No. _____

In the Supreme Court of the United States

STATES OF MISSOURI, NEBRASKA, ALASKA, ARKANSAS, IOWA, KANSAS, NEW HAMPSHIRE, NORTH DAKOTA, SOUTH DAKOTA, AND WYOMING,

Petitioners,

v.

JOSEPH R. BIDEN, JR., *et al.*,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

ADDENDUM TO PETITION FOR WRIT OF CERTIORARI

DOUGLAS J. PETERSON
Nebraska Attorney General
JAMES A. CAMPBELL
Solicitor General

Office of the Nebraska Attorney General
2115 State Capitol
Lincoln, NE 68509
(402) 417-2686
jim.campbell@nebraska.gov

ERIC S. SCHMITT
Missouri Attorney General
D. JOHN SAUER
Solicitor General
Counsel of Record
JESUS A. OSETE
Deputy Attorney General
Office of the Missouri Attorney General
Supreme Court Building
P.O. Box 899
Jefferson City, MO 65102
(573) 751-8870
John.Sauer@ago.mo.gov

Counsel for Petitioners

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APPENDIX A

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

No: 21-3725

State of Missouri, et al.

Appellees

v.

Joseph R. Biden, Jr., in his official capacity as the President of the United States of America, et al.

Appellants

Reliant Care Management Company, L.L.C.

Amicus Curiae American Academy of Family Physicians, et al.

Amici on Behalf of Appellant(s)

Appeal from U.S. District Court for the Eastern District of Missouri – St. Louis (4:21-cv-01329-MTS)

ORDER

Before LOKEN, BENTON, and KELLY, Circuit Judges

In November 2021, the Secretary of Health and Human Services (the "Secretary") issued an interim final rule requiring that participating facilities ensure that their staff are vaccinated

against COVID-19 to receive Medicare and Medicaid funding (unless exempt for medical or religious reasons). *See* 86 Fed. Reg. 61555 (2021).

Many states challenged the rule. Two district courts, including the United States District Court for the Eastern District of Missouri, enjoined its enforcement. *See Missouri v. Biden*, No. 4:21-CV-01329-MTS, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021). The district court ruled that the states were likely to succeed on the merits of their claims that the Secretary lacked statutory authority to issue the rule. *Id.*

The federal government filed an emergency motion in this court to stay the preliminary injunction pending appeal. This court denied the motion.

The federal government petitioned the United States Supreme Court for a stay of the preliminary injunction pending further review by this court. The Supreme Court stayed the preliminary injunction pending the outcome of this appeal. *Biden v. Missouri*, 142 S. Ct. 647 (2022).

Based on the Supreme Court's opinion, this court vacates the preliminary injunction and remands to the district court for a determination of the merits of the State of Missouri's claim for permanent injunctive relief. *See* Fed. R. Civ. P. 65(a)(2).

April 11, 2022

Order Entered at the Direction of the Court:

Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans

APPENDIX B

UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

No: 21-3725

State of Missouri; State of Nebraska; State of Arkansas; State of Kansas; State of Iowa; State of Wyoming; State of Alaska; State of South Dakota; State of North Dakota; State of New Hampshire

Plaintiffs – Appellees

v.

Joseph R. Biden, Jr., in his official capacity as the President of the United States of America; United States of America; United States Department of Health and Human Services; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; Centers for Medicare and Medicaid Services; Chiquita Brooks-LaSure, in her official capacity as Administrator for the Centers for Medicare and Medicaid Services; Meena Seshamani, in her official capacity as Deputy Administrator and Director of Center for Medicare; Daniel Tsai, in his official capacity as Deputy Administrator and Director of Center for Medicaid and CHIP Services

Defendants - Appellants

Reliant Care Management Company, L.L.C.
Amicus Curiae
American Academy of Family Physicians; American Academy of Pediatrics; American College of Chest Physicians; American College of Medical Genetics and Genomics; American College of Physicians; American Geriatrics Society; American Lung Association; American Medical Women's Association; American Society for Clinical Pathology; American Society for Echocardiography; American Society of Hematology; American Thoracic Society

Amici on Behalf of Appellant(s)

Appeal from U.S. District Court for the Eastern District of Missouri - St. Louis (4:21-cv-01329-MTS)

JUDGMENT

Before LOKEN, BENTON and KELLY, Circuit Judges.

The preliminary injunction is vacated and the case is remanded to the district court in accordance with this court's order dated April 11, 2022. Mandate shall issue forthwith.

April 11, 2022

Order Entered at the Direction of the Court:
Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans

APPENDIX C

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

STATE OF MISSOURI, *et al.*,	)	
Plaintiffs,	)	
vs.	)	No. 4:21-cv-01329
JOSEPH R. BIDEN, JR., *in his official capacity as the President of the United States of America, et al.*,	)	
Defendants.	)	

MEMORANDUM AND ORDER

I. INTRODUCTION

This case concerns the Centers for Medicare and Medicaid Services' ("CMS") federal vaccine mandate on a wide range of healthcare facilities. On November 5, 2021, CMS issued an Interim Final Rule with Comment Period ("IFC") entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (the "mandate"), 86 Fed. Reg. 61,555 (Nov. 5, 2021), revising the "requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs." 86 Fed. Reg. 61,555– 601.

Specifically, the mandate requires nearly every employee, volunteer, and third-party contractor working[1] at fifteen[2] categories of healthcare facilities to be vaccinated against SARS- CoV-2 ("COVID") and to have received at least a first dose of the vaccine prior to December 6, 2021. *See id.* at 61,573. On November 10, 2021, Plaintiffs, the States of Missouri, Nebraska, Arkansas, Kansas, Iowa, Wyoming, Alaska, South Dakota, North Dakota, and New Hampshire (collectively, "Plaintiffs") filed a Complaint challenging the mandate. Doc. [1]. The

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[1] The mandate applies to a wide-range of people working at the facilities, including, employees, trainees, students, volunteers, or *contractors*, who provide any care, treatment, or *other* services for the facility. 86 Fed. Reg. at 61,570 (emphasis added).

[2] The CMS vaccine mandate covers fifteen categories of Medicare- and Medicaid-certified providers and suppliers:

(1) Ambulatory Surgical Centers (ASCs); (2) Hospices; (3) Psychiatric residential treatment facilities (PRTFs); (4) Programs of All-Inclusive Care for the Elderly (PACE); (5) Hospitals (acute care hospitals, psychiatric hospitals, long term care hospitals, children's hospitals, hospital swing beds, transplant centers, cancer hospitals, and rehabilitation hospitals); (6) Long Term Care (LTC) Facilities, generally referred to as nursing homes; (7) Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID); (8) Home Health Agencies (HHAs); (9) Comprehensive Outpatient Rehabilitation Facilities (CORFs); (10) Critical Access Hospitals (CAHs); (11) Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services; (12) Community Mental Health Centers (CMHCs); (13) Home Infusion Therapy (HIT) suppliers; (14) Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs); and (15) End-Stage Renal Disease (ESRD) Facilities. 86 Fed. Reg. at 61,569–70.

Complaint seeks preliminary and permanent injunctive and declaratory relief. On November 12, 2021, Plaintiffs filed a motion for a preliminary injunction, Doc. [6], requesting that this Court issue a preliminary injunction enjoining Defendants from imposing the mandate.

Having fully reviewed the administrative record and submitted material, the Court finds that a preliminary injunction is warranted here.

II. DISCUSSION

A. The Court has jurisdiction.

Defendants argue that this Court "lacks jurisdiction" over Plaintiffs' claims because "Congress has withdrawn federal-question jurisdiction over claims like this one that arise under the Medicare statute," citing 42 U.S.C. § 405(h), as incorporated by 42 U.S.C. § 1395ii. Doc. [23] at 15–19. The Court does not agree. As Defendants readily concede, "State governments" such as the Plaintiff States are neither "institution[s]" nor "agenc[ies]" "dissatisfied" with the Secretary's determination regarding eligibility or receipt of benefits under 42 U.S.C. § 1395cc(h)(1) and, therefore, "the States[3] themselves could not use that statute's vehicle for judicial review." *Id.* at 19; *see Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 16 (2000) (explaining that § 405(h) does not apply if application "would mean no review at all"). In addition, Plaintiffs' claims that arise under the

[3] The Plaintiff States bring their claims in a number of capacities: sovereign, quasi-sovereign/*parens patriae*, and proprietary. *See, e.g.*, Doc. [1] ¶¶ 5, 7, 9.

Medicaid Act—as opposed to the Medicare Act— are not subject to the § 405(h)'s jurisdictional bar. *See Avon Nursing & Rehab. v. Becerra*, 995 F.3d 305, 311 (2d Cir. 2021) ("Unlike the Medicare Act, the Medicaid Act does not incorporate the Social Security Act's claim-channeling and jurisdiction-stripping provisions, 42 U.S.C. § 405(g) and (h). Federal courts thus have jurisdiction over claims arising under the Medicaid Act pursuant to 28 U.S.C. § 1331."). Thus, all aspects of the mandate that purport to change a Medicaid regulation are clearly not barred, even under Defendants' arguments. Nonetheless, the Court finds that it has jurisdiction over claims arising under both Medicare and Medicaid.

B. **A preliminary injunction is warranted here.**

Plaintiffs seek a preliminary injunction of the mandate's enforcement pending a full judicial review of the mandate's legality. The Court addresses their request today. Whether a court should issue a preliminary injunction involves consideration of (1) the threat of irreparable harm to the movant; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981). "While no single factor is determinative, the probability of success factor is the most significant." *Home Instead, Inc. v. Florance*, 721 F.3d 494, 497 (8th Cir. 2013) (internal quotations and citations omitted).

Each of these factors favors a preliminary injunction here.

a. Plaintiffs demonstrate a likelihood of success on the merits.

i. **Congress did not grant CMS authority to mandate the vaccine.**

Plaintiffs are likely to succeed in their argument that Congress has not provided CMS the authority to enact the regulation at issue here. "[A]n agency literally has no power to act, let alone pre-empt[4] the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 357 (1986). While the Court agrees Congress has authorized the Secretary of Health and Human Services (the "Secretary") *general* authority to enact regulations for the "administration" of Medicare and Medicaid and the "health and safety" of recipients, the nature and breadth of the CMS mandate requires clear authorization from Congress—and Congressed has provided none.[5] *See Ala. Ass'n of Realtors v. Dep't of*

[4] CMS intends for the mandate to preempt any arguably inconsistent state and local laws regarding vaccination. *See, e.g.*, 86 Fed. Reg. at 61,568 ("We intend . . . that this nationwide regulation preempts inconsistent State and local laws applied to Medicare- and Medicaid-certified providers and suppliers.").

[5] The Court notes that Congress has provided the Secretary of Health and Human Services (the "Secretary") authority to enact regulations "necessary to the efficient administration" of the Social Security Act and regulations "necessary to carry out the administration of" of Medicare. 42 U.S.C. §§ 1302(a),

Health & Hum. Servs., 141 S. Ct. 2485, 2486 (2021) ("It would be one thing if Congress had specifically authorized the action that the CDC has taken. But that has not happened."). Courts have long required Congress to speak clearly when providing agency authorization if it (1) intends for an agency to exercise powers of vast economic and political significance; (2) if the authority would significantly alter the balance between federal and state power; or (3) if an administrative interpretation of a statute invokes the outer limits of Congress' power. Any one of those fundamental principles would require clear

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1395hh(a)(1). Among the regulations the Secretary may promulgate under its power of "administration" is the setting of things like "standards," "criteria," or "requirements" for specific facilities. *See, e.g.*, *Id.* at § 1396d(h)(1)(B)(i) (governing Psychiatric Residential Treatment Facilities ("PRTFs") and mentioning "standards as may be prescribed in regulations by the Secretary"); *Id.* at § 1395i–4(e) (governing Critical Access Hospitals ("CAHs") and mentioning "criteria as the Secretary may require"); *Id.* at § 1395rr(b)(1)(A) (governing End-Stage Renal Disease ("ESRD") facilities and mentioning "requirements as the Secretary shall by regulation prescribe"). For some facilities, Congress has authorized the Secretary to set rules or conditions necessary to, or that will ensure, the "health and safety" of recipients of services. *See, e.g.*, *Id.* at § 1395i–3(d)(4)(B) (addressing LTC facilities and mentioning "requirements relating to the health, safety, and well-being of residents . . . as the Secretary may find necessary"); *Id.* at § 1395x(e)(9) (addressing hospitals and mentioning "requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services"). However, the Court need not decide whether those regulations are properly interpreted by CMS to confer it authority to issue the vaccine mandate that it has. Instead, and irrespective of that determination, the Court's inquiry focuses on whether Congress specifically authorized such action, for reasons discussed above.

congressional authorization for this mandate, but here, all three are present. Even in exigency, the Secretary cannot "bring about an enormous and transformative expansion in [his] regulatory authority without clear congressional authorization." *See Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 324 (2014).

1. ***Given the vast economic and political significance of this vaccine mandate, only a clear authorization from Congress would empower CMS to act.***

First, Congress must "speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 (quoting *Util. Air Reg.*, 573 U.S. at 324). The mandate's economic cost is overwhelming. CMS estimates that compliance with the Mandate—just in the first year—is around 1.38 billion dollars. 86 Fed. Reg. at 61,613. Those costs, though, do not take into account the economic significance this mandate has from the effects on facilities closing or limiting services and a significant exodus of employees that choose not to receive a vaccination.[6][6] Likewise, the political significance of a mandatory coronavirus vaccine is hard to understate,

[6] Medicare and Medicaid programs "touch[] the lives of nearly all Americans" and are two of the "largest federal program[s]" in the country. *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Even "minor changes" to the way those programs are administered "can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." *Id.* at 1816.

especially when forced by the heavy hand of the federal government. Indeed, it would be difficult to identify many other issues that currently have more political significance at this time. Had Congress wished to assign this question fraught with deep economic and political significance to CMS, "it surely would have done so expressly." *See King v. Burwell*, 576 U.S. 473, 486 (2015). "It is especially unlikely that Congress would have delegated this decision to [CMS], which has no expertise in crafting" vaccine mandates. *Id.*

2. **B*ecause this mandate significantly alters the balance between federal and state power, only a clear authorization from Congress would empower CMS.***

Second, Congress must use "exceedingly clear language if it wishes to significantly alter the balance between federal and state power." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 (quoting *United States Forest Service v. Cowpasture River Preservation Assn.*, 140 S. Ct. 1837, 1850 (2020)); *see also United States v. Bass*, 404 U.S. 336, 349 (1971). The regulation at issue alters that balance because it requires vaccination, which CMS has never attempted to do, for millions of individuals who would otherwise be outside the reach of the federal government. This concern is "heightened" since CMS's "administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power." *Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Engineers*, 531 U.S. 159, 173

(2001). It has long been the states' power to legislate health—including vaccination. *Gibbons v. Ogden*, 22 U.S. 1, 203 (1824) (noting "health laws of every description" belong to the states); *BST Holdings, L.L.C. v. Occupational Safety & Health Admin.*, 17 F.4th 604, ---, 2021 WL 5279381, at *7 (5th Cir. 2021) (citing *Zucht v. King*, 260 U.S. 174, 176 (1922) (noting that precedent had long "settled that it is within the police power of a state to provide for compulsory vaccination")). Sometimes "the most telling indication of [a] severe constitutional problem . . . is the lack of historical precedent" for an agency's action. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 549 (2012). With such a history of exclusive state power, the Court is far from certain that Congress intended the *Center for Medicare and Medicaid Services* to require mandatory vaccinations for millions of Americans. *See Bond v. United States*, 572 U.S. 844, 858 (2014) (noting "it is incumbent upon the federal courts to be certain of Congress' intent before finding that federal law overrides the usual constitutional balance of federal and state powers" (internal quotations omitted)).

Truly, the impact of this mandate reaches far beyond COVID.[7] CMS seeks to overtake an area of

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[7] Of course, this situation is novel and messy in that COVID has created a "unique pandemic scenario," 86 Fed. Reg. at 61,568, but equally problematic is that it remains unclear that COVID-19—however tragic and devastating the pandemic has been—poses the kind of grave danger that justifies the federal government trampling on sovereign state rights. Regardless, disrupting this balance of power must have been expressly authorized by Congress, and as discussed, Congress has not.

traditional state authority by imposing an unprecedented demand to federally dictate the private medical decisions of millions of Americans. Such action challenges traditional notions of federalism, as discussed above. "The independent power of the States [] serves as a check on the power of the Federal Government: by denying any one government complete jurisdiction over all the concerns of public life, federalism protects the liberty of the individual from arbitrary power." *NFIB*, 567 U.S. at 536 (quoting *Bond v. United States*, 564 U.S. 211, 222 (2011)). This is especially true, since "a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front." *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

3. ***In the absence of a clear indication that Congress intended for CMS to invoke such significant authority, the Court will not infer congressional intent.***

Third, "[w]here an administrative interpretation of a statute invokes the outer limits of Congress' power," Congress must provide "a clear indication that [it] intended that result." *Solid Waste*, 531 U.S. at 172. This "requirement" stems from the "prudential desire not to needlessly reach constitutional issues."[8]

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[8] A court—especially a district court—should be reluctant to opine on an unsettled constitutional issue when the court can resolve a case on an alternative ground. *See Xiong v. Lynch*, 836

Id. And this requirement is "heightened" here since CMS's claim "alters the federal-state framework by permitting federal encroachment upon a traditional state power." *Id.* Whether Congress itself could impose the vaccination requirement is a tough question, cf. *BST Holdings*, 17 F.4th at ---, 2021 WL 5279381, at *7 (Duncan, J., concurring), one that CMS would force to its crisis. But even if Congress has the power to mandate the vaccine *and* the authority to delegate such a mandate to CMS—topics on which the Court does not opine today—the lack of congressional intent for this monumental policy decision speaks volumes.

In conclusion, even if Congress's statutory language was susceptible to CMS's exceedingly broad reading—which it is most likely not—Congress did not clearly authorize CMS to enact the this politically and economically vast, federalism-altering, and boundary-pushing mandate, which Supreme Court precedent requires.

ii. <u>CMS improperly bypassed notice and comment requirements.</u>

Even if CMS has the authority to implement the vaccine mandate—which the Court finds is unlikely,

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F.3d 948, 950 (8th Cir. 2016) (quoting *Lyng v. Nw. Indian Cemetery Protective Ass'n*, 485 U.S. 439, 445, 108 (1988)) ("A fundamental and longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in advance of the necessity of deciding them."). And, at the very least, the Court should "pause to consider the implications of the [State's] arguments" when confronted with such new conceptions of federal power. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 550 (2012) (quoting *Lopez*,115 S. Ct. at 1624)

as discussed above—the mandate is likely an unlawful promulgation of regulations. Both the Administrative Procedure Act ("APA") and the Social Security Act ordinarily require notice and a comment period before a rule like this one takes effect.[9] 5 U.S.C. § 553; 42 U.S.C. § 1395hh(b)(1). Failure to allow notice and comment, where required, is grounds for invalidating the rule. *Iowa League of Cities v. EPA*, 711 F.3d 844, 876 (8th Cir. 2013) (vacating a rule based on an administrative agency's failure to abide by the APA's notice and comment procedure). The notice and comment requirements do not apply if "good cause" establishes that they "are impracticable, unnecessary, or contrary to the public interest" under the circumstances. 5 U.S.C. § 553(b)(B). The exception is read narrowly and only used in "rare" circumstances. *Nw. Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1321 (8th Cir. 1981) (noting that the good cause exception should be "narrowly construed and only reluctantly countenanced"); *Nat. Res. Def. Council, Inc. EPA*, 683 F.2d 752, 764 (3d Cir. 1982) (noting "circumstances justifying reliance on [the good cause] exception are indeed rare and will be accepted only after the court has examined closely proffered rationales justifying the elimination of public procedures" (internal quotations omitted)).

CMS concedes it did not follow these requirements but attempts to justify its omission under the "good cause" exception. 86 Fed. Reg. at 61,583. Here, Plaintiffs are likely to succeed in their argument that

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[9] The parties do not dispute that the notice and comment requirements applied to the mandate. 86 Fed. Reg. at 61,583.

CMS unlawfully bypassed the APA's notice and comment requirements.

1. ***CMS's own delay undermines its "emergency" justification for bypassing notice and comment requirements.***

Use of the "good cause" exception is "limited to emergency situations" and is "necessarily fact-or context-dependent." *Thrift Depositors of Am., Inc. v. Off. of Thrift Supervision*, 862 F. Supp. 586, 591 (D.D.C. 1994). Here, CMS's delay in requiring mandatory vaccination undermines its contention that COVID is an emergency such that it has the "good cause" necessary to dispense with notice and comment requirements. In justifying the good cause exception, CMS stated that "[t]he data showing the vital importance of vaccination" indicates that it "cannot delay taking this action" to protect peoples' health and safety. 86 Fed. Reg. at 61,583. Yet, CMS's good cause claim is undermined by its *own* delay in promulgating the mandate. *See United States v. Brewer*, 766 F.3d 884, 890 (8th Cir. 2014) ("[C]oncern for public safety further is undermined by [the Attorney General's] own seven-month delay in promulgating the Interim Rule."); *Chamber of Com. v. United States Dep't of Homeland Sec.*, 504 F. Supp. 3d 1077, 1089 (N.D. Cal. 2020) (finding an agency's six-month delay in promulgating rules relating to COVID precluded presumption of urgency); *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2nd Cir. 2018) ("Good cause cannot arise as a result of the agency's own delay, because otherwise, an agency unwilling to provide notice or an opportunity

to comment could simply wait until the eve of a statutory, judicial, or administrative deadline, then raise up the 'good cause' banner and promulgate rules without following APA procedures." (internal quotations and alterations omitted)). The CMS mandate was announced nearly two months[10] before the agency released it, and the mandate itself prominently features yet another one-month delay. Moreover, two vaccines were authorized under Emergency Use Authorization ("EUA")[11] more than ten months before the CMS mandate took effect, and one vaccine was fully licensed by the FDA well over two months before.[12] It is also worth mentioning that since the onset of COVID, CMS has issued five IFC mandates, such as the one here; the most recent on May 13, 2021. 86 Fed. Reg. at 61,561. One could query how an "emergency" could prompt such a slow response; such delay hardly suggests a situation so dire that CMS may dispense with notice and comment

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[10] On September 9, 2021, the President announced his intention to promulgate federal vaccinate mandates, including the CMS vaccine mandate challenged here.

[11] The FDA issued vaccines under Emergency Use Authorization ("EUA") for two COVID vaccines on December 11, 2020 and December 18, 2020. According to CMS, the agency *could have* imposed a vaccine requirement, even when the only vaccines available are those authorized under EUAs. *See* 86 Fed. Reg. at 61,583.

[12] On August 23, 2021, the FDA licensed the first COVID vaccine.

requirements[13] and the important purposes they serve.

The COVID pandemic is an event beyond CMS's control, yet it was completely within its control to act earlier than it did. *See* 86 Fed. Reg. at 61,583 ("CMS initially chose, among other actions, to encourage rather than mandate vaccination[.]"); *see id.* (explaining CMS had authority to impose vaccination requirements even when the only vaccines available were those authorized under EUAs in December 2020). The mere desire or need to have the mandate does not suffice for good cause. *Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir. 1980) ("[G]ood cause to suspend notice and comment must be supported by more than the bare need to have regulations."); *United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009) ("A desire to provide immediate guidance, without more, does not suffice for good cause."). And good cause is not automatically created based on an agency's conclusion that bypassing the notice and comment requirements is necessary to protect public safety.[14] *See Brewer*, 766

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[13] The Court also takes note that CMS reviewed several communications from stakeholders in *favor* of the mandate. Thus, CMS apparently found it quite possible to consult with the interested parties it selected. *See, e.g.*, 86 Fed. Reg. at 61,565.

[14] Other circuits, like the Eighth, have held that protecting the public, without more, is insufficient to waive procedural requirements. *United States v. Reynolds*, 710 F.3d 498, 509 (3rd Cir. 2013); *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011); *United States v. Valverde*, 628 F.3d 1159, 1168 (9th Cir. 2010); *United States v. Cain*, 583 F.3d 408, 421–24 (6th Cir. 2009).

F.3d at 889 (finding agency's stated reason of "protecting the public safety" was insufficient to waive notice and comment requirement); *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) ("To accord deference to an agency's invocation of good cause would be to run afoul of congressional intent."). COVID cannot be a compelling justification forever, *Does 1-3 v. Mills*, --- S. Ct. ---, 2021 WL 5027177, at *3 (U.S. Oct. 29, 2021) (Gorsuch, J., dissenting), and CMS's evidence shows COVID no longer poses the dire emergency it once did. *See, e.g.*, 86 Fed. Reg. at 61,583 (noting "newly reported COVID-19 cases, hospitalizations, and deaths have begun to trend downward at a national level"). Notably, today, there are three widely distributed vaccines. Additionally, there are several therapeutics and treatments, and as CMS states, more are on the horizon. *See, e.g.*, *id.* at 61,609. Thus, CMS's purported "emergency"[15]—one that the entire globe

[15] CMS also asserted that there is an "emergency" *now* (such that CMS must immediately implement the mandate) because "the 2021–2022 influenza season" will soon begin. 86 Fed. Reg. at 61,584. CMS offered this justification while simultaneously admitting that "the intensity of the upcoming 2021-2022 influenza season cannot be predicted" and that "influenza activity during the 2020-2021 season was low throughout the U.S." *Id.* For a "risk of future harm" to "justify a finding of good cause," the "risk must be more substantial than a mere possibility." *Brewer*, 766 F.3d at 890. Thus, CMS did not find a concrete "threat" to remedy but rather speculated as to a mere possibility of harm, and there is a "difference between addressing present legal uncertainty and addressing the possibility of future legal uncertainty." *Id.* Notably, CMS did not mandate flu vaccines, despite mentioning that the flu has been daunting the healthcare system, that recent studies show approximately half

has now endured for nearly two years, and to which CMS itself demonstrated ease in responding to—is unavailing. *United States Reynolds*, 710 F.3d 498, 512–13 (3rd Cir. 2013) ("Most, if not all, laws passed . . . are designed to eliminate some real or perceived harm. If the mere assertion that such harm will continue while an agency gives notice and receives comments were enough to establish good cause, then notice and comment would always have to give way.").

2. ***CMS failed to meet its "good cause" burden, especially in light of the unprecedented, controversial, and health-related nature of the mandate.***

CMS also failed to meet its burden based on the unprecedented, controversial, and health- related nature of the mandate. *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984) (holding that the inquiry into an agency invoking "good cause proceeds case-by-case, sensitive to the totality of the factors at play"). CMS had the burden "to establish that notice and comment need not be provided." *Nat. Res. Def. Council*, 894 F.3d at 113–14. In a situation like here, where there is significant and known opposition to the mandate, "good cause" is even more important than usual. *See, e.g.*, *Asbestos Information Ass'n of N. Am. v. Occupational Safety & Health Admin.*, 727 F.2d 415, 426 (5th Cir. 1984) (explaining that rules "may be

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of healthcare workers refuse the flu vaccine, *id.* at 61,568, and that CMS has evidence that influenza vaccination of health care staff is directly associated with declines in nosocomial influenza in hospitalized patients and nursing home residents. *Id.* at 61,557

more uncritically accepted after public scrutiny, through notice-and-comment rulemaking, especially when the conclusions it suggests are controversial"). The fact that this mandate effects issues relating to health[16] increases the importance even further. *See Nat'l Ass'n of Farmworkers*, 628 F.2d at 621 ("Especially in the context of health risks, notice and comment procedures assure the dialogue necessary to the creation of reasonable rules."); *Cmty. Nutrition Inst. v. Butz*, 420 F. Supp. 751, 754 (D.D.C. 1976) (noting that "when a health-related standard such as this is involved, the good cause exemption may not be used to circumvent the legal requirements designed to protect the public"). Accordingly, CMS's argument that undertaking normal notice and comment requirements would be "contrary to the public interest" based on delaying the mandate, *id.* at 61,586, is unavailing in light of the circumstances. *Alcaraz*, 746 F.2d at 612. Rather, these requirements "serve the public interest by providing a forum for the robust debate of competing and frequently complicated policy considerations having far-reaching implications and, in so doing, foster reasoned decision making." *Id.* They are far from "mere formalities." *Id.*

Moreover, the failure to take and respond to comments feeds into the very vaccine hesitancy CMS acknowledges is so daunting. 86 Fed. Reg. at 61,559, 61,568. Besides fostering reasoned decision making, notice and comment "provide a 'surrogate political

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[16] CMS acknowledges that "[s]erious adverse reactions [] have been reported following COVID-19 vaccines." 86 Fed. Reg. at 61,565.

process' that takes some of the sting out of the inherently undemocratic and unaccountable rulemaking process." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1929 n.13 (Thomas, J., dissenting). Requiring already hesitant individuals to get the vaccine—without giving them an opportunity to be heard—undermines the democratic process that the APA's procedural safeguards are intended to protect and exacerbates the underlying hesitancy problem. *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980) (according notice and comment great importance because it "reintroduce[s] public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies"). Far from being "good cause" for circumventing the normal rulemaking requirements, the unprecedented and controversial mandate affecting personal health constitutes a compelling reason to utilize those procedures, and CMS failed to provide the good cause necessary to overcome these factors.

In conclusion, because CMS's "emergency" does not justify use of the "good cause" exception, see *Thrift*, 862 F. Supp. at 591, and the unprecedented, controversial, and health-related mandate requires more good cause than CMS provided, *Alcaraz*, 746 F.2d at 612, Plaintiffs are likely to succeed in establishing that CMS improperly invoked the 5 U.S.C. § 553(b)(B) "good cause" exception.

iii. <u>The mandate is arbitrary and capricious.</u>

Finally, Plaintiffs are likely to succeed in establishing that the CMS vaccine mandate is arbitrary or capricious. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary" or "capricious." 5 U.S.C. § 706(2)(A). The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained. *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021) ("A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision."). Under this "narrow" and deferential standard of review, a court may not substitute its own policy judgment for that of the agency. *Id.* Rather, the court must ensure there is a "rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

1. ***The mandate is arbitrary and capricious because the record is devoid of evidence regarding the covered healthcare facilities.***

CMS lacks evidence showing that vaccination status has a direct impact on spreading COVID in the mandate's covered healthcare facilities. CMS acknowledges its lack of "comprehensive data" on this matter but attempts to "extrapolate" the abundant data that it does have on Long Term Care Facilities ("LTCs"), generally referred to as nursing homes, to the other dozen-plus Medicare and Medicaid facilities covered by the mandate. 86 Fed. Reg. at 61,585.

However, CMS's path of analysis appears misguided and the inferences it produced are questionable. *State Farm*, 463 U.S. at 43 (finding that in an arbitrary and capricious challenge, the court will "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned"). As CMS's own record shows, COVID disproportionally devastates LTC facilities. Residents of LTC facilities—who make up less than 1-percent of the U.S. population—accounted for more than 35-percent of all COVID deaths during the first twelve months of the pandemic. 86 Fed. Reg. at 61,566. Equally staggering is that "[o]f the approximately 656,000 Americans estimated to have died from COVID through September 10, 2021, 30-percent are estimated to have died during or after an LTC facility stay." *Id.* at 61,601. Thus, CMS's decision to extrapolate LTC data to justify its lack of data regarding the other fourteen facilities covered is likely not reasonable. *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (requiring agencies to engage in "reasoned decision making"); *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016) ("[A]n agency must give adequate reasons for its decisions."). While a wide-sweeping mandate might make sense in the context of LTCs, based on CMS's evidence, CMS presents no similar evidence for imposing a broad-sweeping mandate on the other fourteen covered facilities. *Camp v. Pitts*, 411 U.S. 138, 143 (1973) ("If [a] finding is not sustainable on the administrative record made, then the [agency's] decision must be vacated[.]"). Although the Court appreciates its deferential review, the Court's duty is not to "rubber-stamp" administrative decisions devoid of reasonableness. *Alaska Oil and Gas Ass'n v. Jewell*, 815 F.3d 544 (9th

Cir. 2016) ("A court must not substitute its judgment for that of the agency, but also must not "rubber-stamp" administrative decisions.").

In general, the overwhelming lack of evidence likely shows CMS had insufficient evidence to mandate vaccination on the wide range of facilities that it did. Looking even beyond the evidence deficiencies relating to the specific facilities covered, the lack of data regarding vaccination status and transmissibility—in general—is concerning. Indeed, CMS states that "the effectiveness of the vaccine[s] to prevent disease transmission by those vaccinated [is] not currently known."[17] 86 Fed. Reg. at 61,615.[18] CMS also admits that the continued efficacy of the vaccine is uncertain. *See, e.g.*, *id.* at 61,612 ("[M]ajor uncertainties remain as to the future course of the pandemic, including but not limited to vaccine effectiveness in preventing 'breakthrough' disease transmission from those vaccinated, [and] the long-term effectiveness of vaccination[.]"). No one questions that protecting patients and healthcare workers from contracting COVID is a laudable

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[17] "As explained in various places within this RIA and the preamble as a whole, there are major uncertainties as to the effects of current variants of SARS-CoV-2 on future infection rates, medical costs, and prevention of major illness or mortality. For example, the duration of vaccine effectiveness in preventing COVID-19, reducing disease severity, reducing the risk of death, and the effectiveness of the vaccine to prevent disease transmission by those vaccinated are not currently known." 86 Fed. Reg. at 61,615.

[18] Also, CMS has no data showing forced vaccinations in the healthcare industry has stopped the spread of COVID in hospitals.

objective. But the Court cannot, in good faith, allow CMS to enact an unprecedented mandate that lacks a "rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43; *see also Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) ("Under the APA . . . the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did."). The reasoned explanation and evidentiary requirement "of administrative law, after all, is meant to ensure that agencies offer genuine justifications for important decisions, reasons that can be scrutinized by courts and the interested public." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575 (2019). If judicial review is to be more than an "empty ritual," the Court here must demand something more than the explanation offered for the action taken by CMS here. *Id.*

2. ***The mandate is arbitrary and capricious because CMS improperly rejected alternatives to the mandate.***

CMS failed to consider or rejected obvious alternatives to a vaccine mandate without evidence. For example, CMS rejected daily or weekly testing—an option that even OSHA approved in its ETS—without citing any evidence for such a conclusion. 86 Fed. Reg. at 61,614. Rather, it assured that it "reviewed scientific evidence on testing" but "found that vaccination is a more effective infection control measure." *Id.* at 61,614. As discussed elsewhere, this conclusion comes despite its admission that it lacks

solid evidence[19] regarding transmissibility of COVID by the vaccinated. *Id.* at 61,615, 61,612. Although it is not the Courts duty to ask whether CMS's decision was "the best one possible" or even whether there were "better [] alternatives," *Federal Energy Regulatory Commission v. Electric Power Supply Ass'n*, 136 S. Ct. 760, 782 (2016), the Court must ensure there exists a "rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43.

As another example, CMS rejected[20] mandate alternatives in those with natural immunity by a previous coronavirus infection. 86 Fed. Reg. at 61,614 (noting "many uncertainties" about the immunity in those previously infected "compared to people who are vaccinated"). But, elsewhere, it plainly contradicts itself regarding the value of natural immunity. *Id.* at 61,604 ("[A]bout 100,000 a day have recovered from infection.... These changes reduce the risk to both health care staff and patients substantially, likely by about 20 million persons a month *who are no longer sources of future infections*.") (emphasis added). Such contradictions are tell-tale signs of unlawful agency

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[19] Far from being reasonable to prohibit alternatives to vaccination, this constitutes a compelling reason to utilize, rather than reject, other alternatives before subjecting the public to a never-before CMS vaccine mandate.

[20] CMS also rejected natural immunity, despite an intense public debate and a trove of scientific data on the strength and durability of natural immunity from COVID-19—alone and compared to vaccine-induced immunity. *State Farm*, 463 U.S. at 43 (noting "the agency must examine the relevant data").

actions. *See State Farm*, 463 U.S. at 43 (finding agency action arbitrary and capricious if the agency explained its decision in a way that "runs counter to the evidence before the agency"); *see also Bethesda Health, Inc. v. Azar*, 389 F. Supp. 3d 32, 41 (D.D.C. 2019) (setting aside as arbitrary and capricious agency action that contradicts its own regulations).

3. The mandate is arbitrary and capricious because of its broad scope.

The broad scope of healthcare facilities covered by the mandate renders it arbitrary. The mandate applies equally to the varying healthcare facility types it covers, such as Psychiatric Residential Treatment Facilities ("PRTFs") for individuals under age twenty-one, *see* 86 Fed. Reg. at 61,576, and LTCs, *see id.* at 61,575. But, at the same time, CMS acknowledges that the risk of COVID to those in the former age group is markedly smaller. *See, e.g.*, *id.* at 61,610 n.247 (recognizing that "risk of death from infection from an unvaccinated 75-to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person"); *id.* at 61,601 ("Among those infected, the death rate for older adults age 65 or higher was hundreds of time higher than for those in their 20s during 2020."); *id.* at 61,566 (noting those aged 65 years and older account for more than 80-percent of U.S. COVID-19 related deaths). What is more, besides applying to all facilities equally, the mandate applies to all facilities' staff equally, "*regardless of . . . patient contact*." *Id.* at 61,570 (emphasis added). The mandate goes so far as to cover a third-party vendor's "crew working on a construction project" whose

members use the same bathrooms "during their breaks." *Id.* at 61,571. CMS provides no reasoned[21] explanation for this overbroad approach, and it further belies its asserted interest in protecting patients from COVID.[22] *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) ("Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action.").

4. ***The mandate is arbitrary and capricious due to CMS's sudden change in course***.

CMS failed to adequately explain its contradiction to its long-standing practice of encouraging rather than forcing—by governmental mandate—vaccination. For years, CMS has promulgated regulations setting the conditions for Medicare and Medicaid participation; *never* has it required any

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[21] As explained in *infra* note 24, upping vaccination nationwide is not a "reasonable" reason for CMS to enact its mandate because the agency's powers are limited to Medicare and Medicare—not federalizing healthcare and reaching the general public. Rather, the overbroad approach indicates the pretextual nature of this mandate.

[22] The Court also notes that recently, on November 12, 2021, CMS itself revised its pandemic guidance for nursing home visitation, specifically opening facility visitation *"for all residents at all times" by family and friends who are not required to be vaccinated*. This also belies CMS's asserted interest in protecting patients from COVID, and instead, shows that the mandate's overbreadth is to increase the national vaccination rate by any means necessary.

vaccine for covered facilities' employees—despite concerns over other illnesses and their corresponding low vaccination rates.[23] As recent as this May, CMS adopted an IFC requiring education on COVID vaccines but again decided against forced vaccination.

It is generally "arbitrary or capricious" to depart from a prior policy *sub silentio*; when agencies contradict a prior policy, they must show "good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *accord EPA v. EME Homer City Generation, L.P.*, 572 U.S. 489, 510 (2014) (holding that agency "retained discretion to alter its course [under a regulation] provided it gave a reasonable explanation for doing so"). Here, CMS's purported reason for changing its policy is to force those unwilling or hesitant to receive the vaccine into receiving it, all under the guise of protecting recipients of Medicare and Medicaid. *See* 86 Fed. Reg. at 61,583 (noting "CMS initially chose . . . to encourage rather than mandate vaccination" but "vaccine uptake among health care staff [was not] as robust as hoped for"); *id.* at 61,569 (noting that despite healthcare worker hesitation about the vaccine, "mandates have already been successfully initiated in a variety of

[23] In the Mandate, CMS discusses how influenza is a major problem plaguing the healthcare industry. Nonetheless, CMS states that half of healthcare workers resist the seasonal influenza vaccine nationwide, 86 Fed. Reg. at 61,568, but that it continues to "recommend" influenza vaccination rather than mandate it. *Id.* Even though CMS has evidence that influenza vaccination of health care staff is associated with declines in nosocomial influenza in hospitalized patients and nursing home residents. *Id.* at 61,557.

health care settings, systems, and states"); *id.* at 61,560 (noting it was "compelled to require staff vaccinations for COVID-19" given its "responsibility to protect the health and safety of individuals . . . receiving care and services from for Medicare- and Medicaid-certified providers and suppliers"). But even if forcing the administration of a specific vaccine, into the otherwise unwilling, in an effort to protect the recipients of these programs could be a reasonable explanation to justify the extraordinary action—action that long has been the province of the states, see *Zucht*, 260 U.S. at 176 (noting that precedent had long "settled that it is within the police power of a state to provide for compulsory vaccination"); *Jacobson v. Massachusetts*, 197 U.S. 11, 25–26 (1905) (similar)—CMS has not shown that it is reasonable in this instance.[24] Rather, it specifically notes that the

[24] The inadequacy of the explanation for the reversal is especially true since Plaintiffs will likely succeed in demonstrating it is a pretextual rationale. *See Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575–76 (2019); *id.* at 2583 (Thomas, J., concurring in part and dissenting in part) (noting Court "opened a Pandora's box of pretext-based challenges in administrative law"); *id.* at 2597 (Alito, J., concurring in part and dissenting in part). While a court may not set aside an agency's policymaking decision "solely because it might have been influenced by political considerations or prompted by an Administration's priorities," *Department of Commerce*, 139 S. Ct. at 2573, an agency's change in course "cannot be solely a matter of political winds and currents." *North Carolina Growers' Association, Inc. v. United Farm Workers*, 702 F.3d 755, 772 (4th Cir. 2012) (Wilkinson, J., concurring). Plaintiffs have demonstrated that they could likely show pretext. *See, e.g.*, Doc. [9] at 4 (citing Joseph Biden, Remarks at the White House (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by- president-biden-on-fighting-

vaccines' effectiveness to prevent disease transmission by those vaccinated is not currently known. 86 Fed. Reg. at 61,615 (noting "the duration of vaccine effectiveness in preventing COVID-19, reducing disease severity, reducing the risk of death, and the effectiveness of the vaccine to prevent disease transmission by those vaccinated are not currently known").

