CDC COVID-19 Vaccination Program Provider Agreement for Pharmacies



Please complete Sections A and B of this form as follows:

The Centers for Disease Control and Prevention (CDC) greatly appreciates the participation of

____ (Eligible Pharmacy)

in the COVID-19 vaccination effort. Eligible Pharmacy's participation is a vital service that will protect individuals against SARS-CoV-2, the virus that causes COVID-19. The United States government has acquired the COVID-19 vaccine (COVID-19 Vaccine) and is making these publicly funded vaccines available to certain immunization providers to administer. The United States will also provide publicly funded adjuvant, syringes, needles, or other constituent products and ancillary supplies as set forth in the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.¹

Pharmacy Networks are enrolling their Eligible Pharmacy members in order to provide widespread access to the CDC COVID-19 Vaccination Program. Eligible Pharmacy may enroll in the CDC COVID-19 Vaccination Program through a single Pharmacy Network, or alternatively the relevant state, local, or territorial jurisdiction.

This CDC COVID-19 Vaccination Program Provider Agreement for Pharmacies (Provider Agreement) specifies the conditions for receiving COVID-19 Vaccine from the United States government.

Eligible Pharmacy's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary) collectively, Responsible Officers—must complete and sign the *CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement* (Section A). A *CDC COVID-19 Vaccination Program Provider Location Profile Information* form (Section B) must be completed for each Eligible Pharmacy location that will serve LTCFs. Sections A and B must be submitted to ______, your Pharmacy Network/Administrator.²

Section A. CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement

¹ https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf, September 16, 2020 Version 1.0. The United States government will provide at least the constituent products and ancillary supplies set forth in the September 16, 2020 Version 1.0 of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.

² The terms "Pharmacy Network Administrator," "Pharmacy Network," "Network," or "Administrator" as used in Provider Agreement may include, but are not limited to, a Pharmacy Services Administrative Organization (PSAO), Group Purchasing Organization (GPO), and pharmacy franchise.

ELIGIBLE PHARMACY IDENTIFICATION			
Eligible Pharmacy's legal name:			
Number of affiliated Eligible Pharmacy lo	Number of affiliated Eligible Pharmacy locations covered by Provider Agreement:		
Eligible Pharmacy telephone number:	Email (must be a monitored email a the CDC COVID-19 vaccination progr	2	
Eligible Pharmacy address:			
RESPONSIBLE OFFICERS For the purposes of Provider Agreement will also be accountable for compliance listed below must provide their signature	with the conditions specified in Provi	der Agreement. The individuals	
Chief Medical Officer (or Equivalent)			
Last name	First name	Middle initial	
Title	Licensure (State and Number)		
Telephone number:	Email:		
Address:			
Chief Executive Officer (or Chief Fiduciary)			
Last name	First name	Middle initial	
Title			
Telephone number:	Email:		
Address:			
Primary Eligible Pharmacy Contact for CDC COV	ID-19 Vaccination Program		
Last name	First name	Middle initial	
Title			
Telephone number:	Email:		
Address:			

PROV	IDER AGREEMENT REQUIREMENTS		
l unc	lerstand this is an agreement between Eligible Pharmacy and CDC. This program is a part of		
colla	collaboration under the relevant state, local, or territorial immunization program's cooperative agreement		
with	with CDC. To receive one or more of the publicly funded COVID-19 Vaccines, constituent products, and		
ancil	lary supplies at no cost, Eligible Pharmacy agrees that it will adhere to the following requirements:		
	Eligible Pharmacy must administer COVID-19 Vaccine consistent with all requirements,		
1.	recommendations, and other guidance of CDC and CDC's Advisory Committee on Immunization		
	Practices (ACIP). ³		
	Eligible Pharmacy must record in the vaccine recipient's record and report required information to the		
	relevant state, local, or territorial public-health authority. Details of required information (collectively,		
	Vaccine Administration Data) for recording and reporting can be found on CDC's website. ⁴ Eligible		
	Pharmacy must record Vaccine Administration Data in Eligible Pharmacy's system of records as soon as		
	practicable and no later than 24 hours after administering a dose of COVID-19 Vaccine and adjuvant (if		
	applicable). Eligible Pharmacy must use best efforts to report Vaccine Administration Data as soon as		
	practicable and no later than 72 hours after administering a dose of COVID-19 Vaccine and adjuvant (if		
	applicable), provided that the relevant public-health authority accepts Vaccine Administration Data via		
	HL7 or batch upload. For any public-health authority that does not accept Vaccine Administration Data		
	via HL7 or batch upload, Eligible Pharmacy must follow the applicable reporting requirement set forth		
2.	by that authority as well as provide a HL7 or batch upload to CDC—via a channel designated by CDC—		
	no later than 72 hours after administering a dose of COVID-19 Vaccine and adjuvant (if applicable).		
	Eligible Pharmacy must submit Vaccine Administration Data through either (1) the Immunization		
	Information System (IIS) of the state, local, or territorial jurisdiction or (2) another system designated		
	by CDC according to CDC documentation and data requirements. ⁵		
	Eligible Pharmacy must preserve the vaccine recipient's record for at least 3 years following		
	vaccination, or longer if required by state, local, or territorial law. Eligible Pharmacy must make such		
	records available to any federal, state, local, or territorial public-health department to the extent		
	authorized by law.		
	Eligible Pharmacy must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant,		
3.	syringes, needles, or other constituent products and ancillary supplies that the federal government		
	provides at no cost to Eligible Pharmacy.		

