



Interoffice Memorandum

AGENDA ITEM

January 29, 2021

TO: Mayor Jerry L. Demings
-AND-
County Commissioners

THRU: Yolanda G. Martinez, EdPhD., PhD., Director
Health Services Department

FROM: John Goodrich, Deputy Director
Health Services Department

J. Goodrich

SUBJECT: Ratification of COVID-19 Vaccine Agreements
Consent Agenda – February 9, 2021

The Health Services Department has been working to ensure the county has access to the COVID-19 vaccine as soon as it becomes available and to maximize the number of providers able to administer the vaccine. In order to ensure we were able to receive and administer vaccinations immediately, we needed to immediately execute these agreements.

CDC COVID-19 Vaccination Program Provider Agreement (Medical Clinic) – This will allow the Health Services Department to order the COVID-19 vaccine when direct shipment to the county becomes available.

CDC COVID-19 Vaccination Program Provider Agreement (Orange County Jail-Pharmacy) – This will allow Corrections Health Services to order the COVID-19 vaccine when direct shipment to jails becomes available.

CDC Supplemental COVID-19 Vaccine Redistribution Agreement – This allows the Health Services Department to transfer ownership of the COVID-19 vaccine in the state of Florida SHOTS database. This is needed in order to receive the vaccine for another entity that does not have the proper equipment needed for long-term storage and then transfer it to them at a later date.

Paramedicine Vaccination Agreement – This agreement between the County and the Orange County Health Department lays out the framework for paramedics to perform vaccinations. The agreement is required by Florida Statute 401.272 for paramedics to perform vaccinations.

Vaccination Site Agreement – This agreement allows the Orange County Health Department to transfer vaccine to the county in order to open up a county point of administration site for vaccine administration.

We are also seeking authorization for the Mayor or designee to execute any related modifications or amendments. There is no cost to the county.

ACTION REQUESTED: Ratification of (1) CDC COVID-19 Vaccination Program Provider Agreements for Orange County Medical Clinic and Orange County Jail-Pharmacy; (2) CDC Supplemental COVID-19 Vaccine Redistribution Agreement; (3) Paramedicine Vaccination Agreement between the State of Florida, Department of Health Orange County Health Department and Orange County, Florida; and (4) Vaccination Site Agreement (COVID-19) for an Open Point of Administration between State of Florida, Department of Health Orange County Health Department and Orange County, Florida and authorization for the Mayor or designee to execute any related modifications or amendments. There is no cost to the county. **(Health Services Department)**

Attachments

C: Christian C. Zuver, M.D., EMS Medical Director
Maurice Mascoe, M.D., Corrections Health Services Medical Director
Daniella Sullivan, Health Services Program Administrator

CDC COVID-19 Vaccination Program Provider Agreement

APPROVED BY ORANGE
COUNTY BOARD OF COUNTY
COMMISSIONERS



BCC Mtg. Date: February 9, 2021

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

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization'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)*. In addition, the *CDC COVID-19 Vaccination Program Provider Profile Information (Section B)* must be completed for each vaccination location covered under the Organization listed in Section A.

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

Organization identification

Organization's legal name: Orange County, FL

Number of affiliated vaccination locations covered by this agreement: 2

Organization telephone: 407-836-9225

Email: covid19vaccines@ocfl.net (must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program)

Street address 1: 201 S. Rosalind Ave Street address 2: _____

City: Orlando County: Orange State: FL ZIP: 32801

Responsible officers

For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signatures after reviewing the agreement requirements.

Chief Medical Officer (or Equivalent) Information

Last name: Zuver First name: Christian Middle initial: C.

Title: Medical Director Licensure state: FL Licensure number: ME97144

Telephone: (407) 836-7606 Email: christian.zuver@ocfl.net

Street address 1: 2002A East Michigan St. Street address 2: _____

City: Orlando County: Orange State: FL ZIP: 32806

Chief Executive Officer (or Chief Fiduciary) Information

Last name: Demings First name: Jerry Middle initial: L.

Telephone: 407-836-7370 Email: Mayor@ocfl.net

Street address 1: 201 S. Rosalind Ave. Street address 2: _____

City: Orlando County: Orange State: FL ZIP: 32801

Agreement requirements

I understand this is an agreement between Organization and CDC. This program is part of a collaboration under the relevant state, local, or territorial immunization program's cooperative agreement with CDC.

To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:

1. Organization must administer COVID-19 vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).¹
2. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), Organization 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 reporting can be found on CDC's website.²

Organization must submit Vaccine Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.²

Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3. Organization must not sell or seek reimbursement for COVID-19 vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.
4. Organization must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees.
5. Before administering COVID-19 vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
6. Organization'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.³
7. Organization must comply with CDC requirements for COVID-19 vaccine management. Those requirements include the following:
 - a) Organization 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*, which will be updated to include specific information related to COVID-19 vaccine;
 - b) Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance in CDC's *Vaccine Storage and Handling Toolkit*;
 - c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;
 - d) Organization must monitor and comply with COVID-19 vaccine expiration dates; and
 - e) Organization must preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
8. Organization 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.
9. Organization must comply with all federal instructions and timelines for disposing of COVID-19 vaccine and adjuvant, including unused doses.⁵
10. Organization must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or <http://vaers.hhs.gov/contact.html>).
11. Organization must provide a completed COVID-19 vaccination record card to every COVID-19 vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 vaccine shipment will include COVID-19 vaccination record cards.
12. a) Organization 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) Organization must administer COVID-19 vaccine in compliance with all applicable state and territorial vaccination laws.

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

¹ www.cdc.gov/vaccines/hcp/acip-recs/index.html

² www.cdc.gov/vaccines/programs/iis/index.html

³ www.cdc.gov/vaccines/pandemic-guidance/index.html

⁴ www.cdc.gov/vaccines/hcp/admin/storage-handling.html

⁵ The disposal process for remaining unused COVID-19 vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.

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

CDC COVID-19 Vaccination Program Provider Agreement

By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 vaccine understand and will comply with the agreement requirements listed above and that the information provided in sections A and B is true.

The above requirements are material conditions of payment for COVID-19 vaccine administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare, Medicaid, and the Health Resources and Services Administration COVID-19 Uninsured Program. Reimbursement for administering COVID-19 vaccine is not available under any federal healthcare benefit program if Organization fails to comply with these requirements with respect to the administered COVID-19 vaccine dose. Each time Organization submits a reimbursement claim for COVID-19 vaccine administration to any federal healthcare benefit program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose.

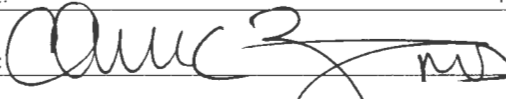
Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 et seq., and other related federal laws, 18 U.S.C. §§ 1001,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

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

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.⁶

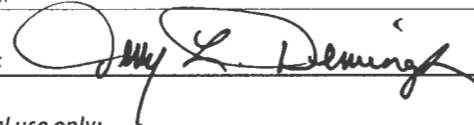
Organization Medical Director (or equivalent)

Last name: Zuver First name: Christian Middle initial: C.

Signature:  Date: 12/01/2020

Chief Executive Officer (chief fiduciary role)

Last name: Demings First name: Jerry Middle initial: L.

Signature:  Date: 12/4/20

For official use only:

IIS ID, if applicable:

Unique COVID-19 Organization ID (Section A)*:

*The jurisdiction's immunization program is required to create a unique COVID-19 ID for the organization named in Section A that includes the awardee jurisdiction abbreviation (e.g., an organization located in Georgia could be assigned "GA123456A." This ID is needed for CDC to match Organizations (Section A) with one or more Locations (Section B). This unique identifier is required even if there is only one location associated with an organization.

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

Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

Organization identification for individual locations

Organization location name: Orange County Medical Clinic	Will another Organization location order COVID-19 vaccine for this site? <input type="checkbox"/> If YES; provide Organization name:
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Contact information for location's primary COVID-19 vaccine coordinator

Last name: Hopwood	First name: Shari	Middle initial:
Telephone: 407-836-9225	Email: covid19vaccines@ocfl.net	

Contact information for location's backup COVID-19 vaccine coordinator

Last name: Ayash	First name: Sally	Middle initial:
Telephone: (407) 836-9225	Email: covid19vaccines@ocfl.net	

Organization location address for receipt of COVID-19 vaccine shipments

Street address 1: 650 North Pine Hills Rd	Street address 2:		
City: Orlando	County: Orange	State: FL	ZIP: 32808
Telephone: (407) 836-2628	Fax:		

Organization address of location where COVID-19 vaccine will be administered (if different from receiving location)

Street address 1: 4801 W. Colonial Dr.	Street address 2:		
City: Orlando	County: Orange	State: FL	ZIP: 32808
Telephone: (407) 836-2628	Fax:		

Days and times vaccine coordinators are available for receipt of COVID-19 vaccine shipments

	Monday	Tuesday	Wednesday	Thursday	Friday
AM: 9:00	AM: 9:00	AM: 9:00	AM: 9:00	AM: 9:00	AM: 9:00
PM: 4:00	PM: 4:00	PM: 4:00	PM: 4:00	PM: 4:00	PM: 4:00

For official use only:

VTrcks ID for this location, if applicable:	Vaccines for Children (VFC) PIN, if applicable:	IIS ID, if applicable:
Unique COVID-19 Organization ID (from Section A):	Unique Location ID**:	

**The jurisdiction's immunization program is required to create an additional unique Location ID for each location completing Section B. The number should include the awardee jurisdiction abbreviation. For example, if an organization (Section A) in Georgia (e.g., GA123456A) has three locations (main location plus two additional) completing section B, they could be numbered as GA123456B1, GA123456B2, and GA123456B3).

COVID-19 vaccination provider type for this location (select one) Health Center-Community (non-FQHC)

- Commercial vaccination service provider
- Corrections/detention health services
- Health center – community (non-Federally Qualified Health Center/ non-Rural Health Clinic)
- Health center – migrant or refugee
- Health center – occupational
- Health center – STD/HIV clinic
- Health center – student
- Home health care provider
- Hospital
- Indian Health Service
- Tribal health
- Medical practice – family medicine
- Medical practice – pediatrics
- Medical practice – internal medicine
- Medical practice – OB/GYN
- Medical practice – other specialty
- Pharmacy – chain
- Pharmacy – independent
- Public health provider – public health clinic
- Public health provider – Federally Qualified Health Center
- Public health provider – Rural Health Clinic
- Long-term care – nursing home, skilled nursing facility, federally certified
- Long-term care – nursing home, skilled nursing facility, non-federally certified
- Long-term care – assisted living
- Long-term care – intellectual or developmental disability
- Long-term care – combination (e.g., assisted living and nursing home in same facility)
- Urgent care
- Other (Specify: _____)

Setting(s) where this location will administer COVID-19 vaccine (select all that apply)

- Child care or day care facility
- College, technical school, or university
- Community center
- Correctional/detention facility
- Health care provider office, health center, medical practice, or outpatient clinic
- Hospital (i.e., inpatient facility)
- In home
- Long-term care facility (e.g., nursing home, assisted living, independent living, skilled nursing)
- Pharmacy
- Public health clinic (e.g., local health department)
- School (K – grade 12)
- Shelter
- Temporary or off-site vaccination clinic – point of dispensing (POD)
- Temporary location – mobile clinic
- Urgent care facility
- Workplace
- Other (Specify: _____)

Approximate number of patients/clients routinely served by this location

Number of children 18 years of age and younger: 100 (Enter "0" if the location does not serve this age group.) Unknown

Number of adults 19 – 64 years of age: 2,700 (Enter "0" if the location does not serve this age group.) Unknown

Number of adults 65 years of age and older: 700 (Enter "0" if the location does not serve this age group.) Unknown

Number of unique patients/clients seen per week on average: 100 Unknown

Not applicable (e.g., for commercial vaccination service providers)

Influenza vaccination capacity for this location

Number of influenza vaccine doses administered during the peak week of the 2019–20 influenza season: 600 Unknown
 (Enter "0" if no influenza vaccine doses were administered by this location in 2019-20.)

