

New York State Vaccine Program Provider Enrollment – Q&A

The following questions are from the October 22 webinar on *New York State Vaccine Program Provider Enrollment* hosted by the New York State Department of Health (DOH), GNYHA, and the Hospital Association for New York State. DOH provided the answers below as follow-up to the webinar.

While DOH has set October 28, 2020 as the deadline, enrollment for hospitals will not “close” at that time. DOH understands that hospitals have been waiting for clarification to complete the applications.

Although not restricted by the October 28 deadline, hospitals are encouraged to submit applications as *soon as possible*. NYS is opening vaccine program enrollment in phases to additional groups. Timely enrollment submission is important so that applications can complete the review and approval process in advance of the first shipments of vaccine, when that becomes available.

Please direct additional questions to COVID19Vaccine@health.ny.gov.

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Consent	
Q:	Is an informed consent form available?
A:	DOH will review with DOH Legal regarding language for informed consent to receive the COVID-19 vaccine and will get back to you.
Q:	Will we need consent from patients to document vaccine receipt into the New York State Immunization Information System (NYSIIS)?
A:	DOH expects that reporting to NYSIIS, part of the New York State Health Commerce System (HCS) will be mandatory and that patient consent to report will not be necessary.

Delivery Site	
Q:	Will deliveries to hospitals go directly to the Pharmacy or be left at the receiving dock?
A:	For the enrollment form, please include the address for where vaccine should be delivered. DOH will provide additional guidance on the delivery process once it is available.

Enrollment Deadlines	
Q:	Is there an enrollment deadline?
A:	Yes. Close of business on Wednesday, October 28.
Q:	Can the enrollment deadline be extended?
A:	<p>While DOH has set October 28, 2020 as the deadline, enrollment for hospitals will not “close” at that time. DOH understands that hospitals have been waiting for clarification to complete the applications.</p> <p>Although not restricted by the October 28 deadline, hospitals are encouraged to submit applications <i>as soon as possible</i>. NYS is opening vaccine program enrollment in phases to additional groups. Timely enrollment submission is important so that applications can complete the review and approval process in advance of the first shipments of vaccine, when that becomes available.</p>

Enrollment for Systems with Sites in New York City and Outside of New York City	
Q:	If a system has sites both inside and outside of New York City, should it enroll through both NYSIIS and the Citywide Immunization Registry (CIR)?
A:	Yes. A hospital system that has sites both inside and outside of New York City would need to enroll through CIR for their New York City sites and NYSIIS for their sites outside of New York City.

Q:	How does an Integrated Delivery Network with a main campus in New York City and sites all over New York (many inside and outside New York City) enroll all these sites? Should it do double enrollment for New York City sites in both CIR and HCS?
A:	A main parent organization (Section A) will need to enroll in both the New York City and DOH programs if the organization has sites both within and outside New York City. Sites (Section B) located in New York City should enroll via the CIR. Sites located outside New York City should enroll with DOH through the New York State Health Commerce System (HCS) application.
Q:	How will allocations for a health system that spans New York City and New York State be handled?
A:	Allocations will be based on the location of the site and the population served. CDC (Centers for Disease Control and Prevention) will make allocations to New York City to sub-allocate to the New York City sites and to DOH to sub-allocate to sites located outside New York City.
Q:	Our academic medical center has hospitals in New York City and New York State. Can our New York State hospitals ship vaccine to a central location in New York City, where we plan to store it in freezers, then transport it to the hospitals in New York State, where we will administer the vaccine?
A:	A main parent organization (Section A) will need to enroll in both the New York City and DOH programs if the organization has sites both inside and outside New York City. Sites (Section B) located in New York City should enroll through the CIR. Sites located outside New York City should enroll with DOH through the HCS application. NOTE: Redistribution requests must be submitted and reviewed by the DOH/New York City Department of Health and Mental Hygiene.
Q:	If our system's main hospital is in New York City, should we put that as Section A, and then our New York State hospitals as Section B?
A:	Section B would include all hospital locations outside the five boroughs of New York City.
Q:	Does an individual [facility] need to enroll in the State and City system, or are both systems the same?
A:	NYSIIS and CIR are separate and based on the provider location. This is one of the reasons enrollment also is based on location.

Flu Vaccine Numbers

Q:	What is the definition of peak week influenza date?
A:	This will vary by provider. It is the week during the 2019-20 influenza season that your organization administered the greatest number of doses of influenza vaccine.
Q:	When looking at influenza numbers for 2019 and 2020, should we include Vaccines for Children numbers in the projection, in addition to private pay?
A:	All patients regardless of insurance status should be included in the projection.