5. ***The mandate is arbitrary and capricious because CMS failed to consider or properly weigh necessary reliance interests***.

Because CMS changed course, it was required to "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Fox Television*, 556 U.S. at 515. Ignoring reliance interests is necessarily arbitrary and capricious. *Id.* Yet, it appears this is what CMS did. An agency is required to assess whether there were reliance interests, determine whether they were

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the-covid-19-pandemic-3/ (decrying "nearly 80 million Americans who have failed to get the shot" while announcing "a new plan to require more Americans to be vaccinated" and explaining that "[i]f you're seeking care at a health facility, you should be able to know that the people treating you are vaccinated. Simple. Straightforward. Period."); *see also* 86 Fed. Reg. at 61,601 ("the protective scope of this rule is far broader than the health care staff that it directly affects"); *see also id.* at 61,612 ("Staff vaccination will also provide significant community benefits when staff are not at work."). The Court "cannot ignore the disconnect between the decision made and the explanation given." *Dep't of Com.*, 139 S. Ct. at 2575.

significant, and weigh any such interests against competing policy concerns. *Regents*, 140 S. Ct. at 1915.

In concluding that the mandate's benefits outweigh the risks to the healthcare industry, CMS did not properly consider *all* necessary reliance interests of facilities, healthcare workers, and patients. 86 Fed. Reg. at 61,607–10. CMS looked only at evidence from interested parties in favor of the mandate, while completely ignoring evidence from interested parties in opposition. *Consumers Union of U. S., Inc. v. Consumer Prod. Safety Comm'n*, 491 F.2d 810, 812 (2d Cir. 1974) (noting agency "must not ignore evidence placed before it by interested parties"). In fact, CMS foreclosed these parties' ability to provide information regarding the mandate's effects on the healthcare industry, while simultaneously dismissing those concerns based on "insufficient evidence." 86 Fed. Reg. at 61,569. But facts do not cease to exist simply because they are ignored, and "[s]tating that a factor was considered[25]

[25] Several times throughout the mandate, CMS acknowledges the countervailing effect it will have on the healthcare industry. *See, e.g.*, 86 Fed. Reg. at 61,607 ("currently there are endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and supplier and these may be made worse if any substantial number of unvaccinated employees leave health care employment altogether"); *id.* at 61,567 ("and the urgent need to address COVID-related staffing shortages that are disrupting patient access to care, provides strong justification as to the need to issue this IFC requiring staff vaccination for most provider and supplier types over which we have authority."). Yet, despite these acknowledged concerns about intensifying an already-existing healthcare crisis, CMS decided to move forward anyway, without properly considering

is not a substitute for considering it." *Texas v. Biden*, 10 F.4th 538, 556 (5th Cir. 2021) (internal quotations and alterations omitted); *Sierra Club*, 459 F. Supp. 2d at 100 ("Merely describing an impact and stating a conclusion of non-impairment is insufficient[.]"); *Gresham v. Azar*, 363 F. Supp. 3d 165, 177 (D.D.C. 2019) ("The bottom line: the Secretary did no more than acknowledge—in a conclusory manner, no less—that commenters forecast a loss in Medicaid coverage."). Had CMS followed the proper procedural requirements, States, healthcare providers, and healthcare workers would have submitted critical information to CMS—instead of to the Courts[26]—showing that the mandate portends a disaster for the healthcare industry, particularly in rural communities. *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816, (2019) (requiring HHS to undertake notice-and-comment rulemaking, in part, because it "neglected to acknowledge the potential

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the totality of interests affected by the mandate, such as rural hospitals.

[26] It is not the job of this Court to collect evidence and opposition from affected parties; rather, this is the role, actually a duty, of CMS when promulgating a rule. *See District of Colombia v. United States Dep't of Agriculture*, 496 F. Supp. 3d 213, 228 (D.D.C. 2020) (emphasizing that one purpose of notice and comment rulemaking is to "give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review"); *Hoctor v. U.S. Dept. of Agriculture*, 82 F.3d 165, 167 (7th Cir. 1996) ("Notice and comment rulemaking . . . facilitates the marshaling of opposition to a proposed rule, and may result in the creation of a very long record that may in turn provide a basis for a judicial challenge to the rule if the agency decides to promulgate it.")

countervailing benefits"); *Time Warner Cable Inc. v. FCC*, 729 F.3d 137, 168 (2nd Cir. 2013) (explaining APA policies are "to ensure the agency has all pertinent information before it when making a decision"). By dispensing with those requirements, CMS ignored evidence showing that the mandate threatens devastating consequences to healthcare providers, staff, and patients throughout the nation.

Even if CMS did properly consider these reliance issues—which this Court finds it most likely did not—the scant evidence of record shows CMS was unable to adequately balance these reliance interests because it placed a rock on one side of the scale and a feather on the other. *Regents*, 140 S. Ct. at 1914 (failing to weigh reliance interests against competing policy concerns is arbitrary and capricious). And as already explained, these evidence deficiencies are solely a product of its own doing. So, either CMS entirely failed to consider an important aspect of the problem or failed to weigh the interests properly; regardless, either way the pendulum swings, CMS's actions, or rather, inaction, violates basic tenants of administrative law. *Id.*; *State Farm*, 463 U.S. at 43 (noting that "entirely fail[ing] to consider an important aspect of the problem" is arbitrary and capricious); *Michigan*, 576 U.S. at 750–52 (noting "agency action is lawful only if it rests on a consideration of the relevant factors" and "important aspects of the problem").

In conclusion, Plaintiffs likely can show the CMS mandate is arbitrary and capricious because the evidence does not show a rational connection to support implementing the vaccine mandate, the mandate's broad scope, the unreasonable rejection of

alternatives to vaccination, CMS's inadequate explanation for its change in course, and its failure to consider or properly weigh reliance interests.

Accordingly, Plaintiffs' challenges to the mandate show a great likelihood of success on the merits, and this fact weighs critically in favor of a preliminary injunction. *Home Instead*, 721 F.3d at 497 ("While no single factor is determinative, the probability of success factor is the most significant." (internal quotations and citations omitted)).

b. ***Plaintiffs demonstrate irreparable harm.***

The Court must next determine whether Plaintiffs have shown that they are "likely to suffer irreparable harm in the absence of preliminary relief." *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). Plaintiffs must show more than a mere "possibility," but they need not show a certainty; rather, they need to demonstrate "irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22. Plaintiffs have done so here.

The Plaintiff States bring their claims in a number of capacities: sovereign, quasi- sovereign/*parens patriae*, and proprietary. *See, e.g.*, Doc. [1] ¶¶ 5, 7, 9. Through their various interests, they have shown irreparable injury is more than likely in the absence of an injunction.

First, Plaintiffs sovereign interests[27] are likely to suffer irreparable harm without a preliminary injunction because they will be unable to enforce their duly enacted laws surrounding vaccination mandates and providing proof of vaccination. *See, e.g.*, Mo. Rev. Stat § 67.265; 2021 Alaska Sess. Laws ch. 2, § 17; Ark. Code § 20-7-143; *see also, e.g.*, Ark. Code § 11-5-118. The mandate notes that it "preempts inconsistent State and local laws as applied to Medicare- and Medicaid-certified providers and suppliers." 86 Fed. Reg. at 61,568. Generally, this preemption would be unremarkable. *See* U.S. Const. art. VI, § 2. But, as here, where CMS likely did not lawfully enact its mandate, Plaintiffs are harmed because they cannot enforce their duly enacted laws and no lawfully enacted regulation preempts them. The injury that results when a state cannot enforce "statutes enacted by representatives of its people" is irreparable. *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (quoting *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, J., in chambers)); *accord Org. for Black Struggle v. Ashcroft*, 978 F.3d 603, 609 (8th Cir. 2020) ("Prohibiting the State from enforcing a statute properly passed . . . would irreparably harm the State.").

Second, Plaintiffs quasi-sovereign interests are likely to suffer irreparable harm without a

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[27] The States also have an interest in seeing their constitutionally reserved police power over public health policy defended from federal overreach, as discussed in depth in section II.B.a.i.2.

preliminary injunction. Unlike the harm Plaintiffs likely would face to their sovereign interests— which though significant, is more abstract—the harm Plaintiffs likely would face to their quasi- sovereign interests would be observable and appreciable. Indeed, the likely harm would be *harm* in the colloquial sense—pain, suffering, distress. Plaintiffs have a quasi-sovereign interest "in the health and well-being—both physical and economic—of [their] residents, *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982), and Plaintiffs have put forth evidence that this mandate would have a detrimental effect on the health and well-bring of their citizens.

Review of the affidavits filed in support of Plaintiffs' motion for preliminary injunction shows the harm to the physical health and well-being of their states' citizens if the mandate is not enjoined. The Plaintiffs' affidavits came from varying healthcare entities and associations in their states impacted by the mandate. The affiants describe existing and significant staffing shortages as well as open and unfilled positions for an extended period of time, some for more than a year. *See, e.g.*, Doc. [9-7] at 3; Doc. [9-11] at 3; Doc. [9-25] at 3; Doc. [9-3] at 4. The affidavits also demonstrate that the mandate will more than likely exacerbate the already-existing staffing problem. Many of the affidavits generally describe the number of individuals employed by the entity and the number or percentage of employees either known or reasonably known to have not been vaccinated.[28] *See,*

[28] CMS itself notes that rural hospitals are less vaccinated than urban. 86 Fed. Reg. at 61,613 (recognizing that "rural

e.g., Doc. [9-4] at 3, 4; Doc. [9-3] at 4. Through talks, surveys, and direct conversations with staff, the affiants know the individuals that will leave employment if CMS goes ahead with its mandate. *See, e.g.*, Doc. [9-4] at 3; Doc. [9-5] at 3; Doc. [9-13] at 4; Doc. [9-19] at 3; Doc. [9-20] at 3. Already, in some cases, the mere announcement of CMS's mandate has compelled some to resign. *See, e.g.*, Doc. [9-26] at 2.

Staff reductions due to implementing the mandate, especially in light of the already understaffed healthcare facilities, will cause a cascade of consequences. *See, e.g.*, Doc. [9-16] at 3–6. The mandate's effect of reducing staff will decrease the quality of care provided at facilities, compromise the safety of patients, and place even more stress on the remaining staff. *See, e.g.*, Doc. [9-11] at 4. The mandate "creates a risk in patient safety" and will create "ongoing ripple effects on . . . patients, remaining employees and [the] community for some time in the future." Doc. [9-18] at 5. An affiant noted that "even if we can technically staff services with extra shift and call, we are already doing that, have been doing that for more than a year, and our vaccinated staff will not be capable of doing it for much longer. At this point, considering it is nearly impossible to recruit clinical staff today, more will resign due to the stress and burnout that will inevitably exist." Doc. [9-23] at 5.

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hospitals are having greater problems with employee vaccination . . . than urban hospitals").

The loss of certain staffing categories will diminish entire areas of care within a facility that inevitably implicate others. *See, e.g.*, Doc. [9-19] at 3 (warning of the loss of the only remaining anesthesiologist); Doc. [9-21] at 3 (warning of the loss of 80% of imaging department); Doc. [9-14] at 3; Doc. [9-18] at 4; Doc. [9-25] at 4. Facilities in rural locations, already hard-pressed to find qualified applicants regardless of vaccination status, will have to evaluate what healthcare services they could still safely provide, if any at all, in the region they serve. *See, e.g.*, Doc. [9-4] at 4; Doc. [9-7] at 3–4; Doc. [9-9] at 2–5; Doc. [9-12] at 4; Doc. [9-13] at 4; Doc. [9-19] at 3; Doc. [9-23] at 4. As an example, for a general hospital located in North Platte, Nebraska, implementation of the mandate would result in the loss of the *only* remaining anesthesiologist. Doc. [9-19] at 3. Understandably, without an anesthesiologist, there could be no surgeries—at all. Thus, such a loss irreparably causes a cascading effect on the entire facility and a wide-range of patients. Other examples show the mandate's far-reaching implications not just on the administration of healthcare itself, but the functioning of the facilities in general. For example, the building manager of a nursing home in Memphis, Missouri states he will leave if the choice is between his job or the vaccine. Doc. [9-9] at 3–4. If the mandate takes effect, then, the nursing home would have "no one competent enough to run [the] building and [perform] all the complicated systems and required inspections." *Id.* Also, this type of position is not the kind that can be filled "quickly, especially with today's workforce and being in a rural setting." *Id.* Other affidavits also detail an especially hard impact

to emergency services in rural areas. *See, e.g.*, Doc. [9-21] at 2–3 ("If we lose our imaging department we will have to divert many of our emergency patients to other facilities; the closest one is 45 miles away."); Doc. [9-11] at 4 (explaining that in the event this hospital closes, the nearest one would be thirty miles away); Doc. [9-12] at 2–3 (similar); Doc. [9-16] at 6 (similar).

Further, the loss of staffing in many instances will result in *no care at all*, as some facilities will be forced to close altogether. For example, the Administrator of the Scotland County Care Center (SCCC), a nursing home located in Memphis, Missouri, notes that out of about sixty-five employees, twenty have indicated that they are opposed to taking the vaccine, and if the mandate is imposed, that they will quit.[29] Doc. [9-9] at 2. A loss of twenty staff members will cause SCCC to "close its doors" and displace residents that have lived in that community their entire lives. *Id.* at 5; *see also* Doc. [9-26] at 4. Thus, if the mandate goes into effect, it will irreparably harm patients[30] by impeding access to care for the elderly and for persons who cannot afford it—directly contrary to Medicare and Medicaid's core objective of providing proper care. In

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[29] This includes SCCC's billing and accounting staff members, which would create a "substantial disruption" in SCCC's business functions, as well as their building plant manager, "that would leave me with no one competent enough to run my building and all the complicated systems and required inspections." *Id.* at 4.

[30] Medicare and Medicaid programs "touch[] the lives of nearly all Americans" and are two of the "largest federal program[s]" in the country. *See Allina Health Servs.*, 139 S. Ct. at 1808.

sum, Plaintiffs' evidence shows that facilities—rural facilities in particular—likely would face crisis standards of care or will have no choice but to close to new patients or close altogether, both of which would cause significant, and irreparable, harm to Plaintiffs' citizens. *Kai v. Ross*, 336 F.3d 650, 656 (8th Cir. 2003) (finding "danger to plaintiffs' health, and perhaps even their lives, gives them a strong argument of irreparable injury").[31]

Besides the harm to physical health that Plaintiffs have shown will likely occur absent a preliminary injunction, the mandate also would have a negative effect on the economies in Plaintiff states, especially, once again, in rural areas.[32] While economic injuries

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[31] "No right is held more sacred, or is more carefully guarded . . . than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891). As already explained, CMS most likely does not have the authority to promulgate the mandate, and clear congressional authorization is also lacking. "Irreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages.'" *Rogers Group, Inc. v. City of Fayetteville, Ark.*, 629 F.3d 784, 789 (8th Cir. 2010) (quoting *Gen. Motors Corp. v. Harry Brown's, L.L.C.*, 563 F.3d 312, 319 (8th Cir. 2009)). It follows then, that forcing individuals to choose "between their job(s) and their jab(s)," *BST Holdings*, 17 F.4th at ---, substantially burdens the liberty interests of individuals, which cannot be fully compensated through an award of damages.

[32] For example, Callaway District Hospital and Medical Clinics is the largest employer in Callaway, Nebraska and is a "significant driver of the local business and agriculture economy." Doc. [9-12] at 4. The expected loss of staff would

normally would be reparable at law, "federal agencies generally enjoy sovereign immunity for any monetary damages." *Wages & White Lion Invs., L.L.C. v. United States Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021); *see also* 5 U.S.C. § 702 (providing for an action seeking relief "other than money damages"). Therefore, the economic loses in Plaintiff states would be unrecoverable and thus irreparable. *Iowa Utls. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of unrecoverable economic loss, however, does qualify as irreparable harm."); *DISH Network Serv. L.L.C. v. Laducer*, 725 F.3d 877, 882 (8th Cir. 2013).

Fourth, and finally, Plaintiffs would likely face irreparable harm to their proprietary interests absent a preliminary injunction. Plaintiffs themselves operate healthcare facilities that CMS's mandate reaches. They therefore would face the same harms any private owner of a facility faces, like the "business and financial effects of a lost or suspended employee, compliance and monitoring costs associated with the Mandate, [or] the diversion of resources necessitated by the Mandate." *BST Holdings*, 17 F.4th at ---. As just noted, since these costs could not be recovered from the federal government, they are irreparable. *Iowa Utls. Bd.*, 109 F.3d at 426.

"almost certainly" lead to closure of the facility. *Id.* "Cherry County Hospital is a leader of employment" for its county. Doc. [9-16] at 6. "Kimball County Manor and Assisted Living employs 55 full time staff and as such is one of the largest employers in Kimball County, a rural county located in Nebraska's western panhandle." Doc. [9- 22] at 3.

For all these reasons, the Court finds that Plaintiffs are likely to suffer significant irreparable harm absent a preliminary injunction.

c. ***The balance of equities tip in favor of Plaintiffs, and the public has an interest in an injunction***.

Finally, the Court must determine whether Plaintiffs have shown that the "balance of equities tips in [their] favor" and that "an injunction is in the public interest." *Winter*, 555 U.S. at 20. Courts "must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." *Id.* at 24. When the party opposing the injunction is the federal government, the balance-of-harms factor "merge[s]" with the public- interest factor. *Nken v. Holder*, 556 U.S. 418, 436 (2009).

The public has an interest in stopping the spread of COVID. No one disputes that. But the Court concludes that the public would suffer little, if any, harm from maintaining the "status quo" through the litigation of this case. Defendants argue that "enjoining the rule would harm the public interest by further exposing Medicare and Medicaid patients and staff—and the Medicare and Medicaid programs—to unvaccinated health care workers." Doc. [23] at 48. But CMS's own conclusions undercut this argument. *See id.* at 61,615 ("[T]he effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known."); *id.* at 61,612. Regardless, the pandemic has continued more than twenty months now. Vaccine rates rise every day, and more

therapeutics and treatments for the virus are available than ever before. The status quo today, without the CMS mandate, is still far better than the public faced even just a few months ago.

And while, according to CMS, the effectiveness of the vaccine to prevent disease transmission by those vaccinated is not currently known, what is own based on the evidence before the Court is that the mandate will have a crippling effect on a significant number of healthcare facilities in Plaintiffs' states, especially in rural areas,[33] create a critical shortage of services (resulting in *no medical care at all* in some instances), and jeopardize the lives of numerous vulnerable citizens. The prevalent, tangible, and irremediable impact of the mandate tips the balance of equities in favor of a preliminary injunction.

To be sure, the Court looks at the principles underlying preliminary injunctions. *Dataphase*, 640 F.2d at 113 n.5 (quoting *Love v. Atchison, T. & S. F. Ry. Co.*, 185 F. 321, 331 (8th Cir. 1911) ("The controlling reason for the existence of the judicial

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[33] The disproportionate impact the mandate will have on rural communities is why CMA's "one-size-fits-all sledgehammer" approach does not work and in fact, undermines CMA's focus on providing proper care. *See BST Holdings*, 17 F.4th at ---. This is why healthcare matters are typically left to the States, because these policy decisions are matters dependent on local factors and conditions, and Federalism allows States to tailor such matters in the best interests of their communities. The Court agrees with Plaintiffs point that whatever might make sense in Chicago, St. Louis, or New York City, could be actually counterproductive and harmful in rural communities like Memphis (MO) or McCook (NE). Doc. [1] at 1–2.

power to issue a [preliminary] injunction is that the court may thereby prevent such a change in the relations and conditions of persons and property as may result in irremediable injury to some of the parties before their claims can be investigated and adjudicated."). Although the parties disagree on the magnitude of the mandate's disruption to the healthcare industry, both agree a disruption is certain and imminent. Thus, the importance of enjoining the mandate, and thus preserving the "status quo," is imperative. *Dataphase*, 640 F.2d at 113 (8th Cir. 1981) ("[T]he question is whether the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined."). And "[t]here is clearly a robust public interest in safeguarding prompt access to health care." *Whitman-Walker Clinic, Inc. v. DHS*, 485 F. Supp. 3d 1, 61 (D.D.C. 2020). The Court finds that in balancing the equities, the scale falls clearly in favor of healthcare facilities operating with some unvaccinated employees, staff, trainees, students, volunteers, and contractors, rather than the swift, irremediable impact of requiring healthcare facilities to choose between two undesirable choices—providing substandard care or providing no healthcare at all.[34] It is true that the Agency would face irreparable harm *if* it is unable to enforce a *properly authorized* and *enacted* regulation. But, as discussed above, the Court

[34] CMS also discusses that the upcoming influenza season will further exacerbate the strain on the healthcare system. However, one would assume that the onset of flu season coupled with COVID would be a reason to *avoid* critical staffing shortages at healthcare facilities—not to exacerbate them.

has concluded CMS likely did not enact the mandate at issue lawfully. Thus, any interest CMS may have in enforcing an unlawful rule is likely illegitimate. *See BST Holdings*, 17 F.4th at ---. By this same conclusion, the public would benefit from the preliminary injunction because it would ensure that federal agencies do not extend their power beyond the express delegation from Congress, as already discussed. And while "it is indisputable that the public has a strong interest in combating the spread of COVID-19," "our system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2490.

In conclusion, CMS mandate raises substantial questions of law and fact that must be determined, as discussed throughout this opinion. Because it is evident CMS significantly understates the burden that its mandate would impose on the ability of healthcare facilities to provide proper care, and thus, save lives, the public has an interest in maintaining the "status quo" while the merits of the case are determined. *Dataphase*, 640 F.2d at 113; *Love*, 185 F. at 331.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Preliminary Injunction, Doc. [6], is GRANTED**.**

Accordingly,

IT IS HEREBY ORDERED that Defendants are preliminarily enjoined from the implementation and enforcement of 86 Fed. Reg. 61,555 (Nov. 5, 2021), the Interim Final Rule with Comment Period entitled "Medicare and Medicaid Programs; Omnibus COVID-

19 Health Care Staff Vaccination," against any and all Medicare- and Medicaid-certified providers and suppliers within the States of Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming pending a trial on the merits of this action or until further order of this Court. Defendants shall immediately cease all implementation or enforcement of the Interim Final Rule with Comment Period as to any Medicare- and Medicaid- certified providers and suppliers within the States of Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming.

IT IS FURTHER ORDERED that no security bond shall be required under Federal Rule of Civil Procedure 65(c).

Dated this 29th day of November, 2021.

MATTHEW T. SCHELP
UNITED STATES DISTRICT JUDGE

APPENDIX D

5 U.S.C. § 706 –Scope of Review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 393.)

APPENDIX E

86 FR 61555-0 (F.R.)
RULES and REGULATIONS
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
42 CFR Parts 416, 418, 441, 460, 482, 483, 484, 485, 486, 491 and 494
[CMS-3415-IFC]
RIN 0938-AU75

Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination

Friday, November 5, 2021

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period revises the requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes are necessary to help protect the health and safety of residents, clients, patients, PACE participants, and staff, and reflect lessons learned to date as a result of the COVID-19 public health emergency. The revisions to the requirements establish COVID-19 vaccination requirements for staff at the included Medicare- and Medicaid-certified providers and suppliers.

DATES:

Effective date: These regulations are effective on November 5, 2021.

Implementation dates: The regulations included in Phase 1 [42 CFR 416.51(c) through (c)(3)(i) and (c)(3)(iii) through (x), 418.60(d) through (d)(3)(i) and (d)(3)(iii) through (x), 441.151(c) through (c)(3)(i) and (c)(3)(iii) through (x), 460.74(d) through (d)(3)(i) and (d)(3)(iii) through (x), 482.42(g) through (g)(3)(i) and (g)(3)(iii) through (x), 483.80(d)(3)(v) and 483.80(i) through (i)(3)(i) and (i)(3)(iii) through (x), 483.430(f) through (f)(3)(i) and (f)(3)(iii) through (x), 483.460(a)(4)(v), 484.70(d) through (d)(3)(i) and (d)(3)(iii) through (x), 485.58(d)(4), 485.70(n) through (n)(3)(i) and (n)(3)(iii) through (x), 485.640(f) through (f)(3)(i) and (f)(3)(iii) through (x), 485.725(f) through (f)(3)(i) through (f)(3)(iii) through (x), 485.904(c) through (c)(3)(i) and (c)(3)(iii) through (x), 486.525(c) through (c)(3)(i) and (c)(3)(iii) through (x), 491.8(d) through (d)(3)(i) and (d)(3)(iii) through (x), 494.30(b) through (b)((3)(i) and (b)(3)(iii) through (x) must be implemented by December 6, 2021.

The regulations included in Phase 2 [42 CFR 416.51(c)(3)(ii), 418.60(d)(3)(ii), 441.151(c)(3)(ii), 460.74(d)(3)(ii), 482.42(g)(3)(ii), 483.80(i)(3)(ii), 483.430(f)(3)(ii), 484.70(d)(3)(ii), 485.70(n)(3)(ii), 485.640(f)(3)(ii), 485.725(f)(3)(ii), 485.904(c)(3)(ii), 486.525(c)(3)(ii), 491.8(d)(3)(ii), 494.30(b)(3)(ii)] must be implemented by January 4, 2022. Staff who have completed a primary vaccination series by this date are considered to have met these requirements, even

if they have not yet completed the 14-day waiting period required for full vaccination.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 4, 2022.

ADDRESSES: In commenting, please refer to file code CMS-3415-IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3415-IFC, P.O. Box 8016, Baltimore, MD 21244-8016.
   Please allow sufficient time for mailed comments to be received before the close of the comment period.
3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3415-IFC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the SUPPLEMENTARY INFORMATION section.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: CMS Office of Communications, Department of Health and Human Services; email press@cms.hhs.gov.

For technical inquiries: Contact CMS Center for Clinical Standards and Quality, Department of Health and Human Services, (410) 786-6633.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

The Centers for Medicare & Medicaid Services (CMS) establishes health and safety standards, known as the Conditions of Participation, Conditions for Coverage, or Requirements for Participation for 21 types of providers and suppliers, ranging from hospitals to hospices and rural health clinics to long term care facilities (including skilled nursing facilities and nursing facilities, collectively known as nursing homes). Most of these providers and suppliers are regulated by this interim final rule with comment period (IFC). Specifically, this IFC directly regulates the following providers and suppliers, listed in the numerical order of the relevant CFR sections being revised in this rule:

- Ambulatory Surgical Centers (ASCs) (§ 416.51)
- Hospices (§ 418.60)
- Psychiatric residential treatment facilities (PRTFs) (§ 441.151)
- Programs of All-Inclusive Care for the Elderly (PACE) (§ 460.74)
- Hospitals (acute care hospitals, psychiatric hospitals, hospital swing beds, long term care hospitals, children's hospitals, transplant centers, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities) (§ 482.42)
- Long Term Care (LTC) Facilities, including Skilled Nursing Facilities (SNFs) and Nursing Facilities (NFs), generally referred to as nursing homes (§ 483.80)

- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) (§ 483.430)
- Home Health Agencies (HHAs) (§ 484.70)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs) (§§ 485.58 and 485.70)
- Critical Access Hospitals (CAHs) (§ 485.640)
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services (§ 485.725)
- Community Mental Health Centers (CMHCs) (§ 485.904)
- Home Infusion Therapy (HIT) suppliers (§ 486.525)
- Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs) (§ 491.8)
- End-Stage Renal Disease (ESRD) Facilities (§ 494.30)

This IFC directly applies only to the Medicare- and Medicaid-certified providers and suppliers listed above. It does not directly apply to other health care entities, such as physician offices, that are not regulated by CMS. Most states have separate licensing requirements for health care staff and health care providers that would be applicable to physician office staff and other staff in small health care entities that are not subject to vaccination requirements under this IFC. We have not included requirements for Organ Procurement Organizations or Portable X-Ray suppliers, as these only provide services under contract to other health care entities and would thus be indirectly subject to the vaccination

requirements of this rule, as discussed in section II.A.1. of this rule. We note that entities not covered by this rule may still be subject to other State or Federal COVID-19 vaccination requirements, such as those issued by Occupational Safety and Health Administration (OSHA) for certain employers.

Currently, the United States (U.S.) is responding to a public health emergency (PHE) of respiratory disease caused by a novel coronavirus that has now been detected in more than 190 countries internationally, all 50 States, the District of Columbia, and all U.S. territories. The virus has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2), and the disease it causes has been named "coronavirus disease 2019" (COVID-19). On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a "Public Health Emergency of International Concern." On January 31, 2020, pursuant to section 319 of the Public Health Service Act (PHSA) (42 U.S.C. 247d), the Secretary of the Department of Health and Human Services (Secretary) determined that a PHE exists for the U.S. (hereafter referred to as the PHE for COVID-19). On March 11, 2020, the WHO publicly declared COVID-19 a pandemic. On March 13, 2020, the President of the United States declared the COVID-19 pandemic a national emergency. The January 31, 2020 determination that a PHE for COVID-19 exists and has existed since January 27, 2020, lasted for 90 days, and was renewed on April 21, 2020; July 23, 2020; October 2, 2020; January 7, 2021; April 15, 2021; July 19, 2021; and October 18, 2021. Pursuant to section 319 of the

PHSA, the determination that a PHE continues to exist may be renewed at the end of each 90-day period.[FN1]

COVID-19 has had significant negative health effects—on individuals, communities, and the nation as a whole. Consequences for individuals who have COVID-19 include morbidity, hospitalization, mortality, and post-COVID conditions (also known as long COVID). As of mid-October 2021, over 44 million COVID-19 cases, 3 million new COVID-19 related hospitalizations, and 720,000 COVID-19 deaths have been reported in the U.S.[FN2] Indeed, COVID-19 has overtaken the 1918 influenza pandemic as the deadliest disease in American history.[FN3]

Given recent estimates of undiagnosed infections and under-reported deaths, these figures likely underestimate the full impact.[FN4] In addition, these figures fail to capture the significant, detrimental effects of post-acute illness, including nervous system and neurocognitive disorders, cardiovascular disorders, gastrointestinal disorders, and signs and symptoms related to poor general well-being, including malaise, fatigue, musculoskeletal pain, and reduced quality of life. Recent estimates suggest more than half of COVID-19 survivors experienced post-acute sequelae of COVID-19 6 months after recovery.[FN5] The individual and public health ramifications of COVID-19 also extend beyond the direct effects of COVID-19 infections. Several studies have demonstrated significant mortality increases in 2020, beyond those attributable to COVID-19 deaths. In some percentage, this could be a problem of misattribution (for example, the cause of death was indicated as "heart disease" but in fact

the true cause was undiagnosed COVID-19), but some proportion are also believed to reflect increases in other causes of death that are sensitive to decreased access to care and/or increased mental/emotional strain. One paper quantifies the net impact (direct and indirect effects) of the pandemic on the U.S. population during 2020 using three metrics: excess deaths, life expectancy, and total years of life lost. The findings indicate there were 375,235 excess deaths, with 83 percent attributable to direct, and 17 percent attributable to indirect effects of COVID-19. The decrease in life expectancy was 1.67 years, translating to a reversion of 14 years in historical life expectancy gains. Total years of life lost in 2020 was 7,362,555 across the U.S. (73 percent directly attributable, 27 percent indirectly attributable to COVID-19), with considerable heterogeneity at the individual State level.[FN6]

One analysis published in February 2021 found that Black and Latino Americans have experienced a disproportionate burden of COVID-19 morbidity and mortality, reflecting persistent structural inequalities that increase risk of exposure to COVID-19 and mortality risk for those infected. The authors projected that COVID-19 would reduce U.S. life expectancy in 2020 by 1.13 years. Furthermore, the estimated reduction for Black and Latino populations is 3-4 times the estimate for the White population, reversing over 10 years of progress in reducing the gaps in life expectancy between Black and White populations and reducing the Latino mortality advantage by over 70 percent. The study further expects that reductions in life expectancy may persist because of continued COVID-19 mortality and term

health, social, and economic impacts of the pandemic.[FN7] Because SARS-CoV-2, the virus that causes COVID-19 disease, is highly transmissible,[FN8] Centers for Disease Control and Prevention (CDC) has recommended, and CMS reiterated, that health care providers and suppliers implement robust infection prevention and control practices, including source control measures, physical distancing, universal use of personal protective equipment (PPE), SARS-CoV-2 testing, environmental controls, and patient isolation or quarantine.[9] 10 11 12 Available evidence suggests these infection prevention and control practices have been highly effective when implemented correctly and consistently.[FN13, 14]

Studies have also shown, however, that consistent adherence to recommended infection prevention and control practices can prove challenging—and those lapses can place patients in jeopardy.[FN15, 16,17,18] A retrospective analysis from England found up to 1 in 6 SARS-CoV-2 infections among hospitalized patients with COVID-19 in England during the first 6 months of the pandemic could be attributed to healthcare-associated transmission.[FN19] In outbreaks reported from acute care settings in the U.S. following implementation of universal masking, unmasked exposures to other health care workers were frequently implicated.[FN20] A retrospective cohort study of health care staff behaviors, exposures, and cases between June and December 2020 in a large health system found more employees were exposed via coworkers than patients—and secondary cases among employees typically followed unmasked interactions with infected colleagues (for example, convening in

breakrooms without proper source control).[FN21] The same study found that cases of health care worker infection associated with patient exposures could often be attributed to failure to adhere to PPE requirements (for example, eye protection). Past experience with influenza, and available evidence, suggest that vaccination of health care staff offers a critical layer of protection against healthcare-associated COVID-19 (HA-COVID-19). For example, evidence has shown that influenza vaccination of health care staff is associated with declines in nosocomial influenza in hospitalized patients [FN22, 23, 24] and among nursing home residents.[FN25, 26, 27, 28, 29, 30, 31] As a result, CDC, the Society for Healthcare Epidemiology of America, and others recommend—and a number of states require—annual influenza vaccination for health care staff. [FN32, 33, 34]

In addition to preventing morbidity and mortality associated with COVID-19, currently approved or authorized vaccines also demonstrate effectiveness against asymptomatic SARS-CoV-2 infection. A recent study of health care workers in 8 states found that, between December 14, 2020 through August 14, 2021, full vaccination with COVID-19 vaccines was 80 percent effective in preventing RT-PCR-confirmed SARS-CoV-2 infection among frontline workers.[FN35] Emerging evidence also suggests that vaccinated people who become infected with the SARS-CoV-2 Delta variant have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk.[FN36] For example, in a study of breakthrough infections among health care workers in the Netherlands, SARS-CoV-2 infectious

virus shedding was lower among vaccinated individuals with breakthrough infections than among unvaccinated individuals with primary infections.[FN37] Fewer infected staff and lower transmissibility equates to fewer opportunities for transmission to patients, and emerging evidence indicates this is the case. The best data come from long term care facilities, as early implementation of national reporting requirements have resulted in a comprehensive, longitudinal, high quality data set. Data from CDC's National Healthcare Safety Network (NHSN) have shown that case rates among LTC facility residents are higher in facilities with lower vaccination coverage among staff; specifically, residents of LTC facilities in which vaccination coverage of staff is 75 percent or lower experience higher rates of preventable COVID-19.[FN38] Several articles published in CDC's Morbidity and Mortality Weekly Reports (MMWRs) regarding nursing home outbreaks have also linked the spread of COVID-19 infection to unvaccinated health care workers and stressed that maintaining a high vaccination rate is important for reducing transmission. [FN39, 40, 41]

There is also some published evidence from other settings that suggest similar dynamics can be expected in other health care delivery settings. For example, a recent analysis from Yale New Haven Hospital (YNHH) found health care units with at least 1 inpatient case of HA-COVID-19 had lower staff vaccination rates.[FN42] Similarly, a small study in Israel demonstrated that transmission of COVID-19 was linked to unvaccinated persons. In 37 cases, patients for whom data were available regarding the source of infection, the suspected source was an

unvaccinated person; in 21 patients (57 percent), this person was a household member; in 11 cases (30 percent), the suspected source was an unvaccinated fellow health care worker or patient.[FN43] While similarly comprehensive data are not available for all Medicare- and Medicaid-certified provider types, the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel CMS to take action.

The threats that unvaccinated staff pose to patients are not, however, limited to SARS-CoV-2 transmission. Unvaccinated staff jeopardize patient access to recommended medical care and services, and these additional risks to patient health and safety further warrant CMS action.

Fear of exposure to and infection with COVID-19 from unvaccinated health care staff can lead patients to themselves forgo seeking medically necessary care. In a small but informative qualitative study of 33 home health care workers in New York City, one of the key themes to emerge from interviews with those workers was a keen recognition that "providing care to patients placed them in a unique position with respect to COVID-19 transmission. They worried . . . about transmitting the virus to [their clients]." They also noted that care for home bound clients might involve other health care staff, and they worried about "transmitting COVID-19 . . . to one another." [FN44]

Anecdotal evidence suggests health care consumers have drawn similar conclusions—and this, too, has implications for overall health and welfare in health care settings. For example, CMS has received anecdotal reports suggesting individuals in care are refusing care from unvaccinated staff, limiting the

extent to which providers and suppliers can effectively meet the health care needs of their patients and residents. Further, nationwide there are reports of individuals avoiding or forgoing health care due to fears of contracting COVID-19 from health care workers[FN45, 46, 47] While avoidance of necessary care appears to have abated somewhat since the first months of the COVID-19 pandemic, it remains an area of concern for many individuals [FN48, 49] Because unvaccinated staff are at greater risk for infection, they also present a threat to health care operations—absenteeism due to COVID-19-related exposures or illness can create staffing shortages that disrupt patient access to recommended care. Data suggest the current surge in COVID-19 cases associated with emergence of the Delta variant has exacerbated health care staffing shortages. For example, 1 in 5 hospitals report that they are currently experiencing a critical staffing shortage.[FN50] Through the week ending September 19, 2021, approximately 23 percent of LTC facilities reported a shortage in nursing aides; 21 percent reported a shortage of nurses; and 10 to 12 percent reported shortages in other clinical and non-clinical staff categories.[FN51] And while some studies suggest overall staffing levels (as defined by nurse hours per resident day) have been relatively stable, this appears to be associated with concurrent decreases in patient demand (for example, resident census in nursing homes)—decreases that have ramifications for patient access to recommended and medically appropriate services[FN52, 53] Over half (58 percent) of nursing homes participating in a recent survey conducted by the American Health Care

Association and National Center for Assisted Living (AHCA/NCAL) indicated that they are limiting new admissions due to staffing shortages.[FN54] Similarly, hospital administrators responding to an OIG pulse survey conducted during February 22-26, 2021, reported difficulty discharging COVID-19 patients to post-acute facilities (for example, nursing homes, rehabilitation hospitals, and hospice facilities) following the acute stage of the patient's illness. These delays in discharge affected available bed space throughout the hospital (for example, creating bottlenecks in ICUs and EDs) and delayed patient access to specialized post-acute care (such as rehabilitation).[FN55] The drivers of this staffing crisis are multi-factorial. They include: Longstanding shortages in certain fields and professions; prolonged physical, mental, and emotional stress and trauma associated with responding to the ongoing PHE; and competing personal or professional obligations (such as child care) or opportunities (for example, new careers). But illnesses and deaths associated with COVID-19 are exacerbating staffing shortages across the health care system. Over half a million COVID-19 cases and 1,900 deaths among health care staff have been reported to CDC since the start of the PHE.[FN56] When submitting case-level COVID-19 reports, State and territorial jurisdictions may identify whether individuals are or are not health care workers. Since health care worker status has only been reported for a minority of cases (approximately 18 percent), these numbers are likely gross underestimates of true burden in this population. COVID-19 case rates among staff have also grown in tandem with broader national incidence trends since

the emergence of the Delta variant. For example, as of mid-September 2021, COVID-19 cases among LTC facility and ESRD facility staff have increased by over 1400 percent and 850 percent, respectively, since their lows in June 2021.[FN57] Similarly, the number of cases among staff for whom case-level data were reported by State and territorial jurisdictions to CDC increased by nearly 600 percent between June and August 2021.[FN58] Vaccination is thus a powerful tool for protecting health and safety of patients, and, with the emergence and spread of the highly transmissible Delta variant, it has been an increasingly critical one to address the extraordinary strain the COVID-19 pandemic continues to place on the U.S. health system. While COVID-19 cases, hospitalizations, and deaths declined over the first 6 months of 2021, the emergence of the Delta variant reversed these trends.[FN59] Between late June 2021 and September 2021, daily cases of COVID-19 increased over 1200 percent; new hospital admissions, over 600 percent; and daily deaths, by nearly 800 percent.[FN60] Available data also continue to suggest that the majority of COVID-19 cases and hospitalizations are occurring among individuals who are not fully vaccinated. In a recent study of reported COVID-19 cases, hospitalizations, and deaths in 13 U.S. jurisdictions that routinely link case surveillance and immunization registry data, CDC found that unvaccinated individuals accounted for over 85 percent of all hospitalizations in the period between June and July 2021, when Delta became the predominant circulating variant.[FN61]

Unfortunately, health care staff vaccination rates remain too low in too many health care facilities and

regions. For example, national COVID-19 vaccination rates for LTC facility, hospital, and ESRD facility staff are 67 percent, 64 percent, and 60 percent, respectively. Moreover, these averages obscure sizable regional differences. LTC facility staff vaccination rates range from lows of 56 percent to highs of over 90 percent, depending upon the State. Similar patterns hold for ESRD facility and hospital staff. [FN62, 63, 64] Given slow but steady increases in vaccination rates among staff working in these settings over time,[FN65] widespread availability of vaccines, and targeted efforts to facilitate vaccine access like the Federal Retail Pharmacy program,[FN66] vaccine hesitancy,[FN67] rather than other factors (for example, staff turnover) is likely to account for suboptimal staff vaccination rates.