Population(s) served by this location (select all that apply)

- General pediatric population
- General adult population
- Adults 65 years of age and older
- Long-term care facility residents (nursing home, assisted living, or independent living facility)
- Health care workers
- Critical infrastructure/essential workers (e.g., education, law enforcement, food/agricultural workers, fire services)
- Military – active duty/reserves
- Military – veteran
- People experiencing homelessness
- Pregnant women
- Racial and ethnic minority groups
- Tribal communities
- People who are incarcerated/detained
- People living in rural communities
- People who are underinsured or uninsured
- People with disabilities
- People with underlying medical conditions* that are risk factors for severe COVID-19 illness
- Other people at higher risk for COVID-19 (Specify: _____)

Does your organization currently report vaccine administration data to the state, local, or territorial immunization information system (IIS)?

If **YES** [List IIS Identifier: QWG28881]

If **NOT**, please explain planned method for reporting vaccine administration data to the jurisdiction's IIS or other designated system as required:

If **NOT APPLICABLE**, please explain:

Estimated number of 10-dose multidose vials (MDVs) your location is able to store during peak vaccination periods (e.g., during back-to-school or influenza season) at the following temperatures:

- Refrigerated (2°C to 8°C): No capacity **OR** Approximately 82,944 additional 10-dose MDVs
- Frozen (-15°C to -25°C): No capacity **OR** Approximately 77,760 additional 10-dose MDVs
- Ultra-frozen (-60°C to -80°C): No capacity **OR** Approximately 178,200 additional 10-dose MDVs

Storage unit details for this location

- List brand/model/type of storage units to be used for storing COVID-19 vaccine at this location:
1. Thermo Scientific TSX2320FA Freezer (x3)
 2. Thermo Scientific TSX40086A Ultra-Low Freezer
 3. Thermo Scientific TSX60086A Ultra-Low Freezer (x3)
 4. Thermo Scientific TSX5005PA Refrigerator (x2)
 5. _____

I attest that each unit listed will maintain the appropriate temperature range indicated above (please sign and date):

Jhan Howard
Medical/pharmacy director or location's vaccine coordinator signature:

12/2/2020
Date:

BCC Mtg. Date: February 9, 2021

CDC COVID-19 Vaccination Program Provider Agreement



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

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization'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)*. In addition, the *CDC COVID-19 Vaccination Program Provider Profile Information (Section B)* must be completed for each vaccination location covered under the Organization listed in Section A.

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

Organization identification

Organization's legal name: **Orange County, FL**

Number of affiliated vaccination locations covered by this agreement: **1**

Organization telephone: **407-836-9225**

Email: **covid19vaccines@ocfl.net** (must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program)

Street address 1: **201 S. Rosalind Ave** Street address 2:

City: **Orlando** County: **Orange** State: **FL** ZIP: **32801**

Responsible officers

For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signatures after reviewing the agreement requirements.

Chief Medical Officer (or Equivalent) Information

Last name: **Mascoe** First name: **Maurice** Middle initial: **W**

Title: **MD** Licensure state: **FL** Licensure number: **ME60047**

Telephone: **(407) 836-7350** Email: **maurice.mascoe@ocfl.net**

Street address 1: **3855 S. John Young Pkwy** Street address 2:

City: **Orlando** County: **Orange** State: **FL** ZIP: **32839**

Chief Executive Officer (or Chief Fiduciary) Information

Last name: **Demings** First name: **Jerry** Middle initial: **L**

Telephone: **407-836-7370** Email: **Mavor@ocfl.net**

Street address 1: **201 S. Rosalind Ave.** Street address 2:

City: **Orlando** County: **Orange** State: **FL** ZIP: **32801**

Agreement requirements

I understand this is an agreement between Organization and CDC. This program is part of a collaboration under the relevant state, local, or territorial immunization program's cooperative agreement with CDC.

To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:

1. Organization must administer COVID-19 vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).¹
2. Within 24 hours of administering a dose of COVID-19 vaccine and adjuvant (if applicable), Organization 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 reporting can be found on CDC's website.²

Organization must submit Vaccine Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.²

Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3. Organization must not sell or seek reimbursement for COVID-19 vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.
4. Organization must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees.
5. Before administering COVID-19 vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
6. Organization'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.³
7. Organization must comply with CDC requirements for COVID-19 vaccine management. Those requirements include the following:
 - a) Organization 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*, which will be updated to include specific information related to COVID-19 vaccine;
 - b) Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance in CDC's *Vaccine Storage and Handling Toolkit*;⁴
 - c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;
 - d) Organization must monitor and comply with COVID-19 vaccine expiration dates; and
 - e) Organization must preserve all records related to COVID-19 vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
8. Organization 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.
9. Organization must comply with all federal instructions and timelines for disposing of COVID-19 vaccine and adjuvant, including unused doses.⁵
10. Organization must report any adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS) (1-800-822-7967 or <http://vaers.hhs.gov/contact.html>).
11. Organization must provide a completed COVID-19 vaccination record card to every COVID-19 vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 vaccine shipment will include COVID-19 vaccination record cards.
12. a) Organization 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) Organization must administer COVID-19 vaccine in compliance with all applicable state and territorial vaccination laws.

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

¹ www.cdc.gov/vaccines/hcp/acip-recs/index.html

² www.cdc.gov/vaccines/programs/iis/index.html

³ www.cdc.gov/vaccines/pandemic-guidance/index.html

⁴ www.cdc.gov/vaccines/hcp/admin/storage-handling.html

⁵ The disposal process for remaining unused COVID-19 vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.

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

CDC COVID-19 Vaccination Program Provider Agreement

By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 vaccine understand and will comply with the agreement requirements listed above and that the information provided in sections A and B is true.

The above requirements are material conditions of payment for COVID-19 vaccine administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare, Medicaid, and the Health Resources and Services Administration COVID-19 Uninsured Program. Reimbursement for administering COVID-19 vaccine is not available under any federal healthcare benefit program if Organization fails to comply with these requirements with respect to the administered COVID-19 vaccine dose. Each time Organization submits a reimbursement claim for COVID-19 vaccine administration to any federal healthcare benefit program, Organization expressly certifies that it has complied with these requirements with respect to that administered dose.

Non-compliance with the terms of 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 related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

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

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.⁶

Organization Medical Director (or equivalent)

Last name: **Mascoe** First name: **Maurice** Middle initial: **W.**

Signature:  Date: **01/30/2020**

Chief Executive Officer (chief fiduciary role)

Last name: **Demings** First name: **Jerry** Middle initial: **L.**

Signature:  Date: **12/4/20**

For official use only:

IIS ID, if applicable:

Unique COVID-19 Organization ID (Section A)*:

*The jurisdiction's immunization program is required to create a unique COVID-19 ID for the organization named in Section A that includes the awardee jurisdiction abbreviation (e.g., an organization located in Georgia could be assigned "GA123456A." This ID is needed for CDC to match Organizations (Section A) with one or more Locations (Section B). This unique identifier is required even if there is only one location associated with an organization.

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

Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

Organization identification for individual locations

Organization location name: Orange County Jail-Pharmacy	Will another Organization location order COVID-19 vaccine for this site? <input checked="" type="checkbox"/> If YES; provide Organization name: Orange County Medical Clinic
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Contact information for location's primary COVID-19 vaccine coordinator

Last name: Hopwood	First name: Shari	Middle initial:
Telephone: (407) 254-8245	Email: covid19vaccines@ocfl.net	

Contact information for location's backup COVID-19 vaccine coordinator

Last name: Walton	First name: Amy	Middle initial:
Telephone: (407) 254-8224	Email: Covid19vaccines@ocfl.net	

Organization location address for receipt of COVID-19 vaccine shipments

Street address 1: 3855 S. John Young Pkwy	Street address 2:		
City: Orlando	County: Orange	State: FL	ZIP: 32830
Telephone: (407) 466-2150	Fax:		

Organization address of location where COVID-19 vaccine will be administered (if different from receiving location)

Street address 1:	Street address 2:		
City:	County:	State:	ZIP:
Telephone:	Fax:		

Days and times vaccine coordinators are available for receipt of COVID-19 vaccine shipments

	Monday	Tuesday	Wednesday	Thursday	Friday
AM:	7:00	7:00	7:00	7:00	7:00
PM:	12:00	12:00	12:00	12:00	12:00

For official use only:

VTrckS ID for this location, if applicable:	Vaccines for Children (VFC) PIN, if applicable:	IIS ID, if applicable:
Unique COVID-19 Organization ID (from Section A):	Unique Location ID**:	

**The jurisdiction's immunization program is required to create an additional unique Location ID for each location completing Section B. The number should include the awardee jurisdiction abbreviation. For example, if an organization (Section A) in Georgia (e.g., GA123456A) has three locations (main location plus two additional) completing section B, they could be numbered as GA123456B1, GA123456B2, and GA123456B3.

COVID-19 vaccination provider type for this location (select one) Corrections/detention health services

- Commercial vaccination service provider
- Corrections/detention health services
- Health center – community (non-Federally Qualified Health Center/ non-Rural Health Clinic)
- Health center – migrant or refugee
- Health center – occupational
- Health center – STD/HIV clinic
- Health center – student
- Home health care provider
- Hospital
- Indian Health Service
- Tribal health
- Medical practice – family medicine
- Medical practice – pediatrics
- Medical practice – internal medicine
- Medical practice – OB/GYN
- Medical practice – other specialty
- Pharmacy – chain
- Pharmacy – independent
- Public health provider – public health clinic
- Public health provider – Federally Qualified Health Center
- Public health provider – Rural Health Clinic
- Long-term care – nursing home, skilled nursing facility, federally certified
- Long-term care – nursing home, skilled nursing facility, non-federally certified
- Long-term care – assisted living
- Long-term care – intellectual or developmental disability
- Long-term care – combination (e.g., assisted living and nursing home in same facility)
- Urgent care
- Other (Specify: _____)

Setting(s) where this location will administer COVID-19 vaccine (select all that apply)

- Child care or day care facility
- College, technical school, or university
- Community center
- Correctional/detention facility
- Health care provider office, health center, medical practice, or outpatient clinic
- Hospital (i.e., inpatient facility)
- In home
- Long-term care facility (e.g., nursing home, assisted living, independent living, skilled nursing)
- Pharmacy
- Public health clinic (e.g., local health department)
- School (K – grade 12)
- Shelter
- Temporary or off-site vaccination clinic – point of dispensing (POD)
- Temporary location – mobile clinic
- Urgent care facility
- Workplace
- Other (Specify: _____)

Approximate number of patients/clients routinely served by this location

- Number of children 18 years of age and younger: (Enter "0" if the location does not serve this age group.) Unknown
- Number of adults 19 – 64 years of age: (Enter "0" if the location does not serve this age group.) Unknown
- Number of adults 65 years of age and older: (Enter "0" if the location does not serve this age group.) Unknown
- Number of unique patients/clients seen per week on average: Unknown
- Not applicable (e.g., for commercial vaccination service providers)

Influenza vaccination capacity for this location

- Number of influenza vaccine doses administered during the peak week of the 2019–20 influenza season: Unknown
 (Enter "0" if no influenza vaccine doses were administered by this location in 2019-20.)

Population(s) served by this location (select all that apply)

- General pediatric population
- General adult population
- Adults 65 years of age and older
- Long-term care facility residents (nursing home, assisted living, or independent living facility)
- Health care workers
- Critical infrastructure/essential workers (e.g., education, law enforcement, food/agricultural workers, fire services)
- Military – active duty/reserves
- Military – veteran
- People experiencing homelessness
- Pregnant women
- Racial and ethnic minority groups
- Tribal communities
- People who are incarcerated/detained
- People living in rural communities
- People who are underinsured or uninsured
- People with disabilities
- People with underlying medical conditions* that are risk factors for severe COVID-19 illness
- Other people at higher risk for COVID-19 (Specify: [redacted])

Does your organization currently report vaccine administration data to the state, local, or territorial immunization information system (IIS)?

