Guidance



Guidance for City and County of San Francisco (CCSF) Healthcare Providers and Contractors Administering COVID-19 Vaccines to Minor Patients November 16, 2021

CCSF is sharing this Guidance in an effort to promote the general welfare, health and safety, and effective patient care as it relates to the administration of COVID-19 vaccines in minors during the COVID-19 pandemic. Anyone reviewing this Guidance must understand the following:

Data, recommendations, and authorizations concerning the administration of COVID-19 vaccines in minors continue to evolve. CCSF developed this Guidance for use by CCSF-affiliated healthcare providers based on current federal, state, and CCSF rules and guidance applicable to COVID-19 vaccinations as of November 16, 2021, including Health Officer Order No. C19-19. This Guidance is based specifically on the data, recommendations, and authorizations concerning the administration of COVID-19 vaccines as of November 16, 2021 and is subject to change without notice.

Providers should consult FDA and CDC guidelines for the current authorizations and recommendations, as well as applicable federal, state, and CCSF law, including but not limited to Health Officer Order No. C19-19, regarding administration of COVID-19 vaccines in minors age 12 years and older.

Providers should also consult with their Health & Safety, Infection Control, Risk Management, and Legal Staff before deciding to use any of the information or processes in this Guidance. Any decision to use all or part of this Guidance rests solely with that provider. In making this Guidance publicly available, CCSF is not assuming or imposing on CCSF, or its officers or employees, any obligation for which it may be liable to any person who claims that this Guidance proximately caused injury.

This guidance will be posted at www.sfcdcp.org/covidvax-administer

Background

During the COVID-19 pandemic, vaccination of the entire population, including minors, is critical to interrupting COVID-19 transmission and reducing morbidity and mortality from COVID-19. In this context, CCSF seeks to avoid unnecessary barriers to vaccination while protecting the rights of minors, parents, and guardians and issues the following guidance to its clinics and healthcare providers.

Guidance

- 1) The U.S. Food and Drug Administration ("FDA") Emergency Use Authorizations for COVID-19 vaccines do not require informed consent to receive a COVID-19 vaccine. The consent language can reference COVID-19 vaccination, but general consent for medical care is all that is formally required.
- 2) Minor is defined as an individual who is under 18 years of age.
- 3) A parent or guardian's consent for medical care is required for COVID-19 vaccination of a minor, except under certain limited circumstances. These circumstances include:
 - a) **Self-sufficient minors** can consent to medical care without the parent or guardian's consent. A self-sufficient minor is defined as: age at least 15 years; <u>and</u> living separate and apart from the minor's parents or legal guardian (regardless of consent of parents/guardian or duration of separate residence); <u>and</u> managing the minor's own financial affairs (regardless of source of income). (California Family Code § 6922).
 - b) *Emancipated minors* can consent to medical care without parental consent or knowledge. An emancipated minor is defined as: a minor who is legally married/established domestic partnership; or on active duty in the U.S. armed forces; or has a court-issued Declaration of Emancipation. (California Family Code §§ 7002, 7050).
 - c) Minors ages 12–17 years who meet the requirements of Health Officer Order No. C19-19, as detailed below.
- 4) Self-sufficient and emancipated minors are not the norm and thus relatively uncommon. For the purposes of COVID-19 vaccination, CCSF-affiliated vaccination providers should reasonably attempt to ascertain a minor's claim of self-sufficient or emancipated status, while avoiding undue burden for the minor that would prevent vaccination. This may include accepting a signed attestation by the minor.
- 5) In all other circumstances prior to COVID-19 vaccination of a minor, CCSF-affiliated providers must obtain consent from the minor's parent or legal guardian by one of the following methods, in order of preference:
 - a) Minor is accompanied by parent or guardian, who signs a consent document in person;
 - b) Minor is not accompanied by parent or guardian, but a consent document signed by the parent or guardian is received by the provider; or
 - c) Minor is not accompanied by parent or guardian, but the provider obtains and documents verbal consent from the parent or guardian via telephone or video call.

- 6) CCSF-affiliated providers must provide to the parent or guardian the age-appropriate Vaccine Information Fact Sheet For Recipients and Caregivers ("Fact Sheet") (for Pfizer-BioNTech vaccines, available here: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#additional). Providers may distribute the Fact Sheet or a link to the Fact Sheet.
- 7) CCSF-affiliated providers must document that the Fact Sheet was provided to the parent or guardian or have the parent or guardian document on the consent form that they received the Fact Sheet. In accordance with California Department of Public Health policy, reading the Fact Sheet to the parent or guardian by phone or video is an acceptable method of providing the Fact Sheet (see: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Pfizer-Vaccine-Minor-Consent-Guidance.aspx).
- 8) CCSF-affiliated providers should use reasonable judgment but may accept as stated by the minor or the adult that the adult is the minor's parent or legal guardian, without requiring formal documentation of that status.
- 9) CCSF-affiliated providers should use reasonable judgment but may accept as stated by the minor (when the minor is allowed to consent), parent, or guardian that the minor is of age to receive COVID-19 vaccine under the conditions of the FDA Emergency Use Authorization (or FDA Approval) for that vaccine, without requiring formal documentation of birthdate. As of the date of this writing the Pfizer-BioNTech COVID-19 vaccine is authorized for minors aged 5 years and over.
- 10) There may be circumstances in which the CCSF-affiliated provider is unable to obtain written or verbal consent by the parent or guardian of a minor. In such a circumstance, for minors age 12 years or older, the provider may be able to rely solely on the minor's consent, but only if the provider adheres to the requirements of Health Officer Order No. C19-19 (see next section for details).

