Cal. Code of Regs., tit. 28, section 1300.67.01 COVID-19 Diagnostic Testing

(a) Applicability. This section applies to a health care service plan offering group or individual health care coverage that includes hospital, medical, or surgical benefits, including a grandfathered health plan as defined in section 1251(e) of the Patient Protection and Affordable Care Act. This section does not apply to Medi-Cal managed care health plans with a contract entered into pursuant to Chapter 7 (commencing with Section 14000), Chapter 8 (commencing with Section 14200), or Chapter 8.75 (commencing with Section 14591) of Part 3 of Division 9 of the Welfare and Institutions Code.

(b) Definitions. The following definitions apply for the purposes of this section:

(1) Relevant state of emergency—Refers to the state of emergency proclaimed by the Governor in response to COVID-19 on March 4, 2020, pursuant to the Emergency Services Act (Gov. Code, § 8550 et seq.).

(2) Clinic—Has the same meaning as defined in Health and Safety Code section 1200, et seq.

(3) COVID-19—Refers to the disease caused by SARS-CoV-2.

(4) Diagnostic testing—Refers to testing administered using “in vitro diagnostic products” as defined in section 809.3 of title 21 of the Code of Federal Regulations, regardless of the purposes for or circumstances under which such testing is administered, and includes items and services related to the diagnostic testing for COVID-19 and the administration of such tests, if the test is:

(A) Approved, cleared, or authorized under sections 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. sections 360(k), 360c, 360e, 360bbb-3);

(B) The subject of a request or intended request for emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3), until the emergency use authorization request has been denied or the developer of the test does not submit a request within a reasonable timeframe;

(C) Developed and authorized by a State that has notified the Secretary of the United States Department of Health and Human Services (U.S. HHS) of its intention to review a test intended to diagnose COVID–19; or

(D) Determined by the Secretary of U.S. HHS as appropriate for the diagnosis of COVID-19.

(5) Essential Worker—Means any of the following:
(A) A person working in the health care sector who has frequent interactions with the public or with people who may have COVID-19 or have been exposed to SARS-CoV-2. The health care sector includes: hospitals; skilled nursing facilities; long-term care facilities; ambulatory surgery centers; health care providers’ offices; health care clinics; pharmacies; blood banks; dialysis centers; hospices; and, home health providers.

(B) A person who provides care to an elderly person or a person with a disability in the home, including a person providing care through California’s In-Home Supportive Services Program.

(C) A person working in a congregate care facility, including shelters for people experience homelessness and residential care facilities for the elderly.

(D) A person working in the retail or manufacturing sectors who has frequent interactions with the public or who works in an environment where it is not practical to maintain at least six feet of space from other workers on a consistent basis.

(E) A person working in the emergency services sector who has frequent interactions with the public or with people who may have COVID-19 or have been exposed to SARS-CoV-2. The emergency services sector includes police and public safety departments, fire departments, and emergency service response operations.

(F) A person working in the food services sector who has frequent interactions with the public. The food services sector includes grocery stores, convenience stores, restaurants, and grocery or meal delivery services.

(G) A person working in the agricultural or food manufacturing sector who has frequent interactions with the public or who works in an environment where it is not practical to maintain at least six feet of space from other workers on a consistent basis. The agricultural or food manufacturing sector includes food production and processing facilities, slaughter facilities, harvesting sites or facilities, and food packing facilities.

(H) A person working in the public transportation sector who has frequent interactions with the public. The public transportation sector includes public transit, passenger rail service, passenger ferry service, public airports, and commercial airlines.

(I) A person working in a correctional facility.

(J) A person working in the education sector who has frequent interactions with students or the public. The education sector includes public and private childcare establishments; public and private pre-kindergarten programs; primary and secondary schools; and public and private colleges and universities.
(6) Testing provider - Means any professional person, organization, health facility, or other person or institution licensed or authorized by the state to deliver or furnish COVID-19 diagnostic tests. Testing providers include:

(A) Physicians and other primary care providers;

(B) Urgent care centers;

(C) State- or county-run clinics or testing sites, including clinics and sites run by COVID-19 testing vendors contracted with the California Department of Public Health or other state or local agencies;

(D) Pharmacies;

(E) University laboratories;

(F) Hospital emergency departments;

(G) Skilled nursing facilities; and,

(H) Any other outpatient provider settings for which the diagnosis of COVID-19 is within the scope of the provider’s state licensure or authorization.