If YES [List IIS Identifier: PZY47703]

If NOT, please explain planned method for reporting vaccine administration data to the jurisdiction's IIS or other designated system as required:
[redacted]

If NOT APPLICABLE, please explain: [redacted]

Estimated number of 10-dose multidose vials (MDVs) your location is able to store during peak vaccination periods (e.g., during back-to-school or influenza season) at the following temperatures:

- Refrigerated (2°C to 8°C): No capacity OR Approximately 1,500 additional 10-dose MDVs
- Frozen (-15°C to -25°C): No capacity OR Approximately [redacted] additional 10-dose MDVs
- Ultra-frozen (-60°C to -80°C): No capacity OR Approximately [redacted] additional 10-dose MDVs

Storage unit details for this location

- List brand/model/type of storage units to be used for storing COVID-19 vaccine at this location:
1. ABS Premier Pharmacy/Vaccine Refrigerator/ Undercounter 5.2 Cu. Ft. (x7)
 2. ABS Standard Pharmacy/Vaccine Refrigerator/ Swing glass door 26 Cu. Ft.
 3. [redacted]
 4. [redacted]
 5. [redacted]

I attest that each unit listed will maintain the appropriate temperature range indicated above (please sign and date):

Shari Higwood
[redacted]
Medical/pharmacy director or location's vaccine coordinator signature:

Date: 11/30/2020

CDC COVID-19 Vaccination Program Provider Agreement

Providers practicing at this facility (additional spaces for providers at end of form)

Instructions: List below all licensed healthcare providers at this location who have prescribing authority (i.e., MD, DO, NP, PA, RPh).

Provider Name	Title	License No.
Mascoe, Maurice	MD	ME60047
Gavric, Boro	MD	ME89199
Fatima, Afshan	PA	PA9107422
Hardy, Trinese	APRN	APRN9449917
Mason, Janet	APRN	APRN11000130
Sahadeo, Khamwatie	APRN	APRN2973392
Wray, Shantell	PA	PA9110293
Enslow, Larhonda	APRN	APRN9256994

SUBMIT FORM

BCC Mtg. Date: February 9, 2021

CDC Supplemental COVID-19 Vaccine Redistribution Agreement



The Centers for Disease Control and Prevention (CDC) plans to ship a minimum order size of COVID-19 vaccine, constituent products, and ancillary supplies at no cost directly to enrolled COVID-19 vaccination providers throughout the United States. The federally contracted vaccine distributor uses validated shipping procedures to maintain the vaccine cold chain and minimize the likelihood of vaccine loss or damage during shipment. There may be circumstances where COVID-19 vaccine needs to be redistributed beyond the identified primary CDC ship-to sites (i.e., for orders smaller than the minimum order size or for large organizations whose vaccine is shipped to a central depot and requires redistribution to additional clinic locations). In these instances, vaccination provider organizations/facilities, third-party vendors, and other vaccination providers may be allowed to redistribute vaccine, if approved by the jurisdiction's immunization program and if validated cold chain procedures are in place in accordance with the manufacturer's instructions

and CDC's guidance on COVID-19 vaccine storage and handling. There must be a signed *CDC Supplemental COVID-19 Vaccine Redistribution Agreement* for the facility/organization conducting redistribution and a fully completed *CDC COVID-19 Vaccination Provider Profile Information* form (Section B of the CDC COVID-19 Vaccination Program Provider Agreement) for each receiving vaccination location.

The parties to this agreement are CDC and healthcare organizations, third-party vendors, and vaccination providers that redistribute COVID-19 vaccine. CDC cannot reimburse costs of redistribution beyond the initial designated primary CDC ship-to site(s), or for purchase of any vaccine-specific refrigerators or qualified containers. Therefore, organizations planning for redistribution of COVID-19 vaccine must carefully assess the associated risks and costs (e.g., vaccine loss due to temperature excursions, purchase of vaccine-specific portable refrigerators and/or containers) before planning this activity.

Organization information

Organization/facility name: Orange County, FL	FOR OFFICIAL USE ONLY	<i>VTrcks ID:</i>
	<i>Unique COVID-19 Organization ID (from Section A):</i>	

Primary address and contact information of COVID-19 vaccination organization

Street address 1: 201 S. Rosalind Ave	Street address 2:		
City: Orlando	County: Orange	State: FL	ZIP: 32801
Telephone: (407) 836-9225	Fax:		

Responsible officers

Medical Director (or Equivalent) Information

Last name: Zuver	First name: Christian	Middle initial: C
Title: Medical Director	Licensure state: FL	Licensure number: ME97144
Telephone: (407) 836-7606	Email: christian.zuver@ocfl.net	

Street address 1: 2002A East Michigan St	Street address 2:		
City: Orlando	County: Orange	State: FL	ZIP: 32806

Chief Executive Officer (or Chief Fiduciary) Information

Last name: Demings	First name: Jerry	Middle initial: L
Telephone number: (407) 836-7370	Email: mayor@ocfl.net	

Street address 1: 201 S. Rosalind Ave	Street address 2:		
City: Orlando	County: Orange	State: FL	ZIP: 32801

CDC Supplemental COVID-19 Vaccine Redistribution Agreement

Primary point of contact responsible for receipt of COVID-19 vaccine
(if different than medical director listed above)

Last name: Hopwood First name: Shari Middle initial: D
Telephone number: (321) 436-3124 Email: covid19vaccines@ocfl.net

Secondary point of contact for receipt of COVID-19 vaccine

Last name: Ayash First name: Sally Middle initial:
Telephone number: (407) 836-9225 Email: covid19vaccines@ocfl.net


COVID-19 vaccination organization redistribution agreement requirements

To redistribute COVID-19 vaccine, constituent products, and ancillary supplies to secondary sites, this organization agrees to:

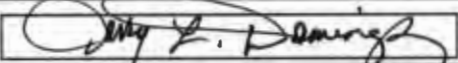
1. Sign and comply with all conditions as outlined in the CDC COVID-19 Vaccination Program Provider Agreement.
2. Ensure secondary locations receiving redistributed COVID-19 vaccine, constituent products, or ancillary supplies also sign and comply with all conditions in the CDC COVID-19 Vaccination Program Provider Agreement.
3. Comply with vaccine manufacturer instructions on cold chain management and CDC guidance in CDC's *Vaccine Storage and Handling Toolkit*, which will be updated to include specific information related to COVID-19 vaccine, for any redistribution of COVID-19 vaccine to secondary locations.
4. Document and make available any records of COVID-19 vaccine redistribution to secondary sites to jurisdiction's immunization program as requested, including dates and times of redistribution, sending and receiving locations, lot numbers, expiration dates, and numbers of doses. Neither CDC nor state, local, or territorial health departments are responsible for any costs of redistribution or equipment to support redistribution efforts.

By signing this form, I understand this is an agreement between my Organization and CDC, implemented and maintained by my jurisdiction's immunization program. I also certify on behalf of myself, my medical practice, or other legal entity with staff authorized to administer vaccines, and all the practitioners, nurses, and others associated with this Organization that I have read and agree to the COVID-19 vaccine redistribution agreement requirements listed above and understand my Organization and I are accountable for compliance with these requirements. Non-compliance with the terms of this Redistribution 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 related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

Organization Medical Director (or equivalent)

Last name: Zuver First name: Christian Middle initial: C
Signature:  Date: 1/20/2021

Chief Executive Officer (chief fiduciary role)

Last name: Demings First name: Jerry Middle initial: L
Signature:  Date: 1/22/21

¹ Requirements incorporated by reference; refer to www.cdc.gov/vaccines/hcp/admin/storage-handling.html.

SUBMIT FORM

BCC Mtg. Date: February 9, 2021

**PARAMEDICINE VACCINATION AGREEMENT
BETWEEN THE
STATE OF FLORIDA, DEPARTMENT OF HEALTH
ORANGE COUNTY HEALTH DEPARTMENT
AND
ORANGE COUNTY, FLORIDA**

This Paramedicine Vaccination Agreement ("Agreement") is made and entered into by the State of Florida, Department of Health, Orange County Health Department, hereinafter referred to as the "Health Department", and Orange County, Florida on behalf of its Health Services Department, EMS/Office of the Medical Director hereinafter referred to as "Orange County" or the "Medical Director," jointly referred to as the "parties."

RECITALS

WHEREAS, the Health Department is responsible to conduct programs for the prevention and control of communicable diseases and vaccine-preventable diseases, pursuant to section 381.003, Florida Statutes ("F.S."); and

WHEREAS, the State Surgeon General and State Health Officer has determined that certain communicable diseases are a threat to public health in Florida; and

WHEREAS, the Health Department seeks the assistance of Orange County for the administration of vaccines in Orange County, Florida; and

WHEREAS, pursuant to section 401.272, F.S., paramedics may partner with the Health Department to administer immunizations and perform health promotion and wellness activities in a nonemergency environment under direction from their Medical Director, to more effectively carry out health care tasks that are consistent with the public health; and

WHEREAS, Orange County has agreed to partner with the Health Department to utilize its paramedics in the administration of immunizations under the direction of the County's Medical Director.

NOW, THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

TERMS

I. Purpose:

The purpose of this Agreement is to improve community public health preparedness and response during a public health incident, public health threat, or other significant public health emergency in Orange County. This Agreement is intended to support the administration of vaccines by Orange County paramedics.

II. Scope:

- A. The provisions of this Agreement apply to activities to be performed to support community-based vaccination programs at the direction of the Health Department.

- B. No provisions of this Agreement limit the activities of the Health Department in performing its local and state functions.

III. Definitions:

- A. Administration/Administering/Administer – Obtaining, preparing, and giving a complete dosage of vaccine by a legally authorized person to a patient.
- B. Florida SHOTS – Centralized online immunization registry, as described in section 381.003(1)(e), F.S. and rule 64D-3.046, F.A.C.

IV. Health Department Responsibilities:

- A. For each disease a vaccine is administered, the Health Department shall provide protocols, policies and procedures which shall be attached to this Agreement as Exhibit A and the name of the disease, e.g. "Exhibit A, COVID 19".
- B. The Health Department shall store, transport and monitor vaccines supplied by Vaccines for Children (VFC) to the Health Department. The Health Department shall arrange to have available vaccine on site for Orange County planned events. Orange County teams will administer the VFC vaccine to vulnerable individuals at the event. Vaccine integrity shall be insured by the Health Department.
- C. The Health Department shall provide vaccine transport to the Orange County Medical Director's location.
- D. The Health Department shall provide training to Orange County EMS paramedics ("paramedics") regarding the dosage, administration, adverse reactions, clinical procedures and documentation of the vaccinations in accordance with Centers for Disease Control and Prevention ("CDC") guidelines and all other applicable guidelines.
- E. Hands-on Clinical Practice. The Health Department shall provide a clinical setting consistent with the training requirements of the public health nursing staff. This training period provided by the Health Department shall continue until both the public health nurse and paramedic are comfortable with the achieved level of knowledge and technique.
- F. The Health Department shall provide oversight of policy, procedure, review of incidents or complaints, etc. related to the performance of Orange County paramedics.
- G. The Health Department shall provide the County with a Vaccine Information Sheet, as prepared by the CDC, for dissemination by Orange County paramedics to all who are vaccinated with Health Department supplied vaccines.
- H. The Health Department shall provide Orange County with a means of documenting the administration of vaccines, consistent with Health Department policies and procedures.
- I. The Health Department shall make available to Orange County its registered nurses and other staff to work with and consult with the Orange County paramedics and to answer vaccination related questions as needed.

- J. Maintain all records and conduct any epidemiological investigation and monitoring for identified COVID-19 Persons Under Investigation and COVID-19 cases resulting from the execution of this Agreement.

V. Orange County Responsibilities:

- A. The Orange County Medical Director shall provide direction and oversight to Orange County paramedics providing vaccination services through the Orange County EMS System pursuant to the requirements of section 401.272, F.S.
- B. The Orange County Medical Director shall provide the Health Department with a signed and completed form DH 1256 verifying vaccine administration training and experience of Orange County EMS system paramedics. The completed form must be maintained at the service location of the licensee and made available to the Health Department upon request.
- C. The Orange County Medical Director shall assign qualified paramedics to administer vaccines. The Orange County Medical Director shall ensure that Orange County paramedics comply with the protocols and procedures established and approved by the Health Department and the Orange County Medical Director.
- D. The Orange County Medical Director shall ensure that Orange County paramedics maintain the confidentiality of all data, files, and records related to the services provided pursuant to this Agreement and shall comply with state and federal laws. The paramedics must also comply with any applicable professional standards of practice with respect to patient confidentiality.
- E. Orange County shall obtain an informed consent from each patient or their parent or guardian, as applicable.
- F. Orange County paramedics shall administer the vaccinations to each patient under the direction of the Orange County Medical Director and using the correct administration procedure, according to established Health Department recommendations.
- G. Orange County shall document vaccinations using the prescribed method by the Health Department.
- H. Orange County shall follow the Health Department's established courtesy standard, which states: "Treat customers, the public and staff with courtesy, respect and dignity and present a positive public image."
- I. Orange County shall consult with the Health Department on any questions that may require more in-depth immunization knowledge or problem solving.

