From: DMHC Licensing eFiling

Subject: APL 22-014 – Senate Bill 510 COVID-19 Testing and Vaccination Coverage Guidance

Date: Monday, April 25, 2022 4:55 PM

Attachments: APL 22-014 – SB 510 COVID-19 Testing and Vaccination Coverage Guidance (4.25.22).pdf

Dear Health Plan Representative,

Please see attached, All Plan Letter (APL) 22-014 – Senate Bill 510 COVID-19 Testing and Vaccination Coverage Guidance. This APL sets forth the Department of Managed Health Care's (DMHC or Department) guidance regarding how plans shall comply with SB 510.

Thank you.

DEPARTMENT OF Managed Health Care

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ALL PLAN LETTER

DATE: April 25, 2022

TO: All Full-Service Commercial and Medi-Cal Managed Care Health Care Service Plans[1]

FROM: Sarah Ream
Chief Counsel, DMHC

SUBJECT: APL 22-014 – Senate Bill 510 COVID-19 Testing and Vaccination Coverage Guidance

On October 8, 2021, Governor Gavin Newsom signed Senate Bill (SB) 510, which requires health care service plans (health plans) to cover, among other things, the costs associated with COVID-19 diagnostic and screening testing and immunization against COVID-19 without cost sharing, prior authorization, utilization management, or in-network requirements.[2] SB 510 took effect on January 1, 2022. This All Plan Letter (APL) sets forth the Department of Managed Health Care's (DMHC or Department) guidance regarding how plans shall comply with SB 510.[3]

I. SB 510 Services

SB 510 requires health plans to cover the costs for "COVID-19 diagnostic and screening testing and health care services related to diagnostic and screening testing approved or granted emergency use authorization by the federal Food and Drug Administration for COVID-19." These services include:

[1] This APL does not apply to Medicare Advantage products or to specialized health care products.

[2] With limited exceptions SB 510's requirements extend beyond the expiration of the federal public health emergency declared on January 31, 2020, pursuant to section 319 of the Public Health Service Act. *See* subdivisions (a)(4)(B) and (b)(E)(ii) of Health and Safety Code section 1342.2.

[3] *See,* Health and Safety Code section 1342.2(c).

- specimen collection and handling
- hospital or health care provider office visits for the purpose of receiving testing for COVID-19
- products related to testing and items and services furnished to an enrollee as part of the testing (e.g., the tests themselves)
- COVID-19 antibody tests (including specimen collection and handling)

SB 510 also requires health plans to cover COVID-19 immunizations, as well as items and services intended to prevent or mitigate COVID-19, if the immunization, item or service has a rating of "A" or "B" in the current recommendations of the United States Preventative Services Task Force or a recommendation from the Advisory Committee on Immunization Practices from the CDC.[4]

For purposes of this APL, the above-described services are referred to as "SB 510 Services."

II. Delegation of financial risk for SB 510 Services

SB 510 prohibits a plan from delegating to a contracted provider the financial risk for SB 510 Services "unless the parties have negotiated and agreed upon a new provision of the parties' contract pursuant to [the Health Care Providers' Bill of Rights]."[5] Accordingly, even if the plan and provider had a pre-pandemic contract under which the provider accepted financial risk for diagnostic testing generally or immunizations generally, the financial risk for SB 510 services remains with the plan unless and until the plan and provider agree that the provider will accept the financial risk for some or all SB 510 Services.

Additionally, if the plan and provider enter into a new contract or an amended contract during the state of emergency related to COVID-19 declared by the Governor of the State of California on March 4, 2020, and that contract or amendment does not specifically delegate the financial risk for the SB 510 Services to the provider, the financial risk for those SB 510 Services not addressed in that contract or amendment shall remain with the plan.

The Department is aware that some health plans specifically agreed to delegate financial risk for certain SB 510 Services, like testing, to non-provider entities such as pharmacy benefit managers (PBM). In the case where the contract between the health plan and PBM states that the PBM shall be financially responsible for certain SB 510 Services, the PBM (or other delegated entity) shall provide reimbursement for these

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[4] Currently, the federal government is covering the costs of COVID-19 vaccine serums. However, if the federal government ceases to cover the costs of the vaccine serums, those costs shall become the responsibility of the health plans.