While a significant number of health care staff have been infected with SARS-CoV-2,[FN68] evidence indicates their infection-induced immunity, also called "natural immunity," is not equivalent to receiving the COVID-19 vaccine. Available evidence indicates that COVID-19 vaccines offer better protection than infection-induced immunity alone and that vaccines, even after prior infection, help prevent reinfections.[FN69] Consequently, CDC recommends that all people be vaccinated, regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection.[FN70]

Further, the risks of unvaccinated health care staff may disproportionately impact communities who experience social risk factors and populations described under Executive Order 13985, Advancing Racial Equity and Support for Underserved

Communities Through the Federal Government, including members of racial and ethnic communities; individuals with disabilities; individuals with limited English proficiency; Lesbian, Gay, Bisexual, Transgender, and Queer (LGBTQ+) individuals; individuals living in rural areas; and others adversely affected by persistent poverty or inequality. CDC data show that across the U.S., physicians and advanced practice providers have significantly higher vaccination rates than aides. [FN71, 72] Among aides, lower vaccination coverage was observed in those facilities located in zip codes where communities experience greater social risk factors. The finding that vaccination coverage among aides was lower among those working at LTC facilities located in zip code areas with higher social vulnerability is consistent with an earlier analysis of overall county-level vaccination coverage by indices of social vulnerability.[FN73] CDC notes that together, these data suggest that vaccination disparities among job categories are likely to mirror social disparities as well as disparities in surrounding communities. In addition, nurses and aides who may have the most patient contact have the lowest rates of vaccination coverage among health care staff. COVID-19 outbreaks have occurred in LTC facilities in which residents were highly vaccinated, but transmission occurred through unvaccinated staff members.[FN74] These findings have implications regarding occupational safety and health outcome equity—national data indicates that aides in nursing homes are disproportionately women and members of racial and ethnic communities with lower hourly wages than physicians and advance practice clinicians,[FN75]

and are also more likely to have underlying conditions that put them at risk for adverse outcomes from COVID-19.[FN76] Ensuring full vaccination coverage across health care settings is critical to addressing these disparities among health care workers, particularly those from communities who experience social risk, and to equitably protecting individuals CMS serves from unnecessary and significant harm associated with COVID-19 cases and the ongoing pandemic.

It is essential to reduce the transmission and spread of COVID-19, and vaccination is central to any multi-pronged approach for reducing health system burden, safeguarding health care workers and the people they serve, and ending the COVID-19 pandemic. Currently FDA-approved and FDA-authorized vaccines in use in the U.S. are both safe and highly effective at protecting vaccinated people against symptomatic and severe COVID-19.[FN77] Higher rates of vaccination, especially in health care settings, will contribute to a reduction in the transmission of SARS-CoV-2 and associated morbidity and mortality across providers and communities, contributing to maintaining and increasing the amount of healthy and productive health care staff, and reducing risks to patients, resident, clients, and PACE program participants.

In light of our responsibility to protect the health and safety of individuals providing and receiving care and services from for Medicare- and Medicaid-certified providers and suppliers, and CMS's broad statutory authority to establish health and safety regulations, we are compelled to require staff vaccinations for COVID-19 in these settings. For

these reasons, we are issuing this IFC based on these authorities and in accordance with established rule making processes. Specifically, sections 1102 and 1871 of the Social Security Act (the Act) grant the Secretary of Health and Human Services authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged under this Act and as may be necessary to carry out the administration of the insurance programs under the Act. The discussions of the provider- and supplier-specific provisions in section II. of this IFC set out the specific authorities for each provider or supplier type. Provider and supplier compliance with the Federal rules issued under these statutory authorities are mandatory for participation in the Medicare and Medicaid programs.

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

A. Regulatory Responses to the PHE

1. Waivers

CMS and other Federal agencies have taken many actions and exercised extensive regulatory flexibilities to help health care providers contain the spread of SARS-CoV-2. When the President declares a national emergency under the National Emergencies Act or an emergency or disaster under the Stafford Act, CMS is empowered to take proactive steps by waiving certain CMS regulations, as authorized under section 1135 of the Act ("1135 waivers"). CMS may also grant certain flexibilities to skilled nursing facilities (SNFs) under Medicare, as authorized separately under section 1812(f) of the Act ("1812(f) flexibilities"). The 1135 waivers and 1812(f) flexibilities allowed us to rapidly expand efforts to help control the spread of SARS-CoV-2. We have issued PHE waivers for most Medicare- and Medicaid-certified providers and suppliers, with the goal of supporting each facility's operational flexibility while preserving health and safety and core health care functions.

2. Rulemaking

Since the onset of the PHE, we have issued five IFCs to help contain the spread of SARS-CoV-2. On April 6, 2020, we issued an IFC (Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (85 FR 19230 through 19292), which established that certain requirements for face-to-face/in-person encounters will not apply during the PHE for COVID-19 effective for claims with dates of service on or after March 1, 2020, and for the duration of the PHE for COVID-19. On May 8, 2020, we issued a second IFC (

Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program (85 FR 27550 through 27629)) ("May 8, 2020 COVID-19 IFC"). This second IFC contained additional information on changes Medicare made to existing regulations to provide flexibilities for Medicare beneficiaries and providers to respond effectively to the PHE for COVID-19. On September 2, 2020, we issued a third IFC (Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (85 FR 54820 through 54874)) ("September 2, 2020 COVID-19 IFC"), that included new requirements for hospitals and CAHs to report data in accordance with a frequency and in a standardized format as specified by the Secretary during the PHE for COVID-19. On November 6, 2020, we issued a fourth IFC (Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency (85 FR 71142 through 71205)). This IFC discussed CMS's implementation of section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which established Medicare Part B coverage and payment for Coronavirus Disease 2019 (COVID-19) vaccine and its administration. This IFC implemented requirements in the CARES Act that providers of COVID-19 diagnostic tests make public their cash prices for those tests and established an enforcement scheme to enforce those requirements. This IFC also

established an add-on payment for cases involving the use of new COVID-19 treatments under the Medicare Inpatient Prospective Payment System (IPPS). Most recently, on May 13, 2021, we issued the fifth IFC (Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff (86 FR 26306)) ("May 13, 2021 COVID-19 IFC"), that revised the infection control requirements that LTC facilities and ICFs-IID must meet to participate in the Medicare and Medicaid programs.

OSHA has also engaged in rulemaking in response to the PHE for COVID-19. On June 21, 2021, OSHA issued the COVID-19 Healthcare Emergency Temporary Standard (ETS) at 29 CFR 1910 subpart U (86 FR 32376) to protect health care and health care support service workers from occupational exposure to COVID-19.[FN78] Health care employers covered by the ETS must develop and implement a COVID-19 plan for each workplace to identify and control COVID-19 hazards in the workplace and implement requirements to reduce transmission of SARS-CoV-2 in their workplaces related to the following: (1) Patient screening and management, (2) standard and transmission-based precautions, (3) personal protective equipment (including facemasks, and respirators), (4) controls for aerosol-generating procedures performed on persons with suspected or confirmed COVID-19, (5) physical distancing, (6) physical barriers, (7) cleaning and disinfection, (8) ventilation, (9) health screening and medical management, (10) training, (11) anti-retaliation, (12)

recordkeeping, and, (13) reporting. In addition, the ETS requires covered employers to support COVID-19 vaccination for each employee by providing reasonable time and paid leave for employees to receive vaccines and recover from side effects.

The ETS generally applies to all workplace settings where any employee provides health care services or health care support services; however, because the ETS targets settings where care is provided for individuals with known or suspected COVID-19, the rule contains several exceptions. The ETS does not apply to: (1) Provision of first aid by any employee who is not a licensed health care provider, (2) dispensing of prescriptions by pharmacists in retail settings, (3) non-hospital ambulatory care settings where all non-employees are screened prior to entry, and people with suspected or confirmed COVID-19 are not permitted to enter, (4) well-defined hospital ambulatory care settings where all employees are fully vaccinated, all non-employees are screened prior to entry, and people with suspected or confirmed COVID-19 are not permitted to enter, (5) home health care settings where all employees are fully vaccinated, all non-employees are screened prior to entry, and people with suspected or confirmed COVID-19 are not present, (6) health care support services not performed in a health care setting (for example, offsite laundry, off-site medical billing), and (7) telehealth services performed outside of a setting where direct patient care occurs. Furthermore, in well-defined areas where there is no reasonable expectation that any person with suspected or confirmed COVID-19 will be present, the ETS

exempts fully vaccinated workers from masking, distancing, and barrier requirements.

Moreover, the ETS requires employers to immediately remove employees from the workplace if they (1) have tested positive for COVID-19, (2) have been diagnosed with COVID-19 by a licensed health care provider, (3) have been advised by a licensed health care provider that they are suspected to have COVID-19, or (4) are experiencing certain symptoms (defined as either loss of taste and/or smell with no other explanation, or fever of at least 100.4 degrees Fahrenheit and new unexplained cough associated with shortness of breath). Employers must also immediately remove an employee who was not wearing a respirator and any other required PPE and had been in close contact with a COVID-19 positive person in the workplace. However, removal from the workplace due to instances of close contact exposure in the workplace is not required for asymptomatic employees who either had COVID-19 and recovered with the last 3 months, or have been fully vaccinated (that is, 2 or more weeks have passed since the final dose).

Complementary to the OSHA ETS, this interim final rule requires certain providers and suppliers participating in Medicare and Medicaid programs to ensure staff are fully vaccinated for COVID-19, unless exempt, because vaccination of staff is necessary for the health and safety of individuals to whom care and services are furnished. Health care staff are at high risk for SARS-CoV-2 exposure, the virus that causes COVID-19, due to interactions with patients and individuals in the community.[FN79] Receiving a complete primary vaccination series reduces the risk

of COVID-19 by 90 percent or more thereby inhibiting the spread of disease to others.[FN80] Furthermore, a COVID-19 vaccination requirement reduces the likelihood of medical removal of health care staff from the workplace, as required by the OSHA COVID-19 Healthcare ETS. This is yet another way in which this interim final rule protects the individuals who receive services from the providers and suppliers to whom the rule applies by minimizing unpredictable disruptions to operations and care.

OSHA is the Federal agency responsible for setting and enforcing standards to ensure safe and healthy working conditions for workers. The COVID-19 Healthcare ETS addresses protections for health care and health care support service workers from the grave danger of COVID-19 exposure in certain workplaces. CMS is the Federal agency responsible for establishing health and safety regulations for Medicare- and Medicaid-certified providers and suppliers. Hence, we are establishing a final rule requiring COVID-19 vaccination of staff to safeguard the health and safety of patients, residents, clients, and PACE program participants who receive care and services from those providers and suppliers. Providers and suppliers may be covered by both the OSHA ETS and our interim final rule. Although the requirements and purpose of each regulation text are different, they are complementary.

B. COVID-19 Vaccine Development and Approval

FDA analysis has shown that all of the currently approved or authorized vaccines are safe and CDC

reports that over 408 million doses of the vaccine have been given through October 18, 2021.[FN81] Bringing a new vaccine to the public involves many steps, including vaccine development, clinical trials, and U.S. Food and Drug Administration (FDA) authorization or approval. While COVID-19 vaccines were developed rapidly, all steps have been taken to ensure their safety and effectiveness. Scientists have been working for many years to develop vaccines against coronaviruses, such as those that cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS). SARS-CoV-2, the virus that causes COVID-19, is related to these other coronaviruses and the knowledge that was gained through past research on coronavirus vaccines helped speed up the initial development of the current COVID-19 vaccines. After initial development, vaccines go through three phases of clinical trials to make sure they are safe and effective. For other vaccines routinely used in the U.S., the three phases of clinical trials are performed one at a time. During the development of COVID-19 vaccines, these phases overlapped to speed up the process so the vaccines could be used as quickly as possible to control the pandemic. No trial phases were skipped.[FN82]

All COVID-19 vaccines currently licensed (approved) [FN83] or authorized for use in the U.S. were tested in clinical trials involving tens of thousands of people. FDA evaluated all of the information submitted to it in requests for Emergency Use Authorization (EUA) for the authorized COVID-19 vaccines and, for the Comirnaty COVID-19 Vaccine, in a Biologics License Application (the conventional path to FDA approval of a vaccine). FDA

determined that these vaccines meet FDA's standards for safety, effectiveness, and manufacturing quality needed to support emergency use authorization and licensure, as applicable. The clinical trials included participants of different races, ethnicities, and ages, including adults over the age of 65.[FN84] Because COVID-19 continues to be widespread, researchers have been able to conduct vaccine clinical trials more quickly than if the disease were less common. Side effects following vaccination are dependent on the specific vaccine that an individual receives, and the most common include pain, redness, and swelling at the injection site, tiredness, headache, muscle pain, nausea, vomiting, fever, and chills.[FN85] After a review of all available information, the Advisory Committee on Immunization Practices (ACIP) and CDC have concluded the lifesaving benefits of COVID-19 vaccination outweigh the risks or possible side effects.[FN86]

The COVID-19 vaccines currently licensed or authorized for use in the U.S. are generally administered as either a single dose or a two-dose series given at least 21 or 28 days apart. Following completion of that primary series, a subsequent dose or doses may be recommended for one of two purposes. In the first instance, an additional dose of vaccine is administered when the immune response following a primary vaccine series is likely to be insufficient. In other words, the additional dose augments the original primary series. Currently, the EUA for the Moderna mRNA COVID-19 vaccine has been amended to include the use of a third primary series dose (that is, "additional dose") in certain immunocompromised individuals 18 years of age or

older. Similarly, the EUA for the Pfizer BioNTech mRNA COVID-19 vaccine has been amended to include the use of an additional, or third primary series, dose in certain immunocompromised individuals 12 years of age and older.

In the second instance, a booster dose of vaccine is administered when the initial immune response to a primary vaccine series is likely to have waned over time. In other words, although an adequate immune response occurred after the primary vaccine series, over time, immunity decreases.[FN87, 88, 89] On September 22, 2021, the FDA amended the EUA for the Pfizer BioNTech mRNA COVID-19 vaccine to allow for use of a single booster dose in certain individuals, to be administered at least 6 months after completion of the primary series. Specifically, this booster dose is authorized for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19.[FN90] Throughout this rule, we will use the terms "additional dose" and "booster" to differentiate between the two use cases outlined above.

Every person who receives a COVID-19 vaccine receives a vaccination record card noting which vaccine and the dose that was received. Vaccine materials specific to each vaccine are located on CDC [FN91] and FDA [FN92] websites. CDC has posted a collection of informational toolkits for specific communities and settings at https://www.cdc.gov/coronavirus/2019-

ncov/vaccines/toolkits.html. These toolkits provide staff, facility administrators, clinical leadership, caregivers, and health care consumers with information and resources.

While we are not requiring participation, we encourage staff who use smartphones to use CDC's smartphone-based tool called "v-safe After Vaccination Health Checker" (v-safe) [FN93] to self-report on one's health after receiving a COVID-19 vaccine. V-safe is a program that differs from the Vaccine Adverse Event Reporting System (VAERS), which we discuss in section I.C. of this rule. Individuals may report adverse reactions to a COVID-19 vaccine to either program. Enrollment in v-safe allows any participating vaccine recipient to directly and efficiently report to CDC how they are feeling after receiving a specific vaccine, including any problems or adverse reactions. When an individual receives the vaccine, they should also receive a v-safe information sheet telling them how to enroll in v-safe or they can register at http://www.vsafe.cdc.gov. Individuals who enroll will receive regular text messages providing links to surveys where they can report any problems or adverse reactions after receiving a COVID-19 vaccine, as well as receive "check-ins," and reminders for a second dose if applicable.[FN94] We note again that participation in v-safe is not mandatory, and further that staff participation and any health information provided is not traced to or shared with employers.

Based on current CDC guidance,[FN95] individuals are considered fully vaccinated for COVID-19 14 days after receipt of either a single-dose vaccine (Janssen/Johnson & Johnson) or the second

dose of a two-dose primary vaccination series (Pfizer-BioNTech/Comirnaty or Moderna). This guidance can also be applied to COVID-19 vaccines listed for emergency use by the World Health Organization (WHO) and some vaccines used in COVID-19 clinical trials conducted in the U.S. These circumstances are addressed in more detail in section I.C. of this IFC. To improve immune response for those individuals with moderately to severely compromised immune systems who receive the Pfizer-BioNTech Vaccine, Comirnaty, or Moderna Vaccine, the CDC advises an additional (third) dose of an mRNA COVID-19 vaccine after completing the primary vaccination series.[FN96] In addition, certain individuals who received the Pfizer-BioNTech COVID-19 Vaccine may receive a booster dose at least 6 months after completing the primary vaccination series.[FN97]

This IFC requires Medicare- and Medicaid-certified providers and suppliers to ensure that staff are fully vaccinated for COVID-19, unless the individual is exempted. Consistent with CDC guidance, we consider staff fully vaccinated if it has been 2 or more weeks since they completed a primary vaccination series for COVID-19. We define completion of a primary vaccination series as having received a single-dose vaccine or all doses of a multi-dose vaccine. Currently, CDC guidance does not include either the additional (third) dose of an mRNA COVID-19 vaccine for individuals with moderately or severely immunosuppression or the booster dose for certain individuals who received the Pfizer-BioNTech Vaccine in their definition of fully vaccinated.[FN98] Therefore, for purposes of this IFC, neither additional (third) doses nor booster doses are required. The

OSHA Emergency Temporary Standard for Healthcare discussed in section I.A.2. of this IFC also defines fully vaccinated in accordance with CDC guidance. Hence, definitions of fully vaccinated are consistent among the requirements in these regulations.

C. Administration of Vaccines Outside the U.S., Listed for Emergency Use by the WHO, Heterologous Primary Series, and Clinical Trials

We expect the majority of staff will likely receive a COVID-19 vaccine authorized for emergency use by the FDA or licensed by the FDA. Currently, this would include the authorized Pfizer-BioNTech (interchangeable with the licensed Comirnaty vaccine made by Pfizer for BioNTech), Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines. We also expect COVID-19 vaccine administration will likely occur within the U.S. for the majority of staff. However, some staff may receive FDA approved or authorized COVID-19 vaccines outside of the U.S., vaccines administered outside of the U.S. that are listed by the WHO for emergency use that are not approved or authorized by the FDA, or vaccines during their participation in a clinical trial at a site in the U.S. For these staff, we defer to CDC guidance for COVID-19 vaccination briefly discussed here. For more information, providers and suppliers should consult the CDC website at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#.

Repeat vaccine doses are not recommended by CDC for individuals who previously completed the primary series of a vaccine approved or authorized by the FDA, even if administration of the vaccine occurred outside of the U.S. Individuals who receive a COVID-19 vaccine for which two doses are required to complete the primary vaccination series should adhere as closely as possible to the recommended intervals. Following completion of their second dose, certain individuals who had received the Pfizer-BioNTech COVID-19 vaccine may receive a booster dose at least 6 months after completion of the primary vaccination series. Moderately to severely immunocompromised individuals who have received 2 doses of an mRNA vaccine may receive a third dose at least 28 days after the second dose. Vaccine administration may occur inside or outside of the U.S.

Furthermore, the WHO maintains a list of COVID-19 vaccines for emergency use.[FN99] The CDC advises that doses of an FDA approved or authorized COVID-19 vaccine are not recommended for individuals who have previously completed the primary series of a vaccine listed for emergency use by the WHO. For those who have not completed the primary series of a vaccine listed for emergency use by the WHO, they may receive an FDA approved or authorized COVID-19 vaccination series. In addition, individuals who have received a COVID-19 vaccine that is neither approved nor authorized by the FDA, nor listed on the WHO emergency use list, may receive an FDA approved or authorized vaccination series. The CDC guidelines recommend at least 28 days between administration of an FDA licensed or authorized vaccine, a non-FDA approved or

authorized vaccine, and a vaccine listed by WHO for emergency use.

For the completion of the primary series of COVID-19 vaccination, individuals should generally avoid using heterologous vaccines—meaning receiving doses of different vaccines—to complete a primary COVID-19 vaccination series. Nevertheless, CDC does recognize that, in certain situations (for example, when the vaccine product given for the first dose cannot be determined or is no longer available), a different vaccine may be used to complete the primary COVID-19 vaccination series. Accordingly, staff may be considered compliant with the requirements within this regulation if they have received any combination of two doses of a vaccine licensed or authorized by the FDA or listed on the WHO emergency use list as part of a two-dose series. Of note, the recommended interval between the first and second doses of a vaccine licensed or authorized by FDA, or listed on the WHO emergency use list, varies by vaccine type. For interpretation of vaccination records and compliance with this rule, people who received a heterologous primary series (with any combination of FDA-authorized, FDA-approved, or WHO EUL-listed products) can be considered fully vaccinated if the second dose in a two dose heterologous series must have been received no earlier than 17 days (21 days with a 4 day grace period) after the first dose.[FN100] Because the science and clinical recommendations are evolving rapidly, we refer individuals to CDC's Interim Public Health Recommendations for Fully Vaccinated People for additional details.

Some staff may receive COVID-19 vaccines due to their participation in a clinical trial at a site in the

U.S. Repeat vaccine doses are not recommended by CDC for participants in a clinical trial who previously completed the primary series of a vaccine approved or authorized by FDA, or listed for emergency use by the WHO. Likewise, for individuals who participated in a clinical trial at a site in the U.S. and received the full series of an "active" vaccine candidate (not placebo) and "vaccine efficacy has been independently confirmed (for example, by a data and safety monitoring board)," CDC does not recommend repeat doses.[FN101]

D. FDA Emergency Use Authorization (EUA) and Licensure of COVID-19 Vaccines

The FDA provides scientific and regulatory advice to vaccine developers and undertakes a rigorous evaluation of the scientific information it receives from all phases of clinical trials; such evaluation continues after a vaccine has been licensed by FDA or authorized for emergency use. On August 23, 2021, FDA licensed the first COVID-19 vaccine. The vaccine had been known as the Pfizer-BioNTech COVID-19 vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 in individuals 16 years of age and older.[FN102] The vaccine continues to be available in the U.S. under EUA, including for individuals 12 through 15 years of age. This EUA has been amended to allow for the use of a third dose for certain immunocompromised individuals 12 years of age and older. This EUA has also been amended to allow for use of a single booster dose in certain individuals. FDA has issued EUAs for two additional vaccines for the prevention of COVID-19, one for the

Moderna COVID-19 vaccine (December 18, 2020) (indicated for use in individuals 18 years of age and older), and the other for Janssen (Johnson & Johnson) COVID-19 Vaccine (February 27, 2021) (indicated for use in individuals 18 years of age and older). The EUA for the Moderna COVID-19 vaccine has been amended to allow for the use of a third dose in certain immunocompromised individuals. Package inserts and fact sheets for health care providers administering COVID-19 vaccines are available for each licensed and authorized vaccine from the FDA.[FN103, 104, 105]

Section 564 of the Federal Food, Drug, and Cosmetic Act authorizes FDA to issue EUAs. An EUA is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. FDA may authorize certain unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.[FN106]

The safety of the approved and authorized COVID-19 vaccines is closely monitored. VAERS is a safety and monitoring system that can be used by anyone to report adverse events after vaccines. For COVID-19 vaccines, vaccination providers and licensed and authorized vaccine manufacturers, must report select adverse events to VAERS following receipt of COVID-19 vaccines (including serious adverse events, cases of multisystem inflammatory syndrome (MIS), and

COVID-19 cases that result in hospitalization or death).[FN107] Providers also must adhere to any revised safety reporting requirements. FDA's website includes letters of authorization and fact sheets and these documents should be checked for any updates that may occur. Other adverse events following vaccination may also be reported to VAERS. Additionally, adverse events are also monitored through electronic health record- and claims-based systems (through CDC's Vaccine Safety Datalink and FDA's Biologics Effectiveness and Safety System (BEST)).

FDA is closely monitoring the safety of the COVID-19 vaccines both authorized for emergency use and licensed use. Vaccination providers are responsible for mandatory reporting to VAERS of certain adverse events as listed on the Health Care Provider Fact Sheets for the authorized COVID-19 vaccines and for Comirnaty.

Vaccine safety is critically important for all vaccination programs. Side effects following vaccinations often include swelling, redness, and pain at the injection site; flu-like symptoms; headache; and nausea; all typically of short duration. [FN108] Serious adverse reactions also have been reported following COVID-19 vaccines; however, they are rare.[FN109, 110] For example, it is estimated that anaphylaxis following the mRNA COVID-19 vaccines occurs in 2-5 individuals per million vaccinated (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html). For these individuals, another shot of an mRNA COVID-19 vaccine is not recommended,[FN111] and they should discuss receiving a different type of COVID-19 vaccine

with their health care practitioner.[FN112] Other rare serious adverse reactions that have been reported to occur following COVID-19 vaccines include thrombosis with thrombocytopenia syndrome (TTS) following the Janssen COVID-19 vaccine and myocarditis and/or pericarditis following the mRNA COVID-19 vaccines (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html). In the face of the COVID-19 pandemic, global researchers were able to build upon decades of vaccine development, research, and use to produce safe vaccines that have been highly effective in protecting individuals from COVID-19. From December 14, 2020, through October 12, 2021, over 403 million doses of COVID-19 vaccine have been administered in the U.S. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html. "CDC recommends everyone 12 years and older get vaccinated as soon as possible to help protect against COVID-19 and the related, potentially severe complications that can occur." [FN113] They state that the "potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis." [FN114]

E. COVID-19 Vaccine Effectiveness

COVID-19 vaccines currently approved or authorized by FDA are highly effective in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death.[FN115] Moreover, available evidence suggests that these vaccines offer protection against known variants,

including the Delta variant (B.1.617.2), particularly against hospitalization and death. [FN116, 117] Furthermore, a recent study found that, between December 14, 2020, and August 14, 2021, full vaccination with COVID-19 vaccines was 80 percent effective in preventing RT-PCR-confirmed SARS-CoV-2 infection among frontline workers, further affirming the highly protective benefit of full vaccination up to and through the 2021 summer COVID-19 pandemic waves in the U.S.[FN118] While vaccine effectiveness point estimates did decline over the course of the study as the Delta variant became predominant, the protection afforded by vaccination remained significant, underscoring the continued importance and benefits of COVID-19 vaccination.[FN119]

Like most vaccines, COVID-19 vaccines are not 100 percent effective in preventing COVID-19. Consequently, some "breakthrough" cases are expected and, as the number of people who have completed a primary vaccination series and are considered fully vaccinated for COVID-19 increases, breakthrough COVID-19 cases will also increase commensurately. However, the risk of developing COVID-19, including severe illness, remains much higher for unvaccinated than vaccinated people. Vaccinated people with a breakthrough COVID-19 case are less likely to develop serious disease, be hospitalized, and die than those who are unvaccinated and get COVID-19.[FN120] The combined protections offered by vaccination and ongoing implementation of other infection control measures, especially source control (masking),[FN121] remain critical to

safeguarding patients, residents, clients, PACE program participants, and staff.

F. Stakeholder Response to Vaccines

There has been growing national interest in COVID-19 vaccination requirements among health care workers, including requests from various national health care stakeholders. In a joint statement released on July 26, 2021, more than 50 health care professional societies and organizations called for all health care employers and facilities to require that all their staff be vaccinated against COVID-19. Included as signatories to this statement were organizations representing millions of workers throughout the U.S. health care industry, including those representing doctors, nurses, pharmacists, physician assistants, public health workers, and epidemiologists as well as long term care, home care, and hospice workers.[FN122]

In addition, a large nonprofit, nonpartisan organization focused on empowering Americans over the age of 50 recently called on all LTC facilities to require vaccinations for staff and residents.[FN123] A non-profit organization dedicated to advancing dignity in aging issued a statement in support of COVID-19 vaccine mandates for staff and residents of long-term care facilities.[FN124] In a policy statement dated July 21, 2021, a large long term care association, "strongly urges all residents and staff in long-term care to get vaccinated" and "supports requiring vaccines for current and new staff in long-term care and other healthcare settings. COVID-19 vaccination should be a condition of employment for

all healthcare workers, including employees, contract staff and others, with appropriate exemptions for those with medical reasons or as specified by federal or state law." [FN125] The statement further notes that "COVID-19 vaccines are safe . . . effective for preventing infection, and especially severe illness and death [and] reduce the risk of spreading the virus." [FN126] Moreover, the statement observes that "the COVID crisis exacerbated long-standing workforce challenges, and some in the sector fear that a vaccine mandate could lead to worker resignations. But providers that have required staff vaccination have reported high vaccine accepted by previously hesitant care professionals, and many providers report that when staff vaccination rates are high, they become providers of choice in their communities." [FN127] A non-profit federation of affiliated State health organizations, representing more than 14,000 non-profit and for-profit nursing homes, assisted living communities, and facilities for individuals with disabilities expressed support for all health care "strongly urges the vaccination of all health care personnel" to "protect all residents, staff and others in our communities from the known and substantial risks of COVID-19." They also assert that "COVID-19 vaccines protect health care personnel when working both in health care facilities and in the community," and "provide strong protection against workers unintentionally carrying the disease to work and spreading it to patients and peers." [FN128]

Numerous health systems and individual health care employers across the country have implemented vaccine mandates independent of this rule. For example, a health care system that is the largest

private employer in Delaware with more than 14,000 employees, a health care system and academic medical center with over 26,000 employees in Texas, and an integrated health system in North Carolina with more than 35,000 employees, to name a few, have all preceded this rule with their own vaccination requirements, achieving rates of at least 97 percent vaccination among their staff.[FN129, 130, 131, 132] These organizations are already realizing the effectiveness of strong vaccination policies. Despite the successes of these organizations in increasing levels of staff vaccination, there remains an inconsistent patchwork of requirements and laws that is only effective at local levels and has not successfully raised staff vaccination rates nationwide. Patients, residents, clients, PACE program participants, and staff alike are not adequately protected from COVID-19.

In September 2021, Jeffrey Zients, the White House Coronavirus Response Coordinator, noted that "vaccination requirements work . . . and are the best path out of the pandemic." He further noted that vaccination requirements are not only key to the nation's path out of the pandemic, but also accelerate our economic recovery, keeping workplaces safer, and helping to curb the spread of the virus in communities, and boost job growth, the labor market, and the nation's overall economy.

G. Populations at Higher Risk for Severe COVID-19 Outcomes

COVID-19 can affect anyone, with symptoms ranging from mild (infections not requiring

hospitalization) to very severe (requiring intensive care in a hospital). Nonetheless, studies have shown that COVID-19 does not affect all population groups equally.[FN133] Age remains a strong risk factor for severe COVID-19 outcomes. Approximately 54.1 million people aged 65 years or older reside in the U.S.; this age group accounts for more than 80 percent of U.S. COVID-19 related deaths. Residents of LTC facilities make up less than 1 percent of the U.S. population but accounted for more than 35 percent of all COVID-19 deaths in the first 12 months of the pandemic.[FN134]

Additionally, adults of any age with certain underlying medical conditions are at increased risk for severe illness from COVID-19. These include, but are not limited to, cancer, cerebrovascular disease, diabetes (Type 1 and Type 2), chronic kidney disease, COPD, heart conditions, Down Syndrome, obesity, substance use, smoking status, and pregnancy.[FN135] The risk of severe COVID-19 also increases as the number of underlying medical conditions increases in a particular individual.

A confluence of structural and epidemiological factors has also contributed to disparate risk for COVID-19 infection, severe illness, and death in certain populations. For example, evidence clearly indicates that racial and ethnic minority groups, including Black and Hispanic or Latino, have disproportionately higher hospitalization rates among every age group, including children aged younger than 18 years.[FN136] These same groups are disproportionately affected by long-standing inequities in social determinants of health, such as poverty and health care access, that increase risk of

severe illness and death from COVID-19.[FN137] People with intellectual disabilities are more likely to have chronic health conditions, live in congregate settings, and face more barriers to health care; some studies suggest they are also more likely to get COVID-19 and have worse outcomes.[FN138] Finally, rural communities often have a higher proportion of residents who live with comorbidities or disabilities and are aged >=65 years; these risk factors, combined with more limited access to health care facilities with intensive care capabilities, place rural dwellers at increased risk for COVID-19-associated morbidity and mortality.[FN139]

In addition, CDC data indicate that vaccination rates are disproportionately low among nurses and health care aides in long term care settings, particularly in communities that experience social risk factors. Further, CDC data indicate that nurses and aides in these settings are more likely to be members of racial and ethnic minority communities.[FN140] This disparity in vaccination coverage may be exacerbating existing and emerging disparities related to COVID-19 cases and impact, placing members of communities who experience social risk factors—those in rural areas with geographic and transportation barriers to care, those in low income areas who experience persistent poverty and inequality, and others—at further increased risk for COVID-19-associated morbidity and mortality.[FN141] This disparity may be, in part, reduced by the potential positive health equity impacts of requiring staff vaccination among provider and supplier types subject to rulemaking.

CMS believes that the developing data about staff vaccination rates and rates of COVID-19 cases, and the urgent need to address COVID-related staffing shortages that are disrupting patient access to care, provides strong justification as to the need to issue this IFC requiring staff vaccination for most provider and supplier types over which we have authority.

H. CMS Authority To Require Staff Vaccinations

CMS has broad statutory authority to establish health and safety regulations, which includes authority to establish vaccination requirements. Section 1102 of the Act grants the Secretary of Health and Human Services authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged under the Act. Section 1871 of the Act grants the Secretary of Health and Human Services authority to prescribe regulations as may be necessary to carry out the administration of the Medicare program. The statutory authorities to establish health and safety requirements for COVID-19 vaccination for each provider and supplier included in this IFC are listed in Table 1 and discussed in sections II.C. through II.F. of this IFC.

TABLE 1: Authorities for All Providers and Suppliers

Provider/Supplier	Statutory Authority
Ambulatory Surgical Centers (ASCs)	Sections 1102, 1832(a)(2)(f)(i), and 1833 (i)(1)(A), and 1871 of the Act
Hospices	Sections 1102,1861(dd), and 1871 of the Act
Psychiatric Residential Treatment Facilities (PRTFs)	Section 1102 and 1905(h)(1) of the Act
Programs of All-Inclusive Care for the Elderly (PACE)	Sections 1102, 1871, 1894, and 1934 of the Act
Hospitals	Sections 1102, 1861(e)(9), and 1871 of the Act
Long Term Care (LTC) Facilities	Sections 1102, 1819, 1871, and 1919 of the Act
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)	Sections 1102 and 1905(d)(1) of the Act
Home Health Agencies (HHAs)	Sections 1102, 1861(m), 1861(o), 1871, and 1891 of the Act
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	Sections 1102, 1861(cc)(2)(J), and 1871 of the Act
Critical Access Hospitals (CAHs)	Sections 1102, 1820(e), and 1871 of the Act
Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (Organizations)	Sections 1102, 1861(p)(4), and 1871 of the Act
Community Mental Health Centers (CMHCs)	Sections 1102, 1861(ff)(3), 1832(a)(2)(J), 1866(e)(2), and 1871 of the Act
Home Infusion Therapy (HIT) Suppliers	Sections 1102, 1861(iii)(3)(D)(i)(IV), and 1871 of the Act
Rural Health Clinics (RHCs)/ Federally Qualified Health Centers (FQHCs)	Sections 1102, 1861(aa), 1871, and 1905(l)(2)(B) of the Act
End-Stage Renal Disease (ESRD) Facilities	Sections 1102, 1871, and 1881(b)(1)(A) of the Act

Section 1863 of the Act provides that "[i]n carrying out his functions, relating to determination of conditions of participation by providers . . . the Secretary shall consult with appropriate State

agencies and recognized national listing or accrediting bodies[.]" For the reasons discussed in greater detail throughout sections I. through III. this IFC, the COVID-19 pandemic presents a serious and continuing threat to the health and to the lives of staff of health care facilities and of consumers of these providers' and suppliers' services. This threat has grown to be particularly severe since the emergence of the Delta variant. Any delay in the implementation of this rule would result in additional deaths and serious illnesses among health care staff and consumers, further exacerbating the newly-arising, and ongoing, strain on the capacity of health care facilities to serve the public. For these reasons, in carrying out the agency's functions relating to determination of conditions of participation, conditions for coverage, and requirements, we intend to engage in consultations with appropriate State agencies and listing or accrediting bodies following the issuance of this rule, and toward that end we invite these entities to submit comments on this IFC. Given the urgent need to issue this rule, however, we do not believe that there exists an entity with which it would be appropriate to engage in these consultations in advance of issuing this IFC, nor do we understand the statute to impose a temporal requirement to do so in advance of the issuance of this rule.

We have not previously required any vaccinations, but we recognize that many health care workers already comply with employer or State government vaccination requirements (for example, influenza, and hepatitis B virus (HBV)) and invasive employer or State government-required screening procedures (such as tuberculosis screening). Further, most of

these individuals met State and local vaccination requirements in order to attend school to complete the necessary education to qualify for health care positions. In addition to these longstanding vaccination requirements, many now require vaccination for COVID-19 as well. However, studies on annual seasonal influenza vaccine uptake consistently show that half of health care workers may resist seasonal influenza vaccination nationwide.[FN142]

Other ongoing CMS staff vaccination programs include hospital quality improvement contractors that provide educational resources to help hospitals and staff overcome vaccine hesitancy, coordinate with State health departments to support vaccine uptake (for COVID-19 and flu), and monitor staff vaccination rates for additional action. ESRD networks also provide education on patient influenza and pneumococcal vaccinations as a part of their work and also recently (in 2020) added a goal of 85 percent of patients vaccinated for flu while also encouraging vaccinations for staff within ESRD facilities. While we have not, until now, required any health care staff vaccinations, we have established, maintained, and regularly updated extensive health and safety requirements (CfCs, CoPs, requirements, etc.) for Medicare- and Medicaid-certified providers and suppliers. These requirements focus a great deal on infection prevention and control standards, often incorporating guidelines as recommended by CDC and other expert groups, as CMS's highest duty is to protect the health and safety of patients, clients, residents, and PACE program participants in all applicable settings.