VI. Terms and Conditions:

A. Laws

Both parties agree to abide by all local, state and federal laws.

B. Information Security and Confidentiality

The Medical Director must maintain confidentiality of all data, files, and records including patient records related to the services provided pursuant to this Agreement and will comply with state and federal laws, including, but not limited to, sections 384.29, 381.004, 392.65 and 456.057, F.S. Procedures must be implemented by the Medical Director to ensure the protection and confidentiality of all confidential information and records. The Medical Director must also comply with any applicable professional standards of practice with respect to patient confidentiality.

C. Liability and Insurance

Each party who is a state agency or subdivision, as defined in section 768.28, F.S., agrees to be fully responsible only to the extent provided by section 768.28, F.S., for the negligent acts or omissions or tortious acts of its own employees, agents or principals which result in claims or suits against the other party (parties), and agrees to be liable for any damages proximately caused by said acts or omissions or torts. Each Party, at its expense, shall maintain ordinary property and liability insurance to the extent authorized by law. Nothing herein is intended to serve as a waiver of sovereign immunity by any party to which sovereign immunity applies. Nothing herein shall be construed as consent by a state agency or subdivision of the State of Florida to be sued by third parties in any matter arising out of this Agreement. No state agency or subdivision indemnifies any other party or person.

D. Amendment

This Agreement contains all the terms and conditions agreed upon by the parties. There are no provisions, terms, conditions, or obligations other than those contained herein. This Agreement may be amended at any time in writing and signed by both parties.

E. Effective Date, Term, Termination

This Agreement shall become effective upon the signature of both parties and remain in effect until otherwise agreed to by the parties. This Agreement may be terminated by either party without cause upon no less than 30 days written notice to the other party, unless a lesser time is mutually agreed upon in writing by both parties. Notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery.

F. Independent Parties

The parties expressly agree that no relationship of employer/employee, principal agent, lessee/lessor, or other association shall be created by this Agreement between the parties or their directors, officers, agents, or employees. The parties agree that they will never incur any obligations on the part of the other party.

G. Inspector General

To the extent applicable, both parties acknowledge and understand their duty to cooperate with the inspector general in any investigation, audit, inspection, review, or hearing pursuant to section 20.055(5), F.S.

H. Financial Obligations

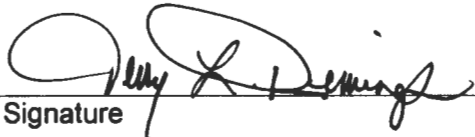
Both parties agree to be responsible for their own costs associated with performing its respective obligations under this Agreement. In the event of a dispute under this Agreement, both parties are responsible for their own attorney fees and costs. Venue for any legal action arising from this Agreement will be in the county of the Health Department.

I. Authority to Bind Principals

The persons executing this Agreement on behalf of their respective agency parties hereby represent and warrant that they have the right, power, legal capacity, and appropriate authority to enter into this Agreement on behalf of the agency for which they sign.

IN WITNESS THEREOF, the parties hereto have caused this Agreement to be executed by their undersigned officials as duly authorized.

ORANGE COUNTY, FLORIDA


Signature

Name: Jerry L. Demings

Title: Orange County Mayor

Date: 12/30/20

STATE OF FLORIDA
DEPARTMENT OF HEALTH
ORANGE COUNTY HEALTH
DEPARTMENT


Signature

Name: Raul Pino, M.D., M.P.H.

Title: Administrator/Health Officer

Date: 11/22/2020

Exhibit A

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-19	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date: July 11, 2019
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Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-19	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date: July 11, 2019
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I. Purpose

To administer vaccines according to the current standard of care, to document all vaccines administered in the CHD, to ensure distribution of risk/benefit information to clients, and to report adverse events.

II. Procedures

Department of Health (DOH) county health department (CHD) staff will administer vaccines according to the current standard of care and document administration of all vaccines administered to CHD clients. All clients or their parent/guardian will be informed of the risks and benefits of each vaccine to be administered. The current Vaccine Information Statement (VIS), prepared by the Centers for Disease Control and Prevention (CDC), will be provided to the client or their parent/guardian. Adverse events associated with the administration of certain vaccines will be reported to the Vaccine Adverse Event Reporting System (VAERS).

A. Vaccine Administration Documentation

Each CHD is required to obtain consent for treatment and care, including immunization services, for all clients receiving immunizations. Documenting consent in the Florida State Health Online Tracking System (SHOTS) is recommended and suffices for electronic signature. The current Department of Children and Families Operating Procedure details statutory authority and outlines under which circumstances a foster parent or shelter care worker may sign to authorize needed immunizations. Contact the local Department of Children and Families district office for specific guidance at www.myflfamilies.com/contact-us.

An education plan that includes competency-based training on vaccine administration should be developed and implemented for all CHD staff who administer vaccines. Individuals shall maintain records of all training documentation in the event of an audit.

When a client presents for immunizations, all client identification and historical immunization data should be reviewed and updated, as needed.

1. Electronic Immunization Clinic Record Form (DH 687)

- a. The Immunization Clinic Record is the permanent medical record for a client's immunizations. The Health Management System (HMS) documents all client services, and Florida SHOTS is used to document historical and administered vaccines.
- b. It is not necessary to maintain a hard copy of current immunizations if the electronic DH 687 form within Florida SHOTS is used.
- c. Enter data in Florida SHOTS according to the guidelines in this policy. All client and immunization information should be entered into Florida SHOTS as soon as possible, preferably during the administration process or at least the same day.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-19	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date: July 11, 2019
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- d. A Florida SHOTS-generated DH 687 form can be printed, if a hard copy is necessary. All doses of all vaccines administered will be documented on this form.
2. Florida SHOTS Notification and Opt Out Form (DH 1478)
 - a. Effective January 1, 2003, all children born in Florida are added to Florida SHOTS as required by section 381.003, Florida Statutes, and Florida Administrative Code Rule 64D-3.046. The Bureau of Vital Statistics provides a birth file for all children born on or after January 1, 2003, for loading into Florida SHOTS. Opt-out forms for these children are provided by the Bureau of Vital Statistics through the birth notice that is mailed to their parent/guardian. The opt-out provision is automatically recorded in Florida SHOTS for these births. There is no need to provide additional opt-out information, unless specifically requested by a parent/guardian. If a parent/guardian does request an opt-out form, the CHD should provide the form and have the parent/guardian follow directions on the form for submission. This form is also available online at www.flshotsusers.com/opt-out.
 - b. All staff who administer vaccines must be added as personnel in Florida SHOTS.
 - c. Technical assistance for Florida SHOTS is available from the *DOH Immunization Section User's Guide to Florida SHOTS: Immunization Registry* and the staff at Florida SHOTS enrollment desk (contact 1-877-888-7468 or email DL HSD IMM FLSHOTS HELPDESK). Web-based training for Florida SHOTS is available and recommended for all users.
 - d. When a child's immunization record is added to Florida SHOTS, the parent/guardian should receive notification of the ability to opt out of sharing immunization records by filling out and submitting a *Florida SHOTS Notification and Opt Out* form (DH 1478). This notification is required by section 381.003, Florida Statutes, and Florida Administrative Code Rule 64D-3.046. Notification can be accomplished by posting a highly visible DH 1478 form at the intake desk where the parent/guardian brings a child for vaccinations.
 - e. The aforementioned posting of the notification is sufficient for a parent/guardian whose child was born prior to January 1, 2003, was added to the registry or who present for the first time from another state. The notification date and the name of the individual recording the date should be added to Florida SHOTS when the client is added to the system for the first time. This information will automatically appear on the electronic DH 687 form in view or print mode. (Opt-out information only has to be provided and documented once in Florida SHOTS).

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-19	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date: July 11, 2019
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3. Religious Exemption from Immunization Form (DH 681)

Effective July 11, 2019, when a parent/guardian requests a *Religious Exemption from Immunization* form (DH 681), CHD staff will provide the DOH *Vaccine Education Form* (DH8005-DCHP-05/2019), located at <https://floridahealth.sharepoint.com/sites/DISEASECONTROL/EPI/Shared%20Documents/epidemiology/immunization/DH8005-DCHP-05-2019.pdf>. **The DH8005-DCHP-05/2019 form is for educational purposes, not counseling.**

- a. Each CHD will designate at least one nurse to offer education regarding the risks and benefits of vaccinations to parents/guardians requesting religious exemption. The preferred designee is a registered nurse; however, a licensed practical nurse may provide this education under the direct supervision of a registered nurse.
- b. The designated CHD nurse will review the child's shot record in Florida SHOTS and indicate the recommended vaccines on the DH8005-DCHP-05/2019 form. If the child does not have a record in Florida SHOTS, the nurse will use current ACIP guidelines to indicate recommended vaccines on the DH8005-DCHP-05/2019 form.
- c. The designated CHD nurse will provide the parent/guardian with a printed copy of the DH8005-DCHP-05/2019 form with the list of recommended vaccines for review.
 1. The designated CHD nurse should allow up to 15 minutes for the parent/guardian to review the DH8005-DCHP-05/2019 form and verbally discuss the risks and benefits of vaccinations. Additional guidance and educational materials to assist staff are available through the resource link on the Immunization Section Website: ImmunizeFlorida.org.
 2. The parent/guardian should sign the DH8005-DCHP-05/2019 form to acknowledge understanding of the risks and benefits of vaccination.
 3. If the parent/guardian refuses vaccine education, the designated CHD nurse must sign the DH8005-DCHP-05/2019 form and proceed with issuance of the Religious Exemption form DH681. No other information should be solicited from the parent/guardian.
- d. The DH8005-DCHP-05/2019 must be maintained by the local CHD for 10 years, in accordance with the DOH Individual Schedules, Schedule #2, Item #2. This record may exist as a component of a medical record or be filed individually with other client immunization records. It is not necessary to keep a hard copy of this form.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-19	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date: July 11, 2019
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- e. The CHD Medical Director/Administrator or designee must use the current DH681 form available electronically in Florida SHOTS, to document that the parent/guardian requests a religious exemption. The preferred designee is a registered nurse; however, a licensed practical nurse may generate the DH 681 form under the direct supervision of a nurse.
 - f. The designated CHD nurse must document issuance of the of DH8005-DCHP-05/2019 form in Florida SHOTS according to guidance in the *Documenting a Vaccine Education Encounter* training guide located at flshotsusers.com/sites/default/files/vaccine_education_encounter.pdf. Provide a completed copy of the *Vaccine Education Form* (DH8005-DCHP-05/2019) for parent/guardian records.
 - g. The CHD Medical Director/Administrator or designee must document issuance of the Religious Exemption form in Florida SHOTS according to guidance in the *DOH Immunization Section User's Guide to Florida SHOTS: Immunization Registry*. Provide a completed *Religious Exemption from Immunization* form (DH 681) and duplicate for parent/guardian records. Refer to the current *Immunization Guidelines for Florida Schools, Childcare Facilities and Family Daycare Homes* at www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/_documents/school-guide.pdf for additional information.
4. Immunization History Update
- a. Add all historical immunizations given by other clinics or private medical providers into Florida SHOTS, unless already available in the system.
 - b. If the client receives services from another provider, instruct the parent/guardian to take the updated immunization record to that practice.
 - c. Review Florida SHOTS Immunization Status page to assist in determining vaccines due and recommended due dates. Assess the client's immunization history to determine which vaccine(s) is needed at each encounter. Review all sources of immunization documentation.
5. Eligibility for Vaccines for Children (VFC) Program
- a. Screen clients (birth through 18 years of age) at each clinic visit to determine their eligibility under the VFC Program. Refer to *the Florida Vaccines for Children Program Provider Handbook* at www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/vfc-provider-handbook-2016.pdf for details.
 - b. Indicate the eligibility status by selecting the appropriate code in Florida SHOTS.