[5] Health and Safety Code section 1342.2(a)(5).

services pursuant to SB 510 and applicable federal law. If a health plan receives a claim for reimbursement from a provider or enrollee which is the responsibility of the PBM, the health plan shall send the claim information to the proper delegated entity, so the PBM or other delegated entity may provide the reimbursement. Neither a provider nor enrollee shall be required to submit an additional claim to the PBM if they already submitted one to the primary health plan.

III. Reimbursement rates for SB 510 Services

SB 510 requires health plans to reimburse out-of-network providers with whom the health plan has no specifically negotiated rates for SB 510 Services "in an amount that is reasonable, as determined in comparison to prevailing market rates for testing items or services in the geographic region where the item or service is rendered."[6]

For purposes of section 1342.2 and this APL:

- a provider is "out-of-network" if: (1) the provider does not have a contract with the plan and the plan and provider have not agreed to a specifically negotiated rate for SB 510 Services; or, (2) the provider has a contract with the plan, but that contract does not include a specifically negotiated rate for SB 510 Services. A contract that delegates financial risk for diagnostic testing generally or vaccinations generally does not include a "specifically negotiated rate" for SB 510 Services.

- an item or service is "rendered" at the location where the enrollee received the SB 510 service (e.g., where the specimen was collected for a COVID-19 test; where the enrollee received a vaccination).

This remainder of this section provides the methodology plans must use to determine the prevailing market rates for SB 510 Services.

A. Medi-Cal managed care plans

While SB 510 does not exclude Medi-Cal managed care plans, Medi-Cal managed care plans should reimburse providers in accordance with federal and state laws and regulations regarding Medi-Cal managed care and guidance issued by the Department of Health Care Services (DHCS) and the Centers for Medicare and Medicaid Services (CMS).

Please note that costs associated with vaccine administration have been "carved out" of the Medi-Cal managed care delivery system and are reimbursed through Medi-Cal fee-for-service. Please refer to DHCS All Plan Letter 20-022 for more information. That All Plan Letter can be found at this link 20-022.

B. Commercial plans

[6] Health and Safety Code section 1342.2, subdivisions (a)(4)(A) and (b)(3)(E).

For commercial health plans, reimbursement for a SB 510 Services is in "an amount that is reasonable" if the plan reimburses the provider in an amount that is at least 125% of the amount Medicare reimburses on a fee-for-service basis for the same or similar services in the general geographic region in which the services were rendered.

Commercial health plans may require out-of-network providers to submit claims for reimbursement through the health plan's existing claims process. Commercial health plans shall reimburse providers according to applicable timeframes set forth in Health and Safety Code section 1371.

IV. Reimbursement per the CARES Act methodology versus SB 510's methodology[7]

A. Reimbursement for COVID-19 tests required to be covered by the CARES Act

During the federal public health emergency, the federal Coronavirus Aid, Relief, and Economic Security (CARES) Act requires commercial health plans to cover COVID-19 tests under certain circumstances. Specifically, during the federal declared public health emergency, the CARES Act requires commercial plans to cover testing of plan enrollees who:

(1) have symptoms of COVID-19;

(2) have recent known or suspect exposure to SARS-CoV-2; or,

(3) are asymptomatic and do not have recent known or suspected exposure to SARS-CoV-2 if the COVID-19 test reflects an "individualized clinical assessment."[8]

For tests required to be covered by the CARES Act, commercial health plans must reimburse the providers administering the tests at either the rate the provider and plan negotiated or at the provider's "cash price" as listed on the provider's public website if the plan and provider do not have a negotiated rate.[9]

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[7] This section does not apply to Medi-Cal managed care plans. The COVID-19 coverage and reimbursement requirements of the CARES Act apply specifically to health care services plans in the commercial group and individual markets, and do not extend to Medicaid managed care plans.