³ https://www.cdc.gov/vaccines/hcp/acip-recs/index.html. Provider Agreement expressly incorporates all recommendations, requirements, and other guidance that Provider Agreement specifically identifies. Eligible Pharmacy must monitor such identified guidance for updates and comply with such updates. Eligible Pharmacy shall provide Administrator with a point-of-contact email address for update notifications. Some of the recommendations, requirements, and other guidance set forth optional measures. *Compare, e.g.,* https://www.cdc.gov/vaccines/pandemic-guidance/index.html ("Wear a medical facemask at all times") with https://www.cdc.gov/vaccines/pandemic-guidance/index.html ("Universal eye protection is considered *optional,* unless otherwise indicated as a part of Standard Precautions." (Emphasis added)). The United States government encourages Eligible Pharmacy to comply with optional measures when appropriate. But under Provider Agreement, compliance with optional measures is not mandatory.

⁴ https://www.cdc.gov/vaccines/programs/iis/index.html.

⁵ https://www.cdc.gov/vaccines/programs/iis/index.html.

4.	Eligible Pharmacy must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees or coverage status. Eligible Pharmacy may seek appropriate reimbursement from a program or plan that covers COVID-19 Vaccine administration fees for the vaccine recipient. ⁶ Eligible Pharmacy may not seek any reimbursement, including through balance billing, from the vaccine recipient. The United States government represents that, for Medicare beneficiaries and uninsured patients, it will arrange for coverage of administration fees for a COVID-19 Vaccine authorized under an Emergency Use Authorization. ⁷ Eligible Pharmacy's compliance with paragraph 4 is contingent on the representation in the prior sentence.	
5.	Before administering COVID-19 Vaccine, Eligible Pharmacy must provide an approved EUA fact sheet or vaccine information statement (VIS), as applicable, to each vaccine recipient, the adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable). If the EUA factsheet or VIS is available electronically, Eligible Pharmacy may provide it electronically if each recipient, the adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable) agrees to accept it electronically in the file format offered by Eligible Pharmacy.	
6.	Eligible Pharmacy's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines. ⁸	
7.	 Eligible Pharmacy must comply with CDC requirements for vaccine management. Those requirements include the following: a. Eligible Pharmacy must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold-chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit,⁹ which will be updated to include specific information related to COVID-19 Vaccine; b. Eligible Pharmacy must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit;¹⁰ c. Eligible Pharmacy must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions; d. Eligible Pharmacy must monitor and comply with vaccine expiration dates; and e. Eligible Pharmacy must preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by federal, state, local, or territorial law. 	
8.	Eligible Pharmacy must report the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction. CDC, through Administrator, will provide further instruction on how to report.	
9.	Eligible Pharmacy must comply with all federal instructions and timelines for disposing COVID-19	

⁶ See, e.g., Coronavirus Aid, Relief, and Economic Securities Act (CARES Act) Sections 3203, 3713; Families First Coronavirus Response Act (FFCRA) Section 6008; https://www.hrsa.gov/CovidUninsuredClaim.

⁷ "Uninsured" will have the same meaning as the term is used in "COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of Uninsured." *See* https://www.hrsa.gov/CovidUninsuredClaim.