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-19	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date: July 11, 2019
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- (1) Eligibility categories:
 - (a) VFC-Eligible—American Indian or Alaskan Native
 - (b) VFC-Eligible—Medicaid/MCO
 - (c) VFC-Eligible—Underinsured
 - (d) VFC-Eligible—Uninsured

6. Distribution of Risk/Benefit Information

a. Provision of the VIS

- (1) By federal law, the National Childhood Vaccine Injury Act requires all vaccine providers to give each patient or their parent/guardian the appropriate CDC VIS form on each occasion a vaccination is given. Florida SHOTS will link to the current version for each vaccine. These forms are available at www.cdc.gov/vaccines/hcp/vis/index.html. Document the VIS given, publication date, to whom the VIS was provided, and the CHD staff providing the VIS in Florida SHOTS. **Note: Both the consent and VIS receipt should be documented in Florida SHOTS.**
- (2) Allow the client or parent/guardian sufficient time to read the VIS. Providers should supplement VIS forms orally, with videotapes, additional printed material, or any other way that will help the client and parent/guardian understand the disease and vaccine, as needed.
- (3) The CHD clinical staff will answer all questions in a client-friendly, culturally sensitive manner.
- (4) Maintain a translation referral list and information to Language Line Services. Translated versions of the VIS for childhood vaccines are available on-line at www.immunize.org/vis/?f=9.
- (5) In the absence of access to Florida SHOTS, use the hard copy of the DH 687 form. Record the CDC publication date of each VIS provided in the "VIS Date" section on the line corresponding with the vaccine given. Document the required information on the DH 687 form after the client and/or parent/guardian have been provided and s/he has read the applicable VIS.

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7. Vaccine Administration

- a. The CHD clinical staff will administer the appropriate vaccines according to the current standard of care, the current *ACIP Recommended Immunization Schedules for Persons Aged 0 through 18 years, United States*, and the latest *Report of the Committee of Infectious Diseases of the American Academy of Pediatrics (Red Book)*. The CHD staff will also document administration of all vaccines administered to CHD clients.
- b. Upon review all sources of immunization documentation and assessment of the client's immunization status, CHD staff will determine which vaccine(s) is (are) needed at each encounter.
- c. CHD staff will provide the needed vaccine(s) according to the CHD's internal standing orders for administering the age-appropriate vaccine(s) due at the time of the encounter. Under these standing orders, eligible CHD clinical staff may vaccinate children and teens who meet any of the criteria.
- d. Screen all patients for contraindications and precautions to the age-appropriate vaccine(s) due at the time of the encounter.

8. Documentation of Doses Given

- a. Only Florida SHOTS registry should be used for documentation of immunizations.
- b. Choose the appropriate vaccine administration route/site from Florida SHOTS. A listing of approved abbreviations is located in the DOH Policy (DOHP) 380-3-14, Clinical Abbreviations/Acronyms/Symbols Policy, available at dohwebdev.doh.ad.state.fl.us/Divisions/Planning_Evaluation/HPE_DOHPolicy/DOHP380-3.pdf.
- c. Varicella Disease: If the client has a valid history of varicella disease, it should be entered as a contraindication by recording the date and source of history (that is physician documentation) in the varicella section in Florida SHOTS.
- d. If using combination vaccines, verify that administration of each antigen is documented. In the absence of access to Florida SHOTS, verify that all information for each antigen is recorded on a hard copy DH 687 form. A blank DH 687 form can be printed from Florida SHOTS.
- e. Inquire about and record all conditions that may indicate allergies, contraindications, and permanent medical exemptions. Reference the list of valid precautions and contraindications from the CDC website at www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm.
- f. A Florida SHOTS-generated *Florida Certification of Immunization* form

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(DH 680) can be provided to the parent/guardian, if needed. Only valid doses of vaccines required for school or child care appear on this form.

- g. A parent/guardian may be issued a DH 680 personal identification number by the CHD or other health care provider for later retrieval of the DH 680 form directly by the parent/guardian.
- h. A Florida SHOTS-generated report, *Immunization History* form (DH 686), can be printed and provided to the parent/guardian, as a personal immunization record. All valid doses of vaccines received and recommended next due dates are listed on this form.
- i. If the client is a Women, Infants and Children Program (WIC) client, add the WIC identification number, if known.

9. Family Planning/STD Confidential Minors and Immunizations

- a. The provider must document in the notes that the confidential minor seeking Family Planning/STD services meets the requirements of the statute, as reflected in TAG 332-4 FAMPLAN4 paragraph C, and has been informed of risks/benefits of the vaccine and given informed consent.
- b. Confidential Family Planning/STD minor clients may receive the human papillomavirus (HPV) vaccine and the hepatitis B vaccine without parental consent.
- c. An uninsured minor (under 19 years of age) may receive these vaccines through a Title X Family Planning/STD Clinic. If an insured minor desires vaccination, but does not have access to the insurance because of confidential circumstances (seeking family planning or STD services), the minor is considered uninsured, which meets eligibility for VFC-funded (PC 01) vaccine. Minors who are insured by Medicaid are also eligible for VFC-funded (PC 01) vaccine.
- d. If a confidential minor begins vaccination series as a Family Planning/STD client, then the minor must complete vaccination series as a Family Planning/STD client. A confidential Family Planning/STD minor client must not be referred to CHD Immunization Clinics to receive follow-up series vaccinations.
- e. Documentation of immunizations for confidential Family Planning/STD minor clients must be performed within the client's electronic health record in Medication Profile/Emdeon and not entered into FLSHOTS.
- f. Within Medication in HMS, choose Standard/Reported. Do not choose minors insurance unless it is Medicaid. On the RxPad page, choose the "Reported RX" button on the right-hand side of the screen. Complete Effective Date;

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enter vaccination type under DRUG. This will record the name of the vaccine and the dose given. Record the following under Notes to Pharmacist:

- (1) VIS with publication date given to client
- (2) Injection site
- (3) Injection route
- (4) Name of vaccine manufacturer
- (5) Vaccine lot number
- (6) Expiration date
- (7) NDC number
- (8) Name and title of vaccinator
- (9) Dose sequence (first, second, or third)
- (10) Next Dose in number weeks or months (for the second and third doses)
 EXAMPLE: HPV VIS (11/15/15) given to client; RDT; IM; Merck & Co; Lot# L018351; Exp 8/11/17; NDC 00006-4119-03; Administered by J. Smith, RN; 1st dose. Next Dose in X weeks.

NOTE: There is limited space in comments and this information must be entered as indicated with no returns

REMOVE PHARMACY by clicking the black X
 SAVE

- g. CHDs should follow the guidance provided in the *Florida VFC Provider Handbook* for inventory management.
- h. Reimbursement of HPV and hepatitis B vaccination services for confidential Family Planning/STD minor clients is limited to billing Medicaid for the administration fee only.
- i. Recommended confidential minor immunization guidelines:
 - (1) Female confidential Family Planning/STD minor clients aged 11–17 years:
 - (a) Should be offered either VFC-funded (PC 01) HPV vaccine for prevention of HPV and cervical cancer if not previously vaccinated
 - (b) Should be offered VFC-funded (PC 01) hepatitis B vaccination if not previously vaccinated

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(2) Male confidential Family Planning/STD minor clients aged 11–17 years:

- (a) Should be offered VFC-funded (PC 01) HPV vaccine, if not previously vaccinated
- (b) Should be offered VFC-funded (PC 01) hepatitis B vaccination if not previously vaccinated

10. Post-Vaccination Parent/Guardian Counseling

- a. Provide client or parent/guardian with information (oral or written) on common adverse events, which may follow immunization.
- b. In case of an adverse event following vaccine administration, provide client or parent/guardian with telephone numbers and explain where and how to obtain medical care during daytime and nighttime hours. Please instruct client or parent/guardian to contact the CHD if any adverse event occurs.
- c. Follow-up activities, such as telephone calls, reminder/recall notices, and home visits, should be documented under contact attempts in Florida SHOTS and/or in the medical record.

B. VAERS

- 1. The VAERS is a passive surveillance system through which individuals report events associated with the administration of certain vaccines.
- 2. According to the National Childhood Vaccine Injury Act, you must report specific adverse events following the administration of specific vaccines in accordance with recommendations provided in the *Morbidity and Mortality Weekly Report (MMWR)* Volume 60, No. RR-2, January 28, 2011.
- 3. The VAERS accepts all reports of adverse events after the administration of any vaccine.
- 4. Any serious adverse events, such as those that require a health care visit, should be reported through the VAERS.
- 5. Health care providers, including CHD staff, are required by law to report certain adverse events.
- 6. Lay people, such as parent/guardian, may also report adverse events to the VAERS. Encourage these individuals to seek the assistance of a health professional in completing the form.

a. VAERS Forms

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- (1) The VAERS reports are submitted electronically at www.vaers.hhs.gov/index.
- (2) For non-electronic submission, copies of the VAERS reporting form and instructions can be found and downloaded from www.vaers.hhs.gov/, by calling toll-free 1-800-822-7967, or by submitting requests to the VAERS at info@vaers.org.

b. Reporting Process

- (1) CHD Staff Responsibilities:
 - (a) Initiate and complete electronic VAERS report submission according to the instructions
 - (b) Print and review the form to ensure that all items are complete. Be sure the dates make chronological sense. For example, the date of birth must precede the date of vaccination. This information is critical to the analysis of the VAERS data
 - (c) Notify the CHD VAERS coordinator and the Immunization Section VAERS coordinator
 - (d) Submit a completed report to VAERS, the Immunization Section VAERS coordinator, and retain a copy for case management

c. Each CHD will appoint a VAERS Coordinator responsible for:

- (1) Receiving VAERS notification from all CHD clinics in the county
- (2) Reviewing the report for completeness, accuracy, and consistency
- (3) Verifying electronic VAERS submission and notification to Immunization Section VAERS Coordinator
- (4) Identify a designated backup staff. Cross training these duties ensures timely and accurate reporting. Performance standards should reflect these responsibilities for the designated individuals
- (5) Enter adverse event(s) into Florida SHOTS on behalf of the client

d. Follow Up of Serious Adverse Events

- (1) Certain serious adverse events require a 60-day and/or one-year follow up. The parameters for follow-up reporting are determined by the VAERS on a case-by-case basis.

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- (2) The Immunization Section VAERS Coordinator will notify the CHD VAERS Coordinator when follow up is due, so that the CHD coordinator can obtain information on the status of the client and report findings back to the Immunization Section VAERS Coordinator.

III. Scope

- A. Personnel: All CHD Medical Doctors, Doctors of Osteopathy, Advanced Practice Registered Nurse, Physician’s Assistants, RNs, and LPNs within constraints of their practice acts, protocols, and responsibilities for immunization services.
- B. Competencies: The CHD management team is responsible for determining the level of knowledge and competency of staff members providing immunization services.
- C. Areas of Responsibility:
1. Distribution of Risk/Benefit Information: Each CHD provider is responsible for ensuring documentation of receipt of the appropriate VIS prior to each vaccination administration under federal law.
 2. Vaccine Administration: The CHD immunizations staff is responsible for administering vaccines according to the current standard of care and following the ACIP recommendations.
 3. Vaccine Administration Documentation: Each CHD is responsible for maintaining proper documentation of vaccine administration.
 4. Vaccine Adverse Event Reporting System: CHD staff is responsible for reporting certain adverse events under federal law.

IV. **Authority:** Sections 381.0011, 381.003, and 1003.22, Florida Statutes, and Florida Administrative Code Rule 640-3.046.

V. Supportive Data

- A. *Epidemiology and Prevention of Vaccine-Preventable Diseases* (The 2015 Pink Book): Vaccine Administration Chapter of Pink Book, 13th edition, 2015; www.cdc.gov/vaccines/pubs/pinkbook/index.html, accessed 03/19.
- B. *User’s Guide to Florida SHOTS: Immunization Registry*, www.flshotsusers.com/, accessed 03/19.
- C. Department of Health, Health Management System, *Clinical Portal Overview*, dohiws/Divisions/Planning_Evaluation/HMS/Training/UserDocumentation/ClinicalEncounter/ClinicianPortal_Overview.pdf, accessed 03/19.
- D. Vaccine Adverse Event Reporting System, vaers.hhs.gov/, accessed 03/19.

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- E. *Immunization Guidelines for Florida Schools, Childcare Facilities and Family Daycare Homes* at www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/_documents/school-guide.pdf, accessed 03/19.
- F. CDC Vaccines for Children Program Operations Guide, www.cdc.gov/vaccines/programs/vfc/index.html, and www.cdc.gov/vaccines/programs/vfc/awardees/index.html, accessed 03/19.
- G. *Florida Vaccines for Children Program Provider Handbook*, www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/provider-handbook.html, accessed 03/19.
- H. Centers for Disease Control and Prevention, www.cdc.gov, accessed 03/19.
- I. Centers for Disease Control and Prevention, *Mortality and Morbidity Weekly Report*, www.cdc.gov/mmwr, accessed 03/19.
- J. Florida Department of Children and Families Operating Procedures, www.dcf.state.fl.us/admin/publications/policies.asp, accessed 03/19.