The Medicare statute's various provisions authorizing the Secretary to impose requirements necessary in the interest of the health and safety of beneficiaries encompass authority to require that staff working in and for Medicare-certified providers and suppliers be vaccinated against specific diseases. In addition, parallel Medicaid statutes provide authority to establish requirements to protect beneficiary health and safety, as reflected in Table 1. We acknowledge that we have not previously imposed such requirements, but, as discussed throughout section I. of this rule, this is a unique pandemic scenario with unique access to effective vaccines. In addition, for many infectious diseases, it is not necessary for CMS to impose such requirements because other entities, including employers, states, and licensing organizations, already impose sufficient standards for those specific diseases. We believe that, given the fast-moving nature of the COVID-19 pandemic and its ongoing threat to the health and safety of individuals receiving health care services in Medicare- and Medicaid-certified providers and suppliers, our intervention is warranted. We understand that some states and localities have established laws that would seem to prevent Medicare- and Medicaid-certified providers and suppliers from complying with the requirements of this IFC. We intend, consistent with the Supremacy Clause of the United States Constitution, that this nationwide regulation preempts inconsistent State and local laws as applied to Medicare- and Medicaid-certified providers and suppliers. CDC estimates that 45.4 percent of U.S. adults are at increased risk for complications from coronavirus disease because of

cardiovascular disease, diabetes, respiratory disease, hypertension, or cancer. Rates increased by age, from 19.8 percent for persons 18-29 years of age to 80.7 percent for persons >80 years of age, and varied by State, race/ethnicity, health insurance status, and employment.[FN143] We expect that individuals seeking health care services are more likely to fall into the high-risk category. While we do not have provider- or supplier-specific estimates, we would anticipate the percentage of high-risk individuals in health care settings is much higher than the general population. Health care consumers seeking services from the provider and suppliers included in this rule are often at significantly higher risk of severe disease and death than their paid care givers.[FN144] As discussed in section I.F. of this IFC, COVID-19 has disproportionally affected minority and underserved populations, who will receive safer care and better outcomes through this requirement.[FN145] Families, unpaid caregivers, and communities will also experience overall benefit.[FN146, 147] Staff will directly benefit from the protective effects of COVID-19 vaccination, but the primary reason that we are issuing this IFC requiring health care workers be vaccinated against COVID-19 is for the protection of residents, clients, patients, and PACE program participants.

I. Vaccination Requirements and Employee Protections

This IFC requires most Medicare- and Medicaid-certified providers and suppliers to ensure that their staff are fully vaccinated for COVID-19. The U.S.

Equal Employment Opportunity Commission (EEOC) enforces workplace anti-discrimination laws and has established that employers can mandate COVID-19 vaccination for all employees that physically enter their facility.[FN148] We are expanding upon that to include all of the staff described in section II.A.1. of this IFC, for the providers and suppliers addressed by this IFC, not just those staff who perform their duties within a health care facility, as many health care staff routinely care for patients and clients outside of such facilities, such as home health, home infusion therapy, hospice, and therapy staff. In addition, there may be other times that staff encounter fellow employees, such as in an administrative office or at an off-site staff meeting, who will themselves enter a health care facility or site of care for their job responsibilities. Thus, we believe it is necessary to require vaccination for all staff that interact with other staff, patients, residents, clients, or PACE program participants in any location, beyond those that physically enter facilities or other sites of patient care.

In implementing the COVID-19 vaccination policies and procedures required by this IFC, however, employers must comply with applicable Federal anti-discrimination laws and civil rights protections. Applicable laws include: (1) The Americans with Disabilities Act (ADA); (2) Section 504 of the Rehabilitation Act (RA); (3) Title VII of the Civil Rights Act of 1964; (4) the Pregnancy Discrimination Act; and (5) the Genetic Information Nondiscrimination Act.[FN149] In addition, other Federal laws may provide employees with additional protections.

These Federal laws continue to apply during the PHE and, in some instances, require employers to offer accommodations for some individual staff members in some circumstances. These laws do not interfere with or prevent employers from following the guidelines and suggestions made by CDC or public health authorities about steps employers should take to promote public health and safety in light of COVID-19, to the extent such guidelines and suggestions are consistent with the requirements set forth in this regulation. In other words, employers following CDC guidelines and the new requirements in this IFC may also be required to provide appropriate accommodations, to the extent required by Federal law, for employees who request and receive exemption from vaccination because of a disability, medical condition, or sincerely held religious belief, practice, or observance.

Vaccination against COVID-19 is a critical protective action for all individuals, especially health care workers, because the SARS-Cov-2 virus poses direct threats to patients, clients, residents, PACE program participants, and staff. COVID-19 disease at this time is resulting in much higher morbidity and mortality than seasonal flu. [FN150,151, 152] These individual vaccinations provide protections to the health care system as a whole, protecting capacity and operations during disease outbreaks.

We also recognize ethical reasons to issue these vaccination requirements. All health care workers have a general ethical duty to protect those they encounter in their professional capacity.[FN153] Patient safety is a central tenet of the ethical codes and practice standards published by health care

professional associations, licensure and certification bodies, and specialized industry groups. Health care workers also have a special ethical and professional responsibility to protect and prioritize the health and well-being of those they are caring for, as well as not exposing them to threats that can be avoided. This holds true not only for health care professionals, but also for all who provide health care services or choose to work in those settings. The ethical duty of receiving vaccinations is not new, as staff have long been required by employers to be vaccinated against certain diseases, such as influenza, hepatitis B, and other infectious diseases.

We are aware of concerns about health care workers choosing to leave their jobs rather than be vaccinated. While we understand that there might be a certain number of health care workers who choose to do so, there is insufficient evidence to quantify and compare adverse impacts on patient and resident care associated with temporary staffing losses due to mandates and absences due to quarantine for known COVID-19 exposures and illness. We encourage providers and suppliers, where possible, to consider on-site vaccination programs, which can significantly reduce barriers that health care staff may face in getting vaccinated, including transportation barriers, need to take time off of work, and scheduling. However, vaccine declination may continue to occur, albeit at lower rates, due to hesitancy among particular communities, and the Assistant Secretary for Planning and Evaluation (ASPE) indicates that vaccination promotion and outreach efforts focused on groups and communities who experience social risk factors could help address inequities.[FN154]

Despite these hesitations, many COVID-19 vaccination mandates have already been successfully initiated in a variety of health care settings, systems, and states. In general, workers across the economy are responding to mandates by getting vaccinated.[FN155] A large hospital system in Texas instituted a vaccine mandate and 99.5 percent of its staff received the vaccine. Further, only a few of their staff resigned rather than receive the vaccine.[FN156] A Detroit-based health system also instituted a vaccine mandate, and reported that 98 percent of the system's 33,000 workers were fully or partially vaccinated or in the process of obtaining a religious or medical exemption when the requirement went into effect, with exemptions comprising less than 1 percent of staffers.[FN157] In addition, a LTC parent corporation established a COVID-19 vaccine mandate for its more than 250 LTC facilities, leading to more than 95 percent of their workers being vaccinated. Again, they noted that very few workers quit their jobs rather than be vaccinated.[FN158] New York enacted a State-wide health care worker COVID-19 vaccine mandate and recorded a jump in vaccine compliance in the final days before the requirements took effect on October 1, 2021.[FN159]

We believe that the COVID-19 vaccine requirements in this IFC will result in nearly all health care workers being vaccinated, thereby benefiting all individuals in health care settings. This will greatly contribute to a reduction in the spread of and resulting morbidity and mortality from the disease, positive steps towards health equity, and an improvement in the numbers of health care staff who are healthy and able to perform their professional

responsibilities. For individual staff members that have legally permitted justifications for exemption, the providers and suppliers covered by this IFC can address those individually.

II. Provisions of the Interim Final Rule With Comment Period

Through this IFC, we are requiring that the following Medicare- and Medicaid-certified providers and suppliers, listed here in order of their appearance in 42 CFR, ensure that all applicable staff are vaccinated for COVID-19:

- Ambulatory Surgical Centers (ASCs)
- Hospices
- Psychiatric residential treatment facilities (PRTFs)
- Programs of All-Inclusive Care for the Elderly (PACE)
- Hospitals (acute care hospitals, psychiatric hospitals, long term care hospitals, children's hospitals, hospital swing beds, transplant centers, cancer hospitals, and rehabilitation hospitals)
- Long Term Care (LTC) Facilities, including SNFs and NFs, generally referred to as nursing homes
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)
- Home Health Agencies (HHAs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals (CAHs)

- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services
- Community Mental Health Centers (CMHCs)
- Home Infusion Therapy (HIT) suppliers
- Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs)
- End-Stage Renal Disease (ESRD) Facilities

For discussion purposes, we have grouped these providers and suppliers into four categories below: (1) Residential congregate care facilities; (2) acute care settings; (3) outpatient clinical care and services; and (4) home-based care. We note that the appropriate term for the individual receiving care and/or services differs depending upon the provider or supplier. For example, for hospitals and CAHs, the appropriate term is patient, but for ICFs-IID, it is client. Further, LTC facilities have residents and PACE Programs have participants. The appropriate term is used when discussing each individual provider or supplier, but when we are discussing all or multiple providers and suppliers we will use the general term "patient." Similarly, despite the different terms used for specific provider and supplier entities (such as campus, center, clinic, facility, organization, or program), when we are discussing all or multiple providers and suppliers, we will use the general term "facility."

A. Provisions of the Interim Final Rule With Comment Period

In this IFC, we are issuing a common set of provisions for each applicable provider and supplier.

As there are no substantive regulatory differences across settings, we discuss the provisions broadly in this section of the rule, along with their rationales. In subsequent sections of the rule we discuss any unique considerations for each setting.

1. Staff Subject to COVID-19 Vaccination Requirements

The provisions of this IFC require applicable providers and suppliers to develop and implement policies and procedures under which all staff are vaccinated for COVID-19. Each facility's COVID-19 vaccination policies and procedures must apply to the following facility staff, regardless of clinical responsibility or patient contact and including all current staff as well as any new staff, who provide any care, treatment, or other services for the facility and/or its patients: Facility employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement. These requirements are not limited to those staff who perform their duties within a formal clinical setting, as many health care staff routinely care for patients and clients outside of such facilities, such as home health, home infusion therapy, hospice, PACE programs, and therapy staff. Further, there may be staff that primarily provide services remotely via telework that occasionally encounter fellow staff, such as in an administrative office or at an off-site staff meeting, who will themselves enter a health care facility or site of care for their job responsibilities. Thus, we believe it is

necessary to require vaccination for all staff that interact with other staff, patients, residents, clients, or PACE program participants in any location, beyond those that physically enter facilities, clinics, homes, or other sites of care. Individuals who provide services 100 percent remotely, such as fully remote telehealth or payroll services, are not subject to the vaccination requirements of this IFC.

In the May 13, 2021 COVID-19 IFC, we included an extensive discussion on the subject of "staff" in relation to the LTC facility staff and to whom the testing, reporting, and education and offering of COVID-19 vaccine requirements of that rule might apply. In that discussion, we considered LTC facility staff to be those individuals who work in the facility on a regular (that is, at least once a week) basis. We note that this includes those individuals who may not be physically in the LTC facility for a period of time due to illness, disability, or scheduled time off, but who are expected to return to work. We also note that this description of staff differs from that in § 483.80(h), established for the LTC facility COVID-19 testing requirements in the September 2, 2020 COVID-19 IFC. As in the May 13, 2021 COVID-19 IFC, we considered applying the § 483.80(h) definition to the staff vaccination requirements in this rule, but previous public feedback and our own experience tells us the definition in § 483.80(h) was overbroad for these purposes.

Stakeholders across settings have reported that there are many individuals providing occasional health care services under arrangement, and that the requirements may be excessively burdensome for facilities to apply the definition at § 483.80(h) because

it includes many individuals who have very limited, infrequent, or even no contact with facility staff and residents. Stakeholders also report that applying the staff vaccination requirements to these individuals who may only make unscheduled visits to the facility would be extremely burdensome. That said, the description in this rule still includes many of the individuals included in § 483.80(h). In addition to facility-employed staff, many facilities have services provided directly, on a regular basis, by individuals under contract or arrangement, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, social workers, and portable x-ray suppliers. Any of these individuals who provide such health care services at a facility would be included in "staff" for whom COVID-19 vaccination is now required as a condition for continued provision of those services for the facility and/or its patients.

In order to best protect patients, families, caregivers, and staff, we are not limiting the vaccination requirements of this IFC to individuals who are present in the facility or at the physical site of patient care based upon frequency. Regardless of frequency of patient contact, the policies and procedures must apply to all staff, including those providing services in home or community settings, who directly provide any care, treatment, or other services for the facility and/or its patients, including employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement. This includes administrative staff, facility leadership,

volunteer or other fiduciary board members, housekeeping and food services, and others. We considered excluding individual staff members who are present at the site of care less frequently than once per week from these vaccination requirements, but were concerned that this might lead to confusion or fragmented care. Therefore, any individual that performs their duties at any site of care, or has the potential to have contact with anyone at the site of care, including staff or patients, must be fully vaccinated to reduce the risks of transmission of SARS-CoV-2 and spread of COVID-19.

Facilities that employ or contract for services by staff who telework full-time (that is, 100 percent of their time is remote from sites of patient care, and remote from staff who do work at sites of care) should identify and monitor these individuals as a part of implementing the policies and procedures of this IFC, documenting and tracking overall vaccination status, but those individuals need not be subject to the vaccination requirements of this IFC. Note, however, that these individuals may be subject to other Federal requirements for COVID-19 vaccination.

We recognize that many infrequent services and tasks performed in or for a health care facility are conducted by "one off" vendors, volunteers, and professionals. Providers and suppliers are not required to ensure the vaccination of individuals who infrequently provide ad hoc non-health care services (such as annual elevator inspection), or services that are performed exclusively off-site, not at or adjacent to any site of patient care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible. Other

individuals who may infrequently enter a facility or site of care for specific limited purposes and for a limited amount of time, but do not provide services by contract or under arrangement, may include delivery and repair personnel.

We believe it would be overly burdensome to mandate that each provider and supplier ensure COVID-19 vaccination for all individuals who enter the facility. However, while facilities are not required to ensure vaccination of every individual, they may choose to extend COVID-19 vaccination requirements beyond those persons that we consider to be staff as defined in this rulemaking. We do not intend to prohibit such extensions and encourage facilities to require COVID-19 vaccination for these individuals as reasonably feasible.

When determining whether to require COVID-19 vaccination of an individual who does not fall into the categories established by this IFC, facilities should consider frequency of presence, services provided, and proximity to patients and staff. For example, a plumber who makes an emergency repair in an empty restroom or service area and correctly wears a mask for the entirety of the visit may not be an appropriate candidate for mandatory vaccination. On the other hand, a crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks would be subject to these requirements due to the fact that they are using the same common areas used by staff, patients, and visitors. Again, we strongly encourage facilities, when the opportunity exists and resources allow, to facilitate the vaccination of all individuals who

provide services infrequently and are not otherwise subject to the requirements of this IFC.

2. Determining When Staff Are Considered "Fully Vaccinated"

In consideration of the different vaccines available for COVID-19, we require that providers and suppliers ensure that staff are fully vaccinated for COVID-19, which, for purposes of these requirements, is defined as being 2 weeks or more since completion of a primary vaccination series. This definition of "fully vaccinated" is consistent with the CDC definition. Additionally, the completion of a primary vaccination series for COVID-19 is defined in the requirements as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

We note that the concept of a "primary series" is commonly understood with respect to vaccinations, particularly among health care professionals as well as the providers and suppliers regulated by this rule. For purposes of this IFC, and if permitted or recommended by CDC, COVID-19 vaccine doses from different manufacturers may be combined to meet the requirements for a primary vaccination series.

We further note that recommendations for booster doses currently vary by vaccine and population, and expect that they will continue to vary for the foreseeable future. We also require that providers and suppliers must have a process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC. Additionally,

some staff members may have been vaccinated during participation in a clinical trial, or in countries other than the U.S. We discuss the applicability of these less common vaccination pathways in section I.B. of this IFC.

Currently, for two of the three vaccines licensed or authorized for use in the U.S., the primary vaccination series consists of a defined number of doses administered a certain number of weeks apart; therefore, we have made this particular requirement effective in two different phases. We discuss these implementation phases further in section II.B. of this IFC, but note here that Phase 1, effective 30 days after publication of this IFC, includes the requirement that staff receive the first dose, or only dose as applicable, of a COVID-19 vaccine, or have requested or been granted an exemption to the vaccination requirements of this IFC. Phase 2, effective 60 days after publication of this IFC, requires that the primary vaccination series has been completed and that staff are fully vaccinated, except for those staff have been granted exemptions, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations. As discussed in section II.B. of this IFC, staff who have completed the primary series for the vaccine received by the Phase 2 implementation date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination.

3. Infection Prevention and Control

We require through this IFC that all applicable providers and suppliers have a process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19. While every health care facility should be following recommended infection control and prevention measures as recommended by CDC as part of their provision of safe health care services, not all of the providers and suppliers subject to the requirements of this IFC have specific infection control and prevention regulations in place. Specifically, there are no infection prevention and control requirements for PRTFs, RHCs/FQHCs, and HIT suppliers. Therefore, for PRTFs, RHCs/FQHCs, and HIT suppliers, we require that they have a process for ensuring that they follow nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19. This process must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19. For the providers and suppliers included in this IFC that are already subject to meeting specific infection prevention and control requirements on an ongoing basis, we require that they have a process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19.

4. Documentation of Staff Vaccinations

In order to ensure that providers and suppliers are complying with the vaccination requirements of this IFC, we are requiring that they track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination, such as recent receipt of monoclonal antibodies or convalescent plasma. Vaccine exemption requests and outcomes must also be documented, discussed further in section II.A.5. of this IFC. This documentation will be an ongoing process as new staff are onboarded.

While provider and supplier staff may not have personal medical records on file with their employer, all staff COVID-19 vaccines must be appropriately documented by the provider or supplier. Examples of appropriate places for vaccine documentation include a facilities immunization record, health information files, or other relevant documents. All medical records, including vaccine documentation, must be kept confidential and stored separately from an employer's personnel files, pursuant to ADA and the Rehabilitation Act.

Examples of acceptable forms of proof of vaccination include:

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

If vaccinated outside of the U.S., a reasonable equivalent of any of the previous examples would suffice.

Providers and suppliers have the flexibility to use the appropriate tracking tools of their choice. For

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

5. Vaccine Exemptions

While nothing in this IFC precludes an employer from requiring employees to be fully vaccinated, we recognize that there are some individuals who might be eligible for exemptions from the COVID-19 vaccination requirements in this IFC under existing Federal law. Accordingly, we require that providers and suppliers included in this IFC establish and implement a process by which staff may request an exemption from COVID-19 vaccination requirements based on an applicable Federal law. Certain allergies, recognized medical conditions, or religious beliefs, observances, or practices, may provide grounds for exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States, accessed at https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf.

As described in section I.I. of this IFC, there are Federal laws, including the ADA, section 504 of the

Rehabilitation Act, section 1557 of the ACA, and Title VII of the Civil Rights Act, that prohibit discrimination based on race, color, national origin, religion, disability and/or sex, including pregnancy. We recognize that, in some circumstances, employers may be required by law to offer accommodations for some individual staff members. Accommodations can be addressed in the provider or supplier's policies and procedures.

Applicable staff of the providers and suppliers included in this IFC must be able to request an exemption from these COVID-19 vaccination requirements based on an applicable Federal law, such as the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964. Providers and suppliers must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the facility's decision on the request, and any accommodations that are provided.

Requests for exemptions based on an applicable Federal law must be documented and evaluated in accordance with applicable Federal law and each facility's policies and procedures. As is relevant here, this IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader exemptions than provided for by Federal law and are inconsistent with this IFC.

For staff members who request a medical exemption from vaccination, all documentation confirming recognized clinical contraindications to COVID-19 vaccines, and which supports the staff member's request, must be signed and dated by a

licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws. Such documentation must contain all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements based on the recognized clinical contraindications.

Under Federal law, including the ADA and Title VII of the Civil Rights Act of 1964 as noted previously, workers who cannot be vaccinated or tested because of an ADA disability, medical condition, or sincerely held religious beliefs, practice, or observance may in some circumstances be granted an exemption from their employer. In granting such exemptions or accommodations, employers must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals, in keeping with their obligation to protect the health and safety of patients. Employers must also follow Federal laws protecting employees from retaliation for requesting an exemption on account of religious belief or disability status. For more information about these situations, employers can consult the Equal Employment Opportunity Commission's website at https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws.

We also direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination [FN160] for information on evaluating and responding to such requests. While employers have the flexibility to establish their own processes and procedures, including forms, we point to The Safer Federal Workforce Task Force's "request for a religious exception to the COVID-19 vaccination requirement" template as an example. This template can be viewed at https://www.saferfederalworkforce.gov/downloads/RELIGIOUSREQUESTFORM-20211004-MH508.pdf.

6. Planning

Despite the near-universal applicability of the requirements described in sections II.A.1. through 5 of this IFC, we recognize that the course of the COVID-19 pandemic remains unpredictable. Due to likely unforeseen circumstances, we require that providers and suppliers make contingency plans in consideration of staff that are not fully vaccinated to ensure that they will soon be vaccinated and will not provide care, treatment, or other services for the provider or its patients until such time as such staff have completed the primary vaccination series for COVID-19 and are considered fully vaccinated, or, at a minimum, have received a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine. This planning should also address the safe provision of services by individuals who have requested an exemption from vaccination while their request is

being considered and by those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations.

While the nature of this rulemaking suggests the potential that virtually all health care staff in the U.S. will be vaccinated for COVD-19 within a matter of months, local outbreaks, new viral variations, changes in disease manifestation, or other factors necessitate contingency planning. Contingency planning may extend beyond the specific requirements of this rule to address topics such as staffing agencies that can supply vaccinated staff if some of the facility's staff are unable to work. Contingency plans might also address special precautions to be taken when, for example, there is a regional or local emergency declaration, such as for a hurricane or flooding, which necessitates the temporary utilization of unvaccinated staff, in order to assure the safety of patients. For example, expedient evacuation of a flooding LTC facility may require assistance from local community members of unknown vaccination status. Facilities may already have contingency plans that meet the requirements of this IFC in their existing Emergency Preparedness policies and procedures.

B. Implementation Dates

Due to the urgent nature of the vaccination requirements established in this IFC, we have not issued a proposed rule, as discussed in section III. of this IFC. While some IFCs are effective immediately upon publication, we understand that instantaneous

compliance, or compliance within days, with these regulations is not possible. Vaccination requires time, especially those vaccines delivered in a series, and facilities may wish to coordinate scheduling of staff vaccination appointments in a staggered manner so that appropriate coverage is maintained. The policies and procedures required by the IFC will also take time for facilities to develop. However, in order to provide protection to residents, patients, clients, and PACE program participants (as applicable), we believe it is necessary to begin staff vaccinations as quickly as reasonably possible.

In order to provide protection as soon as possible, we are establishing two implementation phases for this IFC. Phase 1, effective 30 days after publication, includes nearly all provisions of this IFC, including the requirements that all staff have received, at a minimum, the first dose of the primary series or a single dose COVID-19 vaccine, or requested and/or been granted a lawful exemption, prior to staff providing any care, treatment, or other services for the facility and/or its patients. Phase 1 also includes the requirements for facilities to have appropriate policies and procedures developed and implemented, and the requirement that all staff must have received a single dose COVID-19 vaccine or the initial dose of a primary series by December 6, 2021.

Phase 2, effective 60 days after publication, consists of the requirement that all applicable staff are fully vaccinated for COVID-19, except for those staff who have been granted exemptions from COVID-19 vaccination or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions

and considerations). Although an individual is not considered fully vaccinated until 14 days (2 weeks) after the final dose, staff who have received the final dose of a primary vaccination series by the Phase 2 effective date are considered to have meet the individual vaccination requirements, even if they have not yet completed the 14-day waiting period. For example, an individual may receive the first dose of the Moderna mRNA COVID-19 Vaccine 2 or 3 days prior to the Phase 1 deadline, but must wait at least 28 days before receiving the second dose. This second dose could (and must, for purposes of this IFC) be administered prior to the Phase 2 effective date, but the individual would still be subject to meeting additional precautions as described in section II.A.3. of this IFC until 14 days had passed. This timing flexibility applies only to the initial implementation of this IFC and has no bearing on ongoing compliance. This information is also presented in Table 2.

TABLE 2: Effective Dates

	Date	New Regulatory Provisions	Corresponding Citations (42 CFR)
Phase 1	December 6, 2021	For all providers and suppliers included in this IFC, all requirements except the requirement for completion of a primary vaccination series for COVID-19.	All other provisions of this IFC, except those in Phase 2 at: § 416.51(c) § 418.60(d) § 441.151(c) § 460.74(d) § 482.42(g) § 483.80(d)(3)(v) and 483.80(i) § 483.430(f) § 483.460(a)(4)(v) § 484.70(d) § 485.58(d)(4) and 485.70(n) § 485.640(f) § 485.725(f) § 485.904(c) § 486.525(c) § 491.8(d) § 494.30(b)
Phase 2	January 4, 2022	For all providers and suppliers included in this IFC, the requirement for ensuring that all staff have completed the primary vaccination series for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or who have not completed the primary series for the vaccine received (including those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations). Staff who have completed the primary vaccination series by this date are considered to meet these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination.	§ 416.51(c)(3)(ii) § 418.60(d)(3)(ii) § 441.151(c)(3)(ii) § 460.74(d)(3)(ii) § 482.42(g)(3)(ii) § 483.80(i)(3)(ii) § 483.430(f)(3)(ii) § 484.70(d)(3)(ii) § 485.70(n)(3)(ii) § 485.640(f)(3)(ii) § 485.725(f)(3)(ii) § 485.904(c)(3)(ii) § 486.525(c)(3)(ii) § 491.8(d)(3)(ii) § 494.30(b)(3)(ii)

We note that although this IFC is being issued in response to the PHE for COVID-19, we expect it to remain relevant for some time beyond the end of the formal PHE. Depending on the future nature of the COVID-19 pandemic, we may retain these provisions as a permanent requirement for facilities, regardless of whether the Secretary continues the ongoing PHE declarations. Therefore, this rulemaking's effectiveness is not associated with or tied to the PHE declarations, nor is there a sunset clause. Pursuant to section 1871(a)(3) of the Act, Medicare interim final rules expire 3 years after issuance unless finalized. We expect to make a determination based on public comments, incidence, disease outcomes, and other factors regarding whether it will be necessary to conduct final rulemaking and make this rule permanent.

C. Enforcement

As we do with all new or revised requirements, CMS will issue interpretive guidelines, which include survey procedures, following publication of this IFC. We will advise and train State surveyors on how to assess compliance with the new requirements among providers and suppliers. For example, the guidelines will instruct surveyors on how to determine if a provider or supplier is compliant with the requirements by reviewing the entity's records of staff vaccinations, such as a list of all staff and their individual vaccination status or qualifying exemption. The guidelines will also instruct surveyors to conduct interviews staff to verify their vaccination status. Furthermore, the entity's policy and procedures will

be reviewed to ensure each component of the requirement has been addressed. We will also provide guidance on how surveyors should cite providers and suppliers when noncompliance is identified. Lastly, providers and suppliers that are cited for noncompliance may be subject to enforcement remedies imposed by CMS depending on the level of noncompliance and the remedies available under Federal law (for example, civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement). CMS will closely monitor the status of staff vaccination rates, provider compliance, and any other potential risks to patient, resident, client, and PACE program participant health and safety.

D. Residential Congregate Care Facilities

Individuals residing in congregate care settings such as LTC facilities, intermediate care facilities for individuals with intellectual disabilities (ICFs-IID), and psychiatric residential treatment facilities for individuals under 21 years of age (PRTFs), regardless of health or medical conditions, are at greater risk of acquiring infections. This higher risk applies to most bacterial and viral infections, including SARS-CoV-2. Staff working in these facilities often work across facility types (that is, LTC facilities, group homes, assisted living facilities, in home and community-based services settings, and even different congregate settings within the employer's purview), and for different providers, which may contribute to virus transmission. Other factors impacting virus transmission in these settings might include: Clients

or residents who are employed outside the congregate living setting; clients or residents who require close contact with staff or direct service providers; clients or residents who have difficulty understanding information or practicing preventive measures; and clients or residents in close contact with each other in shared living or working spaces.

1. Long Term Care Facilities (Skilled Nursing Facilities and Nursing Facilities)

Long term care (LTC) facilities, a category that includes Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities (NFs), also collectively called nursing homes, must meet the consolidated Medicare and Medicaid requirements for participation (requirements) for LTC facilities (42 CFR part 483, subpart B) that were first published in the Federal Register on February 2, 1989 (54 FR 5316). These regulations have been revised and added to since that time, principally as a result of legislation or a need to address specific issues. The requirements were comprehensively revised and updated in October 2016 (81 FR 68688), including a comprehensive update to the requirements for infection prevention and control.

CMS establishes requirements for acceptable quality in the operation of health care entities. LTC facilities are required to comply with the requirements in 42 CFR part 483, subpart B, to receive payment under the Medicare or Medicaid programs. In addition to several discrete requirements set out under sections 1819 and 1919 of the Act, Medicare- and Medicaid-participating LTC

facilities "must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary." [FN161] More specifically, the infection control requirements for LTC facilities are based on sections 1819(d)(3)(A) (for skilled nursing facilities) and 1919(d)(3)(A) (for nursing facilities) of the Act, which both require that a facility establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection.

Since the onset of the PHE, we have revised the requirements for LTC facilities through three IFCs focused on COVID-19 testing, data reporting and vaccine requirements for residents and staff. Specifically, we have published the following IFCs:

- The first IFC, "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program" (FR27550) was published on May 8, 2020. The May 8, 2020 COVID-19 IFC established requirements for LTC facilities to report information related to COVID-19 cases among facility residents and staff, we received 299 public comments. About 161, or over one-half of those comments, addressed the requirement for COVID-19 reporting for LTC facilities set forth at § 483.80(g).

- The second IFC, "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (FR54873) was published on September 2, 2020. The September 2, 2020 COVID-19 IFC strengthened CMS' ability to enforce compliance with LTC facility reporting requirements and established a new requirement for LTC facilities to test facility residents and staff for COVID-19. We received 171 public comments in response to the September 2, 2020 COVID-19 IFC, of which 113 addressed the requirement for COVID-19 testing of LTC facility residents and staff set forth at § 483.80(h).
- The third IFC, "Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff" (86FR26306) was published on May 13, 2021. We received 71 public comments in response to the May 13, 2021 COVID-19 IFC, of which most addressed the requirements for COVID-19 educating, offering, and reporting of the uptake of COVID-19 vaccine for LTC facility residents and staff set forth at §§ 483.80(d)(3) and 483.80(g)(1). In that rule, we also required the educating, offering, and recommended voluntary reporting of COVID-

19 vaccine uptake in ICFs-IID facility clients and staff set forth at §§ 483.430, Facility Staffing requirements, and 483.460, Health Care Services for Clients.

Under § 483.80(d)(3), as established in the May 13, 2021 IFC, we require LTC facilities to educate residents and staff on the COVID-19 vaccines and also to offer the vaccine, when available, to all residents and staff. The May 13, 2021 IFC also required LTC facilities to report both resident and staff vaccine uptake and status to CDC's National Healthcare Safety Network (NHSN) (§ 483.80(d)(3)(vii)); this has been a requirement since May 21, 2021. The CDC data collected under this requirement show that vaccination rates for LTC facility staff have stalled, with a 64 percent national average of vaccinated staff according to CDC data as of August 28, 2021, while the number of new LTC facility resident COVID-19 cases reported per week has risen by just over 1455 percent from recorded lows in June 2021 (323 cases in the week ending June 27, 2021; 4701 in the week ending August 22, 2021). There is wide variation among states in staff vaccination rates.

With this IFC, we are amending the requirements at § 483.80, Infection Control, by revising paragraph (d)(3)(v) by deleting the words, "or a staff member," and adding the word, "or" before "resident representative," so that the provision now reads, "the resident, or resident representative, has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision." Retaining the language permitting staff to refuse vaccination would be inconsistent with the goals of this IFC. We are further amending the requirements at § 483.80 to add a new

paragraph (i), titled "COVID-19 Vaccination of facility staff," to specify that facilities must now develop and implement policies and procedures to ensure that all staff are fully vaccinated—that is, staff for whom it has been 2 weeks or more since they completed a primary vaccination series for COVID-19, with the completion of a primary vaccination series for COVID-19 defined as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

For this rule, we have also added a new paragraph at § 483.80(i)(2), which specifies which staff for whom the requirements for staff COVID-19 vaccination will not apply: (1) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff (for whom the requirements do apply) and (2) staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with residents and other staff (for whom the requirements do apply).

Additionally, under the requirements of this IFC, we are adding § 483.80(i)(3) to now require that a facility's policies and procedures for COVID-19 vaccination of staff must include, at a minimum, the components specified in section II.A. of this IFC. New §§ 483.80(i)(3)(i) through (x) specify these required minimum components of the facility's policies and procedures.

2. Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID)

ICFs-IID are residential facilities that provide services for people with intellectual disabilities. ICF-IID clients with certain underlying medical or psychiatric conditions may be at increased risk of serious illness from COVID-19.[FN162] On March 2, 2021, CDC issued Interim Considerations for Phased Implementation of COVID-19 Vaccination and Sub Prioritization Among Recommended Populations, which notes that increased rates of transmission have been observed in these settings, and that jurisdictions may choose to prioritize vaccination of persons living in congregate settings based on local, State, tribal, or territorial epidemiology. CDC further notes that congregate living facilities may choose to vaccinate residents and clients at the same time as staff, due to numerous factors, such as convenience or shared increased risk of disease.

Sections 1905(c) and (d) of the Act gave the Secretary authority to prescribe regulations for intermediate care facility services in facilities for individuals with intellectual disabilities or persons with related conditions. The ICFs-IID Conditions of Participation were issued on June 3, 1988 (53 FR 20496) and were last updated on May 13, 2021 (86 FR 20448). There are currently 5,768 Medicare- and/or Medicaid-certified ICFs-IID. As of April 2021, 4,661 of the 5,770 are small (1 to 8 beds) in size, but there are 1,107 that are larger (14 or more beds) facilities. These facilities serve over 64,812 individuals with intellectual disabilities and other related conditions. All must qualify for Medicaid coverage. While national data about ICFs-IID clients is limited, we take an example from Florida where almost one quarter of clients (23 percent) require 24-hour nursing

services and a medical care plan in addition to their services plans.[FN163] Data from a single State are not nationally representative and thus we are unable to generalize, but it is illustrative.

Currently, the Conditions of Participation: "Health Care Services" at § 483.460(a)(4)(i) require that ICFs-IID offer clients and staff vaccination against COVID-19 when vaccine supplies are available (86 FR 26306). Based on anecdotal reports, this new requirement has not significantly increased vaccination among ICFs-IID staff. We conclude that additional regulatory action is necessary to achieve widespread vaccination among ICFs-IID staff to protect ICFs-IID clients.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 483.430(g) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

3. Psychiatric Residential Treatment Facilities (PRTFs)

PRTFs are non-hospital facilities that provide inpatient psychiatric services to Medicaid-eligible individuals under the age of 21 (also called the "psych under 21 benefit"). There are 357 PRTFs in the U.S. The facilities must meet accreditation standards, the requirements in §§ 441.151 through 441.182, and the Condition of Participation on the use of restraint and seclusion at § 483.350 through § 483.376.

Among the requirements for the psych under 21 benefit are certification of need for inpatient care and a plan of care for active treatment developed by an interdisciplinary team. The psych under 21 benefit is significant as a means for Medicaid to cover the cost of inpatient behavioral health services. The Federal Medicaid program does not reimburse states for the cost of covered services provided to beneficiaries in institutions for mental diseases (IMDs) except in specific, statutorily-authorized exceptions, including for young people who receive this service, and individuals age 65 or older served in an IMD. A PRTF provides comprehensive behavioral health treatment to children and adolescents (youth) who, due to mental illness, substance use disorders, or severe emotional disturbance, need treatment that can most effectively be provided in a residential treatment facility. PRTF programs are designed to offer a short term, intense, focused behavioral health treatment program to promote a successful return of the youth to the community.

As a congregate living setting, PRTFs are subject to many of the same elevated transmission risk factors as LTC facilities and ICFs-IID as set forth in section I. of this IFC. Section 1905(h) of the Act defines inpatient psychiatric hospital services for individuals under 21 as any inpatient facility that the Secretary has prescribed in regulations that in the case of any individual involve active treatment which meets such standards as may be prescribed in regulations by the Secretary. Implementing essential infection control practices, including vaccination, is a basic infection control treatment standard.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 441.151(c) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its clients.

E. Acute Care Settings

Acute care settings are those providers who generally provide active care for short-term medical needs. For our discussion purposes acute care settings include: Hospitals, critical access hospitals (CAHs), and ambulatory surgical centers (ASCs).

1. Hospitals

Hospitals are large health care providers that treat patients with acute care needs including emergency medicine, surgery, labor and delivery, cardiac care, oncology, and a wide variety of other services. Hospitals also administer general and specialty care that cannot safely be provided in other settings, under the supervision of physicians and licensed practitioners. They may operate as independent institutions or as part of a larger health care system or learning institution.

Section 1861(e) of the Act provides that hospitals participating in Medicare and Medicaid must meet certain specified requirements, and the Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of

the individuals who are furnished services in hospitals. Medicare-participating hospitals, which include nearly all hospitals in the U.S., must meet the Conditions of Participation (CoPs) at 42 CFR part 482, originally issued June 17, 1986. In addition to smaller updates over the years, these CoPs were reformed in 2012 (77 FR 29034). Hospital CoPs identify infection control and prevention as a basic hospital function and lay out specific requirements at 42 CFR 482.42. Infection control within a hospital campus is especially important, because hospitals treat individuals with infectious diseases (such as COVID-19) and healthy yet higher-risk individuals (for example, pregnant and post-partum individuals, infants, transplant recipients, etc.) within the same facility. Hospitals that provide emergency care must do so in accordance with the requirements of the Emergency Medical Treatment and Labor Act (EMTALA) of 1986.

Hospitals have borne the brunt of caring for patients with acute COVID-19 during the PHE. Individuals experiencing respiratory problems, cardiac events, kidney failure, and other serious effects of COVID-19 illness have required in-hospital care in large numbers, to the point of occupying or even exceeding most or all critical care or ICU capacity in a facility, city, or region. Despite emergency expansion of critical care units, these waves of severely ill patients have overwhelmed hospitals, health care systems, and the professionals and other staff who work in them. This has had the disastrous effect of limiting access and increasing risk to both routine and emergency hospital care across the U.S.[FN164, 165, 166, 167]

Transplant centers, psychiatric hospitals, and swing beds are governed by the infection control CoPs for hospitals, and are thus subject to the staff vaccination requirements issued in this IFC. We are particularly concerned about transplant center patients, who are among the most severely immunocompromised individuals due to anti-rejection medications that ensure the function of transplanted organs. An additional member of the transplant ecosystem, Organ Procurement Organizations (OPOs) coordinate and support donation, recovery, and placement of organs. As OPO staff do not provide patient care, and typically work in locations removed from health care facilities, we are not issuing vaccination requirements for OPOs in this IFC. That said, we note that the vaccination policies required in this IFC apply to all individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or other arrangement. Accordingly, OPO staff members that provide organ transplantation services directly to hospital and transplant center patients and families must meet the vaccination requirements of this IFC.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 482.42(g) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (including employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

2. Critical Access Hospitals (CAHs)

CAHs are rural hospitals that have been designated as critical access hospitals by the State, in a State that has established a State Medicare Rural Hospital Flexibility Program. These hospitals have 25 or fewer acute care inpatient beds (except as permitted for CAHs having distinct part units under § 485.647, where the beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in § 485.620(a)), must be more than 35 miles away from another hospital, and provide emergency care services 24 hours a day, 7 days a week. On average, acute patients stay in CAHs for less than 96 hours. CAHs may be granted approval to provide post-hospital skilled nursing care, may offer hospice care under the Medicare hospice benefit, and may operate a psychiatric and/or rehabilitation distinct part unit of up to 10 beds each. CAHs also administer general and specialty care that cannot safely be provided in other settings, under the supervision of physicians and licensed practitioners. They may operate as independent institutions or as part of a larger health care system. Generally, they serve to help ensure access to health-care services in rural communities.

Section 1820 of the Act sets forth the conditions for certifying a facility as a CAH to include meeting such other criteria as the Secretary may require. Medicare-certified CAHs must meet the Conditions of Participation (CoPs) at 42 CFR part 485 subpart F, originally issued May 26, 1993 (58 FR 30630). These CoPs contain specific requirements for infection control and prevention at § 485.640. Much like a standard hospital, infection control within a CAH is especially important, because CAHs treat individuals with infectious diseases (such as COVID-19) and

healthy yet higher-risk individuals (for example, pregnant and post-partum individuals, infants, transplant recipients, etc.) within the same facility.

While organ transplants are not performed in CAHs, we note that organ donors may be CAH patients, and organ donation and recovery may occur in CAHs. We note that the vaccination policies required in this IFC apply to all individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or other arrangement. Accordingly, OPO staff members that provide organ donation and transplantation services directly to CAH patients and families must meet the vaccination requirements of this IFC in the same manner as they meet such requirements for hospitals.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 485.640(f) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (including employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

3. Ambulatory Surgical Centers (ASCs)

ASCs are distinct entities that operate exclusively for the purpose of providing surgical services to patients not requiring hospitalization, and in which the expected duration of services would not exceed 24 hours following an admission. The surgical services performed in ASCs generally are scheduled, non-life-threatening procedures that can be safely performed

in either a hospital setting (inpatient or outpatient) or in an ASC. Currently, there are 6,071 Medicare-certified ASCs in the U.S.