Listed Providers

Q:	For the section on listing providers practicing at the facility, do we need to enter names of all physicians?
A:	Please identify the providers that will be responsible for administering the vaccine at your site. There is no need to register all providers. However, for the providers listed, please complete all fields. Verification will be based on license types.
Q:	Can we upload a list of providers?
A:	At this time, all the information must be entered into the online form. We recommend that you identify the subset of providers who will be responsible for prescribing the COVID-19 vaccine and list those providers.

Long-Term Care Facilities

Q:	What is the connection between the Federal pharmacy program for LTCF (long-term care facilities) and the DOH program? Do LTCFs need to enroll through DOH?
A:	A CDC initiative allows LTCFs to sign up to have CVS or Walgreens vaccinate their residents. This is separate and in addition to the New York State enrollment program. LTCFs are encouraged to enroll in the New York State program.
Q:	I have an attached nursing home. Can I enroll it with the hospital on the same form? I provide all their medications.
A:	You may include an affiliated nursing home for which your organization is responsible by adding a Section B profile for the nursing home on your application. If the nursing home does NOT fall under your organization's responsibility but you have a partnership to provide vaccine for them, you should not enroll them (because enrollment is based on the site receiving and administering vaccine) but should include their population in your estimates. Staff would be reported under health care workers and residents would be listed under medically high risk.
Q:	Should LTCFs enroll at this time?
A:	More information will be sent to LTCFs separately.

NYSIIS Registration

Q:	All of the adult practice sites are currently not in NYIIS. Does that need to be completed before or after the application?
A:	If you have sites included in Section B that are not currently in NYSIIS, we will create a NYSIIS Org ID when setting up the enrollment. NYSIIS users will then need to be identified at each of these sites and added to the Org in NYSIIS. NYSIIS user training will be needed if the individual is not already a NYSIIS user. This will be communicated after enrollment has been completed.
Q:	How do we identify our NYSISS number?
A:	The NYSIIS Org ID is located on the Edit Org screen in NYSIIS. Please see slides 31 and 32 of the presentation for screenshots.

Population Served	
Q:	Should hospital staff be included in the patient population estimates?
A:	No, please include hospital staff in the non-patient population projection.
Q:	What should we do with clinical employees who are not at hospitals? Should we include them in our projected counts?
A:	Yes, if your plan is to vaccinate offsite employees at your hospital, you should include them in the non-patient population projections.
Q:	How do we measure the patients served? Per week? Per month?
A:	CDC did not define a time period. With our regular program, we use an annual number, please go with that.
Q:	What constitutes a "unique" patient?
A:	"Unique patients" refers to de-duplicated count of individuals your practice serves in 12 months. This mostly will apply to practices that are medical homes of specific patients. If you don't have a patient population (most hospitals do not), please enter 0.
Q:	In the section for approximate number of patients/clients routinely served by this hospital location- children, adults, over 65, do we answer zero for each?
A:	Unless you are completing for a part of your hospital that serves as a routine point of care (i.e., a medical home) with patients, you can answer 0 for patient population and fill in the non-patient population that you plan to target in that section.

Provider Attestation	
Q:	Is the provider attestation only for standing orders or is it for individual orders also?
A:	The attestation is for the individuals signing the agreement. In Section A, it is the Chief Medical Officer and Chief Executive Office/Chief Fiduciary. In each Section B, the attestation is for the pharmacy/medical director or vaccine coordinator. The later section for Practicing Providers should be filled in to include all with prescribing authority that will prescribe or issue a standing order for the pandemic vaccine. It would be best to identify a subgroup of providers that will have this responsibility at the hospital so as to not need to add 1,000 providers.

Redistribution	
Q:	If a site is going to serve as a redistribution site, does it need to complete both the provider agreement and profile(s)?
A:	The redistribution form is separate from the provider agreement and provider profile. An administration site has to be enrolled in the vaccine program either through NYSIIS or CIR.
Q:	With the Pfizer vaccine, can a facility transfer to another facility if it doesn't use all 1,000?