VI. Distribution List

Deputy Secretary for Health
 Division of Disease Control and Health Protection
 County Health Department Directors/Administrators
 County Health Department Medical Directors
 County Health Department Nursing Directors
 Children's Medical Services Medical Directors
 Children's Medical Services Nursing Directors
 Children's Medical Services Program Managers

VII. History Notes

This IOP replaces and supersedes IOP 340-5-18 dated July 6, 2018, its predecessor IOP 350-5-16 dated June 30, 2016 and its predecessor DOHP 350-5-14 dated February 23, 2014.

VIII. Signature and Effective Date

Signature On File July 11, 2019

 Scott Rivkees, MD
 State Surgeon General

 Date

MESH "CHD Guidebook" DCHP BOE Immunizations VFC "Vaccines For Children" VAERS "VAERS follow-up" reminder recall "VIS documentation" "combination vaccine" "immunization card" "immunization route" "immunization clinic"

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"vaccine documentation" "DH 687" "DH 681" "religious exemption" FLSHOTS "Immun IOP 350-5"

BCC Mtg. Date: February 9, 2021

**VACCINATION SITE AGREEMENT (COVID-19)
FOR AN OPEN POINT OF ADMINISTRATION
BETWEEN
STATE OF FLORIDA, DEPARTMENT OF HEALTH
ORANGE COUNTY HEALTH DEPARTMENT
AND
ORANGE COUNTY, FLORIDA**

This Vaccination Site Agreement for an Open Point of Administration ("Agreement") is made and entered into by the State of Florida, Department of Health, Orange County Health Department, hereinafter referred to as the "Health Department", and Orange County, Florida, hereinafter referred to as the "Organization." Health Department and Organization are jointly referred to as the "parties."

RECITALS

WHEREAS, the Health Department is responsible for conducting programs for the prevention and control of communicable diseases and vaccine-preventable diseases, pursuant to section 381.003, Florida Statutes ("F.S."); and

WHEREAS, the Health Department seeks to collaborate with the Organization to respond to a public health incident, public health threat, or other significant public health emergency; and

WHEREAS, the State Surgeon General and State Health Officer has determined that Coronavirus Disease 2019 (COVID-19) is a threat to public health in Florida and issued a Declaration of Public Health Emergency on March 1, 2020; and

WHEREAS, the parties want to coordinate their collective efforts in providing greater public access to COVID-19 vaccinations to prevent the occurrence and spread of communicable diseases, including COVID-19.

NOW, THEREFORE, in consideration of the foregoing, the parties agree as follows:

TERMS

I. Purpose:

- A. The purpose of this Agreement is to set forth guidance for the designation of the Organization as a Vaccination Site location servicing an Identified Population during a public health incident, public health threat, or other significant public health emergency.
- B. This Agreement outlines the scope of work between the Organization and the Health Department and is aimed at improving community public health preparedness and response in Orange County.

II. Scope:

- A. The provisions of this Agreement apply to activities to be performed resulting from the implementation of Health Department emergency response plans.

- B. No provisions of this Agreement limit the activities of the Health Department in performing its local and state functions.

III. Definitions:

- A. Administration/Administering/Administer: Obtaining, preparing, and administering a single COVID-19 vaccination to a patient by a legally authorized person.
- B. Identified Population: Individuals in the general public who seek a vaccination.
- C. Organization: Cooperating business, government, faith-based or secular organization.
- D. Vaccination Site: Location for administering COVID-19 vaccinations to individuals pursuant to a public health emergency; established to serve the Identified Population of the Organization. Further described in Exhibit A.
- E. Vaccination Supplies: Vaccine and medical supplies to administer the vaccine.

IV. Health Department Responsibilities:

- A. Develop a plan for vaccinating the Identified Population at the Organization's site, to include the number of individuals in the Identified Population who would receive COVID-19 vaccinations at the Vaccination Site.
- B. Provide the Organization with COVID-19 vaccination supplies, to the extent available, and guidance for the storage, recordkeeping, and transportation of the vaccination supplies. This includes transfer of vaccination supplies to the Organization's custody and control from the Health Department.
- C. Provide policies and procedures for administering the COVID-19 vaccination, which shall be attached as Exhibit B to this Agreement prior to the administration of any vaccinations.
- D. Provide a point of contact at the Health Department who may provide training to the Organization's staff on an as-needed basis.
- E. Provide additional COVID-19 vaccination supplies to the Organization if needed and available.

V. Organization Responsibilities:

- A. Provide the Health Department a Vaccination Site address and list of representatives authorized to accept vaccination supplies from the Health Department, as further described in Exhibit A, at least twenty-four (24) hours prior to any scheduled vaccination administration or supplies delivery. Due to the evolving nature of the public health emergency, the Organization may update the Vaccination Site address, identified population, contact information, or representative information contained in Exhibit A without formally amending this Agreement by providing the Health Department with written notice of said changes. By executing this Agreement, the County authorizes the Orange County Medical Director to update Exhibit A without submitting said updates to the Orange County Board of County Commissioners as necessary for the efficient administration of this Agreement.

- B. Identify primary and secondary contacts at the Organization for notifications and receipt of vaccination supplies. Contact information may be updated as needed without amending this Agreement. Each party reserves the right to change its Point of Contact without written notification but must notify the other party within 30 days after such a change.
- C. Ensure that a medical dispensing or administering professional (physician or supervised professional operating under appropriate medical protocols, pharmacist, APRN, PA, dentist, podiatrist, or other medical professional authorized to dispense or administer at the time of the event) is on-site to oversee all vaccinations, including the proper handling and storage of vaccination supplies.
- D. Provide to the Health Department the name and point of contact information of the individual who is expected to fill the medical license requirement listed above and advise the Health Department when this information changes.
- E. Utilize vaccination supplies and related materials from the Health Department to provide COVID-19 vaccinations to the Identified Population.
- F. Collect completed client registration forms for individuals undergoing vaccinations and maintain an inventory of supplies received and/or administered.
- G. Ensure that no fee of any kind is charged to the Identified Population for any function associated with vaccination activities.
- H. Return any unused COVID-19 vaccination supplies to the Health Department and account for all COVID-19 vaccinations administered.
- I. Contact the Health Department if additional vaccination supplies are required.

VI. Financial Obligations of the Parties:

- A. Both parties are responsible for their own costs in performing their obligations under this Agreement.
- B. Designation or utilization of the Organization as a Vaccinations Site will not result in reimbursable transactions or costs between the Organization and the Health Department.
- C. In the event of dispute under this Agreement, both parties are responsible for their own attorney's fees and costs.

VII. Conditions, Amendments, and Termination:

- A. The parties agree that this Agreement is effective upon signature of both parties and will continue in effect for a period of five years, unless terminated earlier by the parties. Both parties agree to review this Agreement during the period, as needed.
- B. Requests for information, confidentiality. This Agreement is governed for public records purposes by Chapter 119, F.S. Additional federal laws may apply. Where federal law forms a basis to prevent disclosure of the terms of this Agreement, the parties agree that neither will disclose the nature of this effort and the terms of this agreement to any person or entity, except as may be necessary to fulfill its mission and statutory and regulatory

responsibilities. The parties agree to notify one another before releasing materials or information relating to this Agreement pursuant to federal or state freedom of information act statutes or similar provisions in law.

- C. Information Security: The Organization must maintain confidentiality of all data, files, and records including client records related to the services provided pursuant to this Agreement and will comply with state and federal laws, including, but not limited to, sections 384.29, 381.004, 392.65 and 456.057, F.S. Procedures must be implemented by the Organization to ensure the protection and confidentiality of all confidential matters. The Organization must also comply with any applicable professional standards of practice with respect to client confidentiality.
- D. The Health Department is a State Agency or Subdivision and is self-insured through the State of Florida Risk Management Trust Fund, established pursuant to section 284.30, F.S., and administered by the Florida Department of Financial Services. The Health Department certifies that it maintains, and agrees to continue to maintain during the term of this Agreement, general and professional liability protection coverage through the Risk Management Trust Fund, and certifies that this protection extends to the Health Department, its officers, employees, and agents, and covers statutory liability exposure to the limitations described in Section 768.28, F.S.
- E. The Organization is a Political Subdivision of the State and is self-insured through its inter-local self-insurance program. The Organization certifies that it maintains, and agrees to continue to maintain during the term of this Agreement, general and professional liability protection coverage through its self-insurance program, and certifies that this protection extends to the Organization, its officers, and employees and covers statutory liability exposure to the limitations described in Section 768.28, F.S.
- F. Any provision of the Agreement later found to be in conflict with Federal law or regulation, or invalidated by a court of competent jurisdiction, will be considered inoperable or superseded by that law or regulation. Any provision found inoperable is severable from this Agreement, and the remainder of the Agreement will remain in full force and effect.
- G. The parties agree that the terms of this Agreement may be revised at any time only by formal written agreement, executed by both parties herein, unless otherwise provided elsewhere in this agreement.
- H. Either party may terminate this Agreement at any time by giving the other party written notice at least 60 days prior to the intended termination date.
- I. The parties expressly agree that no relationship of employer/employee, principal agent, lessee/lessor, or other association shall be created by this Agreement between the parties or their directors, officers, agents, or employees. The parties agree that they will never incur any obligations on the part of the other party.
- J. This Agreement is non-exclusive. Thus, the parties reserve the right to enter into similar agreements of understandings with other parties.
- K. Inspector General: To the extent applicable, both parties acknowledge and understand their duty to cooperate with the inspector general in any investigation, audit, inspection, review, or hearing pursuant to section 20.055(5), F.S.

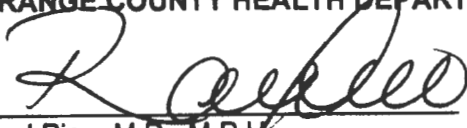
- L. Nothing contained in any part of this Agreement shall constitute a waiver of the either party's sovereign immunity provisions or protections pursuant to Section 768.28, Florida Statutes.

VIII. No Private Right Created:

THIS DOCUMENT IS AN INTERNAL AGREEMENT BETWEEN THE STATE OF FLORIDA AND THE ORGANIZATION AND DOES NOT CREATE OR CONFER ANY RIGHT OR BENEFIT ON ANY OTHER PERSON OR PARTY, PRIVATE OR PUBLIC. NOTHING IN THIS AGREEMENT IS INTENDED TO RESTRICT THE AUTHORITY OF EITHER SIGNATORY TO ACT AS PROVIDED BY LAW OR REGULATION, OR TO RESTRICT ANY AGENCY FROM ENFORCING ANY LAWS WITHIN ITS AUTHORITY OR JURISDICTION.

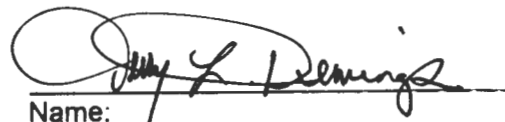
IN WITNESS THEREOF, the parties hereto have caused this Agreement to be executed by their undersigned officials as duly authorized.