Section 1833(i)(1)(A) of the Act authorizes the Secretary to specify those surgical procedures that can be performed safely in an ASC. Section 1832(a)(2)(F)(i) of the Act defines an ASC as a facility "which meets health, safety, and other standards specified by the Secretary in regulations . . .".

The ASC Conditions for Coverage (CfCs) at 42 CFR part 416, subpart C, are the minimum health and safety standards a center must meet to obtain Medicare certification. The ASC CfCs were issued on August 5, 1982 (47 FR 34082), and the Conditions related to infection control were last updated on November 18, 2008 (73 FR 68502, 68813). Section 416.51, Infection control, requires ASCs to maintain an infection control program that seeks to minimize infections and communicable diseases. In this IFC we are adding new § 416.51(c) which requires ASCs to meet the same COVID-19 vaccination of staff requirements as those we are issuing for the other providers and suppliers identified in this rule.

During the COVID-19 pandemic and PHE, hospitals moved many non-elective surgical procedures to ASCs and other outpatient settings. Such movement conserves hospital resources for treating severe COVID-19, performing more urgent procedures, and caring for patients with more critical health needs. Moreover, referring patients in need of suitable procedures to ASCs limits the overall number of individuals visiting the hospital setting, thereby inhibiting spread of infection. ASCs also offer an alternative setting for outpatient surgery for

individuals reluctant to enter a hospital due to fears of COVID-19 exposure. Based on these and other factors, the demand for ASC services has increased.[FN168]

In response to the COVID-19 pandemic, ASCs assumed new roles. CMS's Hospital Without Walls initiative permitted hospitals to provide inpatient care in ASCs and other temporary sites. ASCs have assisted with COVID-19 testing. They provided staff to work in COVID-19 hot spots. These efforts illustrate that staff and patients of ASCs regularly interact with staff and patients of other health care organizations and facilities.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 416.51(c) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

F. Outpatient Clinical Care & Services

These clinical settings provide necessary, ongoing care for individuals who need ongoing therapeutic, and in some cases life-sustaining, care. While many of these settings have been able to provide some services safely and effectively via telehealth during the PHE, many of the services they provide require patients and clients to see staff in person.

1. End-Stage Renal Disease (ESRD) Facilities

ESRD facilities provide a set of life-sustaining services to individuals without kidney function, including dialysis, medication, routine evaluations and monitoring, nutritional counselling, social support, and organ transplantation evaluation and referral. Section 1881(b)(1)(A) of the Act authorizes the Secretary to pay only those dialysis facilities "which meet such requirements as the Secretary shall by regulation prescribe for institutional dialysis services and supplies . . ." also known as CfCs. The ESRD facility CfCs at 42 CFR part 494 are the minimum health and safety rules that all Medicare- and Medicaid-certified dialysis facilities must meet in order to participate in the programs. The ESRD CfCs were initially issued in 1976 and were comprehensively revised in 2008 (73 FR 20370). There are currently 7,893 Medicare-certified ESRD facilities in the U.S., serving over 500,000 patients.

Routine dialysis treatments, typically delivered 3 times per week, remove toxins from a patient's blood and are necessary to sustain life. Dialysis treatments are most often delivered in the ESRD facility but can be performed by the patients themselves at home, or in the patient's nursing facility with assistance. ESRD facilities serve patients whether they are diagnosed with COVID-19 or not, and people receiving dialysis cannot always be adequately distanced from one another during treatment. In-center dialysis precludes social distancing because it involves being in close proximity (<6 feet) to caregivers and fellow patients for extended periods of time (12-15 hours per week). Because dialysis patients are not able to defer dialysis sessions, in-center dialysis patients are at increased risk for developing COVID-19 due in part to

difficulty maintaining physical distancing.[FN169] Many ESRD patients are also residents of LTC facilities or other congregate living settings, which is also a risk factor for COVID-19.[FN170] Further, individuals with kidney failure on dialysis may have a higher risk of worse outcomes.[FN171]

Dialysis health care personnel are considered a priority population for vaccination by the Advisory Committee on Immunization Practices (ACIP), yet ESRD facilities are currently reporting low COVID-19 vaccination coverage among ESRD facility health care personnel, at less than 63 percent as of September 26, 2021.[FN172] Ensuring health care personnel have access to COVID-19 vaccination is critical to protect both them and their medically fragile patients.[FN173]

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 494.30(b) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

2. Community Mental Health Centers (CMHCs)

CMHCs are entities that meet applicable enrollment requirements, and applicable licensing or certification requirements in the State in which they are located. CMHCs provide the set of mental health care services specified in section 1913(c)(1) of the PHS

Act (or, in limited circumstances, provides for such service by contract with an approved organization or entity). Section 4162 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508, enacted November 5, 1990) (OBRA 1990), which added sections 1861(ff) and 1832(a)(2)(J) to the Act, includes CMHCs as entities that are authorized to provide partial hospitalization services under Part B of the Medicare program, effective for services provided on or after October 1, 1991. Section 1861(ff)(3)(B)(iv)(I) of the Act specifically requires CMHCs providing partial hospitalization services under Medicare to meet such additional conditions as the Secretary specifies to ensure the health and safety of individuals being furnished such services. Section 1866(e)(2) of the Act and 42 CFR 489.2(c)(2) recognize CMHCs as providers of services for purposes of provider agreement requirements but only with respect to providing partial hospitalization services. Pursuant to 42 CFR 410.2 and 410.110, a CMHC may receive Medicare payment for partial hospitalization services only if it demonstrates that it provides the core services identified in the requirements. To qualify for Medicare reimbursement, CMHCs must comply with requirements for coverage of partial hospitalization services at § 410.110 and conditions for Medicare payment of partial hospitalization services at 42 CFR 424.24(e).

Currently there are 129 Medicare-certified CMHCs in the U.S. The Secretary has established in regulations, at 42 CFR part 485, subpart J, the minimum health and safety standards a CMHC must meet to obtain Medicare certification. CMHC CoPs were issued on October 29, 2013 (

Section 485.904, Personnel qualifications, establishes requirements for CMHC personnel. In this IFC we are adding new § 485.904(c) which requires the CMHC to meet the same COVID-19 vaccination of staff requirements as those we are issuing for the other providers and suppliers affected by this rule.

CMHCs provide mental health services to treat patients under the Medicare partial hospitalization program and other patients for various mental health conditions. Partial hospitalization programs provide structured, outpatient mental health services that are more intense than office visits with physicians or therapists. Patients in partial hospitalization programs receive treatment for several hours during the day, multiple days a week. In response to the PHE, CMHCs continued to treat patients by using telecommunications, and some centers paused their partial hospitalization programs or reduced the frequency and duration of treatment. However, many centers have begun to see and treat patients in person again and have resumed their customary partial hospitalization programming schedules. With increased in-person services being offered in the CMHC, it is essential to ensure all staff are vaccinated against COVID-19 not only to protect themselves but to prevent the spread of COVID-19 to CMHC patients.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 485.904(c) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who

provide care, treatment, or other services for the provider or its patients.

3. Comprehensive Outpatient Rehabilitation Facilities (CORFs)

CORFs are non-residential facilities that are established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured persons, sick persons, and persons with disabilities, at a single fixed location, by or under the supervision of a physician. In response to the PHE, outpatient rehabilitation facilities suspended operations, reduced their patient care capacity, and transitioned from in-person to telecommunications as able. However, certain rehabilitation services require physical contact with patients, such as fitting or adjusting a prosthesis or assistive device and assessing strength with manual resistance. During the pandemic, some patients in need of rehabilitation chose to delay care and others encountered delays in accessing care. These delays likely contributed to increased disability or illness.[FN174] Moreover, patients admitted to the hospital have been discharged as soon as possible to provide beds for individuals with more critical conditions, including COVID-19. For those patients recovering from severe COVID-19 illness with long-term symptoms, prompt comprehensive outpatient rehabilitation services upon their discharge from inpatient care is necessary to restore physical and mental health.[FN175] All of these factors stress the importance of rehabilitation facilities who are treating patients with increased

morbidity and complex needs. CORFs have resumed operations and are providing services to an increasing number of patients; therefore, COVID-19 vaccination of staff is pivotal for inhibiting spread of infection and ensuring health and safety of patients.

Currently, there are 159 Medicare-certified CORFs in the U.S. Section 1861(cc)(2)(J) of the Act states that the CORF must "meet such conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility, including conditions concerning qualifications of personnel in these facilities." Under this authority, the Secretary has established in regulations, at 42 CFR part 485, subpart B, the minimum health and safety standards a CORF must meet to obtain Medicare certification. The CORF Conditions of Participation were issued on December 15, 1982 (47 FR 56282). Section 485.70, Personnel qualifications, sets forth the qualifications that various personnel must meet, as a condition of participation. We are adding a new paragraph (n) at § 485.70 which requires the CORF to meet the same COVID-19 vaccination of staff requirements as those we are issuing for the other providers and suppliers identified in this rule.

Our rules at § 485.58(d)(4), state that personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. We recognize this sentence is inconsistent with newly added § 485.70(n) which requires vaccination of all facility staff. We also recognize that assisting personnel are used by CORFs. We established our requirements at § 485.70 (a) through (m) to provide a role for personnel that

might not meet our education and experience qualifications. We do not believe that this exception for employees that do not meet our professional requirements should prohibit us from issuing staff qualifications referencing infection prevention, which we intend to apply to all personnel. Hence, we are revising § 485.58(d)(4) to state that personnel that do not meet the qualifications specified in § 485.70(a) through (m) may be used by the facility in assisting qualified staff. However, such assisting staff will not be exempt from the newly added requirements in paragraph (n).

As with other parallel regulations for our facilities, we are revising § 485.58(d)(4) as previously discussed. For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 485.70(n) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

4. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Section 1861(aa) and 1905(l)(2)(B) of the Act sets forth the RHC and FQHC services covered by the Medicare program; section 1905(l) cross-references the Medicare provision for Medicaid program purposes. The Act requires that RHCs be located in an area that is both rural and underserved, are not rehabilitation agencies or facilities primarily for the

care and treatment of mental diseases, and meet such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic. Likewise, 42 CFR 491.2 defines a FQHC as an entity as defined in § 405.2401(b). The definition at § 405.2401 includes an entity that has entered into an agreement with CMS to meet Medicare Program requirements under § 405.2434. And at 42 CFR 405.2434, the content and terms of the agreement require FQHCs to maintain compliance with requirements set forth in part 491, except the provisions of § 491.3 Certification procedures. Conditions for certification for RHCs and Conditions of Coverage for FQHCs are found at 42 CFR part 491, subpart A.

RHCs and FQHCs, as essential contributors to the health care infrastructure in the U.S., provide care and services to medically underserved areas and populations. They play a critical role in helping to alleviate access to care barriers and health equity gaps in these communities. RHCs and FQHCs provide primary care, diagnostic laboratory, and immunization services, and they have incorporated COVID-19 screening, triage, testing, diagnosis, treatment, and vaccination into these services. However, the medically underserved communities in the U.S. have been disproportionately affected by COVID-19. Hence, the Health Resources and Services Administration (HRSA) has established new programs to help RHCs and FQHCs meet the needs of their communities and ensure continuity of health care services during the PHE.[FN176, 177,,178] For example: (1) The Rural Health Clinic COVID-19

Testing and Mitigation Program which helps RHCs with COVID-19 testing and mitigation strategies to prevent the spread of infection; (2) the Rural Health Clinic Vaccine Distribution Program which strengthens COVID-19 vaccine allocations for RHCs; (3) the Rural Health Clinic Vaccine Confidence Program that helps RHCs with outreach efforts to improve vaccination rates in rural areas with nearly 2,000 RHCs across the nation participating; (4) the Health Center COVID-19 Vaccine Program whereby FQHCs receive direct allocations of vaccines; (5) the Department of Defense (DoD) and HHS partnered to provide point-of-care rapid COVID-19 testing supplies to FQHCs through the Health Center COVID-19 Testing Supply Distribution Program; and (6) delivery of 5.1 million adult and 7.4 million child masks between April and August 2021 to FQHCs at no cost for subsequent distribution to patients, staff, and community members. To implement these programs and to provide services and care, RHC/FQHC staff must interact with patients and members of the community at large. Hence, a requirement for these staff to receive COVID-19 vaccination is necessary to assure health and safety for the individuals residing in their respective service areas and their patients.

Currently, there are 4,933 Medicare-and Medicaid-certified RHCs and 10,384 FQHCs that participate in the Medicare and Medicaid programs in the U.S. The Conditions at 42 CFR part 491, subpart A are the minimum health and safety standards a center or clinic must meet to participate in the Medicare and Medicaid programs. The conditions were issued on June 12, 1992 (57 FR 27106), and the conditions related to staffing and staff responsibilities

were last updated on May 12, 2014 (79 FR 27106). Section 491.8, Staffing and staff responsibilities, establishes requirements for RHC and FQHC staffing and staff responsibilities. We are adding new § 491.8(d) which requires the clinic or center to meet the same COVID-19 vaccination of staff requirements as those we are issuing for the other providers and suppliers identified in this rule.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 491.8(d) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

5. Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

Under the authority of section 1861(p) of the Act, the Secretary has established CoPs that clinics, rehabilitation agencies, and public health agencies (collectively, "organizations") must meet when they provide outpatient physical therapy (OPT) and speech-language pathology (SLP) services. Under section 1861(p) of the Act, the Secretary is responsible for ensuring that the CoPs and their enforcement are adequate to protect the health and safety of individuals receiving OPT and SLP services from these entities. The CoPs are set forth at 42 CFR part

485, subpart H. Section 1861(p) of the Act describes outpatient physical therapy services to mean physical therapy services furnished by a provider of services, a clinic, rehabilitation agency, or a public health agency, or by others under an arrangement with, and under the supervision of, such provider, clinic, rehabilitation agency, or public health agency to an individual as an outpatient. The patient must be under the care of a physician. The term "outpatient physical therapy services" also includes physical therapy services furnished to an individual by a physical therapist (in the physical therapist's office or the patient's home) who meets licensing and other standards prescribed by the Secretary in regulations, other than under arrangement with and under the supervision of a provider of services, clinic, rehabilitation agency, or public health agency. Pursuant to the statutory requirement set out at section 1861(p)(4)(A) and (B) of the Act, the furnishing of such services by a clinic, rehabilitation agency, or public health agency must meet such conditions relating to health and safety as the Secretary may find necessary. The term also includes SLP services furnished by a provider of services, a clinic, rehabilitation agency, or by a public health agency, or by others under an arrangement.

Currently, there are 2,078 clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language services. In the remainder of this rule and throughout the requirements, we use the term "organizations" instead of "clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services" for

consistency with current regulatory language. Patients receive services from organizations due to loss of functional ability associated with injury or illness. Hence, these patients experience episodic issues and seek care to restore their level of functioning and wellness to baseline. In response to the PHE, organizations experienced a reduction in patients. They supplemented in-person care with telecommunications. However, just over 50 percent of physical therapists report in-person care results in better outcomes than care provided virtually and the majority of patients are less satisfied with care received by telecommunications.[FN179] Although the data is limited, we believe these findings are consistent with other therapeutic services including occupational therapy and speech pathology. Comprehensive assessment of balance, strength, range-of-motion, and proper exercise technique is supported by physical touch, and three-dimensional visualization of the patient. Organizations have begun seeing more patients, and those patients are presenting with more severe functional issues. Organizations care for patients recovering from COVID-19 and those who delayed receiving non-COVID-19 related care due to fears of exposure to illness after the onset of the pandemic. These factors underscore the need to ensure safety and health of individuals who receive care from organizations with a requirement for COVID-19 vaccination of staff.

The CoPs for organizations at 42 CFR part 485, subpart H are the minimum health and safety standards an organization must meet to obtain Medicare certification. The CoPs were first issued May 21, 1976 (41 FR 20863), and the Conditions

related to infection control were last updated on September 29, 1995 (60 FR 50446). Section 485.725, Infection control, requires organizations to establish an infection-control committee with responsibility for overall infection control. We are adding new paragraph (f) to § 485.725, which requires the organizations to meet the same COVID-19 vaccination of staff requirements as those we are issuing for the other providers and suppliers identified in this rule.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 485.725(f) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

G. Home-Based Care

Home-based care providers provide necessary care and services for individuals who need ongoing therapeutic, and in some cases life-sustaining, care. These settings require that health care staff enter the patient's personal home (regardless of location in a private home, assisted living facility, or another setting) to provide services and care in person, thus exposing patients and other members of their household, to the staff. Home-based provider staff also often serve multiple patients in different homes in the same day, week, or month, which presents opportunities for transmission of infectious diseases

across households. Because home-based providers work outside of a regulated health care facility, there is also the potential for staff to either not use the appropriate PPE or use it improperly because on-site oversight mechanisms are not in place, that could increase the risk of transmission of COVID-19 or other infectious diseases across households. We also believe these patients are especially vulnerable to COVID-19 due to receiving care in their homes. Many patients have serious illnesses that increases the risk of morbidity and mortality from COVID-19. For hospice patients that are receiving non-curative but supportive care, we are concerned that contracting COVID-19 could increase their discomfort, decrease their quality of life, or perhaps even hasten their death. In addition, the patients' homes may have poor ventilation or members of the household may not be complying with recommended safety precautions. Thus, COVID-19 vaccination mandates will provide patients and their household members with safety assurances that will facilitate acceptance of home care services, and will protect the patients, staff, and the other members of the patients' households.

1. Home Health Agencies (HHAs)

Under the authority of sections 1861(m), 1861(o), and 1891 of the Act, the Secretary has established in regulations the requirements that a home health agency (HHA) must meet to participate in the Medicare program, our regulations at 42 CFR 440.70(d) require that Medicaid-participating home health agencies meet Medicare conditions of participation. Section 1861(o)(6) of the Act requires

that home health agencies "meet the conditions of participation specified in section 1891(a) and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization." The CoPs for home health services are found in Title 42, Part 484, subparts A through C, §§ 484.40 through 484.115. HHAs provide care and services for qualifying older adults and people with disabilities who are beneficiaries under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program. These services include skilled nursing care, physical, occupational, and speech therapy, medical social work and home health aide services which must be furnished by, or under arrangement with, an HHA that participates in the Medicare program and must be provided in the beneficiary's home. As of September 1, 2021, there were 11,649 HHAs participating in the Medicare program. The majority of HHAs are for-profit, privately owned agencies. The effective delivery of quality home health services is essential to the care of the HHA's patients to provide necessary care and services and prevent hospitalizations. Since patients and other members of their households will be exposed to HHA staff, it is essential that staff be vaccinated against COVID-19 for the safety of the patients, members of their households, and the staff themselves.

With so many patients depending on the services of HHAs nationwide, it is imperative that HHAs have processes in place to address the safety of patients and staff and the continued provision of services. Because these patients are at home, essential care must be

provided, regardless of COVID-19 vaccination or infection status. In addition, by going into patients' homes, HHA employees are exposed to numerous individuals who might not be vaccinated or perhaps are asymptomatic but infected. Therefore, it is imperative that HHAs have appropriate procedures to ensure the continued provision of care and services for their patients. Section 484.70 Condition of participation: Infection prevention and control (a) requires that the "HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases."

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 484.70(d) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

2. Hospice

Section 122 of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97-248, enacted September 3. 1982) (TEFRA), added section 1861(dd) to the Act to provide coverage for hospice care to terminally ill Medicare beneficiaries who elect to receive care from a Medicare-participating hospice. Under the authority of section 1861(dd) of the Act, the Secretary has established the CoPs that a hospice must meet in order to participate in Medicare and

Medicaid. Under section 1861(dd)(2)(G) of the Act, the Secretary may impose "such requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization." The CoPs found at part 418, subparts C and D apply to a hospice, as well as to the services furnished to each patient under hospice care. These requirements are set forth in §§ 418.52 through 418.116.

Hospice care provides palliative care rather than curative treatment to terminally ill patients. Palliative care improves the quality of life of patients and their families and caregivers facing the challenges associated with terminal illness through the prevention and relief of suffering by means of early identification, assessment, and treatment of pain and other issues. Hospice care allows the patient to remain at home by providing support to the patient and family and caregiver and by keeping the patient as comfortable as possible while maintaining his or her dignity and quality of life. Hospices use an interdisciplinary approach to deliver medical, social, physical, emotional, and spiritual services through the use of a broad spectrum of support.

Hospices are unique health care providers because they serve patients, families, and caregivers in a wide variety of settings. Hospice patients may be served in their place of residence, whether that residence is a private home, an LTC facility, an assisted living facility, or even a recreational vehicle, as long as such locations are determined to be the patient's place of residence. Hospice patients may also be served in inpatient facilities, including those operated by the hospice itself.

With so many patients depending on the services of hospice services nationwide, it is imperative that hospices have processes in place to address the safety of patients and staff and the continued provision of services. The goal of hospice care is to provide non-curative, but supportive care of an individual during the final days, weeks, or months of a terminal illness. Contracting any infectious disease, especially COVID-19, could result in additional pain or perhaps even accelerate a patient's death. Thus, it is critical that hospices protect patients and staff from contracting or transmitting COVID-19. As of September 1, 2021, there were 5,556 hospices. Section 418.60(a), Condition of participation: Infection Control, requires that the "hospice must follow accepted standards of practice to prevent the transmission of infections and communicable disease, including the use of standard precautions."

The effective delivery of hospice services is essential to the care of the hospice's patients and their families and caregivers. Since patients and other members of their households will be exposed to hospice staff, it is essential that staff be vaccinated against COVID-19 for the safety of the patients, members of their households, and the staff themselves.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 418.60(d) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (including employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who

provide care, treatment, or other services for the provider or its patients.

3. Home Infusion Therapy Suppliers (HIT) Suppliers

Section 5012 of the 21st Century Cures Act (Pub. L. 114-255, enacted December 13, 2016) (Cures Act) created a separate Medicare Part B benefit category under 1861(s)(2)(GG) of the Act for coverage of home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously for periods of 15 minutes or more in the patient's home through a pump that is an item of durable medical equipment. Section 1861(iii)(3)(D)(i)(IV) of the Act requires qualified home infusion therapy (HIT) suppliers to meet, in addition to specified qualifications, "such other requirements as the Secretary determines appropriate." The regulatory requirements for home therapy infusion (HIT) suppliers are located at 42 CFR part 486, subpart I, §§ 486.500 through 486.525.

The nature of the home setting presents different challenges than in-center services as well as the administration of the particular medications. The items and equipment needed to perform home infusion include the drug (for example, immune globulin), equipment (a pump), and supplies (for example, tubing and catheters) which are covered under the Durable Medical Equipment benefit. Skilled professional visits, such as those from nurses, often play a critical role in the provision of home infusion and are covered under the home infusion therapy benefit. For example, nurses typically train

the patient or caregiver to self-administer the drug, educate on side effects and goals of therapy, and visit periodically to provide catheter and site care. Depending on patient acuity or the complexity of the drug administration, certain skilled professional visits may require more time. The HIT infusion process typically requires coordination among multiple entities, including patients, the responsible physicians and practitioners, hospital discharge planners, pharmacies, and, if applicable, home health agencies.

The current requirements for HIT suppliers do not contain specific infection prevention and control requirements. However, § 486.525, Required services, does state that these providers must "provide home infusion therapy services in accordance with nationally recognized standards of practice, and in accordance with all applicable state and federal laws and regulations." We believe that "nationally recognized standards of practice" include appropriate policies and procedures for infection prevention and control.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding a new regulatory requirement at § 486.525(c) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services for the provider or its patients.

4. Programs of All-Inclusive Care for the Elderly (PACE) Organizations

The Programs of All-Inclusive Care for the Elderly (PACE) program provides a model of managed care service delivery for frail older adults, most of whom are dually eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for LTC facility placement according to the Medicaid standards established by their respective states. PACE organizations furnish comprehensive medical, health, and social services that integrate acute and long-term care, and these services must be furnished in at least the PACE center, the home, and inpatient facilities. The PACE model involves a multidisciplinary team of providers known as the interdisciplinary team (IDT) that comprehensively assesses and meets the needs of each PACE participant by planning and coordinating all participant care. PACE organizations must provide all Medicare-covered items and services, all Medicaid-covered items and services, and any other services determined necessary by the IDT to improve and maintain the participant's overall health status, either directly or under contract with third party service providers.

The statutory authorities that permit Medicare payments and coverage of benefits under the PACE program, as well as the establishment of PACE organizations as a State option under Medicaid to provide for Medicaid payments and coverage of benefits under the PACE program, are under sections 1894 and 1934 of the Act. These statutory authorities are implemented at 42 CFR part 460, where CMS has set out the minimum requirements an entity must meet to operate a PACE program under Medicare and Medicaid.

There are 141 PACE organizations nationally. These organizations serve approximately 52,000 participants, all in need of the comprehensive services provided by PACE organizations. Due to their health status, PACE participants are at high risk of severe COVID-19 and as such have been among the populations prioritized for vaccination since the vaccines were authorized. Participants' regular interactions with PACE organization staff and contractors indicate that those staff and contractors should also be vaccinated against COVID-19.

For these reasons and the reasons set forth in section II.A. of this IFC, we are adding new regulatory requirements at § 460.74(d) related to establishing and implementing policies and procedures for COVID-19 vaccination of all staff (includes employees; licensed practitioner; students, trainees, and volunteers; and other individuals) who provide care, treatment, or other services on behalf of a PACE organization.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule before the provisions of the rule take effect, in accordance with the Administrative Procedure Act (APA), 5 U.S.C. 553, and section 1871 of the Act. Specifically, section 553(b) of the APA requires the agency to publish a notice of the proposed rule in the Federal Register that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the

subjects and issues involved. Section 553(c) further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the Federal Register and a period of not less than 60 days for public comment. Section 553(b)(B) of the APA and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures, however, if the agency finds good cause that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

The 2021 outbreaks associated with the SARS-Cov-2 Delta variant have shown that current levels of COVID-19 vaccination coverage up until now have been inadequate to protect health care consumers and staff. The data showing the vital importance of vaccination indicate to us that we cannot delay taking this action in order to protect the health and safety of millions of people receiving critical health care services, the workers providing care, and our fellow citizens living and working in communities across the nation.

Although section 564 of the FDCA does not prohibit public or private entities from imposing vaccination requirements, even when the only vaccines available are those authorized under EUAs (https://www.justice.gov/olc/file/1415446/download), CMS initially chose, among other actions, to encourage rather than mandate vaccination, believing that a combination of other Federal actions, a variety

of public education campaigns, and State and employer-based efforts would be adequate. However, despite all of these efforts, including CMS's mandate for vaccination education and offering of vaccines to LTC facility and ICF-IID staff, residents, and clients (86 FR 26306), OSHA's June 21, 2021 ETS to protect health care and health care support service workers from occupational exposure to COVID-19 (86 FR 3276), and ongoing CDC information and encouragement, vaccine uptake among health care staff has not been as robust as hoped for and have been insufficient to protect the health and safety of individuals receiving health care services from Medicare- and Medicaid-certified providers and suppliers, particularly given the advent of the Delta variant and the potential for new variants.

As discussed throughout the preamble of this IFC, the PHE continues to strain the U.S. health care system. Over the first 6 months of 2021, COVID-19 cases, hospitalizations and deaths declined. The emergence of the Delta variant reversed these trends.[FN180] Between late June 2021 and September 2021, daily cases of COVID-19 increased over 1200 percent; new hospital admissions, over 600 percent; and daily deaths, by nearly 800 percent.[FN181] Available data also continue to suggest that the majority of COVID-19 cases and hospitalizations are occurring among individuals who are not fully vaccinated. From January through May 2021, of the more than 32,000 laboratory-confirmed COVID-19-associated hospitalizations in adults over 18 years of age for whom vaccination status is known, less than 3 percent of hospitalizations occurred in fully vaccinated persons.[FN182] More recently

published data continue to suggest that fully vaccinated persons account for a minority (□10 percent) of COVID-19 related hospitalizations.[FN183] For all adults aged 18 years and older, the cumulative COVID-19-associated hospitalization rate was about 12-times higher in unvaccinated persons.[FN184] Consequently, some hospitals and health care systems are currently experiencing tremendous strain due to high case volume coupled with persistent staffing shortages due, at least in part, to COVID-19 infection or quarantine following exposure.

We recognize that newly reported COVID-19 cases, hospitalizations, and deaths have begun to trend downward at a national level; nonetheless, they remain substantially elevated relative to numbers seen in May and June 2021, when the Delta variant became the predominant strain circulating in the U.S.[FN185] And while cases are trending downward in some states, there are emerging indications of potential increases in others—particularly northern states where the weather has begun to turn colder. This is not surprising: Respiratory virus infections typically circulate more frequently during the winter months, with peaks in pneumonia and influenza deaths typically during winter months.[FN186] Similarly, the U.S. experienced a large COVID-19 wave in the winter of 2020. Approximately 1 in 3 people 12 years of age and older in the U.S. remain unvaccinated—and they could pose a threat to the country's progress on the COVID-19 pandemic, potentially incurring a fifth wave of COVID-19 infections.[FN187]

The onset of the 2021-2022 influenza season presents an additional threat to patient health and safety. Although influenza activity during the 2020-2021 season was low throughout the U.S.,[FN188] the intensity of the upcoming 2021-2022 influenza season cannot be predicted. Several factors could make this flu season more severe; these include return to school by children with no prior exposure to flu (and therefor lower immunity), waning protection over time from previous seasonal influenza vaccination, and the fact that adult immunity (especially among those who were not vaccinated last season) will now partly depend on exposure to viruses two or more seasons earlier.[FN189, 190] COVID-19 vaccination thus remains an important tool for decreasing stress on the U.S. health care system during ongoing circulation of influenza. As previously noted, health system strain can adversely impact patient access to care and care quality.

Furthermore, data on the health consequences of coinfection with influenza and SARS-CoV-2 are limited. Preliminary evidence suggests that a combination of infections with influenza and SARS-CoV-2 would result in more severe health outcomes for patients than either infection alone.[FN191, 192, 193] However, COVID-19 is more infectious and has greater rates of mortality, hospitalizations, and severe illness than influenza. Accordingly, it is imperative that the risk for healthcare-associated COVID-19 transmission be minimized during the influenza season. Influenza is most common during the fall and winter with the highest incidence of cases reported between December through March.[FN194] COVID-19 vaccines require time after administration

for the body to build an immune response. Hence, given that the influenza season is imminent, a staff COVID-19 vaccination requirement for the providers and suppliers identified in this rule cannot be further delayed. The impact of unvaccinated populations on the health-care system and the inconsistent web of State, local, and employer COVID-19 vaccination requirements have established a pressing need for a consistent Federal policy mandating staff vaccination in health care settings that receive Medicare and Medicaid funds. The current patchwork of regulations undermines the efficacy of COVID-19 vaccine mandates by encouraging unvaccinated workers to seek employment at providers that do not have such patient protections, exacerbating staffing shortages, and creating disparities in care across populations. This includes workers moving between various types of providers, such as from LTC facilities to HHAs and others, creating imbalances. As discussed in section I. of this IFC, we have received numerous requests from diverse stakeholders for Federal intervention to implement a health-care staff vaccine mandate.[FN195] Of particular note, several representatives of the long-term care community (not limited to Medicare- and Medicaid-certified LTC facilities) expressed concerns about inequities that would result from imposition of a mandate on only one type of provider and strongly recommended a broad approach.[FN196] While there is opposition to the vaccine mandate, a combination of factors now have persuaded us that a vaccine mandate for health care workers is an essential component of the nation's COVID-19 response, the delay of which would contribute to additional negative health outcomes for

patients including loss of life. These include, but are not limited to, the following: Failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements; ongoing risk of new COVID-19 variants; potential harmful impact of unvaccinated healthcare workers on patients; continuing strain on the health care system, particularly from Delta-variant-driven surging case counts beginning in summer 2021; demonstrated efficacy, safety and real-world effectiveness of available vaccines; FDA's full licensure of the Pfizer-BioNTech's Comirnaty vaccine; our observations of the efficacy of COVID-19 vaccine mandates in other settings; and the calls from numerous stakeholders for Federal intervention. Moreover, a further delay in imposing a vaccine mandate would endanger the health and safety of additional patients and be contrary to the public interest.

We note that health care workers were among the first groups provided access to vaccinations, which were initially authorized for emergency use. EUA status may have been a factor in some individual decisions to delay or refuse vaccination. The Pfizer-BioNTech COVID-19 vaccine was first authorized for emergency use on December 11, 2020. The vaccine continues to be available in the U.S. under EUA, and the EUA was subsequently amended to include use in individuals 12 through 15 years of age, to allow for the use of an additional dose in the primary series for certain immunocompromised individuals, and to allow for use of a single booster dose to be administered at least 6 months after completion of the primary series in certain individuals. FDA has issued

EUAs for two additional vaccines for the prevention of COVID-19, one to Moderna (December 18, 2020) (indicated for use by individuals 18 years of age and older), and the other to Janssen (Johnson & Johnson) (February 27, 2021) (indicated for use by individuals 18 years of age and older). Fact sheets for health care providers administering vaccine are available for each vaccine product from FDA. However, on August 23, 2021, FDA licensed Pfizer-BioNTech's Comirnaty Vaccine. Health care workers whose hesitancy was related to EUA status now have a fully licensed COVID-19 vaccine option. Despite this, as noted earlier, health care staff vaccination rates remain sub-optimal in too many health care facilities and regions. For example, national COVID-19 vaccination rates for LTC facility, hospital, and ESRD facility staff are 67 percent, 64 percent, and 60 percent, respectively. Moreover, these averages obscure sizeable regional differences. LTC facility staff vaccination rates range from lows of 56 percent to highs of over 90 percent, depending upon the State. Similar patterns hold for ESRD facility and hospital staff. [FN197, 198, 199].

Over half a million COVID-19 cases and 1,900 deaths among health care staff have been reported to CDC since the start of the PHE.[FN200] When submitting case-level COVID-19 reports, State and territorial jurisdictions may identify whether individuals are or are not health care workers. Since health care worker status has only been reported for a minority of cases (approximately 18 percent), these numbers are likely gross underestimates of true burden in this population. COVID-19 case rates among staff have also grown in tandem with broader

national incidence trends since the Delta variant's emergence. For example, as of mid-September 2021, COVID-19 cases among LTC facility and ESRD facility staff have increased by over 1400 percent and 850 percent, respectively, since their lows in June 2021.[FN201] Similarly, the number of cases among staff for whom case-level data were reported by State and territorial jurisdictions to CDC increased by nearly 600 percent between June and August 2021.[FN202] Because they are at greater risk for developing COVID-19 infection and severe disease [FN 203, 204, 205] unvaccinated staff present a risk of exacerbating ongoing staffing shortages—particularly during periods of community surges in SARS-CoV-2 infection, when demand for health care services is most acute. Health care staff who remain unvaccinated may also pose a direct threat to patient, resident, workplace, family, and community safety and population health. Data from CDC's National Healthcare Safety Network (NHSN) have shown that case rates among LTC facility residents are higher in facilities with lower vaccination coverage among staff; specifically, residents of LTC facilities in which vaccination coverage of staff is 75 percent or lower experience higher crude rates of preventable SARS-CoV-2 infection.[FN206] Similarly, several articles published in CDC's Morbidity and Mortality Weekly Reports (MMWRs) regarding nursing home outbreaks have also linked the spread of COVID-19 infection to unvaccinated health care workers and stressed that maintaining a high vaccination rate is important for reducing transmission [FN207, 208, 209] And multiple studies have demonstrated SARS-CoV-2 transmissions between health-care workers and

patients in hospitals, despite universal masking and other protocols [FN210, 211, 212, 213] Acute and LTC facilities engage many, if not all, of the same health care professionals and support services of other provider and supplier types. As a result, while similarly comprehensive data are not available for all Medicare- and Medicaid-certified provider and supplier types, we believe the LTC facilities experience may generally be extrapolated to other settings.

The efficacy of COVID-19 vaccinations has been demonstrated.[FN214] An ASPE report published on October 5, 2021, found that COVID-19 vaccines are a key component in controlling the COVID-19 pandemic. Clinical data show vaccines are highly effective in preventing COVID-19 cases and severe outcomes including hospitalization and death. The ASPE analysis of individual-level health data and county-level vaccination rates found that higher county vaccination rates were associated with significant reductions in the odds of COVID-19 infection, hospitalization, and death among Medicare fee-for-service (FFS) beneficiaries between January and May 2021. Further, comparing the rates of these outcomes to what ASPE modeling predicted would have happened without any vaccinations, we estimate COVID-19 vaccinations were linked to estimated reductions of approximately 107,000 infections, 43,000 hospitalizations, and 16,000 deaths in our study sample of 25.3 million beneficiaries. The report also noted that the difference in vaccination rates for those age 65 and older between the lowest (34 percent) and highest (85 percent) counties and states by the end of May highlights the continued opportunity to

leverage COVID-19 vaccinations to prevent COVID-19 hospitalizations and deaths.[FN215] Vaccines continue to be effective in preventing COVID-19 associated with the now-dominant Delta variant.[FN216, 217]

In addition to preventing morbidity and mortality associated with COVID-19, the vaccines also appear to be effective against asymptomatic SARS-CoV-2 infection. A recent study of health care workers in 8 states found that, between December 14, 2020, through August 14, 2021, full vaccination with COVID-19 vaccines was 80 percent effective in preventing RT-PCR-confirmed SARS-CoV-2 infection among frontline workers.[FN218] Emerging evidence also suggests that vaccinated people who become infected with Delta have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk.[FN219] For example, in a study of breakthrough infections among health care workers in the Netherlands, SARS-CoV-2 infectious virus shedding was lower among vaccinated individuals with breakthrough infections than among unvaccinated individuals with primary infections.[FN220]

As noted earlier in this section, a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to patients from unvaccinated health-care workers, and continuing strain on the health care system and known efficacy and safety of available vaccines, have persuaded us that a vaccine mandate for health care workers is an essential component of the nation's COVID-19 response. Further, it would

endanger the health and safety of patients, and be contrary to the public interest to delay imposing it. Therefore, we believe it would be impracticable and contrary to the public interest for us to undertake normal notice and comment procedures and to thereby delay the effective date of this IFC. We find good cause to waive notice of proposed rulemaking under the APA, 5 U.S.C. 553(b)(B), and section 1871(b)(2)(C) of the Act. For those same reasons, as authorized by the Small Business Regulatory Enforcement Fairness Act of 1996 (the Congressional Review Act or CRA), 5 U.S.C. 808(2), we find it is impracticable and contrary to the public interest not to waive the delay in effective date of this IFC under section 801 of the CRA. Therefore, we find there is good cause to waive the CRA's delay in effective date pursuant to section 808(2) of the CRA.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the Federal Register and solicit public comment before a collection of information requirement (ICR) is submitted to the Office of Management and Budget (OMB) for review and approval. The ICRs in this section will be included in an emergency revision of the information collection request currently approved under the appropriate OMB Control number. All PRA-related comments received in response to this IFC will be reviewed and addressed in a subsequent, non-emergency, submission of the information collection request. The emergency approval is only valid for 6 months. Within that 6-month approval

period, CMS will seek a regular, non-emergency, approval and as required by the PRA, this action will be announced in the requisite 60-day and 30-day Federal Register notices.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

For the estimated costs contained in the analysis below, we used data from the U.S. Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the positions used in this analysis.[FN221] For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. The total costs used in this analysis are indicated in Table 3.