(c) During the relevant state of emergency:

(1) Diagnostic testing for COVID-19 is a medically necessary basic health care service for enrollees who are essential workers as defined by this regulation, regardless of whether the enrollee has symptoms of COVID-19 infection or is asymptomatic or whether the enrollee has a known or suspected exposure to a person with COVID-19.

(B) A health plan shall not impose utilization management requirements on COVID-19 diagnostic tests for essential workers.

(A) A health plan may inquire as to whether an enrollee is an essential worker as defined by this rule, but shall require no further evidence or verification of the enrollee’s essential worker status when determining whether the enrollee is an essential worker.

(2) For enrollees who are not essential workers, a health plan may impose ordinary utilization management procedures allowed by the Knox-Keene Act when determining whether a COVID-19 test is medically necessary for an enrollee, unless otherwise specified by state or federal law.

(3) Health plans may subject enrollees to any applicable cost-sharing amounts incurred as a result of COVID-19 diagnostic testing, unless otherwise specified by state or federal law. However, a testing provider, at its discretion, may waive any applicable co-payment or co-insurance amounts.
(4) Health plans may deny coverage for a COVID-19 test if the enrollee failed to attempt to access a COVID-19 diagnostic test from an in-network provider or failed to contact the health plan to locate an in-network testing provider before accessing a COVID-19 diagnostic test through a non-contracted provider, unless otherwise specified by state or federal law.

(5) Medically necessary COVID-19 testing is “urgent care” as defined by Section 1300.67.2.2 (b)(7) of Title 28. Health plans shall not extend the applicable wait time for a COVID-19 testing appointment, even if such an extension would otherwise be permitted by Section 1300.67.2.2 (c)(5)(G) of title 28.

(A) If the health plan does not offer an appointment with a contracted testing provider that will occur within the applicable time frames specified in Section 1300.67.2.2 (c)(5) and at a location within 15 miles or 30 minutes of the enrollee’s residence or workplace, the enrollee may obtain a COVID-19 diagnostic test from any available testing provider, regardless of whether that testing provider contracts with the health plan.

(B) In such instances, the health plan shall reimburse the testing provider at either the contracted rate, if the health plan has a contract with the testing provider. If the health plan and the testing provider do not have a contract that encompasses COVID-19 testing, the health plan shall reimburse the provider at the provider’s cash price, when required by federal law. In all other instances, the health plan shall reimburse the provider for the reasonable and customary value of the services, determined in accordance with subdivision (a)(3)(B) of section 1300.71 of title 28.

(d) Delegation of Financial Risk for Diagnostic Testing. Changes to a contract between a health plan and a provider delegating financial risk for COVID-19 diagnostic testing, including related items and services, shall be considered a material change to the parties’ contract. A health plan shall not delegate the financial risk to a contracted provider for the cost of enrollee services provided under this rule unless the parties have negotiated and agreed upon a new provision of the parties’ contract pursuant to Health and Safety Code section 1375.7.

(e) Timeframes for Submission and Payment of Claims for Diagnostic Testing and Related Items and Services.

(1) The timeframes specified in Health and Safety Code section 1371 and title 28, section 1300.71 apply for the submission and payment of claims for COVID-19 diagnostic testing and related items and services.

(2) A health plan shall not delay or deny payment of a testing provider’s claim for services received by an enrollee pursuant to this section:

(A) Due to delegation of claims payment functions to another entity, or based upon a dispute with a provider over delegated financial risk for the cost of the COVID-19 diagnostic testing; or,
(B) For testing of enrollees who are essential workers, based upon an assertion by the health plan that the claim is incomplete if the health plan has received a statement or verification that the enrollee is an essential worker and sufficient information to establish the enrollee was enrolled with the health plan at the time the provider administered the COVID-19 diagnostic test.

(3) For the purposes of submission of claims pursuant to this rule, “provider” includes the State of California, university laboratories, and state- or county-run clinics or other testing sites.

(f) Failure by a health plan to comply with the requirements of this section may constitute a basis for disciplinary action against the health plan. The Director shall have the civil, criminal, and administrative remedies available under the Knox-Keene Act, including Health and Safety Code section 1394.

AUTHORITY: Health and Safety Code sections 1343 and 1344. REFERENCE: Government Code section 8550 et seq. and Health and Safety Code sections 1367, 1367.001, 1367.01, and 1367.03.