⁸ https://www.cdc.gov/vaccines/pandemic-guidance/index.html.

⁹ https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html.

¹⁰Id.

	vaccine and adjuvant, including unused doses. ¹¹				
	Eligible Pharmacy must report the following adverse events (AEs) after vaccination, and other AEs if				
	later revised by CDC, to the Vaccine Adverse Event Reporting System (VAERS): ¹²				
10.	 later revised by CDC, to the Vaccine Adverse Event Reporting System (VAERS):¹² a. Vaccination administration errors, whether or not associated with an AE b. Severe COVID-19 illness (<i>e.g.</i>, resulting in hospitalization) c. Serious AEs regardless of causality. Serious AEs are defined as: i. Death ii. A life-threatening AE iii. Inpatient hospitalization or prolongation of existing hospitalization iv. Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions v. A congenital anomaly/birth defect vi. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above. Eligible Pharmacy is also encouraged to report to VAERS any AEs considered to be clinically significant. 				
	That reporting requirement applies to AEs that Eligible Pharmacy knew or should have known had				
	occurred. Eligible Pharmacy must also comply with any other applicable reporting requirements under federal, state, local, and territorial law.				
11.	Eligible Pharmacy must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable). Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.				
12.	 a. Eligible Pharmacy must comply with all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine. b. Eligible Pharmacy must administer COVID-19 Vaccine in compliance with all applicable federal, state, local, and territorial vaccination laws. c. Eligible Pharmacy must comply with applicable patient assent or consent laws for administration of COVID-19 vaccination. 				
	Eligible Pharmacy must submit to CDC, on a daily basis through designated methods, the number of doses of COVID-19 Vaccine that Eligible Pharmacy:				
13.	a. has ordered on hand at each location in each state, locality, and territory; andb. has distributed to each Eligible Pharmacy location in each state, locality, and territory.				

¹¹ The disposal process for remaining unused COVID-19 Vaccine and adjuvant may be different from the process for other vaccines; unused (but still usable—*e.g.*, unexpired and properly maintained) vaccines must remain under storage and handling conditions noted in Paragraph 7 until CDC, through Administrator, provides disposal instructions; CDC will make website URL available.

¹² https://vaers.hhs.gov/reportevent.html.

	Eligible Pharmacy must submit the information in Paragraph 13. a - b to state, local, and territorial public health authorities insofar as the information relates to COVID-19 Vaccine distribution and administration in the respective state, locality, or territory. Eligible Pharmacy must use reasonable efforts to report such information as soon as practicable and in compliance with any state, local, and territorial reporting requirements.
14.	Eligible Pharmacy must order COVID-19 Vaccine through the Administrator, which will submit orders for each Eligible Pharmacy through the CDC vaccine order and tracking system (VtrckS). COVID-19 Vaccine orders will be fulfilled within the allocation available to Administrator for all Eligible Pharmacies taking into account vaccination prioritization during the vaccination program.
	To facilitate planning, Eligible Pharmacy must submit in writing to Administrator its minimum capacity for vaccine administration, including
15.	 a. the number of Eligible Pharmacy facilities that will administer COVID-19 Vaccine; b. the location of each of those facilities, estimated cold-chain capacity within the facility for refrigerated (2°C to 8°C) and frozen (-15° to -25°C), and ultra-frozen storage condition (-60° to -80°C); and enrollment verification in the Medicare or Medicaid programs; c. the Eligible Pharmacy facilities that currently report to state, local, or territorial Immunization Information Systems (IIS); d. the number of COVID-19 Vaccine doses that each facility will be able to administer, within the defined period; and e. point of contact that jurisdictions can contact for questions related to allocation of vaccine in Eligible Pharmacy facilities in their jurisdiction area.
	Eligible Pharmacy will not receive COVID-19 Vaccine unless CDC, through Administrator, accepts the proposal. Once accepted, Eligible Pharmacy must notify Administrator within 24 hours, in writing, of any proposed changes. If any of those changes are unacceptable to CDC or Administrator, CDC may decline to provide further COVID-19 Vaccine.
	Eligible Pharmacy must include the information provided under Paragraph 15 in Section B for each location upon CDC approval of Eligible Pharmacy's COVID-19 vaccination program proposal.
16.	Any Eligible Pharmacy location receiving COVID-19 Vaccine must report supply levels at least daily using the online web platform VaccineFinder. Supply quantities will not be made publicly available through this platform. Making information reported into VaccineFinder public will be at the discretion of the Eligible Pharmacy.
	Eligible Pharmacy must have processes to ensure timely and proper acceptance of COVID-19 Vaccine. Those processes must include but are not limited to procedures for accepting COVID-19 Vaccine delivery through a delivery service or services as designated by CDC. Administrator will notify Eligible Pharmacy of a CDC-designated delivery service or services no later than two weeks before delivery commences or no later than two weeks before a delivery service or services change.
17.	To facilitate planning, Eligible Pharmacy must propose, in writing by the date provided by Administrator, its hours for accepting COVID-19 Vaccine deliveries at each receiving Eligible Pharmacy location. If Eligible Pharmacy's current wholesale supplier for such receiving location is servicing that receiving location using the same delivery process that that wholesale distributor uses to deliver other pharmaceutical products to that location, Eligible Pharmacy need not propose that receiving location's hours for accepting COVID-19 Vaccine deliveries. Eligible Pharmacy will not receive COVID-19 Vaccine unless CDC, through Administrator, accepts the proposal. Once accepted, Eligible Pharmacy must