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TABLE 3: Summary Information of Estimated Mean Hourly and Adjusted Hourly Wages

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1228	Physicians, All Others; and Ophthalmologist, except Pediatric) (General Medical and Surgical Hospitals)	LTC Facility Medical Director	$85.70	$171
29-1141	Registered Nurses (Nursing Facilities/ Skilled Nursing Facilities)	LTC Facility Registered Nurse (RN): LTC Facility Infection Preventionist (IP); ICFs-IID RN	$34.66	$69
29-1141	Registered Nurses (Home Health Care Services)	HHA RN; RN HIT; ESRD RN	$36.48	$73
29-1141	Registered Nurses (General Medical and Surgical Hospitals)	RN Hospice; RN Hospital; RN CAH	$39.27	$79
29-1141	Registered Nurses (Psychiatric and Substance Abuse Hospitals)	RN PRTF	$37.14	$74
11-9111	Medical and Health Services Managers (Nursing Facilities/Skilled Nursing Facilities)	LTC Facility Director of Nursing (DON); ICFs-IID Administrator	$48.15	$96
11-9111	Medical and Health Services Managers (General Medical and Surgical Hospitals)	Hospice Administrator; Hospital Administrator; Hospital DON; CAH DON; CAH Administrator; PRTF Administrator	$61.22	$122
11-9111	Medical and Health Services Managers (Home Health Care Services)	HHA Administrator; HIT Administrator; ESRD Administrator	$48.50	$97
29-1215	Family Medicine Physicians (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Physician and Medical Director	$105.75	$212

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage ($/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) ($/hour) (rounded to nearest dollar)
29-1071	Physician Assistants (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Physician Assistant	$55.34	$111
29-1171	Nurse Practitioners (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Nurse Practitioner	$53.51	$107
29-1123	Physical Therapists (Ambulatory Health Care Services, Offices of Other Health Practitioners)	Physical Therapist	$41.91	$84
29-1141	Registered Nurses (national mean hourly wage)	Ambulatory Surgery Center (ASC) Infection Control Professional (ICP)	$38.47	$77
11-9111	Medical and Health Services Managers (Ambulatory Health Care Services, Offices of Physicians)	Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Administrator	$54.18	$108
11-9111	Medical and Health Services Managers (Ambulatory Health Care Services, Outpatient Care Centers)	Community Mental Health Center (CHMC) Administrator	$56.34	$113
11-9111	Medical and Health Services Managers (Ambulatory Health Care Services, Other Ambulatory Health Care Services)	Ambulatory Surgery Center (ASC) Administrator, Organization Administrator, and Comprehensive Outpatient Rehabilitation Facility (CORF) Administrator	$49.03	$98
29-9092	General Counselors (Ambulatory Health Care Services, Outpatient Care Centers)	Community Mental Health Center (CHMC) Mental Health Counselor	$59.17	$118

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In this analysis, we used specific resources to estimate the burden for the providers and suppliers in this rule. Based upon our experience, there are minimal fluctuations in the numbers of providers and suppliers monthly. Thus, unless otherwise indicated, all of the numbers for the providers and suppliers in this analysis were located on September 1, 2021 on the Quality, Certification & Oversight Reports (QCOR) website at https://qcor.cms.gov/main.jsp. For the number of employees for each provider and supplier, those numbers were obtained from Table 5: Estimates of Number of Staff by Type of Provider (thousands) located in section VI.B. of this IFC.

This analysis is also based upon certain assumptions. We believe that many of the providers and suppliers covered in this rule have already either encouraged their employees to get vaccinated for COVID-19 or have mandates for the vaccine. Mandates for employees to be vaccinated for COVID-19 can result from State, county, or local actions or result from a decision by the facility. These facilities would likely have already developed policies and procedures, as well as documentation requirements, related to their employees being vaccinated for COVID-19. However, we have no reliable method to estimate the number or percentage of these facilities. In addition, it is likely that those facilities would not comply with all of the requirements in this rule. For example, many facilities might not define "employees" as set forth in this rule. Each facility would have to review its policies, procedures, and documentation requirements to ensure that they comply with the requirements in this rule. Hence, based upon these assumptions, this analysis will assess the burden for

all facilities and employees for each provider and supplier type.

We also made some assumption regarding analysis of the burden for the documentation requirements. If an employee receives the appropriate vaccinations, reviewing and documenting that the employee has been vaccinated would likely only require 1 to 3 minutes, depending upon how the facility is documenting the vaccination, which is likely to vary substantially between facilities. However, for employees that request exemptions or have to be contacted repeatedly for the appropriate documentation, it would likely take more time to comply with this requirement. At a minimum, both the initial request for the exemption and the final determination would have to be documented. In cases where the exemption was denied and the employee receives the appropriate vaccinations, those vaccine doses would also have to be documented. There might also be additional documentation that would need to be copied or scanned for their records. While the documentation for employees requesting an exemption would require more burden, we believe that there would only be a small percentage of employees that would request an exemption. Since we have no reliable method for estimating a number or percentage of employees who would be in each category, we will analyze the burden for the documentation requirements using 5 minutes or 0.0833 hours for each employee.

The position of the individual who would perform the activities related to the documentation requirement would also vary depending upon the type of provider or supplier and whether the employee

requested an exemption. If the employee has been vaccinated in compliance with this rule, an administrative support person might review their vaccination card and document that the employee has been vaccinated. However, if an administrative support person performs these activities, we believe an administrator or another member of the health care staff would be responsible for overseeing these activities. For other providers and suppliers, a nurse would likely be assigned to verify and document vaccination status. If an employee requests an exemption, we believe that a nurse, another health care professional, or an administrator would likely review the request and document it. Some other providers or suppliers might have an administrator or another member of the health care staff perform these activities. Thus, for this analysis, if a provider is required to have at least one infection preventionist (IP), such as hospitals, we believe the IP would be responsible for documenting the vaccination status for all employees. For other providers and suppliers, we assessed the burden using a registered nurse (RN), another member of the health care staff, such as a physical therapist, or an administrator.

The estimates that follow are largely based on our experience with these various providers. However, given the uncertainty and rapidly changing nature of the current pandemic, we acknowledge that there will likely need to be revisions to these requirements over time. We welcome comments that might improve these estimates.

A. ICRs Regarding the of Development of Policies and Procedures for ASCs § 416.51(c), "COVID-19 Vaccination of Staff"

1. Policies and Procedures

At § 416.51(c), we require ASCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and track and maintain documentation of their vaccination status. Each ASC must also have a contingency plan for any staff that are not fully vaccinated according to this rule.

The ICRs for this section would require each ASC to develop the policies and procedures needed to satisfy all of the requirements in this section. Based upon our experience with ASCs, we believe some centers have already developed policies and procedures requiring COVID-19 vaccination for staff. However, each ASC will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC, especially that their policies and procedures cover all of the center staff as identified in this IFC. Hence, we will base our estimate for this ICR on all 6,071 ASCs. We believe activities associated with this IFC would be performed by the RN functioning as the designated and qualified infection control professional (ICP) and ASC administrator as analyzed below.

The ICP would conduct research and then either modify or develop the policies and procedures needed to comply with this section's requirements. The ICP would work with the ASC administrator in developing these policies and procedures. For the ICP, we

estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the ICP's total hourly cost is $77. Thus, for each ASC, the burden for the ICP would be 8 hours at a cost of $616 (8 x $77). For the ICPs in all 6,071 ASCs, the burden would be 48,568 hours (8 x 6,071) at an estimated cost of $3,739,736 ($616 x 6,071).

As discussed above, the revision and approval of these initial policies and procedures would also require activities by the ASC administrator. The administrator would need to have meetings with the ICP to discuss the revisions and approve the final policies and procedures. We estimate this would require 2 hours for the administrator. According to Table 3, the total hourly cost for the administrator is $98. The burden for the administrator in each ASC would be 2 hours at an estimated cost of $196 (2 x $98). For the administrators in all 6,071 ASCs, the burden would be 12,142 hours (2 x 6,071) at an estimated cost of $1,189,916 ($196 x 6,071).

Therefore, for all 6,071 ASCs, the estimated burden associated with the requirement for policies and procedures would be 67,010 hours (48,568 + 12,142) at a cost of $4,929,652 ($3,739,736 + $1,189,916).

2. Documentation and Storage

Section 416.51(c) also requires ASCs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the center's policies and procedures for

these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $77 for each employee. According to Table 3, ASCs have 200,000 employees. Hence, the burden for these documentation requirements for all 6,071 ASCs would be 16,660 (0.0833 x 200,000) hours at an estimated cost of $1,282,820 (16,660 x $77).

The total burden for all 6,071 ASCs for this IFC would be 83,670 (67,010 + 16,660) hours at an estimated cost of $6,212,472 ($4,929,652 + $1,282,820).

The requirements and burden will be submitted to OMB under OMB control number 0938-0266 (expiration date July 31, 2024).

B. ICRs Regarding the Development of Policies and Procedures for Hospices § 418.60(d), "COVID-19 Vaccination of Facility Staff"

1. Policies and Procedures

At § 418.60(d), we require hospices to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The hospice must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each hospice to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations are set forth at

Condition of participation: Infection control, and require each hospice to maintain and document an infection control program to prevent and control infections and communicable diseases. The hospice must also follow accepted standards of practice, including the use of standard precautions to prevent the transmission of infections and communicable diseases. Thus, all hospices should already have infection prevention and control policies and procedures, but they likely do not comply with all of the requirements in this IFC.

All hospices would need to review their current policies and procedures and modify them to comply with all of the requirements in § 418.60(d) as set forth in this IFC. While we believe that many hospices have already addressed COVID-19 vaccination with their staff, we have no reliable means to estimate that number. Therefore, we will assess the burden for these requirements for all 5,556 hospices. We believe these activities would be performed by the RN and an administrator. According to Table 3, an RN in these settings has a total hourly cost of $79. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each hospice, the burden for the RN would be 8 hours at a cost of $632 (8 hours x $79). For all 5,556 hospices, the burden would be 44,448 hours (8 hours x 5,556) at an estimated cost of $3,511,392 ($632 x 5,556).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator

would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator in this setting is $122. Hence, for each hospice, the burden would be 2 hours at an estimated cost of $244 (2 x $122). For all 5,556 hospices, the total burden would be 11,112 hours (2 x 5,556) at an estimated cost of $1,355,664 (5,556 x $244).

Thus, the total burden for hospices to comply with the requirements for policies and procedures in this IFC is 55,560 hours (44,448 + 11,112) at an estimated cost of $4,867,056 ($3,511,392 + $1,355,664).

2. Documentation and Storage

Section 418.60(d) also requires hospices to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the hospice's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $79 for each employee. According to Table 3, hospices have 340,000 employees. Hence, the burden for these documentation requirements for all 5,556 hospices would be 28,322 (0.0833 x 340,000) hours at an estimated cost of $2,237,438 (28,322 x 79).

Therefore, the total burden for all 5,556 hospices for this rule would be 83,882 (55,560 + 28,322) hours at an estimated cost of $7,104,494 (4,867,056 + 2,237,438).

The requirements and burden will be submitted to OMB under OMB control number 0938-1067 (expiration date March 31, 2024).

C. ICRs Regarding the Development of Policies and Procedures for PACE Organizations § 460.74(d), "COVID-19 Vaccination of PACE Organization Staff"

1. Policies and Procedures

Section 460.74(d) requires that programs for all-inclusive care for the elderly (PACE) organizations to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. Each PACE organization must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each PACE organization to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 460.74 already require that each PACE organization follow accepted policies and standard procedures with respect to infection control in place. Thus, all PACE organizations should have policies and procedures regarding infection prevention and control. We also believe that many have already addressed COVID-19 vaccination policies for their staff. However, since we do not have a reliable method to estimate how many have, we will assess the burden for all 141 PACE organizations.

All PACE organizations would need to review their current infection prevention and control policies and

procedures and develop or modify them to satisfy the requirements in this section. We believe these activities would require an RN and an administrator. According to Table 3, an RN's total hourly cost is $74. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each PACE organization, the burden for the RN would be 8 hours at a cost of $592 (8 hours x $74). For all 141 PACE organizations, the burden would be 1,128 hours (8 hours x 141) at an estimated cost of $83,472 (592 x 141).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator is $122. Hence, for each PACE organization, the burden would be 2 hours at an estimated cost of $244 (2 x 122). For all 141 PACE organizations, the total burden would be 282 hours (2 x 141) at an estimated cost of $34,404 (141 x $244).

Thus, the total burden for all 141 PACE organizations to comply with the requirements for the policies and procedures is 1,410 hours (1,128 + 282) at an estimated cost of $117,876 (83,472 + 34,404).

2. Documentation and Storage

Section 460.74(d) also requires PACE organizations to track and securely maintain the

required documentation of staff COVID-19 vaccination status. Any burden for modifying the PACE organization's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $74 for each employee. According to Table 3, PACE organizations have 10,000 employees. Hence, the burden for these documentation requirements for all 141 PACE organizations would be 833 (0.0833 x 10,000) hours at an estimated cost of $61,642 (833 x 74).

Therefore, the total burden for all 141 PACE organizations for this rule would be 2,243 (1,410 + 833) hours at an estimated cost of $179,518 (117,876 + 61,642).

The requirements and burden will be submitted to OMB under OMB control number 0938-1326 (expiration date April 20, 2023).

D. ICRs Regarding the Development of Policies and Procedures for Hospitals § 482.42(g), "COVID-19 Vaccination of Hospital Staff"

1. Policies and Procedures

At § 482.42(g), we require hospitals to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The hospital must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each hospital to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs already require hospitals to have an infection prevention and control program (IPCP) and an infection preventionist (IP). The IPCP must have methods to prevent and control the transmission of infection within the hospital and between the hospital and other settings. Thus, all 5,194 hospitals should already have infection prevention and control policies and procedures. However, each hospital would need to review their current policies and procedures and modify them, if necessary, to ensure compliance with all of the requirements in this IFC, especially that their policies and procedures cover all of the eligible facility staff identified in this IFC. Based upon our experience with hospitals, we believe many hospitals have already developed policies and procedures requiring COVID-19 vaccination for staff. Since we have no reliable means to estimate the number of hospitals that may have already addressed COVID-19 vaccination of their staff, we will base our estimate for these requirements on all 5,194 hospitals.

We believe these activities would be performed by the IP, the director of nursing (DON), and an administrator. The IP would need to research COVID-19 vaccines, modify the policies and procedures, as necessary, and work with the DON and administrator to develop the policies and procedures and obtain appropriate approval. For the IP, we estimate these activities would require 8 hours. According to Table 3,

the IP's total hourly cost is $79. Thus, for each hospital, the burden for the IP would be 8 hours at a cost of $632 (8 hours x 79). For the IPs in all 5,194 hospitals, the burden would be 41,552 hours (8 hours x 5,194) at an estimated cost of $3,282,608 (632 x 5,194).

As discussed above, the revision and approval of these policies and procedures would also require activities by the DON and an administrator. We believe these activities would require 2 hours each for the DON and an administrator. According to Table 3, the total adjusted hourly wage for both the DON and an administrator is $122. Hence, for each hospital, the burden would be 4 hours (2 x 2) at an estimated cost of $488 (4 x $122). The total burden for all 5,194 hospitals would be 20,776 hours (4 x 5,194) at an estimated cost of $2,534,672 (5,194 x 488).

Therefore, for all 5,194 hospitals, the total burden for the requirements for policies and procedures is 62,328 hours (41,552 + 20,776) at an estimated cost of $5,817,280 (3,282,608 + 2,534,672).

2. Documentation and Storage

Section 482.42(g) also requires hospitals to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the hospital's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $79 for each employee. According to Table 3, hospitals have 6,070,000 employees. We could not locate a reliable number for

critical access hospital (CAH) employees so they are included here with the hospital employees. Hence, the burden for these documentation requirements for all 5,194 hospital and 1,358 CAHs would be 505,631 (0.0833 x 6,070,000) hours at an estimated cost of $39,944,849 (505,631 x 79).

Therefore, the total burden for this rule for all 5,194 hospitals and 1,358 CAHs (documentation burden only) would be 567,959 (62,328 + 505,631) hours at an estimated cost of $45,762,129 (5,817,280 + 39,944,849).

The requirements and burden will be submitted to OMB as an emergency reinstatement of an existing OMB control number 0938-0328.

E. ICRs Regarding the Development of Policies and Procedures for LTC Facilities § 483.80(i), "COVID-19 Vaccination of Facility Staff"

1. Policies and Procedures

At § 483.80(i), we require LTC facilities to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The LTC facility must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each LTC facility to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 483.80(d)(1) and (2) already require LTC facilities to have policies and procedures to educate, offer, and document vaccination status for

residents regarding the influenza and pneumococcal immunizations. In addition, § 483.80(d)(3) requires LTC facilities to educate, offer, and document the vaccination status for residents and staff for the COVID-19 immunizations. Based upon our experience with LTC facilities, we believe some facilities have already developed policies and procedures requiring COVID-19 vaccination for staff, including COVID-19 vaccine mandates. However, we have no reliable means to estimate the number or percentage of LTC facilities that have already mandated vaccination. Hence, we will base our estimate for this ICR on all 15,401 LTC facilities.

Each LTC facility would need to review its policies and procedures for § 483.80(d) and modify them to comply with the requirements in this rule at § 483.80(i) and obtain the appropriate review and approval. This would require conducting research and revising the policies and procedures as needed. We believe these activities would be performed by the infection preventionist (IP), director of nursing (DON), and medical director for the first year and the IP in subsequent years as analyzed below.

The IP would need to work with the DON and medical director to revise and finalize the policies and procedures. For the IP, we estimate this would require 2 hours initially to perform research and revise the policies and procedures to meet these requirements. According to Table 3, the IP's total hourly cost is $69. Thus, for each LTC facility, the burden for the IP would be 2 hours at a cost of $138 (2 hours x 69). For the IPs in all 15,401 LTC facilities, the burden would be 30,802 hours (2 hours x 15,401 facilities) at an estimated cost of $2,125,338 (138 x 15,401).

As discussed above, the revision and approval of these policies and procedures would also require activities by the DON and medical director. Both the DON and medical director would need to have meetings with the IP to discuss the revision, evaluation, and approval of the policies and procedures. We estimate this would require 1 hour for both the DON and medical director. According to Table 3, the total hourly cost for the DON is $96. The burden in the first year for the DON in each LTC facility would be 1 hour at an estimated cost of $96 (1 hour x 96). The burden would be 15,401 hours (1 x 15,401) at an estimated cost of $1,478,496 (96 x 15,401) for all LTC facilities.

For the medical director, we have estimated the revision of policies and procedures would also require 1 hour. According to the chart above, the total hourly cost for the medical director is $171. For each LTC facility, this would require 1 hour for the medical director during the first year at an estimated cost of $171 (1 hour x $171). the burden for all LTC facilities would be 15,401 hours (1 x 15,401) at an estimated cost of $2,633,571 (171 x 15,401).

Therefore, for all 15,401 LTC facilities in the first year, the estimated burden for the policies and procedures requirement would be 61,604 hours (30,802 + 15,401 + 15,401) at a cost of $6,237,405 (2,125,338 + 1,478,496 + 2,633,571).

2. Documentation and Storage

Section 483.80(i) also requires LTC facilities to track and securely maintain the required documentation of staff COVID-19 vaccination status.

Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. The PRA package submitted under OMB Control No. 0938-1363 already provides for the documentation burden for the IP for the LTC facility's infection prevention and control program (IPCP) under which the requirements in this rule will also be located. We believe the burden for the documentation requirements in this rule should be included in that burden. Therefore, we will not assess any additional burden for the documentation requirements in this rule.

The requirements and burden will be submitted to OMB under OMB control number 0938-1363 (expiration date June 30, 2022).

F. ICRs Regarding the Development of Policies and Procedures for PRTFs § 441.151(c), "COVID-19 Vaccination of Facility Staff"

1. Policies and Procedures

Section 441.151(c) requires psychiatric residential treatment facilities (PRTFs) to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The PRTF must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each PRTF to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations for PRTFs do not address infection

prevention and control or vaccinations. Hence, although we believe that at least some PRTFs have already addressed COVID-19 vaccination of their staff, we will assess the burden for all 357 PRTFs.

We believe these activities would be performed by an RN and an administrator. According to Table 3, an RN's total hourly cost is $74. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each PRTF, the burden for the RN would be 8 hours at a cost of $592 (8 hours x 74). For all 357 PRTFs, the burden would be 2,856 hours (8 hours x 357) at an estimated cost of $211,344 (592 x 357).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator is $122. Hence, for each PRTF, the burden would be 2 hours at an estimated cost of $244 (2 x 122). For all 357 PRTFs, the total burden would be 714 hours (2 x 357) at an estimated cost of $87,108 (357 x 244).

Thus, the total burden for all 357 PRTFs to comply with the policies and procedures requirements in this IFC for policies and procedures is 3,570 hours (2,856 + 714) at an estimated cost of $298,452 (211,344 + 87,108).

2. Documentation and Storage

Section 441.151(c) also requires PRTFs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation an adjusted hourly wage of $74 for each employee. According to Table 3, PRTFs have 30,000 employees. Hence, the burden for these documentation requirements for all 357 PRTFs would be 2,499 (0.0833 x 30,000) hours at an estimated cost of $184,926 (2,499 x 74).

Therefore, the total burden for all 357 PRTFs for this rule would be 6,069 (3,570 + 2,499) hours at an estimated cost of $483,378 (298,452 + 184,926)

The requirements and burden will be submitted to OMB under OMB control number 0938-0833 (expiration date May 31, 2022).

G. ICRs Regarding the Development of Policies and Procedures for ICFs-IID § 483.430(f), "COVID-19 Vaccination of Facility Staff"

1. Policies and Procedures

At § 483.430(f), we require ICFs-IID to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The ICFs-IID must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each ICFs-IID to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 483.470(l) Standard: Infection control requires that the ICFs-IID must provide a sanitary environment to avoid sources and transmission of infections. The facility must also implement successful corrective action in affected problem areas, maintain a record of incidents and corrective actions related to infections, and prohibit employees with symptoms or sign of a communicable disease from direct contact with clients and their food. Hence, ICFs-IID should already have policies and procedures for infection prevention and control.

We believe these activities would be performed by the RN. According to Table 3, an RN's total hourly cost is $69. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each ICFs-IID, the burden for the RN would be 8 hours at a cost of $552 (8 hours x 69). For all 5,780 ICFs-IID, the burden would be 46,240 hours (8 hours x 5,780) at an estimated cost of $3,190,560 (552 x 5,780).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator is $96. Hence, for each ICFs-IID, the burden would be 2 hours at an estimated cost of $192

(2 x 96). For all 5,780 ICFs-IID, the total burden would be 11,560 hours (2 x 5,780) at an estimated cost of $1,109,760 (5,780 x 192).

Thus, the total burden for all 5,780 ICFs-IID to comply with the requirements for policies and procedures is 57,800 hours (46,240 + 11,560) at an estimated cost of $4,300,320 (3,190,560 + 1,109,760).

2. Documentation and Storage

Section 483.430(f) also requires ICFs-IID to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $69 for each employee. According to Table 3, ICFs-IID have 80,000 employees. Hence, the burden for these documentation requirements for all 5,780 ICFs-IID would be 6,664 (0.0833 x 80,000) hours at an estimated cost of $459,816 (6,664 x $69).

Therefore, the total burden for all 5,780 ICFs-IID for this rule would be 64,464 (57,800 + 6,664) hours at an estimated cost of $4,760,136 (4,300,320 + 459,816).

The requirements and burden will be submitted to OMB under OMB control number 0938-1402 (expiration date September 30, 2024).

H. ICRs Regarding the Development of Policies and Procedures for HHAs § 484.70(d), "COVID-19 Vaccination of Home Health Agency Staff"

1. Policies and Procedures

At § 483.70(d), we require HHAs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The HHA must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each HHA to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 483.70, Condition of participation: Infection prevention and control require each HHA to maintain and document an infection control program to prevent and control infections and communicable diseases. The HHA must follow accepted standards of practice, including the use of standard precautions to prevent the transmission of infections and communicable diseases. Thus, all HHA should already have infection prevent and control policies and procedures, but they likely do not comply with all of the requirements in this IFC.

All HHAs would need to review their current policies and procedures and modify them to comply with all of the requirements in § 483.70(d), as set forth in this IFC. While we believe that many HHAs have already addressed COVID-19 vaccination with their staff, we have no reliable means to estimate that number. Therefore, we will assess the burden for these requirements for all 11,649 HHAs. We believe these activities would be performed by the RN and an administrator. According to Table 3, an RN in home health services total hourly cost is $73. Since there are

not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each HHA, the burden for the RN would be 8 hours at a cost of $584 (8 hours x 73). For all 11,649 HHAs, the burden would be 93,192 hours (8 hours x 11,649) at an estimated cost of $6,803,016 (584 x 11,649).

As discussed above, the revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator in home health services is $97. Hence, for each HHA, the burden would be 2 hours at an estimated cost of $194 (2 x 97). For all 11,649 HHAs, the total burden would be 23,298 hours (2 x 11,649) at an estimated cost of $2,259,906 (11,649 x 194).

Thus, the total burden for all 11,649 HHAs to comply with the policies and procedures requirements for policies and procedures is 116,490 hours (93,192 + 23,298) at an estimated cost of $9,062,922 (6,803,016 + 2,259,906).

2. Documentation and Storage

Section 483.70(d) also requires HHAs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the agency's policies and procedures for these activities is already accounted for above. We

believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $73 for each employee. According to Table 3, HHAs have 2,110,000 employees. Hence, the burden for these documentation requirements for all 11,649 HHAs would be 175,763 (0.0833 x 2,110,000) hours at an estimated cost of $12,830,699 (175,763 x 73).

Therefore, the total burden for all 11,649 HHAs for this rule would be 292,253 (116,490 + 175,763) hours at an estimated cost of $21,893,621 (9,062,922 + 12,830,699).

The requirements and burden will be submitted to OMB under OMB control number 0938-1299 (expiration date June 30, 2024).

I. ICRs Regarding the Development of Policies and Procedures for CORFs § 485.70(n), "COVID-19 Vaccination of Facility Staff"

1. Policies and Procedures

At § 485.70(n), we require CORFs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. Each CORF must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each CORF to develop the policies and procedures needed to satisfy all of the requirements in this section. This IFC requires CORF staff to receive the COVID-19 vaccine unless medically contraindicated as

determined by a physician, advance practice registered nurse, or physician assistant acting within their respective scope of practice as defined by and in accordance with all applicable State and local laws. Based upon our experience with CORFs, we believe some facilities have already developed policies and procedures requiring COVID-19 vaccination for staff unless medically contraindicated. However, each CORF will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC, especially that their policies and procedures cover all of the organization staff identified in this IFC. Hence, we will base our estimate for this ICR on all 159 CORFs. The CORF's governing body appoints an administrator who implements and enforces the facility's policies and procedures. Hence, we believe activities associated with this IFC would be performed by the administrator as analyzed below. The governing body would also need to review these policies and procedures, which would be included in its "legal responsibility for establishing and implementing policies regarding the management and operation of the facility."

The administrator would conduct research to either modify or develop policies and procedures. For the administrator, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the administrator's total hourly cost is $98. Thus, for each CORF, the burden for the administrator would be 8 hours at a cost of $784 (8 x 98). For the administrators in all 159 organizations, the burden would be 1,272

hours (8 x 159) at an estimated cost of $124,656 (784 x 159).

The administrator would need to spend time attending governing body meetings to discuss and obtain approval for the policies and procedures; however, that would be a usual and customary business practice. Therefore, activities for the administrator associated with governing body approval for the policies and procedures are exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

2. Documentation and Storage

Section 485.70(n) also requires CORFs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an administrator 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $98 for each employee. According to Table 3, CORFs have 10,000 employees. Hence, the burden for these documentation requirements for all 159 CORFs would be 833 (0.0833 x 10,000) hours at an estimated cost of $81,634 (833 x 98).

Therefore, the total burden for all 159 CORFs for this rule would be 2,105 (1,272 + 833) hours at an estimated cost of $206,290 (124,656 + 81,634).

The requirements and burden will be submitted to OMB under OMB control number 0938-1091 (expiration date November 30, 2022).

J. ICRs Regarding the Development of Policies and Procedures for CAHs §

485.640(f), "COVID-19 Vaccination of CAH Staff"

1. Policies and Procedures

At § 485.640(f), we require critical access hospitals (CAHs) to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The CAH must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each CAH to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs already require CAHs to have an infection prevention and control program (IPCP) and an infection preventionist (IP). The IPCP must have methods to prevent and control the transmission of infection within the hospital and between the hospital and other settings. Thus, all 1,358 CAHs should already have infection prevention and control policies and procedures. However, each CAH would need to review their current policies and procedures and modify them, if necessary, to ensure compliance with all of the requirements in this IFC, especially that their policies and procedures cover all of the eligible facility staff identified in this IFC. Based upon our experience with CAHs, we believe many CAHs have already developed policies and procedures requiring COVID-19 vaccination for staff. Since we have no reliable means to estimate the number of

CAHs that may have already addressed COVID-19 vaccination of their staff, we will base our estimate for these requirements on all 1,358 CAHs.

We believe these activities would be performed by the IP, the director of nursing (DON), and an administrator. The IP would need to research COVID-19 vaccines, modify the policies and procedures, as necessary, and work with the DON and administrator to develop the policies and procedures and obtain appropriate approval. For the IP, we estimate these activities would require 8 hours. According to Table 3, the IP's total hourly cost is $79. Thus, for each hospital, the burden for the IP would be 8 hours at a cost of $632 (8 hours x 79). For the IPs in all 1,358 CAHs, the burden would be 10,864 hours (8 hours x 1,358) at an estimated cost of $858,256 (632 x 1,358).

As discussed above, the revision and approval of these policies and procedures would also require activities by the DON and an administrator. We believe these activities would require 2 hours each for the DON and an administrator. According to Table 3, the total adjusted hourly wage for both the DON and an administrator is $122. Hence, for each CAH the burden would be 4 hours (2 x 2) at an estimated cost of $488 (4 x $122). The total burden for all 1,358 CAHs would be 5,432 hours (4 x 1,358) at an estimated cost of $662,704 (1,358 x 488).

Therefore, for all 1,358 CAHs the total burden for the requirements for policies and procedures is 16,296 hours (10,864 + 5,432) at an estimated cost of $1,520,960 ($858,256 + $662,704).

2. Documentation and Storage

Section 485.640(f) also requires CAHs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the CAH's policies and procedures for these activities is already accounted for above. Since we were unable to located a reliable number for CAH employees, the documentation burden for CAHs resulting from the documentation requirement in this rule is included in the hospitals' burden above.

The requirements and burden for CAHs without DPUs will be submitted to OMB under OMB control number 0938-1043 (expiration date March 31, 2024). The requirements and burden for CAHs with DPUs will be submitted to OMB under OMB control number 0938-0328(expired).

K. ICRs Regarding the Development of Policies and Procedures for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services (Organizations) § 485.725(f), "COVID-19 Vaccination of Organization Staff"

1. Policies and Procedures

At § 485.725(f), we require organizations to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and the appropriate documentation is tracked and maintained. The organization must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each organization to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 485.725(a) require organizations to establish an infection-control committee of representative professional staff with overall responsibility for infection control. This committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure compliance with those policies and procedures. Based upon these requirements and our experience with organizations, we believe some organizations have already developed policies and procedures requiring COVID-19 vaccination for staff unless medically contraindicated. However, since we have no reliable means to estimate how many organizations have done this, we will assess the burden for all 2,078 organizations. All organizations would need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC.

The types of therapists at each organization vary depending upon the services offered. For the purposes of determining the COI burden, we will assume that the therapist is a physical therapist. We believe activities associated with this IFC would be performed by a physical therapist and administrator. A physical therapist would need to conduct research on the COVID-19 vaccines and then develop or modify policies and procedures that comply with the requirements in this IFC. The physical therapist would need to work with an administrator to make the

necessary revisions. For the physical therapist, we estimate this would require 8 hours to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the physical therapist's total hourly cost is $84. Thus, for each organization, the burden for the physical therapist would be 8 hours at a cost of $672 (8 x 84). For the physical therapists in all 2,078 organizations, the burden would be 16,624 hours (8 x 2,078) at an estimated cost of $1,396,416 (672 x 2,078).

As discussed above, the revision and approval of these policies and procedures would also require activities by the administrator. The administrator would need to have meetings with the physical therapist to discuss the revisions and draft any necessary policies and procedures, as well as approve the final policies and procedures. We estimate this would require 2 hours for the administrator. According to Table 3, the total hourly cost for the administrator is $98. The burden for the administrator in each organization would be 2 hours at an estimated cost of $196 (2 x 98). For the administrators in all 2,078 organizations, the burden would be 4,156 hours (2 x 2,078) at an estimated cost of $407,288 (4,156 x 98).

Therefore, for all 2,078 organizations, the total burden for the requirements for policies and procedures is 20,780 hours (16,624 + 4,156) at an estimated cost of $1,803,704 (1,396,416 + 407,288).

2. Documentation and Storage

Section 485.725(f) also requires organizations to track and securely maintain the required

documentation of staff COVID-19 vaccination status. Any burden for modifying the organization's policies and procedures for these activities is already accounted for above. We believe that this would require a physical therapist 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $84 for each employee. According to Table 3, these organizations have 10,000 employees. Hence, the burden for these documentation requirements for all 2,078 organizations would be 833 (0.0833 x 10,000) hours at an estimated cost of $69,972 (833 x 84).

Therefore, the total burden for all 2,078 organizations for this rule would be 21,613 (20,780 + 833) hours at an estimated cost of $1,873,676 (1,803,704 + 69,972).

The requirements and burden will be submitted to OMB under OMB control number 0938-0273 (expiration date June 30, 2024).

L. ICRs Regarding the Development of Policies and Procedures for CMHCs § 485.904(c), "COVID-19 Vaccination of Center Staff"

1. Policies and Procedures

At § 485.904(c), we require CHMCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. Each facility must maintain documentation of their staff's vaccination status. Also, each facility must have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each CHMC to develop the policies and procedures needed to satisfy all of the requirements in this section. Based upon our experience with CHMCs, we believe some centers have already developed policies and procedures requiring COVID-19 vaccination for staff unless medically contraindicated. However, since we do not have a reliable means to estimate how many CMHCs have done so, we will estimate the burden based on all 129 CHMCs.

Each CMHC will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC. Based on these requirements and our experience with CHMCs, we believe these activities would be performed by the CHMC administrator and a mental health counselor. The administrator would conduct research regarding the COVID-19 vaccines and then either modify or develop the policies and procedures necessary to comply with the requirements in this IFC. The administrator would send any recommendations for changes or additional policies or procedures to the mental health counselor. The administrator and mental health clinician would need to make the necessary revisions and draft any necessary policies and procedures. For the administrator, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the administrator's total hourly cost is $113. Thus, for each CMHC, the burden for the administrator would be 8 hours at a cost of $904 (8 x 113). The burden for the administrators in all 129

CHMCs would be 1,032 hours (8 x 129) at an estimated cost of $116,616 (904 x 129).

As discussed above, the revision and approval of these initial policies and procedures would also require activities by the mental health counselor. The administrator would need to have meetings with the mental health counselor to discuss the revisions and draft any necessary policies and procedures. We estimate this would require 2 hours for the mental health counselor. According to Table 3, the total hourly cost for the mental health counselor is $118. The burden for the mental health counselor in each CHMC would be 2 hours at an estimated cost of $236 (2 x 118). For the mental health counselors in all 129 CMHCs, the burden would be 258 hours (2 x 129) at an estimated cost of $30,444 (129 x 236).

Therefore, for all 129 CMHCs, the total burden for the requirements for policies and procedures is 1,290 hours (1,032 + 258) at an estimated cost of $147,060 (116,616 + 30,444).

2. Documentation and Storage

Section 485.904(c) also requires CMHCs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the center's policies and procedures for these activities is already accounted for above. We believe that this would require an administrator 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $113 for each employee. According to Table 3, CMHCs have 140,000 employees. Hence, the burden for these documentation requirements for all 129 CMHCs

would be 11,662 (0.0833 x 140,000) hours at an estimated cost of $1,317,806 (11,662 x 113).

Therefore, the total burden for all 129 CMHCs for this rule would be 12,952 (1,290 + 11,662) hours at an estimated cost of $1,464,866 (147,060 + 1,317,806).

The requirements and burden will be submitted to OMB under OMB control number 0938-1245 (expiration date April 30, 2023).

M. ICRs Regarding the Development of Policies and Procedures for HIT Suppliers § 486.525(c), "COVID-19 Vaccination of Facility Staff"

1. Policies and Procedures

Section 486.525(c) requires home infusion therapy (HIT) suppliers to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. The HIT supplier must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each HIT supplier to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 486.525 already require that HIT suppliers provide their services in accordance with nationally recognized standards of practice. Thus, we believe most HIT suppliers should already have infection prevention and control policies and procedures, including COVID-19 vaccination. However, we have no reliable means to estimate how many suppliers have done so. Thus, we will base our burden estimate on all 337 HIT suppliers.

All HIT suppliers would need to review their current policies and procedures and develop or modify them to comply with all of the requirements in § 486.525(c) as set forth in this IFC. We believe these activities would be performed by the RN and an administrator working for the HIT supplier. According to Table 3, an RN working with for a HIT supplier would have a total hourly cost of $73. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each HIT supplier, the burden for the RN would be 8 hours at a cost of $584 (8 hours x 73). For all 337 HIT suppliers, the burden would be 2,696 hours (8 hours x 337) at an estimated cost of $24,601 (337 x 73).

The development and/or revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator working for a HIT supplier is $97. Hence, for each HIT supplier, the burden would be 2 hours at an estimated cost of $194 (2 x 97). For all 337 HIT suppliers, the total burden for the administrator would be 674 hours (2 hours x 337) at an estimated cost of $65,378 (337 x 194).

Therefore, for all 337 HIT suppliers, the total burden for the requirements for policies and procedures is 3,370 hours (2,696 + 674) at an estimated cost of $89,979 (24,601 + 65,378).

2. Documentation and Storage

Section 486.525(c) also requires HIT suppliers to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the supplier's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at adjusted hourly wage of $73 for each employee. According to Table 3, HIT suppliers have 20,000 employees. Hence, the burden for these documentation requirements for all 337 HIT suppliers would be 1,666 (0.0833 x 20,000) hours at an estimated cost of $121,618 (1,666 x 73).

Therefore, the total burden for all 337 HIT suppliers for this rule would be 5,036 (3,370 + 1,666) hours at an estimated cost of $211,597 (89,979 + 121,618).

The requirements and burden will be submitted to OMB under OMB control number 0938-855B (expiration date March 31, 2024).

N. ICRs Regarding the Development of Policies and Procedures for RHCs and FQHCs § 491.8(d), "COVID-19 Vaccination of Staff"

1. Policies and Procedures

At § 491.8(d), we require RHCs/FQHCs to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and that appropriate documentation of those vaccinations are tracked and maintained. Each RHC/FQHC must also

have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each RHC/FQHC to develop the policies and procedures needed to satisfy all of the requirements in this section. This IFC requires clinic or center staff to receive the COVID-19 vaccine unless medically contraindicated as determined by a physician, advance practice registered nurse, or physician assistant acting within their respective scope of practice as defined by and in accordance with all applicable State and local laws. Based upon experience with RHCs/FQHCs, we believe some clinics or centers have already developed policies and procedures requiring COVID-19 vaccination for staff unless medically contraindicated. However, since we do not have a reliable means to estimate how many facilities have already done so, we will base the burden analysis for this estimate on all 15,317 RHC/FQHCs (4,933 RHCs and 10,384 FQHCs).

Each RHC/FQHC will need to review their current policies and procedures and modify them, if necessary, to ensure compliance with the requirements in this IFC, especially that their policies and procedures cover all of the clinic or center staff identified in this IFC. Current regulations require a physician, nurse practitioner, and physician assistant to participate in the development, execution, and periodic review of the policies and procedures.[FN222] Moreover, the RHC/FQHC operates under the medical direction of a physician. Based on these requirements and our experience with RHCs/FQHCs, we believe activities associated with this IFC would be performed by the RHC administrator, physician, nurse practitioner,

physician assistant, and medical director as analyzed below.

The administrator would conduct research to either modify or develop policies and procedures. The administrator would send any recommendations for changes or additional policies or procedures to the physician, nurse practitioner, and physician assistant. The administrator, physician, nurse practitioner, and physician assistant would need to make the necessary revisions and draft any necessary policies and procedures. The administrator would need to work with the medical director to obtain approval for the policies and procedures to be implemented. For the administrator, we estimate this would require 8 hours initially to perform research and revise or develop the policies and procedures to meet these requirements. According to Table 3, the administrator's total hourly cost is $108. Thus, for each RHC/FQHC, the burden for the administrator would be 8 hours at a cost of $864 (8 x 108). For the administrators in all 15,317 RHCs/FQHCs, the burden would be 122,536 hours (8 x 15,317) at an estimated cost of $13,233,888 (864 x 15,317).

As discussed above, the revision and approval of these initial policies and procedures would also require activities by the physician, nurse practitioner, physician assistant, and medical director. The administrator would need to have meetings with the physician, nurse practitioner, and physician assistant to discuss the revisions and draft any necessary policies and procedures. The administrator would also need to have meetings with the medical director to obtain approval for the policies and procedures. We estimate this would require 2 hours each for the

physician, nurse practitioner, and physician assistant. For the medical director, we estimate 1 hour would be required to perform this function. According to Table 3, the total hourly cost for the physician is $212. The burden for the physician in each RHC/FQHC would be 2 hours at an estimated cost of $424 (2 x 212). For the physicians in all 15,317 RHCs/FQHCs, the burden would be 30,634 hours (2 x 15,317) at an estimated cost of $6,494,408 (424 x 15,317). The hourly cost for the nurse practitioner is $107. The burden for the nurse practitioner in each RHC/FQHC would be 2 hours at an estimated cost of $214 (2 x 107). For the nurse practitioners in all 15,317 RHCs/FQHCs, the burden would be 30,634 hours (2 x 15,317) at an estimated cost of $3,277,838 ($214 x 15,317). The hourly cost for the physician assistant is $111. The burden for the physician assistant in each RHC/FQHC would be 2 hours at an estimated cost of $222 (2 x 111). For the physician assistants in all 15,317 RHCs/FQHCs, the burden would be 30,634 hours (2 x 15,317) at an estimated cost of $3,400,374 (15,317 x 222). The hourly cost for the medical director is $212. The burden for the medical director in each RHC/FQHC would be 1 hour at an estimated cost of $212. For the medical directors in all 15,317 RHCs/FQHCs, the burden would be 15,317 hours (1 x 15,317) at an estimated cost of $3,247,204 (15,317 x 212).