A:	DOH is seeking specific guidance from CDC on whether ultra-cold vaccine can be redistributed. More info will be shared once available. Organizations should enroll all sites interested in administering vaccine and plan on direct shipments regardless of ultra-cold storage (remember: Pfizer vaccine is not the only one under development and clinical trial). DOH will review requests for redistribution approval on a case by case basis and make a determination based on CDC guidance and need.
Q:	Does a health system need a redistribution agreement to receive the vaccine and provide it to a nursing home or medical practice location within the system?
A:	Redistribution is considered to be anyone that receives vaccine from a method other than direct ship from the manufacturer or distributor. Every site seeking to receive vaccine either through direct shipment or redistribution must have a Section B added to the enrollment form. DOH must approve redistribution requests.
Q:	We are a large system. Can all the vaccine be delivered to our "mother ship" hospital, and then we distribute to our additional hospitals from there?
A:	This is not encouraged. Vaccine has very specific cold chain requirements, and it is always safest shipping it directly to the site administering the vaccine. If a site is too small or has inadequate storage, we may consider redistribution to reduce wastage. DOH must approve redistribution requests.
Q:	If we are receiving vaccines at a Section A location and sending supplies from Section A to Section B locations ONLY (in other words, only redistributing within a system), do we need to fill out a redistribution agreement?
A:	Yes. Redistribution is considered anyone that receives vaccine from a method other than direct ship from the manufacturer or distributor. Every site seeking to receive vaccine either through direct shipment or redistribution must have a Section B added to the enrollment form. DOH must approve redistribution requests.
Q:	Is the CDC Supplemental Redistribution Agreement and the CDC Vaccination Program Provider Agreement one and the same thing?
A:	No, the provider agreement enrolls all sites that plan to administer vaccine. All sites that will administer vaccine must enroll, whether they receive direct shipment or redistribution. Direct ship to the administration site is always best practice. Redistribution is the transfer of vaccine that is delivered to one site and then to another site. DOH cannot guarantee approval of a redistribution request.
Q:	Assuming the redistribution agreement is approved for our site, should we still complete Section B for offsites?
A:	Yes, all sites that seek vaccine either through direct shipment or redistribution must have a Section B added to the enrollment form.

Reporting

Q:	Do hospitals have to report all vaccine recipients? What is the process?
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A:	Yes, every dose administered must be reported via NYSIIS within 24 hours (as specified in the agreement terms). Data exchange from an electronic health record is possible. More information and guidance on NYSIIS and reporting will be forthcoming.
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Responsible Parties

Q:	Who is supposed to receive the hard copies?
A:	The forms are provided for use by your organization. We recommend that each site listed retain a copy for its records. Do not submit hard copies of the forms to DOH if you completed the online form in HCS.
Q:	Can a Chief Medical Officer start the application and someone else finish the agreement forms?
A:	The form on HCS only allows one user to fill out the application. It is encouraged that each person signing Section A and Section B sign the fillable PDF or a hard (printed) copy so that the individual completing the information on HCS can check the attestation box and type in the person's name. The hard (printed) copy of that form would be maintained at the organization.
Q:	Please confirm, we get signatures on the hard copy and we type the signatures in on part A.
A:	It is encouraged that each person signing Section A and Section B sign the fillable PDF or a hard (printed) copy so that the individual completing the information on HCS can check the attestation box and type the name.
Q:	Are there specific requirements for the vaccine coordinator(s) and backups?
A:	A vaccine coordinator is the Point of Contact for receiving vaccine shipments, monitoring storage unit temperatures, managing vaccine inventory, etc. It is preferable if that individual is the same person in NYSIIS that is monitoring doses.

Section A vs. Section B: System Considerations and Site Profiles

Q:	If multiple sites operate within a single hospital system, do they all need to fill out a Section B profile? What level of site needs to complete a Section B provider profile?
A:	Section B profiles are for every physical location that seeks to receive and administer vaccine. Each needs to be identified to CDC for tracking vaccine.
Q:	Can you clarify that Section B should be completed for each outpatient clinic that seeks to administer the vaccine? Does a hospital have to list each of its clinic sites on Section B? For a standalone hospital, not a health system, would all individual primary care clinic locations need to be added to enrollment? They are all on the same operating certificate/number.
A:	Yes, every site interested in administering vaccine should enroll. The parent organization may enroll them (adding a Section B under their Section A) or they may enroll independently (complete both Section A and Section B). This will give organizations more flexibility. Hospital sites are the enrollment priority right now, but outpatient clinic sites may be included in the