	notify Administrator within 24 hours, in writing, of any proposed changes. If any of those changes are unacceptable to CDC or Administrator, CDC may decline to provide further COVID-19 Vaccine.
	Eligible Pharmacy must report any COVID-19 Vaccine that is damaged upon delivery pursuant to the process provided by the delivery service and to Administrator within 24 hours. Administrator will provide procedures for reporting.
18.	Eligible Pharmacy must comply with all applicable COVID-19 testing requirements as set forth in the Centers for Medicare & Medicaid Services (CMS) Interim Final Rule CMS-3401-IFC, ¹³ "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," related to Requirements for Long-Term Care (LTC) Facilities to Test Facility Residents and Staff for COVID-19. Under Provider Agreement, Eligible Pharmacy must ensure that any Eligible Pharmacy personnel entering an LTCF to organize or provide COVID-19 vaccination services are tested pursuant to the requirements for "staff" or "facility staff." ¹⁴ Eligible Pharmacy shall bear the cost of such COVID-19 testing.
19.	Eligible Pharmacy must maintain, and provide to Administrator, records for all vaccinating providers, including title and license number of each provider for each vaccination site listed in Section B.
20.	Eligible Pharmacy may use contractors to perform some or all of Eligible Pharmacy's duties under Provider Agreement. Eligible Pharmacy must ensure that any contractor performs its duties in full compliance with Provider Agreement and Eligible Pharmacy is responsible under Provider Agreement for any non-compliance with Provider Agreement by any of its contractors. Furthermore, any knowledge concerning or resulting from performance of Provider Agreement by any of Eligible Pharmacy's contractors is imputed to Eligible Pharmacy.
21.	Administrator oversees Eligible Pharmacy's participation in the CDC COVID-19 vaccination program. Eligible Pharmacy agrees to fully cooperate with Administrator by participating in Administrator- provided training; timely providing to Administrator all documentation as set forth in Provider Agreement, as required by CDC, and as required by applicable law—except Eligible Pharmacy must report as directed in Paragraphs 10, 13, and 16 of Provider Agreement; and informing Administrator within 24 hours of any non-compliance with any provision of Provider Agreement and corrective actions. CDC reserves the right to not provide COVID-19 Vaccine to an Eligible Pharmacy.
involv	ning this form, I certify that all relevant officers, directors, employees, and agents of Eligible Pharmacy red in handling COVID-19 Vaccine understand and will comply with Provider Agreement requirements above and that the information provided in sections A and B is true.
admir limite Resou mater and re	raphs 1-21 of Provider Agreement set forth material conditions of payment for COVID-19 Vaccine histration claims submitted by Eligible Pharmacy to any federal healthcare program, including but not d to Medicare and Medicaid, or any HHS-sponsored COVID-19 relief program, including the Health irces & Services Administration COVID-19 Uninsured Program. Paragraphs 1-21 do not, however, list all rial conditions of payment for these programs. Eligible Pharmacy must review the applicable statutes egulations governing each federal healthcare program and any HHS-sponsored COVID-19 relief program ogram-specific conditions. Reimbursement for administering COVID-19 Vaccine is not available under

¹³ 85 Fed. Reg. 54,820 (Sept. 2, 2020), and as may be amended.