Therefore, for all 15,317 RHCs/FQHCs, the estimated burden associated with the policies and procedures requirement would be 229,755 hours (122,536 + 30,634 + 30,634 + 30,634 + 15,317) at a cost of $29,653,712 (13,233,888 + 6,494,408 + 3,277,838 + 3,400,374 + 3,247,204).

2. Documentation and Storage

Section 491.8(d) also requires RHCs/FQHCs to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the clinic's or center's policies and procedures for these activities is already accounted for above. We believe that this would require an administrator 5 minutes or 0.0833 hours to perform the required documentation at an adjusted hourly wage of $108 for each employee. According to Table 3, RHCs have 40,000 employees and FQHCs have 110,000 employees for a total of 150,000 employees. Hence, the burden for these documentation requirements for all 15,317 RHCs and FQHCs would be 12,495 (0.0833 x 150,000) hours at an estimated cost of $1,349,460 (12,495 x 108).

Therefore, the total burden for all 15,317 RHCs and FQHCs for this rule would be 242,250 (229,755 + 12,495) hours at an estimated cost of $31,003,172 (29,653,712 + 1,349,460).

The requirements and burden will be submitted to OMB under OMB control number 0938-0334 (expiration date March 31, 2023).

O. ICRs Regarding the Development of Policies and Procedures for ESRD Facilities § 494.30(b), "COVID-19 Vaccination of Facility Staff"

1. Policies and Procedures

Section 494.30(b) requires the ESRD facilities to develop and implement policies and procedures to ensure their staff are vaccinated for COVID-19 and

that appropriate documentation of those vaccinations are tracked and maintained. The ESRD facility must also have a contingency plan for all staff not fully vaccinated according to this rule.

The ICRs for this section would require each ESRD facility to develop the policies and procedures needed to satisfy all of the requirements in this section. Current regulations at § 494.30 already require that ESRD facilities follow standard infection control precautions. Thus, all ESRD facilities should have infection prevention and control policies and procedures. We believe that many ESRD facilities have already addressed COVID-19 vaccination for their staff. However, we have no reliable means to estimate how many ESRD facilities have done so. Thus, we will base our burden estimate on all 7,893 ESRD facilities.

All ESRD facilities would need to review their current policies and procedures and develop or modify them to comply with all of the requirements in § 494.30(b) as set forth in this IFC. We believe these activities would be performed by the RN and an administrator. According to Table 3, an RN working with for an ESRD facility would have a total hourly cost of $73. Since there are not any current requirements that address COVID-19 vaccination, we estimate it would require 8 hours for the RN to research, draft, and work with an administrator to finalize the policies and procedures. Thus, for each ESRD facility, the burden for the RN would be 8 hours at a cost of $584 (8 hours x $73). For all ESRD facilities, the burden would be 63,144 hours (8 hours x 7,893) at an estimated cost of $4,609,512 (7,893 x 584).

The development and/or revision and approval of these policies and procedures would also require activities by an administrator. The administrator would need to work with the RN to develop the policies and procedures, and then review and approve the changes. We estimate this would require 2 hours. According to Table 3, the total hourly cost for the administrator at an ESRD facility is $97. Hence, for each ESRD, the burden for the administrator would be 2 hours at an estimated cost of $194 (2 x 97). For all ESRD facilities, the total burden would be 15,786 hours (2 x 7,893) at an estimated cost of $1,531,242 (7,893 x 194). Thus, the total burden for all ESRD facilities for the policies and procedures requirement would be 78,930 hours (63,144 + 15,786) at an estimated cost of $6,140,754 ($4,609,512 + $1,531,242).

2. Documentation and Storage

Section 494.30(b) also requires ESRD facilities to track and securely maintain the required documentation of staff COVID-19 vaccination status. Any burden for modifying the facility's policies and procedures for these activities is already accounted for above. We believe that this would require an RN 5 minutes or 0.0833 hours to perform the required documentation at an adjusted hourly wage of $73 for each employee. According to Table 3, ESRD facilities have 170,000 employees. Hence, the burden for these documentation requirements for all 7,893 ESRD facilities would be 14,161 (0.0833 x 170,000) hours at an estimated cost of $1,033,753 (14,161 x 73).

Therefore, the total burden for all 7,893 ESRD facilities for this rule would be 93,091 (78,930 + 14,161) hours at an estimated cost of $ 7,174,507 (6,140,754 + 1,033,753).

The requirements and burden will be submitted to OMB under OMB control number 0938-0386 (expiration date March 31, 2024).

Based upon the above analysis, the total burden for all of the ICRs in this IFC is 1,555,487 hours at an estimated cost of $136,088,221.

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TABLE 4: Summary of Information Collection Burdens

Regulation (§) - Provider or Supplier	OMB Control No.	No. of Respondents	No. of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Labor Costs ($)
416.51(c) - Ambulatory Surgical Centers (ASCs) – Policies and Procedures	0938-0266	6,071	6,071	11	67,010	4,929,652
416.51(c) - ASCs - Documentation	0938-0266	6,071	200.000	0.0833	16,660	1,282,820
418.60(d) Hospices – Policies and Procedures	0938-1067	5,556	5,556	10	55,560	4,867,056
418.60(d) Hospices – Documentation	0938-1067	5,556	340,000	0.0833	28,322	2,237,438
441.151(c) - Psychiatric Residential Treatment Facilities (PRTFs) – Policies and Procedures	0938-1384	357	357	10	3,570	298,452
441.151(c) – PRTFs - Documentation	0938-1384	357	30,000	0.0833	2,499	184,926
460.74(d) - Programs for All Inclusive Care for the Elderly (PACE) – Policies and Procedures	0938-1326	141	141	10	1,410	117,876
460.74(d) – PACE - Documentation	0938-1326	141	10,000	0.0833	833	61,642
482.42(g) – Hospitals – Policies and Procedures	0938-0328	5,194	5,194	12	62,328	5,817,280
482.42(g) – Hospitals - Documentation	0938-0328	5,194	6,070,000	0.0833	505,631*	39,944,849
483.80(i) - Long Term Care (LTC) –Facilities (SNFs and NFs) – Policies and Procedures **	0938-1363	15,401	15,401	4	61,604	6,237,405
483.430(f) - Intermediate Care Facilities for	0938-1402	5,780	5,780	10	57,800	4,300,320

Regulation (§) - Provider or Supplier	OMB Control No.	No. of Respondents	No. of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Labor Costs ($)
Individuals with Intellectual Disabilities (ICFs-IIDs) – Policies and Procedures						
483.430(f) – ICFs-IID - Documentation	0938-1402	5,780	80,000	0.0833	6,664	459,816
484.70(d) - Home Health Agencies (HHAs) – Policies and Procedures	0938-1299	11,649	11,649	10	116,490	9,062,922
484.70(d) – HHAs - Documentation	0938-1299	11,649	2,110,000	0.0833	175,763	12,830,699
485.70(n) - Comprehensive Outpatient Rehabilitation Facilities (CORFs) – Policies and Procedures	0938-1091	159	156	8	1,272	124,656
485.70(n) – CORFs - Documentation	0938-1091	159	10,000	0.0833	833	81,634
485.58(d) - Critical Access Hospitals (CAHs) – Policies and Procedures	0938-1043 and 0938-0328	1,358	1,358-	12	16,296	1,520,960
485.725(f) – Organizations Policies and Procedures	0938-0273	2,078	2,078	10	20,780	1,803,704
485.725(f) – Organizations - Documentation	0938-0273	2,078	10,000	0.0833	833	69,972
485.704(c) - Community Mental Health Centers (CMHCs) – Policies and Procedures	0938-1245	129	129	10	1,290	147,060
485.704(c) – CMHCs - Documentation	0938-1245	129	140,000	0.0833	11,662	1,317,806
486.525(c) - Home Infusion Therapy (HIT) Suppliers – Policies and Procedures	0938-1377	337	337	10	3,370	89,979
486.525(c) – HITs - Documentation	0938-1377	317	20,000	0.0833	1,666	121,618
491.8(d) - Rural Health Clinics	0938-0334	15,317	15,317	15	229,755	29,653,712

Regulation (§) - Provider or Supplier	OMB Control No.	No. of Respondents	No. of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Total Labor Costs ($)
(RHCs) and Federally Qualified Health Clinics (FQHCs) – Policies and Procedures						
491.8(d) – RHCs and FQHCs - Documentation	0938-0334	15,317	150,000	0.0833	12,495	1,349,460
494.30(b) - End Stage Renal Disease (ESRD) Facilities – Policies and Procedures	0938-0386	7,893	7,893	10	78,930	6,140,754
494.30(b) ESRD Facilities - Documentation	0938-0386	7,893	170,000	0.0833	14,161	1,033,753
Totals					**1,555,487**	**$136,088,221**

*We were not able to locate a reliable number for CAH employees only. The number for hospital employees includes both hospital and CAH employees.

**Since the documentation burden for the IPCP is already accounted for in the current PRA package, OMB Control No. 0938-1363, a separate burden for this rule was not assessed.

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If you comment on these information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the ADDRESSES section of this IFC.

Comments must be received on/by January 4, 2022.

V. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

The COVID-19 pandemic has precipitated the greatest public health crisis in the U.S. since the 1918 Influenza pandemic. The population of older adults, and LTC facility residents in particular, have been hard hit by the impacts of the pandemic. Among those infected, the death rate for older adults age 65 or higher was hundreds of time higher than for those in their 20s during 2020.[FN223] Of the approximately 656,000 Americans estimated to have died from COVID-19 through September 10, 2021,[FN224] 30 percent are estimated to have died during or after an LTC facility stay, although these numbers are decreasing as vaccination rates increase in residents and staff as shown in the CDC Data Tracker. Despite the recent nation-wide surge in infections from the Delta variant of COVID-19, uptake of vaccines and other measures (masking, screening visitors, and social distancing in particular) to prevent COVID-19, in combination with available therapeutic options to treat, has reduced COVID-19-related patient deaths in all settings. But reductions in COVID-19-related morbidity and mortality depend critically on

continued success in vaccination of all health care staff and patients. The May 13, 2021 COVID-19 IFC (86 FR 26306) required offering vaccination to residents and staff, but did not mandate vaccination. Recently, however the Departments of Defense and Veterans Affairs staff, and civilian Federal Government employees have become subject to requirements similar to those imposed in this rule.[FN225] This IFC will close a gap in current regulations for all categories of health care provider whose health and safety practices are directly regulated by CMS. Almost all CMS-regulated providers and suppliers disproportionately serve people who are older, disabled, chronically ill, or who have complex health care needs.[FN226] Because the health care sector has such widespread and direct contact with hundreds of millions of patients, clients, residents, and program participants, the protective scope of this rule is far broader than the health care staff that it directly affects.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared an RIA that, taken together with COI section and other sections of the preamble, presents to the best of our ability the costs and benefits of the rulemaking.

This RIA focuses on the overall costs and benefits of the rule, taking into account vaccination uptake to date or anticipated over the next year that is not due to this rule, and estimating the likely additional effects of this rule on both provider staff and the patients with whom they come in contact. We analyze both the costs of the required actions and the payment of those costs. As intended under these requirements, this RIA's estimates cover only those costs and benefits that are likely to be the effects of this rule. There are also several unknowns that may affect current progress or this rule or both. These include the duration of strong vaccine protection with or without a booster shot and the possibility of new virus variants that reduce the effectiveness of currently authorized and approved vaccines. We cannot estimate the effects of each of the possible interactions among them, but throughout the analysis we point out some of the most important assumptions we have made and the possible effects of alternatives to those assumptions. The providers and suppliers regulated under this rule are diverse in nature, management structure, and size. That said, we believe that the costs faced by regulated entities will be very similar on a "per person vaccinated" basis. Tables 5 and 6 show the full scope of provider and supplier types, facility structures, and staff sizes, taking into account part-time staff (Table 5) and estimated staff turnover (Table 6). As explained earlier in the preamble, this rule includes facility contractors and consulting specialists as well as other persons providing part-time or occasional services to these providers and suppliers and their patients.

In Table 5 we provide a rough estimate of the likely number of full-time employees and other employees and contractors subject to this rule. The "total staff" number in the rightmost column is the number of individual staff directly affected at the time this rule takes effect (adding the number of full-time employees to the number of part-time employees, contractors, and other business persons who have recurring patient or staff interactions).

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TABLE 5: Estimates of Number of Staff by Type of Provider and Supplier (thousands)

Provider or Supplier Type	Number of Providers/Suppliers	Full-Time Employees (thousands)	Add-on Percent for Part-time Employees & Business Visitors	Number Part-time Employees & Business Visitors (thousands)	Total Staff Estimate (thousands)
Long Term Care (LTC) Facilities	15,401	950	10%	100	1,050
Skilled Nursing Care*	*	*	*	*	*
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)	5,780	70	10%	10	80
Psychiatric Residential Treatment Facilities (PRTFs)	357	30	10%	-	30
Hospitals (inpatient)	5,194	5,520	10%	550	6,070
Hospitals (outpatient)**	**	**	**	**	**
Community Access Hospitals (CAHs)	**	**	**	**	**
Ambulatory Surgical Centers (ASCs)	6,071	180	10%	20	200
End-Stage Renal Disease (ESRD) Facilities	7,893	150	10%	20	170
Community Mental Health Centers (CMHCs)	129	130	10%	10	140
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	159	10	10%	-	10
Federally Qualified Health Centers (FQHCs)	10,384	100	10%	10	110
Clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language services (Organizations)	2,078	10	10%	-	10
Rural Health Clinics (RHCs)	4,933	40	10%	-	40
Home Health Agencies (HHAs)	11,649	1,920	10%	190	2,110
Hospices	5,556	310	10%	30	340
Programs of All-Inclusive Care for the Elderly (PACE)	141	10	10%	-	10
Home Infusion Therapy (HIT) Suppliers	329	20	10%	-	20
TOTAL	76,054	9,450		940	10,390

* Included in total for Long Term Care (LTC) Facilities.
** Included in total for Hospitals.

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This rule presents additional difficulties in estimating both costs and benefits due to the high degree to which all current provider and supplier staff

have already received information about the benefits and safety of COVID-19 vaccination, and the rare serious risks associated with it. Despite this progress, the proportion of fully vaccinated health care staff has approached but not hit the 70 percent with significant variation among states. Moreover, among the general population more than 600,000 persons a day are currently being vaccinated with the first or second shot and about 100,000 a day have recovered from infection and are only in very rare cases still infectious. These changes reduce the risk to both health care staff and patients substantially, likely by about 20 million persons a month who are no longer sources of future infections.[FN227] This in turn reduces the number of newly infected cases (currently about 100,000 a day and decreasing rapidly). Yet another variable of importance is the increasing number of providers and suppliers that are mandating employee vaccination, and the increasing number of states that are doing so as well. To characterize the baseline scenario of no new regulatory action, from which we estimate the incremental impacts of the interim final rule, we assume that when Phase 1 of this IFC goes into effect, 75 percent of provider staff, 90 percent of LTC facility residents, and 80 percent of all other patients and clients will have been vaccinated, and that these rates will improve over time as a result of both this rule and the other factors previously discussed.[FN228]

These numbers leave a large range for the likely effects of this rule over time. They do indicate, however, that many cases of death or severe illness can be prevented by increasing the number of vaccinated persons, both for those vaccinated and for

others they might otherwise infect. As estimated in Table 6, the number of unvaccinated health care workers still remains in the millions despite recent progress. As discussed later in this analysis, we use the concept of the value per statistical life and per statistical case to capture this major potential benefit, as recommended by the Office of the Assistant Secretary for Planning and Evaluation based on standard practices in cost-benefit analysis.[FN229]

One additional factor affecting our estimates is remaining life expectancy. Life expectancy varies by age, being about 40 years across an entire population, close to 80 years for a younger population, and a relatively fewer number of years for an older population. These numbers, of course, are overall averages and mask substantial differences by race and sex (among other factors), including access to affordable health care and prevalence of untreated or insufficiently controlled disease. Individuals with diabetes, for example, are disproportionately African American and disproportionately older, which leads to greater risks from kidney failure and other adverse health effects, including greater susceptibility to the ravages of COVID-19.[FN230] Health care staff of most types of providers and suppliers are of typical working ages. But hospital patients, LTC facility residents, ESRD patients treated for kidney failure, and most other patients are heavily weighted towards older ages and are disproportionately members of African American and Native American minority groups. This means that the morbidity and mortality reductions from this rule when they are adjusted for the age ranges affected disproportionally benefit racial minorities.

In particular, LTC facility residents are near the upper end of the age spectrum. For a statistically average LTC facility resident, the average pre-COVID-19 life expectancy if death occurs while in the facility is likely to be on the order of 3 years or fewer but taking into account residents who recover and leave the facility and those enrolled for skilled nursing services we estimate overall life expectancies to be about 5 years.[FN231] We also estimate that vaccination reduces the chance of infection by about 95 percent, and the risk of death from the virus to a fraction of 1 percent.[FN232] In Israel, of the first 2.9 million people vaccinated with two doses there were only about 50 infections involving severe conditions resulting from the virus after the 14th day and of these so few deaths that they were not reported in statistical summaries. These data also show that COVID-19 vaccines are effective for both older and younger recipients. Of those who have received a full primary vaccine series, after the 14th day after vaccination only 46 people over the age of 60 became infected and had a severe case, compared to 6 people under the age of 60. Given that these numbers are compared against 2.9 million recipients of the second dose, both rates are near zero.[FN233]

C. Anticipated Costs of the Interim Final Rule With Comment Period

We note that our cost estimates assume that all additional vaccination costs for providers and suppliers regulated by this rule are due to this rule. We estimate on this basis because we have no reliable way to estimate how much of these costs might be

equally due to independent employer decisions, to other Federal standards, to State and local mandates, or even to individual personal choices.

In our cost estimates we cover all providers regulated by CMS for health and safety standards, but we often use LTC facilities for examples because they pose some of the greatest risks for COVID-19 morbidity and mortality. As documented subsequently in this analysis and in a research report on this issue, about 1.5 million individuals work in LTC facilities at any one time.[FN234] A number of these individuals work in multiple LTC facilities which may play additional roles in transmission.[FN235, 236]These individuals are at high risk both to become ill with COVID-19 and to transmit the SARS-CoV-2 virus to residents or visitors, or among themselves. Far more than most occupations, LTC facility work requires sustained close contact with multiple persons daily.

In Table 6 we present estimates of total numbers of staff individuals regulated under this rule, distinguishing between numbers at the beginning of a year and at any one time during the year, versus the much higher numbers when turnover is considered. In Table 6 we assume that the number departing each year is the same as the number entering each year, which is a reasonable approximation to changes in just a few years, but do not take account of the aging of the population over time. We note that our estimates do not include a deduction for the overlap among individuals who work in more than one LTC facility. We know that this number is substantial, but have no basis for estimating its precise magnitude and, more importantly, how it may change after this

rule goes into effect and facilities change their staffing and hiring patterns. One recent study found about 17% of LTC nursing staff held second jobs, and another recent study found that about 5% held more than one LTC job. The second study, moreover, found that facilities with substantial staff sharing were disproportionally associated with as many as 49% of nursing home COVID-19 cases.[FN237]

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TABLE 6: Estimates of Number and Vaccination Status of Staff by Provider and Supplier Type (thousands)

Provider or Supplier Type	Beginning of First Year	New Hires During First Year	Total for First Year	Percent Vaccinated by BOY	Number Vaccinated by BOY	Unvaccinated by BOY	Unvaccinated New Staff	Total To Be Vaccinated First Year
Long Term Care (LTC) Facilities	1,050	760	1,810	75%	790	260	40	300
Skilled Nursing Care*	*	*	*	*	*	*	*	*
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID)	80	60	140	75%	60	20	-	20
Psychiatric Residential Treatment Facilities (PRTFs)	30	10	40	80%	20	10	-	10
Hospitals (inpatient)	6,070	1,210	7,280	80%	4,860	1,210	60	1,270
Hospitals (outpatient)**	**	**	**	**	**	**	**	**
Community Access Hospitals (CAHs)	**	**	**	**	**	**	**	**
Ambulatory Surgical Centers (ASCs)	200	40	240	75%	150	50	-	50
End-Stage Renal Disease (ESRD) Facilities	170	30	200	75%	130	40	-	40
Community Mental Health Centers (CMHCs)	140	30	170	75%	110	30	-	30
Comprehensive Outpatient Rehabilitation Facilities (CORFs)	10	-	10	75%	10	-	-	-
Federally Qualified Health Centers (FQHCs)	110	20	130	75%	80	30	-	30
Clinics, rehabilitation agencies, and public health agencies that provide outpatient physical therapy and speech-language services (Organizations)	10	-	10	75%	10	-	-	-
Rural Health Clinics (RHCs)	40	10	50	75%	30	10	-	10
Home Health Agencies (HHAs)	2,110	420	2,530	75%	1,580	530	20	550
Hospices	340	70	410	75%	260	80	-	80
Program of All-Inclusive Care for the Elderly (PACE)	10	-	10	75%	10	-	-	-
Home Infusion Therapy (HIT) Suppliers	20	-	20	75%	20	-	-	-
TOTAL	10,390	2,660	13,050		8,120	2,270	120	2,390

* Included in total for Long Term Care (LTC) Facilities.
** Included in total for Hospitals.

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These figures are approximations, because none of the data that is routinely collected and published on

resident populations or staff counts focus on numbers of individuals residing or working in the facility during the course of a year or over time. Depending on the average length of stay (that is, turnover) in different facilities,an average population at any one time of, for example, 100 persons could be consistent with radically different numbers of individuals, such as 112 individuals in one facility if one person left each month and was replaced by another person, compared to 365 if one person left each day and was replaced that same day by another person.

As a specific example, we assume that about 90 percent of existing LTC facility residents and 75 percent of existing staff will have been vaccinated by the date Phase 1 of this IFC takes effect (we use the same or similar assumptions for all provider types). There will be many new persons in each category during the first full year of the regulation, and likely almost all of these will have been vaccinated elsewhere (for simplicity we also assume a base rate 95 percent for this group, almost all of whom will have previously worked in a health care facility requiring vaccination).

As presented in the third numeric column of Table 6, the total number of employees or otherwise compensated individuals working in all these different facilities over the course of a year is about 13 million persons, which is almost half again larger than the annual average number of staff shown in the first numeric column. A recent study, using data from detailed payroll records, found that median turnover rates for all nurse staff in long term care facilities is approximately 90 percent a year, although other estimates are far lower (see subsequent

discussion).[FN238] We have not seen figures this high for other provider types but some may approach this level—home health care is well known for high turnover rates.[FN239] Of course, most of these persons will have been vaccinated through other means when they enter the facilities during the next year. That said, it is likely that there will be approximately 2.4 million staff at the beginning or during the first year after this rule is published who will require vaccination (rightmost column of Table 6), possibly preceded in some cases by counseling efforts or employer inducements.

While this IFC does not expressly require COVID-19 vaccine counseling or education, we anticipate that some providers and suppliers will conduct such activities as a part of their procedures for ensuring compliance with the provisions of this rule. Some staff counseling can take place in group settings and some will take place on a one-to-one level. What works best will depend on the circumstance of the employee and the best method for conveying the information and answering questions. Staff education, using CDC or FDA materials, can also take place in various formats and ways. Individualized counseling, staff meetings, posters, bulletin boards, and e-newsletters are all approaches that can be used. Informal education may also occur as staff go about their daily duties, and some who have been vaccinated may promote vaccination to others. Facilities may find that reward techniques, among other strategies, may help. For example, monetary or other benefits such as paid days off could be given to staff who agree to vaccination. Even simpler, the employer can bring vaccination providers onsite to vaccinate staff (or both staff and

unvaccinated patients). Of importance in such efforts, the value of immunization as a crucial component of keeping patients healthy and well is already conveyed to staff about influenza and pneumococcal vaccines. COVID-19 vaccine persuasion can build upon that knowledge. The most important inducement will be the fear of job loss, coupled with the examples set by fellow vaccine-hesitant workers who are accepting vaccination more or less simultaneously.

One hundred percent success is unlikely. The HHS Guidelines for Regulatory Impact Analysis note that "[i]n most cases, the analysis focuses on estimating the incremental compliance costs incurred by the regulated entities, assuming full compliance with the regulation, and government costs." These guidelines further recommend that "[a]nalysts should consider the uncertainty associated with an assumption of full compliance and provide analysis of alternative assumptions, as appropriate." [FN240] In preparing this analysis, we have identified several significant sources of uncertainty for these full-compliance estimates, one of which stands out.

If only one health care provider in an area required staff vaccination, then those who refuse vaccination could quit and obtain employment at another location in the same field or type of position.[FN241] But with many employers already mandating vaccination, and with nearly all local (and distant) health care employers requiring vaccination under this rule, we expect that such effects will be minimized (with exceptions for medical or other exemptions as required by law). That said, currently there are endemic staff shortages for almost all categories of employees at almost all kinds of health care providers

and supplier and these may be made worse if any substantial number of unvaccinated employees leave health care employment altogether. In this regard, we note that because CMS does not regulate health and safety in physician and dental offices, or in non-health care settings such as assisted living facilities, those entities may provide alternative places of employment for some of the staff currently working for providers and suppliers subject to this IFC who refuse vaccinations. On the other hand, staff shortages might be offset by persons returning to the labor market who were unwilling to work at locations where some other employees are unvaccinated and hence provide some risk, to those who have completed the primary vaccination series for COVID-19. Despite these uncertainties, we have developed an estimate of staffing disruption costs, primarily to provide a complete cost picture even if this element is particularly uncertain. We note that these costs and benefits are highly dependent on whether, for example, staff vaccination refusals in coming months are closer to 1 percent than to 10 percent, and the extent to which increased confidence in the safety of working in a health care setting leads to offsetting increases in the return of former health care employees to the workforce. Both variables, in turn, may depend in significant ways on the overall labor market and on the ability of telehealth measures to replace in-person staff to patient encounters. The net outcomes of staff turnover over time could easily exceed or offset the administrative and vaccination costs we have estimated. We welcome comments and information on these issues.

The techniques for staff counseling, education, and incentives are so numerous and varied that there is no simple way to estimate likely costs. Staff hesitancy may and likely will change over time as the benefits of vaccination become clear to increasing numbers of individuals working in health care settings. For purposes of estimation, we assume that, on average, one hour of staff time or the equivalent will be devoted to counseling or incentives for each unvaccinated staff person, at the same average hourly cost of about $75 estimated for RNs in the Information Collection analysis. We assume that these efforts occur during paid working hours and that all costs will be borne by the facility. Since we estimate that about 2.4 million employees will need to be vaccinated (or replaced) in the first year (rightmost column of Table 6), most in the first two months after this rule is published, total costs would be about $180 million. This estimate assumes that the 2.4 million will be some mix of existing and replacement staff. For example, if 95% of the existing unvaccinated staff were vaccinated, and 5% of the unvaccinated staff terminated, then in addition to the normal turnover of 2.7 million new hires (second column of Table 6) an additional 114 thousand (.05 x 2,270) persons would need to be hired, with 95% of them already fully vaccinated and the remainder getting vaccinated as a condition of hiring. For purposes of this estimate we ignore the existence of exemptions.

A third major cost component of compliance with this IFC is the vaccination, including both administration and the vaccine itself. We estimate that the average cost of a vaccination is what the government pays under Medicare: $20 x 2 = $40 for

two doses of a vaccine, and $20 x 2 for vaccine administration of two doses, for a total of $80 per employee. For purposes of estimation (and not reflecting any more knowledge than recent press accounts), we further assume that there will be a "booster" shot at the same cost, for a total vaccination cost of $120 per employee. While these vaccine costs are currently incurred by the Federal Government, we include them to provide an estimate of total costs, regardless of who pays. In addition, we expect that a significant amount of time—one hour on average—will be used per employee in vaccine planning, arrangement, and administration, and related activities for three vaccinations per currently unvaccinated employee. Together with the additional assumption that there will be an hour RN time or the equivalent needed for arranging or administering vaccination, at an average cost for that hour of $75, the total cost for vaccination compliance will be $195 per employee. We apply that cost to all currently unvaccinated employees. Like counseling and incentives, if 5% of the existing unvaccinated staff leave and are replaced by a slightly higher number of new hires than would otherwise be needed, a roughly equivalent fraction of the new hires will need to be vaccinated before they have patient contact. As a result, we estimate the total costs of vaccination to be approximately $466 million (2,390,000 unvaccinated employees x $195). We note again that these estimates do not reflect the factor that multiple vaccine mandates already do or will soon apply to many and perhaps most providers covered by our rule (employers' own self-imposed mandates, State and local mandates, and OSHA ETS, among others). This

means the costs of this rule are overestimated due to this factor, a conservative assumption.

Our fourth and final major cost category is staffing and service disruptions. As discussed previously, it is possible there may be disruptions in cases where substantial numbers of health care staff refuse vaccination and are not granted exemptions and are terminated, with consequences for employers, employees, and patients. We do not have a cost estimate for those, since there are so many variables and unknowns, and it is unclear how they might be offset by reductions in current staffing disruptions caused by staff illness and quarantine once vaccination is more widespread. We believe, however, that the disruptive forces are weaker than the return to normality. As shown in Table 6, it is normal for there to be roughly 2.66 million new hires (column two) in the health care settings we address in this rule, compared to a baseline of roughly 10.4 million staff (column one). These new hires replace a roughly equal number of employees leaving for one reason or another. Health care providers are already in the business of finding and hiring replacement workers on a large scale. The terminated or self-terminated workers are not going to disappear. They still need to earn a living. Many of the non-clinical staff may will find employment situations in settings that are not subject to vaccination mandates. Cooks, for example, may migrate to restaurant jobs. But in those cases, a cook who would otherwise have been hired by a restaurant may find a newly vacant health care position requiring vaccination and accept (or more likely already have) vaccination. Similarly, nurses may find jobs in health care settings that are not

subject to vaccination mandates, such as most schools or physician offices. But that means that nurses who would otherwise have been hired in schools or physician offices may find jobs in vacant jobs in health care settings requiring vaccination and accept (or more likely already have) vaccination. In a dynamic labor market such behaviors occur continuously on a massive scale. If net employment opportunities and job-seeking behaviors do not change (and there is no reason to believe they will), these continuous adjustments will leave health care providers and suppliers subject to this rule with their desired staff levels, and former employees who refused vaccination in jobs that do not require vaccination. Because job seeking and worker seeking are already operating on a massive scale in the health care sector, there is no reason to expect any massive new costs in such routine functions as advertising jobs, checking applicant employment history, familiarizing new employees with the nuances of the new employment setting, training, and all the other steps and costs involved in the normal workings of the labor market.

As an example of the likely magnitude of hiring costs, one analysis of direct hiring costs for workers in the long-term care sector (including LTC facilities, home health care, and ICFs-IID) found that the direct costs of hiring new workers was on average about $2,500 in 2004.[FN242] Assuming that this amount should be raised to $4,000 based on inflation since then, that a comparable estimate for higher skills health care professions would be $6,000, and that health care workers covered by this rule are half lower skilled and half higher skilled, the recruitment and hiring cost for additional hires equal to 5 percent of

the normal annual hiring total of 2.4 million workers would be $600 million (an average of $5,000 x 120,000). (Costs could actually be lower because this study is almost a decade old and internet services have in recent years made recruitment and job application procedures far easier.)

An additional cost category may result from COVID-19-related staff shortages, discussed extensively earlier in this IFC. Although, as noted earlier, COVID-related staff shortages are occurring absent the rule due to numerous factors, such as infection, quarantine and staff illness. Shortages at their most acute prevent facilities from admitting as patients, clients, residents, or participants persons they would normally admit for treatment of diseases or conditions that would in many cases result in death or serious disability. We are not aware of any data that would enable a reasonably accurate estimate of the total medical morbidity and mortality involved, but it is certainly massive. While it is true that compliance with this rule may create some short-term disruption of current staffing levels for some providers or suppliers in some places, there is no reason to think that this will be a net minus even in the short term, given the magnitude of normal turnover and the relatively small fraction of that turnover that will be due to vaccination mandates. Moreover, the benefits of vaccination are not just the lives directly saved, but the resources that vaccination frees up because hospital, LTC facility, and rehabilitation beds are now available and because health care staff themselves are not being incapacitated or killed by COVID-19 infection. The data on cumulative COVID-19 cases among health care personnel show 677,000 cases

(most of which incapacitated workers at least temporarily), and 2,200 deaths, all of which permanently eliminated those workers as sources of future care.[FN243]

Table 7 shows all of the costs that we have estimated. As previously explained, much and perhaps most of these costs would be incurred under other concurrent mandates, including employer-specific decisions, other Federal standards, and some State and local government mandates. Since these efforts overlap in scope, reach, and timing, there is no basis for assigning most of these costs to this rule or any other similar rule.

TABLE 7: Estimate of Total First Year Costs ($millions)

Cost Category	Estimate
Information Collection Costs	136
Counseling and Incentive Costs	180
Vaccination Costs	466
Disruptions to Staffing and Services	600
TOTAL	1,382

There are major uncertainties in these estimates. One obvious example is whether vaccine efficacy will last more than the approximately 1 year proven to date and whether boosters are needed.[FN244] Some in the scientific community believe that "booster" vaccinations after 6 or 8 months would be desirable to maintain a high level of protection against the predominant Delta version of the virus. Delta may be overtaken by other virus mutations, which creates

another uncertainty. Booster vaccination or use of vaccines whose licenses or EUAs have been amended to address new variants would likely maintain the effectiveness of vaccination for residents and staff. At this time, as to second (and succeeding) year effects we assume no further major changes in vaccine effectiveness. Yet another uncertainty is treatment costs, with a recently announced antiviral pill that could potentially provide substantial reductions in severity of illness and subsequent treatment costs, on a time schedule as yet unknown.[FN245]

D. Anticipated Benefits of the Interim Final Rule With Comment Period

There will be more than 180 million staff, patients, and residents employed or treated each year in the facilities covered by this rule. In our analysis of first-year benefits of this rule we focus first on prevention of death among staff of facilities as well as on reduction in disease severity. Second, we focus on resulting benefits from avoiding infection by unvaccinated staff among patients served in these facilities, who are likely to benefit more substantially because patients receiving health care in such facilities are disproportionately older than working age adults and are therefore more susceptible to severe illness or death from COVID-19. A third group of beneficiaries are staff family members and caregivers and many other persons outside the health care settings who staff might subsequently infect if not vaccinated. We focus initially on LTC facilities because their residents and patients have been among the most severely affected by COVID-19 as well as

illustrating all the estimating issues involved, but the same estimates, uncertainties, and calculations apply to all types of providers and suppliers in varying degrees.

HHS's Guidelines for Regulatory Impact Analysis outline a standard approach to valuing the health benefits of regulatory actions. The approach for valuing mortality risk reductions is based on the value per statistical life (VSL), which estimates individuals' willingness to pay (WTP) to avoid fatal risks. The approach to valuing morbidity risk reductions is based on measures of the WTP to avoid non-fatal risks when specific estimates are available, and based on measures of the duration and severity of the illness, including quality of life consequences, when suitable WTP estimates are not available.[FN246] Based on this approach, the Office of the Assistant Secretary for Planning and Evaluation published a report that develops an approach for valuing COVID-19 mortality and morbidity risk reductions.

In addition to the avoided death and human suffering, one of the major benefits of vaccination is that it lowers the cost of treating the disease among those who would might otherwise be infected and have serious morbidity consequences. The largest part of those costs is for hospitalization. As discussed later in the analysis we provide data on the average costs of hospitalization of these patients (it is, however, unclear as to how much that cost will change over time due to improving treatment options).

There is a potential offset to benefits that we have not estimated because we believe it is at this time not relevant in the U.S. If vaccine supplies did not meet all demands for vaccination, giving priority to some

persons over others necessarily meant that some persons would become infected who would not have been infected had the priorities been reversed. In this case, however, the priority for older adults (virtually all of whom have risk factors) who comprise the majority of hospital inpatients and the vast majority of LTC facility residents has already been established and is largely met. This rule provides a priority for staff at a far lower risk of mortality and severe disease that benefits both groups.[FN247] It achieves this benefit because by preventing the spread of COVID-19 from provider and supplier staff, it actually provides a higher mortality and morbidity reduction for patients at far higher risk than the staff who become vaccinated.[FN248]

The HHS "Guidelines for Regulatory Impact Analysis" explain in some detail the concept of Quality Adjusted Life Years (QALYs).[FN249] QALYs, when multiplied by a monetary estimate such as the Value of a Statistical Life Year (VSLY), are estimates of the value that people are willing to pay for life-prolonging and life-improving health care interventions of any kind (see sections 3.2 and 3.3 of the HHS Guidelines for a detailed explanation). The QALY and VSLY amounts used in any estimate of overall benefits are not meant to be precise, but instead are rough statistical measures that allow an overall estimate of benefits expressed in dollars.

Under a common approach to benefit calculation, we can use a Value of a Statistical Life (VSL) to estimate the dollar value of the life-saving benefits of a policy intervention, for a person who more broadly represent a mixture of ages. We use the VSL of approximately $11.5 million in 2021 as described in

the HHS Guidelines, adjusted for changes in real income and inflated to 2020 dollars using the Consumer Price Index.[FN250] Using LTC facilities as an example, and assuming that the average rate of death from COVID-19 (following SARS-CoV-2 infection) at typical LTC facility resident ages and conditions is 5 percent, and the average rate of death after vaccination is essentially zero, the expected value of each resident who would, in the absence of this rule, otherwise be infected with SARS-CoV-2 is about $575,000 ($11.5 million x .05). For staff, who are generally of working ages in roughly the same proportions as the population at large, the typical rate of death for the full course of two vaccines (or possibly three with a booster) is roughly 1 percent of the older adult rate, and the expected value for each employee receiving the same vaccinations is about $57,500 ($11.5 million x .005).[FN251] For community residents who unvaccinated staff might infect, the resulting calculation is similar (actually somewhat lower because the risk of death from COVID-19 is even lower for those below employment ages).

Under a second approach to benefit calculation, we can estimate the monetized value of extending the life of LTC facility residents, which is based on expectations of life expectancy and the value per life-year. As explained in the HHS Guidelines, the average individual in studies underlying the VSL estimates is approximately 40 years of age, allowing us to calculate a value per life-year of approximately $590,000 and $970,000 for 3 and 7 percent discount rates respectively. This estimate of a value per life-year corresponds to 1 year at perfect health. (These amounts might reasonably be halved for average LTC

facility residents, since non-institutionalized U.S. adults aged 80-89 years report average health-related quality of life (HRQL) scores of 0.753, and this figure is likely to be lower for LTC facility residents.[FN252]) Assuming that the average life expectancy of long term care residents is 5 years, the monetized benefits of saving one statistical life would be about $3.0 million ($590,000 x annually for 5 years) at a 3 percent discount rate and about $4.8 million ($970,000 x annually for 5 years) at a 7 percent discount rate. Assuming that the average rate of death from COVID-19 (SARS-CoV-2 infection) at LTC facility resident ages and conditions is 5 percent, and the average rate of death after vaccination is essentially zero, the expected life-extending value of each resident who would otherwise be infected is $150 thousand at a 3 percent discount rate and $240 thousand at a 7 percent discount rate. A similar calculation can be made for staff and for the community residents they might infect, who will gain many more years of life but whose risk of death is far smaller since their age distribution is so much younger. Deaths from COVID-19 in unvaccinated LTC facility residents during 2020 were about 130,000, or close to one tenth of the average LTC facility resident census of 1.4 million, a huge contrast to the handful of deaths in the vaccination results from Israel.[FN253] We do not have sufficient data so as to accurately estimate annual resident inflows and outflows over time, but it is clear that over two million new residents and over 700,000 new employees make the total number of individuals involved during the year far higher than point in time or average counts. Moreover, these counts do not include family members

and other visitors, whose total visits certainly number in the millions.

