week, or $739,604 over a 3-month time horizon.

We report a total weekly cost of communicating and learning current masking requirements of $129,346. Over a 3-month time horizon, the total cost of communicating and learning these requirements is $1,687,278.

Costs of Establishing an Evidence-Based COVID–19 Mitigation Policy

We also identify a cost to Head Start programs to develop an evidence-based COVID–19 mitigation policy in consultation with their Health Services Advisory Committee. For each of the 1,604 grant recipients, we assume that developing an evidence-based COVID–19 mitigation policy will take an average of 8 hours. We Across all programs, we estimate that developing these mitigation policies will take a total of 12,832 hours. To monetize this impact, we apply an estimate of the value of time for on-the-job activities of supervisors, described in the Appendix, of $45.50 per hour. Multiplying this hourly value of time by the number of hours results in a one-time cost of $583,856.

Net Impact on Costs

Table 6 summarizes the costs under our Baseline of the IFC, and costs under the final rule and reports the net impact on costs of the revisions to the IFC. All estimates are reported over a 3-month time horizon in year-2021 dollars. In total, we estimate that the final rule will result in about $9.2 million in cost savings. Table 6 also reports the net impacts over an alternative time horizon of a year.

TABLE 6—PRIMARY ESTIMATES OF THE NET IMPACT ON COSTS OF THE FINAL RULE, 2021 DOLLARS, 3-MONTH TIME HORIZON

Cost element	Cost under IFC	Cost under final rule	Net impact	Net impact (year)
Masking Requirement	$13,886,709	$2,370,120	−$11,516,589	−46,066,357
Communicating and Learning	0	1,687,278	1,687,278	6,749,112
Establishing a Policy	0	583,856	583,856	583,856
Total	13,886,709	4,641,254	−9,245,455	−38,733,389

Note that negative net impacts in this table correspond to cost savings attributable to the revisions of the final rule.

D. Analysis of Policy Alternatives to the Final Rule

ACF considered many policy alternatives beyond the regulatory option of the final rule. We analyzed and quantified the impacts of five policy alternatives related to the masking requirements. Specifically, we considered the following alternative masking requirements:

(1) Adopting the approach of the IFC, which required mask wearing for all adults and children two years of age and older in certain in-person Head Start settings.

(2) Adopting a policy alternative to require masks for all adults and children two years of age and older, in certain in-person Head Start settings in counties with a High COVID–19 Community Level.

(3) Adopting a policy alternative to require masks for all adults and children two years of age and older in certain in-person Head Start settings in counties with a Medium or High COVID–19 Community Level.

(4) Adopting a policy alternative to require masks for all adults and children two years of age and older in certain in-person Head Start settings in counties with High or Substantial Community Transmission.

(5) Adopting a policy alternative to rescind the masking requirement, without adopting the requirement for an evidence-based COVID–19 mitigation policy.

We anticipate that Head Start centers will incur costs of communicating and learning current masking requirements, except for the two masking alternatives that do not depend on the COVID–19 Community Level or COVID–19 County Level of Community Transmission. Table 7 reports the net cost savings of each policy alternative over a 3-month time horizon.

TABLE 7—COST SAVINGS FOR MASKING POLICY ALTERNATIVES, MILLIONS OF 2021 DOLLARS, 3-MONTH TIME HORIZON

Masking alternative	Cost of masking	Cost of communicating and learning	Cost of establishing a policy	Total costs	Cost savings
Baseline	$13,886,709	$0	$0	$13,886,709	$0
Final Rule	2,370,120	1,687,278	583,856	4,641,254	9,245,455
Universal	13,886,709	0	0	13,886,709	0
High Level	2,370,120	1,687,278	0	4,057,398	9,829,311
High or Medium Level	6,036,562	1,687,278	0	7,723,840	6,162,869
Community Transmission	11,979,414	1,687,278	0	13,666,692	220,017
Voluntary	0	0	0	0	$13,886,709

Note that negative net impacts in this table correspond to cost savings attributable to the revisions of the final rule.

E. Uncertainty and Sensitivity Analyses

Uncertainty Over COVID–19 Projections

Our primary estimates of the cost savings of the final rule incorporate estimates of the share of the population covered by the requirements, based on historic averages of the observed share of the population in counties with a High COVID–19 Community Level for masking. Projecting this metric is inherently uncertain. To address this uncertainty, we use a bootstrap estimator of the mean share, sampling with replacement weekly observations of the share of the population from the historic data. We use this process to generate a 90% confidence interval around our estimated means. Table 8 reports our primary estimate and a 5% (Low) and 95% (High) confidence bounds of this mean. For this analysis, we used Stata/MP 17.0 and 100,000 replications.

TABLE 8—SHARE OF POPULATION IN COUNTIES WITH REQUIREMENT IN EFFECT

Scenario	Share		
	Primary	Low	High
1: Universal	100.0%	100.0%	100.0%
2: High Level	17.1%	12.1%	22.1%
3: High or Medium Level	43.5%	35.9%	51.0%
4: Community Transmission	86.3%	84.2%	88.3%
5: Voluntary	0.0%	0.0%	0.0%
Scenario	Impact on Costs, Masking		
1: Universal	$0	$0	$0
2: High Level	−$11,516,589	−$12,212,383	−$10,820,796
3: High or Medium Level	−$7,850,147	−$8,898,821	−$6,801,473
4: Community Transmission	−$1,907,295	−$2,190,078	−$1,624,510
5: Voluntary	−$13,886,709	−$13,886,709	−$13,886,709

Analysis of Alternative Baseline Scenarios

In our primary analysis of the final rule, we adopt a baseline scenario of the requirements of the IFC in effect nationally over the time horizon of our analysis (''IFC'' in Table 9 below). We also performed a sensitivity analysis that adopts two alternative baseline scenarios. Our first alternative baseline scenario (''Injunction'') accounts for two federal court injunctions.[49] We estimate that these injunctions jointly cover about 45.5% of Head Start staff. Thus, under our alternative baseline that accounts for the federal court injunctions, we reduce the costs of masking by 45.5% compared to our primary baseline. We also assess the impact of the final rule under a second alternative baseline of ''No IFC.'' Table 9 reports the costs under each of these baselines, the costs under the final rule, and presents the impact on costs under each of the baselines. For this analysis, we assume that the final rule will be in effect at all Head Start programs.