¹⁴ See, e.g., 42 CFR. § 483.80(h) ("The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19."); 42 CFR § 483.80(h)(5) ("Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.").

any federal healthcare program or any HHS-sponsored COVID-19 relief program if Eligible Pharmacy fails to comply with Paragraphs 1-21 or any other material condition of payment with respect to the administered COVID-19 Vaccine dose. Each time Eligible Pharmacy submits a reimbursement claim for COVID-19 Vaccine administration to any federal healthcare program or any HHS-sponsored COVID-19 relief program, Eligible Pharmacy expressly certifies that it has complied with all conditions of payment, including but not limited to Paragraphs 1-21, with respect to that administered dose.

Non-compliance with the terms of Provider Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and other federal laws, including but not limited to 18 U.S.C. § 1001, 1035, 1347, 1349.

Either party may terminate Provider Agreement, effective upon written notice to the other party ("Defaulting Party"), (i) if Defaulting Party materially breaches Provider Agreement, and such breach is incapable of cure and/or poses an imminent risk to the public's health; or (ii) with respect to a material breach capable of cure, if Defaulting Party does not cure such breach within thirty (30) days after receipt of written notice of such breach. Should CDC desire to modify Provider Agreement, CDC will provide the Administrator with at least two weeks' written notice of the modified terms. If the Eligible Pharmacy does not agree with the changes, Eligible Pharmacy may withdraw from Provider Agreement with two weeks' notice. Either party may terminate Provider Agreement with two week's written notice.

By entering Provider Agreement, Eligible Pharmacy does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Eligible Pharmacy if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.¹⁵ Chief Medical Officer (or Equivalent)

Last name	First name	Middle initial
Signature:		Date:
Chief Executive Officer (or Chief Fiduciary)		
Last name	First name	Middle initial
Signature:		Date:
For official use only:		
IIS ID, if applicable:		
Unique Eligible Pharmacy ID*:		

¹⁵ See Pub. L. No. 109-148, Public Health Service Act § 319F-3 and § 319F-4, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

* CDC will issue unique identifiers for the Eligible Pharmacy and locations covered under Provider Agreement. This ID is needed for CDC to delineate Eligible Pharmacies (Section A) and to match them with one or more Locations (Section B).

Section B. CDC COVID-19 Vaccination Program Provider Location Profile Information

PLEASE PROVIDE A LINE LIST OF ALL ELIGIBLE PHARMACY LOCATIONS TO ADMINISTRATOR THAT WILL RECEIVE COVID-19 VACCINE SHIPMENTS, INCLUDING THE FOLLOWING INFORMATION FOR EACH:

- Store's Eligible Pharmacy-assigned ID number
- Location address, telephone and fax number
- Contact information for location's COVID-19 vaccine coordinator (name, telephone, email)
- Contact information for location's backup COVID-19 vaccine coordinator (name, telephone, email)
- Days and Times vaccine coordinators are available for receipt of COVID-19 Vaccine shipments
- Ability to make appointment for vaccination services (Y/N)
- If the store currently reports vaccine administration data to state, local, or territorial Immunization Information System (IIS) (Y/N)
- If the store is currently enrolled in VaccineFinder (Y/N)
- Does store accept
 - Medicaid? (Y/N) If yes, list Medicaid ID:
 - Medicare? (Y/N) If yes, list Medicare ID: ______
 - Other insurance? (Y/N)
- Storage capacity

unique ID.

- Refrigerated (2°C to 8°C) (Y/N)
 - Please list capacity: Approximately _____10-dose MDVs
- Frozen (-15° to -25°C): (Y/N)
 - Please list capacity: Approximately _____10-dose MDVs
- Ultra-frozen (-60° to -80°C) (Y/N)
 - Please list capacity: Approximately 10-dose MDVs
- Estimated daily number of COVID-19 Vaccine doses that location will be able to administer ______

Eligible Pharmacies should be prepared to use a portion or all of the stores—this will vary based on amount of supply, demand, and populations prioritized to receive vaccine.

For official use only:	
Vaccines for Children (VFC) PIN, if applicable:	
IIS ID, if applicable**:	Unique COVID-19 Eligible Pharmacy ID (from Section A):
Unique Location ID***	-
** Does this location currently report vaccine admini	istration data to a state, local, or territorial Immunization Information System (IIS)?
YES: NO:	
*** CDC will create a unique Location ID for each loc	cation listed in Section B that will be linked to the Eligible Pharmacy's separate