Most of the preceding calculations address residential long-term care. Long term care residents are a major group within LTC facilities and are generally in the LTC facility because their needs are more substantial and they need assistance with the activities of daily living, such as cooking, bathing, and dressing. These long-term stays are primarily funded by the Medicaid program (also, through long term care insurance or self-financed), and the custodial care services these residents receive are not normally covered by Medicare or any other health insurance.[FN254] A second major group within the same facilities receives short-term skilled nursing care services. These services are rehabilitative and generally last only days, weeks, or months. They usually follow a hospital stay and are primarily funded by the Medicare program or other health insurance. The importance of these distinctions is that the numbers of residents and typical ages in each category regulated under this rule in each category are different. The average number of persons in facilities for long term care over the course of a year is about 1.2 million residents (as is the point-in-time number), and the total number of persons over the course of a year is about 1.6 million. The average number in skilled nursing care at any one time is about 2 thousand persons, because the average length of stay is weeks rather than years and the median length of stay is days rather than weeks.[FN255] The annual turnover in this group is such that about 2.3 million residents are served each year. There is some overlap between these two populations and the same

person may be admitted on more than one occasion. For purposes of this analysis (these are rough estimates because there are no data routinely published on patient and resident turnover or providing unduplicated counts of persons served), we assume that the expected longevity for each group is identical on average, and that a total of 3.9 million different persons are served each year. The employee staff are a third group and the direct target of these rules. Since both long-term and short-term residents are for the most part served in the same facilities, their care is managed and provided by the same facility staff.

These nursing facilities have about 950,000 full-time equivalent employees at any one time and another 100,000 visiting staff or the equivalent, all covered by this rule. For these persons, the average age is about 45, which creates two offsetting effects: they have more years of life expectancy than residents, but their risk of death from COVID-19 is far lower. For purposes of this analysis, we assume that vaccination against COVID-19 is effective for at least 1 year and use a 1-year period as our primary framework for calculation of potential benefits, not as a specific prediction but as a likely scenario that avoids forecasting major and unexpected changes that are either strongly adverse or strongly beneficial. If we were adding up totals for benefits we would assume that the risk of death after COVID-19 infection is likely only one-half of one percent (one tenth of the resident rate) or less for the unvaccinated members of this group, reflecting the far lower mortality rates for persons who are almost all in the 18 to 65 year old age ranges compared to the far older

residents.[FN256] We assume that the total number of individual employees is 50 percent higher than the full-time equivalent but that only half that number are primarily employed at only one nursing facility, two offsetting assumptions about the number of employees working at each facility (many employees are part-time consultants or the equivalent who serve multiple nursing facilities on a part-time basis). We further assume that employee turnover is 80 percent a year, lower than the results for nurses previously cited. Accordingly, we estimate that 80 percent of 950,000, or 760,000, are new employees each year and must be offered vaccination (again, most are already vaccinated), for a total of 1,710,000 eligible employees over the course of a year. (This number would likely drop in future years as employers decide to hire only persons previously vaccinated and as vaccine uptake increases due to Federal, State, local, or employer requirements, as well as individual choice.)

We have some data on the costs of treating serious illness among the unvaccinated who become infected, are hospitalized, and survive. Among those age 65 years or above, or with severe risk factors, over 30 percent of those known to be infected required hospitalization in the first year of the pandemic.[FN257] That fraction is far lower now as treatments have improved and as vaccinations have greatly reduced severity of the disease. Among adults aged 21 years to 64 years, about 10 percent of those infected once required hospitalization, but that fraction is now far lower for the same reasons. For our estimates, we assume a 10 percent hospitalization rate among people aged 65 years or older in LTC facilities, reflecting both that their conditions are

significantly worse than those of similarly aged adults living independently, and that pre-hospitalization treatments have improved. For staff we assume one fifth of this rate, or 2 percent. Using LTC facilities as our main example, the LTC facility candidates for vaccination in the first year covered by this rule, about three-fourths are age 65 years or above. Hence, the age-weighted hospitalization rate that we project is about 8 percent. Among those hospitalized at any age, the average cost is about $20,000.[FN258]

To put these cost, benefit, and volume numbers in perspective, vaccinating one hundred previously unvaccinated LTC facility residents who would otherwise become infected with SARS-CoV-2 and have a COVID-19 illness would cost approximately $18,000 ($183 x 100) in vaccination costs. Using the VSL approach to estimation would produce life-saving benefits of about $400,000 for these 100 people ($20,000 x 100 x .05), again assuming the death rate for those ill from COVID-19 of this age and condition is one in twenty. Reductions in health care costs from hospitalization would produce another $160,000 ($20,000 x 100 x .08) in benefits for this group assuming that 8 percent would otherwise be hospitalized. However, this comparison should be taken as necessarily hypothetical and contingent due to the analytic, data, and uncertainty challenges discussed throughout this regulatory impact assessment. Patient benefits are simply a consequence of fewer infections among staff. Vaccinating one hundred previously unvaccinated LTC facility employees would be higher than for staff. Life-saving benefits to employees would be about $5,300,000 ($10,600,000 VSL x 100 x .005) for 100

people assuming that the death rate for these far younger 100 people is 1 in 500 hundred. Reductions in health care costs from hospitalizations of employees would produce another $20,000 ($20,000 x 100 x .01).

There remain difficult questions of estimating (1) likely numbers of individuals in staff and patient categories who are likely to be unvaccinated when the rule goes into effect and (2) numbers of staff likely to be willing to accept vaccination in the coming months and years.[FN259] Both sets of numbers vary substantially by provider and supplier type. LTC facility and home health care patients are on average both the oldest and most health-impaired of those in settings covered by this rule. At the other extreme, rural and other community-care oriented health centers serve the full age spectrum and a lower fraction of severely health-impaired.

We do know that the life-saving benefits for staff are probably small but significant. During the entire period of COVID-19 infections, since March 2020, there have been over 2,000 health care staff deaths recorded by the CDC through October 3, 2021.[FN260] Of these, the great majority were in the year 2020. Even during the recent Delta variant surge, health care staff deaths decreased to lower levels. Specifically, during the last 6 months, April through September 2021, total staff deaths were 202, an average of 34 per month and no clear trend (the last 4 weeks, all in September, 2021 produced fewer than 20 deaths). This is not surprising as the most effective precautions other than vaccination—masks, social distancing, and ventilation—have been essentially universal in the health care sector during all of 2021. Even more importantly, vaccination rates

are considerably higher than in the population at large (although still well below optimal levels). Yet, using the last 6 months of CDC Data Tracker information, on an annual basis more than 400 deaths could be expected. These data, moreover, are almost all among unvaccinated persons and are probably undercounted in current data.

A major caution about these estimates: None of the sources of enrollment information for these programs regularly collect and publish information on client or staff turnover during a year. These data have not previously been found useful in program management for individual agencies or programs, or when needed have been addressed through one-time research projects. The estimates in this analysis are based on inferences from scattered data on average length of stay, mortality, job vacancies, news accounts, and other sources that by happenstance are available for one type of facility or type of resident or another. Nor do we have data on the number of persons in these settings who will be vaccinated through other means during the remainder of the year.

All these data and estimation limitations apply to even the short-term impacts of this rule, and major uncertainties remain as to the future course of the pandemic, including but not limited to vaccine effectiveness in preventing "breakthrough" disease transmission from those vaccinated, the long-term effectiveness of vaccination, the emergence of treatment options, and the potential for some new disease variant even more dangerous than Delta.

Another unknown is what currently unvaccinated employees would do when the vaccination deadline is reached, and how rapidly those quitting rather than

being vaccinated could be replaced. Even a small fraction of recalcitrant unvaccinated employees could disrupt facility operations. On the other hand, there have been significant reductions in provider and supplier staffing needs in some categories. For example, LTC facility admissions have declined in the last year, as families and caregivers sought to avoid the risks of exposing a care recipient to unvaccinated residents and staff in LTC facilities. The new vaccination requirement may reduce such fears and bring higher numbers of residents to these facilities and the essential services they provide. Again, we have no way to estimate such behavioral changes.

Regardless, we believe it is clear that reductions in patient/resident fatalities through avoiding staff-generated infections are both likely to be a significantly larger benefit from staff vaccination than direct benefits to staff. Staff vaccination will also provide significant community benefits when staff are not at work. Hence, total lives saved under this rule may well reach several hundred a month or perhaps several thousand a month for all three groups in total. Patient and resident benefits are especially likely to be many times higher because the risks of death and serious disease complications are so many times higher among older persons and people with multiple chronic conditions.

As indicated by the preceding analysis, predicting the full range of benefits and costs in either the short run or the next full year with any degree of estimating precision is all but impossible. As the minimum benefit level needed for benefits to exceed costs, however, we estimate that either saving 120 lives, or preventing 600 hundred hospitalizations for serious

illness, or any combination of these two magnitudes, would produce benefits that exceed our estimate of costs over the next year. There have been about 200 staff deaths in the last 6 months and this is a likely undercount for this one category of persons alone, and potential life-saving benefits to more than 150 million mostly elderly patients and residents (about 10 percent of whom are likely to remain unvaccinated) who are exposed to provider staff probably would be many times higher. We note, however, as discussed in the preceding section on costs, much of these benefits could be as well attributed to other concurrent and parallel vaccination mandates and campaigns.

E. Other Effects

1. Sources of Payment

The initial costs of this rule fall almost entirely on health care providers and suppliers and are extremely small in comparison to the $4 trillion a year spent on health care, mostly through these same entities. In particular, the costs of the vaccines are paid by the Federal Government and vaccine costs are about two-thirds of the total costs we have estimated. Moreover, through the treatment cost savings to the hospitals and other care providers resulting from the vaccinations that will be made due to this rule, significant savings would accrue to payers. It is likely that half or more of these savings would primarily accrue to Medicare given the age or disability status of most clients and Medicare's role as primary payer, but there would also be substantial savings to Medicaid, private insurance paid by employers and employees, and private out-of-pocket payers including

patients and residents. In some rare cases funds under the CARES Act and the American Rescue Plan Act of 2021 might be available at State or local discretion, but it is hard to foresee any substantial budgetary impact on any insurance plan or service provider that would justify or require such assistance.

2. Regulatory Flexibility Act

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. Under the RFA, "small entities" include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. For purposes of the RFA, we estimate that most health care facilities are small entities as that term is used in the RFA because they are either nonprofit organizations or meet the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). HHS uses an increase in costs or decrease in revenues of more than 3 to 5 percent as its measure of "significant economic impact." The HHS standard for "substantial number" is 5 percent or more of those that will be significantly impacted, but never fewer than 20.

As estimated previously, the total costs of this rule for 1 year are about $1.3 billion, most of which is directly proportional to number of employees. Spread over 10.4 million full-time equivalent employees, this is about $125 per employee. Assuming a fully loaded average wage per employee of $90,000, the first-year cost does not approach the 3 percent threshold.

Moreover, since much of these costs (in particular, the vaccine costs paid by the Federal Government) will not fall on providers or suppliers, the financial strain on these facilities should be negligible. Finally, as previously discussed, there are other concurrent mandates and much of these costs could as well be attributed to those efforts. Therefore, the Department has determined that this IFC will not have a significant economic impact on a substantial number of small entities and that a final RIA is not required. Finally, this IFC was not preceded by a general notice of proposed rulemaking and the RFA requirement for a final regulatory flexibility analysis does not apply to final rules not preceded by a proposed rule. Regardless, this RIA and the main preamble, taken together, would meet the requirements for either an Initial or Final Regulatory Flexibility Analysis.

3. Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare an RIA if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. For purposes of this requirement, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Because this rule has only the small impact per employee calculated for RFA purposes, the Department has determined that this IFC will not have a significant impact on the operations of a substantial number of small rural hospitals. This IFC is also exempt because that provision of law only applies to final rules for which a proposed rule was published. That said, early

indications are that rural hospitals are having greater problems with employee vaccination refusals than urban hospitals, and we welcome comments on ways to ameliorate this problem.

4. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates will impose spending costs on State, local, or tribal governments, or by the private sector, require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This rule contains no State, local, or tribal governmental mandates, but does contain mandates on private sector entities that exceed this amount. However, this IFC was not preceded by a notice of proposed rulemaking, and therefore the requirements of UMRA do not apply. The analysis in this RIA and the preamble as a whole would, however, meet the requirements of UMRA.

5. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This rule would pre-empt some State laws that prohibit employers from requiring their employees to be vaccinated for COVID-19. Consistent with the

Executive Order, we find that State and local laws that forbid employers in the State or locality from imposing vaccine requirements on employees directly conflict with this exercise of our statutory health and safety authority to require vaccinations for staff of the providers and suppliers subject to this rule. Similarly, to the extent that State-run facilities that receive Medicare and Medicaid funding are prohibited by State or local law from imposing vaccine mandates on their employees, there is direct conflict between the provisions of this rule (requiring such mandates) and the State or local law (forbidding them). As is relevant here, this IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader grounds for exemptions than provided for by Federal law and are inconsistent with this IFC. In these cases, consistent with the Supremacy Clause of the Constitution, the agency intends that this rule preempts State and local laws to the extent the State and local laws conflict with this rule. The agency has considered other alternatives (for example, relying entirely on measures such as voluntary vaccination, source control alone, and social distancing) and has concluded that the mandate established by this rule is the minimum regulatory action necessary to achieve the objectives of the statute. Given the contagion rates of the existing strains of coronavirus and their disproportionate impacts on Medicare and Medicaid beneficiaries, we believe that vaccination of almost all staff of covered providers and suppliers is necessary to promote and protect patient health and safety. The agency has examined case studies from other employers and concludes that vaccine mandates are vastly more

effective than other measures at achieving ideal vaccination rates and the resulting patient protections from morbidity and mortality. Given the emergency situation with respect to the Delta variant detailed more fully above, time did not permit usual consultation procedures with the States, and such consultation would therefore be impracticable. We are, however, inviting State and local comments on the substance as well as legal issues presented by this rule, and on how we can fulfill the statutory requirements for health and safety protections of patients if we were to exempt any providers or suppliers based on State or local opposition to this rule.

F. Alternatives Considered

As discussed earlier in the preamble, a major substantive alternative that we considered was to limit COVID-19 vaccination requirements to full-time employees rather than to all persons who may provide paid or unpaid services, such as visiting specialists or volunteers, who are not on the regular payroll on a weekly or more frequent basis that is, individuals who work in the facility and in some cases infrequently or unpredictably, as well as individuals who are not on the payroll at all. We concluded that covering these persons would be readily manageable without creating major issues for compliance, enforcement, and record-keeping. We did not, however, include some categories of visitors who do not have a business relationship with the provider, such as family member visitors. There are also many issues such as social isolation and loneliness related to potential

discouragement of visiting volunteers or family members.

We also considered whether it would be appropriate to limit COVID-19 vaccination requirements to staff who have not previously been infected by SARS-CoV-2. There remain many uncertainties about as to the strength and length of this immunity compared to people who are vaccinated, and—in recognizing that—the CDC recommends that previously infected individuals get vaccinated. Exempting previously infected individuals would have potentially reduced benefits while reducing costs, both roughly in proportion to the number affected. It would have also, complicated administration and likely require standards that do not now exist for reliably measuring the declining levels of antibodies over time in relation to risk of reinfection. Because of current CDC guidance and understanding of relevant scientific findings, we found that it was not warranted to exempt previously infected individuals.

Another option would be to devise a standard with graduated compliance expectations such as 90 percent and then 95 percent and then 100 percent of staff vaccinated and a time period in which to reach each level. A variation of this would be to put providers on a probationary period if they failed to reach 100 percent compliance by the date set in the rule, and were allowed additional time in which to cross that last threshold. Yet another variation would be to reduce payment to providers and suppliers not meeting the standard after the initial deadline. We recently put a phased system in place for Organ Procurement Organizations (OPOs), so we are not

reflexively opposed to such options.[FN261] Nonetheless, there are two major arguments against such a system in the context of this rule. First, to have any usefulness the time periods would have to have a reasonably extensive duration, such as a month each. But that would be almost the same as extending this rule's deadline for an extra several months. We do not believe that extending the deadline to extend the employment of staff who will simply delay vaccination or final refusal to the last possible moment is in the interest of other staff, patients, and patients who would utilize the provider for needed health care if they did not fear unvaccinated staff. Second, it would not only delay the achievement of both staff and patient safety, but encourage procrastination. For those few staff absolutely unwilling to accept vaccination, it would simply delay the day of final action and the day of hiring a vaccinated replacement. In the case of the OPO rule, an entire organization had to be slowly reformed to achieve compliance. In the context of this rule, and the lives at stake, there is no obvious ethical or managerial reason to give a relative handful of vaccination-resisting individuals more time until they leave the organization. It would give management more time to find replacements, but it is not at all clear that this would be a fruitful grace period.

As for a variation reducing payment to non-performing providers, perhaps by 20 percent per patient over some applicable time period, this would arguably provide something better than an “all of nothing” removal from provider status. It would require legislation but that is not a barrier to meeting E.O. 12866 analysis standards and in some rules may

be essential to a valid benefit-cost analysis. The problem with this variation, however, is that for most providers and suppliers is it unlikely to be a realistic choice. Rather than accept lower payment levels, management can simply terminate the unvaccinated employees, a power they have with or without the reduced payment alternative. Moreover, it would be hard to devise a system that treated equally and fairly providers of all sizes—whether with 5 or 50 employees. We further note that CMS already has and uses discretion in enforcement when inspectors find a violation. Termination of provider status is not normally an immediate consequence, as entities are typically given the opportunity to correct deficiencies. Regardless, we welcome comments on this overall option and its variations, and on the closely-related option of simply adding a month to the compliance deadline in this rule. We considered what standards to apply regarding proof of compliance with exemptions requests base on medical contraindications and religious objections. We decided to establish minimal compliance burdens for both categories of exemptions. This decision on the evidentiary standards could be revisited should an abuse problem arise on a significant scale. This may open the door to forged documents or false statements, and therefore validation of such claims raises administrative costs. Accordingly, we have allowed for relatively relaxed standards for verification in our administrative provisions and cost estimates but may reconsider in the future. We considered alternative timelines for implementation but decided that this would not only delay badly needed live-saving compliance, but also provide little real management

benefit to providers and suppliers. Staff have had almost a year to consider COVID-19 vaccinations that are in their own interests as well as vital to patient protections and the protection of other workers. In this regard we note that one of the claimed barriers to vaccination has recently been removed, now that one vaccine is now no longer emergency-authorized, but fully licensed. We believe our requirements provide more than enough time for reasonable counselling and other management measures.

Finally, we considered requiring daily or weekly testing of unvaccinated individuals. We have reviewed scientific evidence on testing and found that vaccination is a more effective infection control measure. As such, we chose not to require such testing for now but welcome comment. Of course, nothing prevents a provider from exercising testing precautions voluntarily in addition to vaccination. We note that nothing in this rule removes the obligation on providers and suppliers to meet existing requirements to prevent the spread of infection, which in practice means that these entities may also conduct regular testing alongside such actions as source control and physical distancing. CMS will continue to review the evidence and stakeholder feedback on this issue.

These and some lesser options are presented and discussed in the main preamble. We do not have reliable dollar estimates for either costs or benefits of any alternatives, for the reasons already discussed in the RIA regarding the options we chose. We welcome comments on these or other options.

G. Accounting Statement and Table

The Accounting Table summarizes the quantified impact of this rule. It covers only 1 year because there will likely be many developments regarding treatments and vaccinations and their effects in future years and we have no way of knowing which will most likely occur. A longer period would be even more speculative than the current estimates. Nonetheless, assuming no major unforeseen events that would impinge on our estimates, we would expect lower costs in future years if for no other reason than increases in the fraction of new hires already vaccinated as well as other positive results from the President's plan or individual vaccination decisions. We further note that the vaccinations, and hence the benefits and costs, estimated for this rule are more or less simultaneously being created voluntarily by some employers (self-mandates), through the OSHA vaccination rule applicable to employers of 100 or more persons, and by some State or local mandates. There is no simple and non-arbitrary way to disentangle which vaccination benefits and which vaccination costs are due to which source.

As explained in various places within this RIA and the preamble as a whole, there are major uncertainties as to the effects of current variants of SARS-CoV-2 on future infection rates, medical costs, and prevention of major illness or mortality. For example, the duration of vaccine effectiveness in preventing COVID-19, reducing disease severity, reducing the risk of death, and the effectiveness of the vaccine to prevent disease transmission by those vaccinated are not currently known. These

uncertainties also impinge on benefits estimates. For those reasons we have not quantified into annual totals either the life-extending or medical cost-reducing benefits of this rule and have used only a 1-year projection for the cost estimates in our Accounting Statement (our first-year estimates are for the last two months of 2021 and the first ten months of 2022). We also show a large range for the upper and lower bounds of potential costs to emphasize the uncertainty as to several major variables, such as changes in voluntary vaccination levels, longer term effects, and others previously discussed. We welcome comments on all of our assumptions and welcome any additional information that would narrow the ranges of uncertainty or guide us in any important revisions to the requirements established in what is an "interim" final rule.

TABLE 8: Accounting Statement—Classification of Estimated Costs and Savings ($millions)

Category	Primary Estimate	Lower Bound	Upper Bound	Units		
				Year Dollars	Discount rate (%)	Period Covered
Benefits: Lives Extended (not annualized or monetized)				2020	7%	2021-2022
Reduced Medical Expenditures (not annualized or monetized)				2020	3%	2021-2022
Benefits Notes: The two largest benefits categories are staff and patient lives extended through vaccinations for COVID-19 and reduced medical costs for vaccinated persons who would otherwise be hospitalized. Patient benefits are larger than staff benefits.						
Costs: Annualized and Monetized ($million/year)	1,380	1040	1730	2020	7%	2021-2022
	1,400	1040	1730	2020	3%	2021-2022
Cost Notes: Administrative costs from increased staff vaccinations.						
Transfers	None					

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 19, 2021

List of Subjects

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 441

Aged, Family planning, Grant programs—health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Incorporation by reference, Individuals with disabilities, Medicaid, Medicare, Religious discrimination, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant program—-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 484

Administrative practice and procedure, Grant programs—health, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 486

Administrative practice and procedure, Grant programs—health, Health facilities, Home infusion therapy, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 491

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural and urban areas.

42 CFR Part 494

Diseases, Health facilities, Incorporation by reference, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 416—AMBULATORY SURGICAL SERVICES

1. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

42 CFR § 416.51

2. Amend § 416.51 by adding paragraph (c) to read as follows:

42 CFR § 416.51

§ 416.51 Conditions for coverage—Infection control.

* * * * *

(c) Standard: COVID-19 vaccination of staff. The ASC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following center staff, who provide any care, treatment, or other services for the center and/or its patients:

(i) Center employees;

(ii) Licensed practitioners;

iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the center and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following center staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the center that are performed exclusively outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine, prior to staff providing any care, treatment, or other services for the center and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully

vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the center has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination,

has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized or licensed COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the center's COVID-19 vaccination requirements based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

PART 418—HOSPICE CARE

3. The authority citation for part 418 continues to read as follow:

Authority: 42 U.S.C. 1302 and 1395hh.

42 CFR § 418.60

4. Amend § 418.60 by adding paragraph (d) to read as follows:

42 CFR § 418.60

§ 418.60 Condition of participation: Infection control.

* * * * *

(d) Standard: COVID-19 Vaccination of facility staff. The hospice must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following hospice staff, who provide any care, treatment, or other services for the hospice and/or its patients:

(i) Hospice employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the hospice and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following hospice staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the hospice that are performed exclusively outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have

received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the hospice and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those

staff who have requested, and for whom the hospice has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the hospice's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including,

but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

5. The authority citation for part 441 continues to read as follows:

Authority: 42 U.S.C. 1302.

42 CFR § 441.151

6. Amend § 441.151 by adding paragraph (c) to read as follows:

42 CFR § 441.151

§ 441.151 General requirements.

* * * * *

(c) COVID-19 Vaccination of facility staff. The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the

administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the center setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination

must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring that the facility follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19

vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be

temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

7. The authority citation for part 460 continues to read as follow:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u-4(f).

42 CFR § 460.74

8. Amend § 460.74 by adding paragraph (d) to read as follows:

42 CFR § 460.74

§ 460.74 Infection control.

* * * * *

(d) COVID-19 Vaccination of PACE organization staff. The PACE organization must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a

primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or participant contact, the policies and procedures must apply to the following PACE organization staff, who provide any care, treatment, or other services for the PACE organization and/or its participants:

(i) PACE organization employees;

(ii) Licensed practitioners providing services on behalf of the PACE organization;

(iii) Students, trainees, and volunteers providing services on behalf of the PACE organization; and

(iv) Individuals who provide care, treatment, or other services on behalf of the PACE organization, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following PACE organization staff:

(i) Staff who exclusively provide telehealth or telemedicine services for the PACE organization and/or its participants and who do not have any direct contact with participants and other PACE organization staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the PACE organization and/or its participants and who do not have any direct contact with participants and other PACE organization staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the PACE organization and/or its participants;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the PACE organization has granted, an exemption from the staff COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff

member be exempted from the PACE organization's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

9. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr, unless otherwise noted.

42 CFR § 482.42

10. Amend § 482.42 by adding paragraph (g) to read as follows:

42 CFR § 482.42

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(g) Standard: COVID-19 Vaccination of hospital staff. The hospital must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following hospital staff, who provide any care, treatment, or other services for the hospital and/or its patients:

(i) Hospital employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following hospital staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the hospital setting and who do not have any direct contact with patients and other staff specified in paragraph (g)(1) of this section; and

(ii) Staff who provide support services for the hospital that are performed exclusively outside of the hospital setting and who do not have any direct contact with patients and other staff specified in paragraph (g)(1) of this section.

(3) The policies and procedures must include, at minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (g)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the hospital and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (g)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for

all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (g)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the hospital has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to

receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the hospital's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-.

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

11. The authority citation for part 483 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1395i, 1395hh and 1396r.

42 CFR § 483.80

12. Amend § 483.80 by revising paragraph (d)(3)(v) and adding paragraph (i) to read as follows:

§ 483.80 Infection control.

(d) * * *

(3) * * *

(v) The resident or resident representative, has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision; and

* * * * *

(i) COVID-19 Vaccination of facility staff. The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:
   (i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section; and
   (ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:
   (i) A process for ensuring all staff specified in paragraph (i)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents;
   (ii) A process for ensuring that all staff specified in paragraph (i)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination

must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (i)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and

in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

42 CFR § 483.430

13. Amend § 483.430 by revising paragraph (f) to read as follows:

42 CFR § 483.430

§ 483.430 Condition of participation: Facility staffing.

* * * * *

(f) Standard: COVID-19 Vaccination of facility staff. The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or client contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its clients:
   (i) Facility employees;
   (ii) Licensed practitioners;
   (iii) Students, trainees, and volunteers; and
   (iv)Individuals who provide care, treatment, or other services for the facility and/or its clients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:
   (i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with clients and other staff specified in paragraph (f)(1) of this section; and
   (ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any

direct contact with clients and other staff specified in paragraph (f)(1) of this section.

(3)The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its clients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status

of all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff

member be exempted from the facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

42 CFR § 483.460

14. Amend § 483.460 by revising paragraph (a)(4)(v) to read as follows:

42 CFR § 483.460

§ 483.460 Condition of participation: Health care services.

* * * * *

(a) * * *

(4) * * *

(v) The client, or client's representative, has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision;

* * * * *

PART 484—HOME HEALTH SERVICES

15. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

42 CFR § 484.70

16. Amend § 484.70 by adding paragraph (d) to read as follows:

42 CFR § 484.70

§ 484.70 Condition of participation: Infection prevention and control.

* * * * *

(d) Standard: COVID-19 Vaccination of Home Health Agency staff. The home health agency (HHA) must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following HHA staff, who provide any care,

treatment, or other services for the HHA and/or its patients:

(i) HHA employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the HHA and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following HHA staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the HHA that are performed exclusively outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and

considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the HHA and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those

staff who have requested, and for whom the HHA has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the HHA's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received

monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

17. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

42 CFR § 485.58

18. Amend § 485.58 by revising paragraph (d)(4) to read as follows:

42 CFR § 485.58

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

* * * * *

(d) * * *

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70(a) through (m) may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified

individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.

* * * * *42 CFR § 485.70

19. Amend § 485.70 by adding paragraph (n) to read as follows:

42 CFR § 485.70

§ 485.70 Personnel qualifications.

* * * * *

(n) The CORF must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (n)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (n)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (n)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (n)(1) of this section are fully

vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (n)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed

and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

42 CFR § 485.640

20. Amend § 485.640 by adding paragraph (f) to read as follows:

42 CFR § 485.640

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(f) Standard: COVID-19 Vaccination of CAH staff. The CAH must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following CAH staff, who provide any care, treatment, or other services for the CAH and/or its patients:
   (i) CAH employees;
   (ii) Licensed practitioners;
   (iii) Students, trainees, and volunteers; and
   (iv) Individuals who provide care, treatment, or other services for the CAH and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following CAH staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the CAH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section; and

(ii) Staff who provide support services for the CAH that are performed exclusively outside of the CAH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the CAH and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended

by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the CAH has granted, an exemption from the staff COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their

respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the CAH's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

42 CFR § 485.725

21. Amend § 485.725 by adding paragraph (f) to read as follows:

42 CFR § 485.725

§ 485.725 Condition of participation: Infection control.

* * * * *

(f) Standard: COVID-19 vaccination of organization staff. The organization that provides outpatient physical therapy must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following organization staff, who provide any care, treatment, or other services for the organization and/or its patients:
   (i) Organization employees;
   (ii) Licensed practitioners;
   (iii) Students, trainees, and volunteers; and
   (iv) Individuals who provide care, treatment, or other services for the organization and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following organization staff:
   (i) Staff who exclusively provide telehealth or telemedicine services outside of the organization setting and who do not have any direct contact

with patients and other staff specified in paragraph (f)(1) of this section; and

(ii) Staff who provide support services for the organization that are performed exclusively outside of the organization setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the organization and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the organization has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted

from the organization's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

42 CFR § 485.904

22. Amend § 485.904 by adding paragraph (c) to read as follows:

42 CFR § 485.904

§ 485.904 Condition of participation: Personnel qualifications.

* * * * *

(c) Standard: COVID-19 vaccination of center staff. The CMHC must develop and implement policies and procedures to ensure that all center staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a

primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or client contact, the policies and procedures must apply to the following center staff, who provide any care, treatment, or other services for the center and/or its clients:

(i) Center employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the center and/or its clients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following center staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the center setting and who do not have any direct contact with clients and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the center that are performed exclusively outside of the center setting and who do not have any direct contact with clients and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for

whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the CMHC and/or its clients;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the CMHC has

granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the CMHC's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

23. The authority citation for part 486 continues to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b-8, and 1395hh.

42 CFR § 486.525

24. Amend § 486.525 by adding paragraph (c) to read as follows:

42 CFR § 486.525

§ 486.525 Required services.

* * * * *

(c) COVID-19 Vaccination of facility staff. The qualified home infusion therapy supplier must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the

administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following qualified home infusion therapy supplier staff, who provide any care, treatment, or other services for the qualified home infusion therapy supplier and/or its patients:

(i) Qualified home infusion therapy supplier employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the qualified home infusion therapy supplier and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following qualified home infusion therapy supplier staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where home infusion therapy services are provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the qualified home infusion therapy supplier that are performed exclusively outside of the settings where home infusion therapy services are provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the qualified home infusion therapy supplier and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring that the facility follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status for

all staff specified in paragraph (c)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the qualified home infusion therapy supplier has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains;

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the qualified home infusion therapy supplier's

COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES

25. The authority citation for part 491 continues to read as follows:

Authority: 42 U.S.C. 263a and 1302.

42 CFR § 491.8

26. Amend § 491.8 by adding paragraph (d) to read as follows:

42 CFR § 491.8

§ 491.8 Staffing and staff responsibilities.

* * * * *

(d) COVID-19 vaccination of staff. The RHC/FQHC must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following clinic or center staff, who provide any care, treatment, or other services for the clinic or center and/or its patients:

(i) RHC/FQHC employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the clinic or center and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following clinic or center staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section; and

(ii) Staff who provide support services for the clinic or center that are performed exclusively outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the clinic or center and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring that the clinic or center follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (d)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains;

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the clinic's or center's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

27. The authority citation for part 494 continues to read as follows:

Authority: 42 U.S.C. l302 and l395hh.

28. Amend § 494.30 by—

a. Redesignating paragraphs (b) and (c) as paragraphs (c) and (d) respectively, and

b. Adding a new paragraph (b).

The addition reads as follows:

§ 494.30 Condition: Infection control.

* * * * *

(b) COVID-19 Vaccination of facility staff. The facility must develop and implement policies and

procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its patients:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (b)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (b)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (b)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

* * * * *

Xavier Becerra,
Secretary, Department of Health and Human Services.

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FOOTNOTES

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3 https://www.statnews.com/2021/09/20/covid-19-set-to-overtake-1918-spanish-flu-as-deadliest-disease-in-american-history.

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226 For data on the massive differences in healthcare usage by age, see the National Health Expenditure Date at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.

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decreasing from about 150,000 to about 90,000. Once the disease runs its course, almost all these people will have recovered. Hence, we use the rough estimate that about 100,000 a day have recovered in recent weeks.

228 Among long term care residents, the vaccinated percentage is now very close to 90 percent, but other categories of patients are undoubtedly lower. That said, patients are heavily age-skewed towards higher ages where vaccination percentages are higher.

229 See "Valuing COVID-19 Mortality and Morbidity Risk Reductions in U.S. Department of Health and Human Services Regulatory Impact Analyses, https://aspe.hhs.gov/reports/valuing-covid-19-risk-reductions-hhs-rias.

230 For an NIH summary of the racial disparities, see https://www.niddk.nih.gov/health-information/kidney-disease/race-ethnicity.

231 At age 80, the average life expectancy of a male is about 8 years and of females about 10 years, or an overall average of about 9 years. Long term care nursing home residents, however, have shorter life expectancies because they have severe health problems or would not have been admitted to a facility. For those who remain in a facility until death the average life expectancy is about 2 years. But some recover and leave so we have used 5 years as a reference point. See discussion at David B. Reuben, "Medical Care for the Final Years of Life: When you're 83, It's not going to be 20 years," JAMA, Dec. 23, 2009, 2686-2694.

232 For patients in skilled nursing facilities, average length of stay is less than a month. Hence, turnover is far higher.

233 See Dvir Aran, Estimating real-world COVID-19 vaccine effectiveness in Israel using aggregated counts, medRxiv, February 28, 2021, at https://www.medrxiv.org/content/10.1101/2021.02.05.21251139v3.full.pdf and Noa Dagan et al, "BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting," The New England Journal of Medicine, 2/24/2021, at https://www.nejm.org/doi/full/10.1056/NEJMoa2101765.

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237 See Courtney Harold Van Houtven, Nicole DePasquale, and Norma B. Coe, "Essential Long-Term Care Workers Commonly Hold Second Jobs and Double- or Triple-Duty Caregiving Roles," Journal of the American Geriatrics Society, 27 April 2020, at https://agsjournals.onlinelibrary.wiley.com/doi/full/10.1111/jgs.16509 and M. Keith Chen, Judith A. Chevalier, and Elisa F. Long, "Nursing home staff networks and COVID-19," PNAS, January 5, 2021, at https://www.pnas.org/content/118/1/e2015455118.

238 Ashvin Gandhi et al, "High Nursing Staff Turnover In Nursing Homes Offers Important Quality Information," Health Affairs, March 2021, pages 384-391.

239 Ashvin Gandhi et al, "High Nursing Staff Turnover In Nursing Homes Offers Important Quality Information," Health Affairs, March 2021, pages 384-391. Published estimates vary widely. For example, two recent sources said home health care staff turnover is about 65 percent. See https://www.hcaoa.org/newsletters/caregiver-turnover-rate-is-652-2021-home-care-benchmarking-study and https://www.leadingage.org/sites/default/files/DirectCareWorkersReportFINAL-2˙.pdf.

240 At https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf, page 24.

241 See https://www.washingtonpost.com/local/covid-vaccine-mandate-hospitals-virginia/2021/10/01/b7976d16-21ff-11ec-8200-5e3fd4c49f5e_story.html.

242 Dorie Seavey, The Cost of Frontline Turnover in Long-Term Care," Better Jobs Better Care Report,

Washington, DC: Institute for the Future of Aging Services, American Association of Homes and Services for the Aging. 2004.

243 CDC Data Tracker, October 17, 2021 data, at https://covid.cdc.gov/covid-data-tracker/#health-care-personnel.

244 For a discussion of this issue, see Sumathi Reddy, "How Long Do Covid-19 Vaccines Provide Immunity?", The Wall Street Journal, April 13, 2021, at https://www.wsj.com/articles/how-long-do-covid-19-vaccines-provide-immunity-11618258094.

245 See Rebecca Robbins, "Merck Says It Has the First Antiviral Pill Found to Be Effective Against Covid," The New York Times, October 1, 2021.

246 As noted above, various populations are directly or indirectly affected by this rule. Lessened risk to patients due to staff vaccination, especially in a setting such as a LTC facility, is arguably an externality (a canonical market failure), and thus use of a VSL or VSLY estimate per avoided fatality or life extension does not represent a divergence from the concept of revealed preference. On the other hand, staff members' own risk raises the question of how to interpret their hesitation or unwillingness, in the absence of regulation, to accept an intervention that achieves extensive health protection for themselves, with little or no out-of-pocket cost, and ever-lessening time or inconvenience cost; a simplistic revealed-preference monetization of the rule's effect would be that it yields minimal or negative benefits for such staff members, even the ones for whom it prevents or reduces severity of COVID-19 infection. However, given the dynamic nature of the pandemic, it may be that long-run equilibrium for COVID-19 vaccines has not been reached, in which case the simplistic approach just mentioned may be misleading—and the use of a standard VSL or VSLY for staff-member risk evaluation may reflect misunderstandings of either vaccine risks or vaccine benefits.

247 The risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than

the risk for an 18- to 29-years old person. CDC, "Risk for COVID-19 Infection, Hospitalization, and Death by Age Group", at https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html.

248 We note that as long as most of the world's population remains unvaccinated, another variant of the vaccine might arise and create new risks or shifts in risks within the U.S. That said, the world-wide shortage of vaccines is essentially over taking into account both stocks and existing manufacturing capacity and the biggest problem abroad is getting the available vaccines rapidly into the billions of people who need them.

249 https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis.

250 We note that the VSL is based on a sample of individuals whose average age is 40, This leads to complexities in estimates for populations who are much younger or older, including LTC residents. See Lisa Robinson and James K. Hammit, "Valuing Reductions in Fatal Illness Risks: Implications of Recent Research," Health Economics, August 2016, pp. 1039-1052.

251 For the full likelihood distributions for all age ranges, see the CDC age distribution table previously referenced .

252 Hanmer, J. W.F. Lawrence, J.P. Anderson, R.M. Kaplan, D.G. Fryback. 2006. "Report of Nationally Representative Values for the Noninstitutionalized US Adult Population for 7 Health-Related Quality-of-Life Scores." Medical Decision Making. 26(4): 391-400.

253 Deaths are from COVID-19 Nursing Home Data, CMS, Week Ending 2/21/2021, at https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg/.

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255 In fact, the average length of stay for skilled nursing care is about 25 days. See MEDPAC, Report to the Congress: Medicare Payment Policy, March 2019, "Skilled nursing facility services," page 200.

256 See the previously cited CDC report on risks by age group. In the age intervals used by CDC, the 40-49-year-old group is in the middle of typical employment age ranges. The risk of death in this age group is one tenth that of those aged 65-74. We emphasize with round numbers that nothing about these data is fixed and unlikely to change (for example, as better future treatments are used to treat severe cases).

257 The New York Times "Nearly One-Third of U.S. Coronavirus Deaths Are Linked to Nursing Homes, June 1, 2021.

258 This is not a robust estimate but is supported by several sources. See for example Jiangzhuo Chen et al, "Medical costs of keeping the US economy open during COVID-19," Scientific Reports, Nature.com, July 19 2020, at https://pubmed.ncbi.nlm.nih.gov/32743613/, and Michel Kohli et al, "The potential public health and economic value of a hypothetical COVID-19 vaccine in the United States: Use of cost-effectiveness modeling to inform vaccination prioritization," Science Direct, February 12, 2021, at https://pubmed.ncbi.nlm.nih.gov/33483216/.

259 For a survey of the evidence on this issue, see Gillian K. Steelfisher et al, "An Uncertain Public—Encouraging Acceptance of Covid-19 Vaccines," The New England Journal of Medicine, March 3, 2021.

260 CDC Data Tracker at https://covid.cdc.gov/covid-data-tracker/#health-care-personnel_healthcare-deaths.

261 See Medicare and Medicaid Programs: Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 FR page 77898, December 2, 2020.