	application. However, if that is a significant workload, you may start by enrolling your hospitals and then enrolling the other providers once we are ready for that provider type.
Q:	We have a large hospital-based primary care network with offices in the community. Do we need to list every office where our pharmacy will distribute vaccine to their patients?
A:	Organizations may enroll all sites under their main organization or independently. This will give organizations more flexibility. If you want to include them in your initial application, you may, but if that is a significant workload, you may start by enrolling your hospitals and then enroll the other providers once we are ready for that provider type.
Q:	Do we need to separately register every single possible administration location?
A:	Every practice location must be enrolled. If you plan to do offsite vaccination in the community (such as a drive-through test site or with a community partner), we do not need those locations enrolled. Section B is specific to the practice receiving and administering the vaccine, not the place it is physically administered.
Q:	Can you complete Section B without completing Section A?
A:	Section A must be included. The parent organization may enroll a site them (adding a Section B under their Section A) or the site may enroll independently (complete both Section A and Section B). This is up to the organization.
Q:	If a location within a health care system is for administration only, not receiving, does it need to be included in Section B?
A:	Yes, every site interested in administering vaccine should enroll. The parent organization may enroll them (adding a Section B under their Section A) or they may enroll independently (complete both Section A and Section B).
Q:	Are offsite practices (ambulatory) considered different locations?
A:	Yes, any site receiving vaccine should have a Section B completed. Each site should enroll and fill out their location information as though they will receive direct shipments. If it is decided that a central/redistribution site will be allowed, it will need to be appropriately enrolled to receive a redistribution from a central location and administer vaccine.
Q:	If a hospital is part of a system, but submits the application as a standalone due to logistical reasons, will it be denied?
A:	Hospitals may enroll independently or as part of a system. We suggest coordinating with your system to decide how you will approach enrollment. Organizations may enroll all sites under their main organization or independently.
Q:	Can independent/individual providers (non-hospitals) that are not affiliated with a system enroll?
A:	Not yet.

Storage Requirements	
Q:	For ultra-cold storage, what is the guidance on keeping vaccines cold with dry ice (e.g., need to replace it once a day)?
A:	The Pfizer vaccine with its ultra-low temperature storage requirements will be transported in a special container filled with dry ice and will have to have the dry ice replaced upon receipt, and then again every five days. The vaccine comes in five-dose vials with no preservatives. The individual vaccine vials can be refrigerated up five days but only at room temperature for two hours. Pfizer will need the containers back within 10 days. CDC will be issuing an addendum on storage and handling recommendations for COVID-19 vaccine in the near future.
Q:	Do you know the physical size of one vial of the Pfizer or Moderna vaccines so we can estimate maximum storage capacity?
A:	The Moderna vaccine will be a 10-dose vial and the Pfizer vaccine will be a five-dose vial. Pfizer's transportation (shipping) containers will have between one and five trays. Each tray (also known as a "pizza box") contains 195 five-dose vials or 975 doses. The dimensions of a single tray are 9.5" x 9.5" x 2". The transportation container will be larger. We do not have size information on the Moderna vaccine.
Q:	Where can we order the ultra-cold freezers?
A:	Providers are not being asked to purchase ultra-cold freezers at this time.
Q:	What if the site does not currently have capacity for freezers but plans on procuring?
A:	Providers are not being asked to purchase ultra-cold freezers at this time. If you do procure an ultra-cold freezer after you submit your application, you can inform us of the change so we can update your data.
Q:	Is there a plan for New York State to reimburse health systems for purchasing the ultra-cold freezer?
A:	There is no plan currently to fund the purchase of ultra-cold freezers.
Q:	If one location has ultra-cold freezers and another does not, but both have regular freezer capacity, how do we register the locations for shipment?
A:	Each site should enroll and fill out its location information as though it will receive direct shipments. If it is decided that a central distribution will be allowed through a redistribution request, each receiving site will need to be, they will be appropriately enrolled to receive a redistribution from the central location and administer vaccine.

Training and Coordination	
Q:	Will there be a separate presentation on how to order vaccine and data submission?
A:	Training on ordering and reporting in NYSIIS will be provided later.
Q:	How are local county health departments coordinating efforts with local hospitals and other organizations in the areas?

A:	DOH will work with local health departments to coordinate vaccine administration efforts. At this point, enrollment is the focus.
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Updating Enrollment Information

Q:	What is the process for updating enrollment information?
A:	You will be able to add a new prescribing provider by requesting an edit to your application. You will need to send an e-mail to address corrections, and we will reply with next steps. DOH has access to the agreements and can make edits and re-submit on a system's behalf and will send a PDF of the update.
Q:	Should a system try to submit for all potential administration sites even if unsure, or will there be a way to add sites after submission?
A:	There is no harm in enrolling more sites than are needed. It is strongly preferred that all locations be added with the initial application. Currently, the focus is on hospital locations. At a minimum, all hospital sites should be included with the initial enrollment. It will be possible to add sites later.