TABLE 9—COST ANALYSIS UNDER ALTERNATIVE BASELINES

Cost element	Baseline costs			Costs under final rule	Impact on costs		
	IFC	Injunction	No IFC		IFC	Injunction	No IFC
Masking Requirement	$13.9	$7.6	$0.0	$2.4	−$11.5	−$5.2	$2.4
Communicating and Learning	0.0	0.0	0.0	1.7	1.7	1.7	1.7
Establishing a Policy	0.0	0.0	0.0	0.6	0.6	0.6	0.6
Total	13.9	7.6	0.0	4.6	−9.2	−2.9	4.6

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).[50] 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 final rule will impact small entities in NAICS category 624410, Child Day Care Services, which has a size standard of $8.5 million dollars. We assume that all 20,085 Head Start centers are below this threshold and are considered small entities.

B. Description of the Impacts of the Rule on Small Entities

Compared to our Baseline Scenario of the IFC, this final rule will result in cost savings for Head Start programs associated with modifications to the masking requirement, costs associated with communicating current requirements, and costs associated with

revisions to policies and procedures. As outlined in Table 6, we estimate that the incremental impact of the final rule is about $9.2 million in net cost savings for Head Start programs. Across 20,085 centers, we estimate that these cost savings will average $460.32 in cost savings per center. This analysis concludes that the final rule is not likely to result in a significant impact on a substantial number of small entities.

IV. Appendix

A. Value of Time Calculations

On-the-Job Activities for Supervisors

For changes in time use for on-the-job activities for supervisors, we adopt an hourly value of time based on the cost of labor, including wages and benefits, and also indirect costs, which ''reflect resources necessary for the administrative oversight of employees and generally include time spent on administrative personnel issues (*e.g.,* human resources activities such as hiring, performance reviews, personnel transfers, affirmative action programs), writing administrative guidance documents, office expenses (*e.g.,* space rental, utilities, equipment costs), and outreach and general training (*e.g.,* employee development).'' [51]

For supervisors, we identify a pre-tax hourly wage of Education and Childcare Administrators, Preschool and Daycare, in the Child Day Care Services industry. According to the U.S. Bureau of Labor Statistics, the hourly median wage for these individuals is $22.75 per hour.[52] We assume that benefits plus indirect costs equal approximately 100 percent of pre-tax wages, and adjust this hourly rate by multiplying by two, for a fully loaded hourly wage rate of $45.50. We adopt this as our estimate of the hourly value of time for changes in time use for on-the-job activities for supervisors.

On-the-Job Activities for Non-Supervisory Staff

For non-supervisory staff, we identify a pre-tax hourly wage of Preschool and Kindergarten Teachers in the Child Day Care Services industry. According to the U.S. Bureau of Labor Statistics, the hourly median wage for these individuals is $14.10 per hour.[53] We assume that benefits plus indirect costs equal approximately 100 percent of pre-tax wages, and adjust this hourly rate by multiplying by two, for a fully loaded hourly wage rate of $28.20. We adopt this as our estimate of the hourly value of time for changes in time use for on-the-job activities for non-supervisory staff.

IX. 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.

January Contreras, Assistant Secretary of the Administration for Children and Families, approved this document on December 7, 2022.

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.

Dated: December 27, 2022.

Xavier Becerra,

Secretary, Department of Health and Human Services.

For reasons discussed in the preamble, 45 CFR part 1302 is amended 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. Amend§ 1302.47 by:
■ a. Adding the word ''and'' at the end of (b)(5)(iv).
■ b. Removing the word ''and'' from paragraph (b)(5)(v).
■ c. Removing paragraph (b)(5)(vi).
■ d. Adding paragraph (b)(9).

The addition reads as follows:

§ 1302.47 Safety practices.

* * * * *

(b) * * *

(9) *COVID–19 mitigation policy.* The program has an evidence-based COVID–19 mitigation policy developed in consultation with their Health Services Advisory Committee (HSAC) that can be scaled up or down based on the impact of COVID–19 in the community to protect staff, children, and families from COVID–19 infection.

* * * * *

Endnotes

[1] Exceptions were 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; 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.

[2] *https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-childcare-guidance.html.*

[3] 86 FR 68052.

[4] Not all the listed considerations are included because they are only relevant to certain standards, such as curriculum.

[5] *https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html.*

[6] 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.*

[7] 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.

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

[9] *Texas et al.* v. *Becerra, et al.,* 577 F. Supp. 3d 527 (N.D. Tex. 2021)

[10] *Louisiana, et al.* v. *Becerra, et al.,* No. 21–cv–04370, 2022 WL 4370448,—F. Supp. 3d—(W.D. La. Sept. 21, 2022); *Louisiana, et al.* v. *Becerra, et al.,* No. 21–cv–04370, 577 F. Supp. 3d 483 (W.D. La. 2022).)

[11] Note: January 2022 center status is not included due to a system error with the Head Start Enterprise System, causing unusually high unreported values.

[12] OHS acknowledges that we do not know what impacts on enrollment would have been in states that did not implement the requirements.

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[40] Ibid.

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[FR Doc. 2022–28451 Filed 1–5–23; 8:45 a.m.]

BILLING CODE 4184–01–P