**STATE OF FLORIDA
DEPARTMENT OF HEALTH
ORANGE COUNTY HEALTH DEPARTMENT**



Raul Pino, M.D., M.P.H.
Administrator/Health Officer
Date: 12/22/2020

ORANGE COUNTY, FLORIDA



Name: _____
Title: _____
Date: 12/30/20

Exhibit A – Demographic and Contact Information

A. Address of Vaccination Site

Due to the evolving nature of the public health emergency, the Vaccination Site location is subject to change pursuant to Section V. ("Organization Responsibilities") of the Agreement. As of the date of this Agreement's execution, the parties anticipate the Address of the Vaccination Site to be as follows:

Orange County Convention Center
9400 Universal Boulevard
Orlando, Florida 32819

B. Vaccination Site Demographic Information

Identified Population:

Estimated adult population to receive vaccination: To Be Determined

C. Vaccination Site Contact Information:

Primary Contact

Name: Todd Stalbaum, Program Manager
Mailing Address: 2002A East Michigan Street, Orlando, Florida 32806
Office Phone: (407) 836-6515
Mobile Phone: (407) 408-5005
Email: Todd.Stalbaum@ocfl.net

Secondary Contact

Name: Shari Hopwood, Pharmacy Director
Mailing Address: 101 S. Westmoreland Drive, Orlando, Florida 32805
Office Phone: (407) 836-7160
Mobile Phone: (321) 436-3124
Email: Shari.Hopwood@ocfl.net

D. Vaccination Site representative authorized to accept Health Department vaccination supplies:

Due to the evolving nature of the public health emergency, the representatives authorized to accept Health Department vaccination supplies are subject to change in accordance with Section V. ("Organization Responsibilities") of the Agreement, especially if the Vaccination Site address changes. As of the date of this Agreement's execution, the parties anticipate the following representatives to be authorized to accept Health Department vaccination supplies at the Vaccination Site:

Primary Contact

Name: Shari Hopwood, Pharmacy Director
Mailing Address: 101 S. Westmoreland Drive, Orlando, Florida 32805
Office Phone: (407) 836-7160
Mobile Phone: (321) 436-3124

Email: Shari.Hopwood@ocfl.net

Secondary Contact

Name: Todd Stalbaum, Program Manager

Mailing Address: 2002A East Michigan Street, Orlando, Florida 32806

Office Phone: (407) 836-6515

Mobile Phone: (407) 408-5005

Email: Todd.Stalbaum@ocfl.net

E. Health Department Contacts:

Primary Contact

Name: Deborah Collinge, Preparedness and Response Program Manager

Mailing Address: 8026 Sunport Drive, Suite 311, Orlando, FL 32809

Office Phone: 407-723-5366

Mobile Phone: 407-488-9953

Email: Deborah.Collinge@FLHealth.gov

Secondary Contact

Name: Ihab Osman, Cities Readiness Initiative Coordinator

Mailing Address: 8026 Sunport Drive, Suite 311, Orlando, FL 32809

Office Phone: 407-723-5364

Mobile Phone: 407-495-8155

Email: Ihab.Osman@FLHealth.gov

Exhibit B – Policies and Procedures for Administering the COVID-19 Vaccination

Division of Disease Control and Health Protection Bureau of Epidemiology Immunization Section	IOP 340-5-19	Vaccine Administration, Distribution of Risk/Benefit Information Documentation, and the Vaccine Adverse Event Reporting System Effective Date: July 11, 2019
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I. Purpose

To administer vaccines according to the current standard of care, to document all vaccines administered in the CHD, to ensure distribution of risk/benefit information to clients, and to report adverse events.

II. Procedures

Department of Health (DOH) county health department (CHD) staff will administer vaccines according to the current standard of care and document administration of all vaccines administered to CHD clients. All clients or their parent/guardian will be informed of the risks and benefits of each vaccine to be administered. The current Vaccine Information Statement (VIS), prepared by the Centers for Disease Control and Prevention (CDC), will be provided to the client or their parent/guardian. Adverse events associated with the administration of certain vaccines will be reported to the Vaccine Adverse Event Reporting System (VAERS).

A. Vaccine Administration Documentation

Each CHD is required to obtain consent for treatment and care, including immunization services, for all clients receiving immunizations. Documenting consent in the Florida State Health Online Tracking System (SHOTS) is recommended and suffices for electronic signature. The current Department of Children and Families Operating Procedure details statutory authority and outlines under which circumstances a foster parent or shelter care worker may sign to authorize needed immunizations. Contact the local Department of Children and Families district office for specific guidance at www.myflfamilies.com/contact-us.

An education plan that includes competency-based training on vaccine administration should be developed and implemented for all CHD staff who administer vaccines. Individuals shall maintain records of all training documentation in the event of an audit.

When a client presents for immunizations, all client identification and historical immunization data should be reviewed and updated, as needed.

1. Electronic Immunization Clinic Record Form (DH 687)

- a. The Immunization Clinic Record is the permanent medical record for a client's immunizations. The Health Management System (HMS) documents all client services, and Florida SHOTS is used to document historical and administered vaccines.
- b. It is not necessary to maintain a hard copy of current immunizations if the electronic DH 687 form within Florida SHOTS is used.
- c. Enter data in Florida SHOTS according to the guidelines in this policy. All client and immunization information should be entered into Florida SHOTS as soon as possible, preferably during the administration process or at least the same day.

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- d. A Florida SHOTS-generated DH 687 form can be printed, if a hard copy is necessary. All doses of all vaccines administered will be documented on this form.
2. Florida SHOTS Notification and Opt Out Form (DH 1478)
 - a. Effective January 1, 2003, all children born in Florida are added to Florida SHOTS as required by section 381.003, Florida Statutes, and Florida Administrative Code Rule 64D-3.046. The Bureau of Vital Statistics provides a birth file for all children born on or after January 1, 2003, for loading into Florida SHOTS. Opt-out forms for these children are provided by the Bureau of Vital Statistics through the birth notice that is mailed to their parent/guardian. The opt-out provision is automatically recorded in Florida SHOTS for these births. There is no need to provide additional opt-out information, unless specifically requested by a parent/guardian. If a parent/guardian does request an opt-out form, the CHD should provide the form and have the parent/guardian follow directions on the form for submission. This form is also available online at www.flshotsusers.com/opt-out.
 - b. All staff who administer vaccines must be added as personnel in Florida SHOTS.
 - c. Technical assistance for Florida SHOTS is available from the *DOH Immunization Section User's Guide to Florida SHOTS: Immunization Registry* and the staff at Florida SHOTS enrollment desk (contact 1-877-888-7468 or email DL HSD IMM FLSHOTS HELPDESK). Web-based training for Florida SHOTS is available and recommended for all users.
 - d. When a child's immunization record is added to Florida SHOTS, the parent/guardian should receive notification of the ability to opt out of sharing immunization records by filling out and submitting a *Florida SHOTS Notification and Opt Out* form (DH 1478). This notification is required by section 381.003, Florida Statutes, and Florida Administrative Code Rule 64D-3.046. Notification can be accomplished by posting a highly visible DH 1478 form at the intake desk where the parent/guardian brings a child for vaccinations.
 - e. The aforementioned posting of the notification is sufficient for a parent/guardian whose child was born prior to January 1, 2003, was added to the registry or who present for the first time from another state. The notification date and the name of the individual recording the date should be added to Florida SHOTS when the client is added to the system for the first time. This information will automatically appear on the electronic DH 687 form in view or print mode. (Opt-out information only has to be provided and documented once in Florida SHOTS).

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3. Religious Exemption from Immunization Form (DH 681)

Effective July 11, 2019, when a parent/guardian requests a *Religious Exemption from Immunization* form (DH 681), CHD staff will provide the DOH *Vaccine Education Form* (DH8005-DCHP-05/2019), located at <https://floridahealth.sharepoint.com/sites/DISEASECONTROL/EPI/Shared%20Documents/epidemiology/immunization/DH8005-DCHP-05-2019.pdf>. **The DH8005-DCHP-05/2019 form is for educational purposes, not counseling.**

- a. Each CHD will designate at least one nurse to offer education regarding the risks and benefits of vaccinations to parents/guardians requesting religious exemption. The preferred designee is a registered nurse; however, a licensed practical nurse may provide this education under the direct supervision of a registered nurse.
- b. The designated CHD nurse will review the child's shot record in Florida SHOTS and indicate the recommended vaccines on the DH8005-DCHP-05/2019 form. If the child does not have a record in Florida SHOTS, the nurse will use current ACIP guidelines to indicate recommended vaccines on the DH8005-DCHP-05/2019 form.
- c. The designated CHD nurse will provide the parent/guardian with a printed copy of the DH8005-DCHP-05/2019 form with the list of recommended vaccines for review.
 1. The designated CHD nurse should allow up to 15 minutes for the parent/guardian to review the DH8005-DCHP-05/2019 form and verbally discuss the risks and benefits of vaccinations. Additional guidance and educational materials to assist staff are available through the resource link on the Immunization Section Website: ImmunizeFlorida.org.
 2. The parent/guardian should sign the DH8005-DCHP-05/2019 form to acknowledge understanding of the risks and benefits of vaccination.
 3. If the parent/guardian refuses vaccine education, the designated CHD nurse must sign the DH8005-DCHP-05/2019 form and proceed with issuance of the Religious Exemption form DH681. No other information should be solicited from the parent/guardian.
- d. The DH8005-DCHP-05/2019 must be maintained by the local CHD for 10 years, in accordance with the DOH Individual Schedules, Schedule #2, Item #2. This record may exist as a component of a medical record or be filed individually with other client immunization records. It is not necessary to keep a hard copy of this form.

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- e. The CHD Medical Director/Administrator or designee must use the current DH681 form available electronically in Florida SHOTS, to document that the parent/guardian requests a religious exemption. The preferred designee is a registered nurse; however, a licensed practical nurse may generate the DH 681 form under the direct supervision of a nurse.
 - f. The designated CHD nurse must document issuance of the of DH8005-DCHP-05/2019 form in Florida SHOTS according to guidance in the *Documenting a Vaccine Education Encounter* training guide located at flshotsusers.com/sites/default/files/vaccine_education_encounter.pdf. Provide a completed copy of the *Vaccine Education Form* (DH8005-DCHP-05/2019) for parent/guardian records.
 - g. The CHD Medical Director/Administrator or designee must document issuance of the Religious Exemption form in Florida SHOTS according to guidance in the *DOH Immunization Section User's Guide to Florida SHOTS: Immunization Registry*. Provide a completed *Religious Exemption from Immunization* form (DH 681) and duplicate for parent/guardian records. Refer to the current *Immunization Guidelines for Florida Schools, Childcare Facilities and Family Daycare Homes* at www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/_documents/school-guide.pdf for additional information.
4. Immunization History Update
- a. Add all historical immunizations given by other clinics or private medical providers into Florida SHOTS, unless already available in the system.
 - b. If the client receives services from another provider, instruct the parent/guardian to take the updated immunization record to that practice.
 - c. Review Florida SHOTS Immunization Status page to assist in determining vaccines due and recommended due dates. Assess the client's immunization history to determine which vaccine(s) is needed at each encounter. Review all sources of immunization documentation.
5. Eligibility for Vaccines for Children (VFC) Program
- a. Screen clients (birth through 18 years of age) at each clinic visit to determine their eligibility under the VFC Program. Refer to *the Florida Vaccines for Children Program Provider Handbook* at www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/_documents/vfc-provider-handbook-2016.pdf for details.
 - b. Indicate the eligibility status by selecting the appropriate code in Florida SHOTS.

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(1) Eligibility categories:

- (a) VFC-Eligible—American Indian or Alaskan Native
- (b) VFC-Eligible—Medicaid/MCO
- (c) VFC-Eligible—Underinsured
- (d) VFC-Eligible—Uninsured

6. Distribution of Risk/Benefit Information

a. Provision of the VIS

- (1) By federal law, the National Childhood Vaccine Injury Act requires all vaccine providers to give each patient or their parent/guardian the appropriate CDC VIS form on each occasion a vaccination is given. Florida SHOTS will link to the current version for each vaccine. These forms are available at www.cdc.gov/vaccines/hcp/vis/index.html. Document the VIS given, publication date, to whom the VIS was provided, and the CHD staff providing the VIS in Florida SHOTS. **Note: Both the consent and VIS receipt should be documented in Florida SHOTS.**
- (2) Allow the client or parent/guardian sufficient time to read the VIS. Providers should supplement VIS forms orally, with videotapes, additional printed material, or any other way that will help the client and parent/guardian understand the disease and vaccine, as needed.
- (3) The CHD clinical staff will answer all questions in a client-friendly, culturally sensitive manner.
- (4) Maintain a translation referral list and information to Language Line Services. Translated versions of the VIS for childhood vaccines are available on-line at www.immunize.org/vis/?f=9.
- (5) In the absence of access to Florida SHOTS, use the hard copy of the DH 687 form. Record the CDC publication date of each VIS provided in the "VIS Date" section on the line corresponding with the vaccine given. Document the required information on the DH 687 form after the client and/or parent/guardian have been provided and s/he has read the applicable VIS.