Health Officer Order No. C19-19

COVID-19 vaccination providers should review all provisions of Order No. C19-19 (the "Order") which is posted here: https://www.sfdph.org/dph/alerts/coronavirus-healthorders.asp

In brief:

 The Order allows minors in the City and County of San Francisco who are 12 years old or older to consent to receive a COVID-19 vaccine; however, the provider must first reasonably attempt to notify the parent or guardian and allow that person the opportunity to object to the administration of that dose.

- The Order does not authorize the provider to administer a COVID-19 vaccine under the Order to a minor if the parent or guardian objects, or if a COVID-19 vaccine is not FDAauthorized for that minor's age.
- The Order does not authorize the provider to administer a COVID-19 vaccine to a minor aged 11 years or younger without the parent or guardian's consent.
- The Order does not mandate notice to a parent or guardian of a minor who is emancipated or self-sufficient.
- The Order invokes liability protection under Section 8659 of the California Government Code for physicians or surgeons, hospitals, pharmacists, respiratory care practitioners, nurses, or dentists who administer COVID-19 vaccine to a minor under the provisions of the Order. The San Francisco Department of Public Health has accordingly limited its own employees authorized to administer a vaccine to a minor under the Order when there is no consent of a parent or guardian to employees who are licensed as a physician or surgeon, pharmacist, respiratory care practitioner, or nurse.

Q & A for Health Officer Order No. C19-19

Q: What constitutes a reasonable attempt to notify the parent or guardian?

A: Because individual circumstances vary considerably, the Order does not specify a method, number of number of attempts, or waiting period required to notify the parent or guardian. It is left to the provider, considering the particularities of the vaccination clinic or event, or the minor's family or custody situation, to determine what constitutes a reasonable notification attempt.

Q: What about liability protection for health professionals other than those listed in the Order?

A: Section 8659 of the Government Code affords immunity to only the specific people and entities listed in the section so long as they comply with the requirements of the section, which includes complying with a Health Officer instruction. Best practice is to use the listed types of professionals to administer the vaccine under the Order when parent or guardian consent cannot be not obtained. But others are not prohibited from reliance on the Order.

Q: How can we minimize the need for minors to consent?

A: Providers are encouraged to make parent/guardian consent forms available to be signed prior to the vaccination visit, so that the parent, guardian, or minor can transmit the consent to the provider in advance, or the minor can bring a copy to the vaccination visit. Providers are also encouraged to inform minors that if they are unable to have the parent or guardian present at the visit or bring a consent form already signed by the parent or guardian, then they should arrange for the parent or guardian to be available at the time of the vaccination visit to receive a phone call from the provider.

Q: What if the minor indicates awareness that the parent or guardian objects to vaccination, but the parent or guardian is not present or reachable to voice that objection?

A: Best practice would be not to proceed with vaccination under these circumstances, unless or until the parent or guardian can be reached and provides consent to vaccinate.

Q: What if the minor is in foster care (Juvenile Dependency)?

A: There is a separate San Francisco Health Officer Order that applies in the context of dependent juveniles; providers should check with the dependent juvenile's case worker.

Sample Minor Consent Workflow

The sample workflow below is intended as an example of how to implement the guidance expressed in this document. Providers may adapt for their own circumstances. The consent document is intended to be a separate document, should have a signature block for the parent/guardian or minor, and should be retained by the provider.

Name of Minor:	Date of Birth://
[] Parent or guardian present, signs and dates consent for	orm
[] Parent or guardian absent, provided with age-appropr and dated by parent or guardian	iate Fact Sheet, consent form received, signed
[] Parent or guardian absent, telephone consent attemp	ted
[] Reached; parent or guardian provided with ag vaccination	e-appropriate Fact Sheet, verbally consents to
[] Reached; verbally objects to vaccination – do	not vaccinate
[] Unable to reach; provider follows Health Offic	er Order No. C19-19
Parent/Guardian Name	/ Telephone
Provider	/ Date and Time
[] Emancipated Minor provided with age-appropriate Fa	ct Sheet, signs and dates consent form
Attestation: At least one of the following is true	
[] I am married/in domestic partnership or have	been married/in domestic partnership.
[] I am on active duty with the US armed forces.	
[] I am age 14 years or older and have been ema	ncipated by court order.
[] Self-Sufficient Minor provided with age-appropriate Fa	act Sheet, signs and dates consent form
Attestation: All 3 of the following are true	
[] I am age 15 years or older.	
[] I live separate and apart from my parents or le	egal guardian.
[] I manage my own financial affairs.	