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7. Vaccine Administration

- a. The CHD clinical staff will administer the appropriate vaccines according to the current standard of care, the current *ACIP Recommended Immunization Schedules for Persons Aged 0 through 18 years, United States*, and the latest *Report of the Committee of Infectious Diseases of the American Academy of Pediatrics (Red Book)*. The CHD staff will also document administration of all vaccines administered to CHD clients.
- b. Upon review all sources of immunization documentation and assessment of the client's immunization status, CHD staff will determine which vaccine(s) is (are) needed at each encounter.
- c. CHD staff will provide the needed vaccine(s) according to the CHD's internal standing orders for administering the age-appropriate vaccine(s) due at the time of the encounter. Under these standing orders, eligible CHD clinical staff may vaccinate children and teens who meet any of the criteria.
- d. Screen all patients for contraindications and precautions to the age-appropriate vaccine(s) due at the time of the encounter.

8. Documentation of Doses Given

- a. Only Florida SHOTS registry should be used for documentation of immunizations.
- b. Choose the appropriate vaccine administration route/site from Florida SHOTS. A listing of approved abbreviations is located in the DOH Policy (DOHP) 380-3-14, Clinical Abbreviations/Acronyms/Symbols Policy, available at dohwebdev.doh.ad.state.fl.us/Divisions/Planning_Evaluation/HPE_DOHPolicy/DOHP380-3.pdf.
- c. Varicella Disease: If the client has a valid history of varicella disease, it should be entered as a contraindication by recording the date and source of history (that is physician documentation) in the varicella section in Florida SHOTS.
- d. If using combination vaccines, verify that administration of each antigen is documented. In the absence of access to Florida SHOTS, verify that all information for each antigen is recorded on a hard copy DH 687 form. A blank DH 687 form can be printed from Florida SHOTS.
- e. Inquire about and record all conditions that may indicate allergies, contraindications, and permanent medical exemptions. Reference the list of valid precautions and contraindications from the CDC website at www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm.
- f. A Florida SHOTS-generated *Florida Certification of Immunization* form

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(DH 680) can be provided to the parent/guardian, if needed. Only valid doses of vaccines required for school or child care appear on this form.

- g. A parent/guardian may be issued a DH 680 personal identification number by the CHD or other health care provider for later retrieval of the DH 680 form directly by the parent/guardian.
- h. A Florida SHOTS-generated report, *Immunization History* form (DH 686), can be printed and provided to the parent/guardian, as a personal immunization record. All valid doses of vaccines received and recommended next due dates are listed on this form.
- i. If the client is a Women, Infants and Children Program (WIC) client, add the WIC identification number, if known.

9. Family Planning/STD Confidential Minors and Immunizations

- a. The provider must document in the notes that the confidential minor seeking Family Planning/STD services meets the requirements of the statute, as reflected in TAG 332-4 FAMPLAN4 paragraph C, and has been informed of risks/benefits of the vaccine and given informed consent.
- b. Confidential Family Planning/STD minor clients may receive the human papillomavirus (HPV) vaccine and the hepatitis B vaccine without parental consent.
- c. An uninsured minor (under 19 years of age) may receive these vaccines through a Title X Family Planning/STD Clinic. If an insured minor desires vaccination, but does not have access to the insurance because of confidential circumstances (seeking family planning or STD services), the minor is considered uninsured, which meets eligibility for VFC-funded (PC 01) vaccine. Minors who are insured by Medicaid are also eligible for VFC-funded (PC 01) vaccine.
- d. If a confidential minor begins vaccination series as a Family Planning/STD client, then the minor must complete vaccination series as a Family Planning/STD client. A confidential Family Planning/STD minor client must not be referred to CHD Immunization Clinics to receive follow-up series vaccinations.
- e. Documentation of immunizations for confidential Family Planning/STD minor clients must be performed within the client's electronic health record in Medication Profile/Emdeon and not entered into FLSHOTS.
- f. Within Medication in HMS, choose Standard/Reported. Do not choose minors insurance unless it is Medicaid. On the RxPad page, choose the "Reported RX" button on the right-hand side of the screen. Complete Effective Date;

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enter vaccination type under DRUG. This will record the name of the vaccine and the dose given. Record the following under Notes to Pharmacist:

- (1) VIS with publication date given to client
- (2) Injection site
- (3) Injection route
- (4) Name of vaccine manufacturer
- (5) Vaccine lot number
- (6) Expiration date
- (7) NDC number
- (8) Name and title of vaccinator
- (9) Dose sequence (first, second, or third)
- (10) Next Dose in number weeks or months (for the second and third doses)
 EXAMPLE: HPV VIS (11/15/15) given to client; RDT; IM; Merck & Co; Lot# L018351; Exp 8/11/17; NDC 00006-4119-03; Administered by J. Smith, RN; 1st dose. Next Dose in X weeks.

NOTE: There is limited space in comments and this information must be entered as indicated with no returns
 REMOVE PHARMACY by clicking the black X
 SAVE

- g. CHDs should follow the guidance provided in the *Florida VFC Provider Handbook* for inventory management.
- h. Reimbursement of HPV and hepatitis B vaccination services for confidential Family Planning/STD minor clients is limited to billing Medicaid for the administration fee only.
- i. Recommended confidential minor immunization guidelines:
 - (1) Female confidential Family Planning/STD minor clients aged 11–17 years:
 - (a) Should be offered either VFC-funded (PC 01) HPV vaccine for prevention of HPV and cervical cancer if not previously vaccinated
 - (b) Should be offered VFC-funded (PC 01) hepatitis B vaccination if not previously vaccinated

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(2) Male confidential Family Planning/STD minor clients aged 11–17 years:

- (a) Should be offered VFC-funded (PC 01) HPV vaccine, if not previously vaccinated
- (b) Should be offered VFC-funded (PC 01) hepatitis B vaccination if not previously vaccinated

10. Post-Vaccination Parent/Guardian Counseling

- a. Provide client or parent/guardian with information (oral or written) on common adverse events, which may follow immunization.
- b. In case of an adverse event following vaccine administration, provide client or parent/guardian with telephone numbers and explain where and how to obtain medical care during daytime and nighttime hours. Please instruct client or parent/guardian to contact the CHD if any adverse event occurs.
- c. Follow-up activities, such as telephone calls, reminder/recall notices, and home visits, should be documented under contact attempts in Florida SHOTS and/or in the medical record.

B. VAERS

- 1. The VAERS is a passive surveillance system through which individuals report events associated with the administration of certain vaccines.
- 2. According to the National Childhood Vaccine Injury Act, you must report specific adverse events following the administration of specific vaccines in accordance with recommendations provided in the *Morbidity and Mortality Weekly Report (MMWR)* Volume 60, No. RR-2, January 28, 2011.
- 3. The VAERS accepts all reports of adverse events after the administration of any vaccine.
- 4. Any serious adverse events, such as those that require a health care visit, should be reported through the VAERS.
- 5. Health care providers, including CHD staff, are required by law to report certain adverse events.
- 6. Lay people, such as parent/guardian, may also report adverse events to the VAERS. Encourage these individuals to seek the assistance of a health professional in completing the form.
 - a. VAERS Forms

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- (1) The VAERS reports are submitted electronically at www.vaers.hhs.gov/index.
 - (2) For non-electronic submission, copies of the VAERS reporting form and instructions can be found and downloaded from www.vaers.hhs.gov/, by calling toll-free 1-800-822-7967, or by submitting requests to the VAERS at info@vaers.org.
- b. Reporting Process
- (1) CHD Staff Responsibilities:
 - (a) Initiate and complete electronic VAERS report submission according to the instructions
 - (b) Print and review the form to ensure that all items are complete. Be sure the dates make chronological sense. For example, the date of birth must precede the date of vaccination. This information is critical to the analysis of the VAERS data
 - (c) Notify the CHD VAERS coordinator and the Immunization Section VAERS coordinator
 - (d) Submit a completed report to VAERS, the Immunization Section VAERS coordinator, and retain a copy for case management
- c. Each CHD will appoint a VAERS Coordinator responsible for:
- (1) Receiving VAERS notification from all CHD clinics in the county
 - (2) Reviewing the report for completeness, accuracy, and consistency
 - (3) Verifying electronic VAERS submission and notification to Immunization Section VAERS Coordinator
 - (4) Identify a designated backup staff. Cross training these duties ensures timely and accurate reporting. Performance standards should reflect these responsibilities for the designated individuals
 - (5) Enter adverse event(s) into Florida SHOTS on behalf of the client
- d. Follow Up of Serious Adverse Events
- (1) Certain serious adverse events require a 60-day and/or one-year follow up. The parameters for follow-up reporting are determined by the VAERS on a case-by-case basis.

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- (2) The Immunization Section VAERS Coordinator will notify the CHD VAERS Coordinator when follow up is due, so that the CHD coordinator can obtain information on the status of the client and report findings back to the Immunization Section VAERS Coordinator.

III. Scope

- A. Personnel: All CHD Medical Doctors, Doctors of Osteopathy, Advanced Practice Registered Nurse, Physician's Assistants, RNs, and LPNs within constraints of their practice acts, protocols, and responsibilities for immunization services.
- B. Competencies: The CHD management team is responsible for determining the level of knowledge and competency of staff members providing immunization services.
- C. Areas of Responsibility:
 - 1. Distribution of Risk/Benefit Information: Each CHD provider is responsible for ensuring documentation of receipt of the appropriate VIS prior to each vaccination administration under federal law.
 - 2. Vaccine Administration: The CHD immunizations staff is responsible for administering vaccines according to the current standard of care and following the ACIP recommendations.
 - 3. Vaccine Administration Documentation: Each CHD is responsible for maintaining proper documentation of vaccine administration.
 - 4. Vaccine Adverse Event Reporting System: CHD staff is responsible for reporting certain adverse events under federal law.

IV. **Authority:** Sections 381.0011, 381.003, and 1003.22, Florida Statutes, and Florida Administrative Code Rule 640-3.046.

V. Supportive Data

- A. *Epidemiology and Prevention of Vaccine-Preventable Diseases* (The 2015 Pink Book): Vaccine Administration Chapter of Pink Book, 13th edition, 2015; www.cdc.gov/vaccines/pubs/pinkbook/index.html, accessed 03/19.
- B. *User's Guide to Florida SHOTS: Immunization Registry*, www.flshotsusers.com/, accessed 03/19.
- C. Department of Health, Health Management System, *Clinical Portal Overview*, dohiws/Divisions/Planning_Evaluation/HMS/Training/UserDocumentation/ClinicalEncounter/ClinicianPortal_Overview.pdf, accessed 03/19.
- D. Vaccine Adverse Event Reporting System, vaers.hhs.gov/, accessed 03/19.

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- E. *Immunization Guidelines for Florida Schools, Childcare Facilities and Family Daycare Homes* at www.floridahealth.gov/programs-and-services/immunization/children-and-adolescents/_documents/school-guide.pdf, accessed 03/19.
- F. CDC Vaccines for Children Program Operations Guide, www.cdc.gov/vaccines/programs/vfc/index.html, and www.cdc.gov/vaccines/programs/vfc/awardees/index.html, accessed 03/19.
- G. *Florida Vaccines for Children Program Provider Handbook*, www.floridahealth.gov/programs-and-services/immunization/vaccines-for-children/provider-handbook.html, accessed 03/19.
- H. Centers for Disease Control and Prevention, www.cdc.gov, accessed 03/19.
- I. Centers for Disease Control and Prevention, *Mortality and Morbidity Weekly Report*, www.cdc.gov/mmwr, accessed 03/19.
- J. Florida Department of Children and Families Operating Procedures, www.dcf.state.fl.us/admin/publications/policies.asp, accessed 03/19.

VI. Distribution List

Deputy Secretary for Health
 Division of Disease Control and Health Protection
 County Health Department Directors/Administrators
 County Health Department Medical Directors
 County Health Department Nursing Directors
 Children's Medical Services Medical Directors
 Children's Medical Services Nursing Directors
 Children's Medical Services Program Managers

VII. History Notes

This IOP replaces and supersedes IOP 340-5-18 dated July 6, 2018, its predecessor IOP 350-5-16 dated June 30, 2016 and its predecessor DOHP 350-5-14 dated February 23, 2014.

VIII. Signature and Effective Date

Signature On File	July 11, 2019
_____ Scott Rivkees, MD State Surgeon General	_____ Date

MESH "CHD Guidebook" DCHP BOE Immunizations VFC "Vaccines For Children" VAERS "VAERS follow-up" reminder recall "VIS documentation" "combination vaccine" "immunization card" "Immunization route" "immunization clinic"

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"vaccine documentation" "DH 687" "DH 681" "religious exemption" FLSHOTS "Immun IOP 350-5"