[8] *FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act, Implementation Part 44*, issued by the federal Departments of Labor, Health and Human Services, and Treasury on February 26, 2021. These FAQs are hereinafter reviewed to as the "Feb. 26, 2021 FAQs Part 44" and are available at this link Feb 26, 2021 FAQs Part 44 (last accessed 3/7/2022).

[9] Section 3202(a) of the CARES Act.

However, the CARES Act's requirement to reimburse providers at their cash price does not apply to all providers who may be involved in an enrollee receiving a COVID-19 test. Rather, the Interim Final Rule issued by CMS, the Department of Labor, and the Internal Revenue Service on November 6, 2020, clarifies that only those providers who hold a Clinical Laboratory Improvement Amendments (CLIA) certificate (including a CLIA Certificate of Waiver) are considered "providers" for purposes of being reimbursed at the provider's cash price.[10]

B. Reimbursement for tests required to be covered by SB 510 but not required to be covered by the CARES Act

For providers who are not CLIA certified labs, commercial plans must reimburse the providers per state law. For example, one provider (who is not CLIA certified) may take the sample from the enrollee. That provider then sends the sample to a CLIA certified lab for testing. The lab then returns the results to the provider who took the sample, and the provider communicates the results to the enrollee. In this scenario, the commercial health plan must reimburse the CLIA certified lab at the cash price the lab posted on its website. The commercial health plan must reimburse the provider who took the sample per SB 510's requirements.

Like the CARES Act, SB 510 requires plans to cover COVID-19 testing for symptomatic enrollees, enrollees with known or suspected exposure, and enrollees without symptoms or exposure if the test reflects an individualized clinical assessment. However, during the federal public health emergency, commercial plans must follow the CARES Act methodology when determining the appropriate provider reimbursement amount for tests in these circumstances. After the federal public health emergency ends, commercial plans must follow SB 510's methodology.

The CARES Act does not require commercial health plans to cover COVID-19 testing for "public health surveillance or employment purposes."[11] However, SB 510 expressly requires commercial health plans to cover COVID-19 "screening testing," including testing of asymptomatic workers in workplace settings and asymptomatic students, faculty, and staff in school settings.

In those instances where the CARES Act *does not* require commercial health plans to cover COVID-19 testing (e.g., in employment settings, in school settings), but SB 510 *does* require coverage, commercial plans shall determine the reimbursement amount based on SB 510.

After the expiration of the federal public health emergency, commercial health plans shall follow SB 510's requirements when determining reimbursement amounts for all SB 510 Services, unless federal law dictates otherwise.

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[10] The Interim Final Rule can be found at this link Federal Register 2022-11-06 (last accessed on 3/7/2022).

[11] *See* Feb. 26, 2021 FAQs Part 44, Q2.

The table below identifies various scenarios in which a commercial health plan enrollee might obtain a covered COVID-19 test and whether the commercial plan must follow the CARES Act or SB 510 when determining the amount to reimburse the provider who performed the test:

	Circumstances under which COVID-19 test given	**CARES Act**	**SB 510**
1.	Enrollee has COVID-19 symptoms		
	During the federal public health emergency	x	
	After the federal public health emergency		x
2.	Enrollee is asymptomatic for COVID-19, but has known recent or suspected exposure to SARS-CoV-2[12]		
	During the federal public health emergency	x	
	After the federal public health emergency		x
3.	Enrollee is asymptomatic and does not have known or recent suspected exposure, but the test reflects “an individualized clinical assessment”		
	During the federal public health emergency	x	
	After the federal public health emergency		x
4.	Test for travel purposes		
	During the federal public health emergency	x	
	After the federal public health emergency		x
5.	Test in a workplace setting or for employment purposes		x
6.	Test in a school setting		x

[12] Includes testing a person as a result of contract tracing efforts.

Regardless of whether a commercial plan must cover COVID-19 testing due to the CARES Act or SB 510, the plan may not charge enrollees any type of cost sharing and may not require enrollees to obtain prior authorization or obtain the test from an in-network provider. Similarly, providers may not charge enrollees cost-sharing for SB 510 Services and providers are reminded that they may not balance bill enrollees for the difference between the amount the provider billed the plan and the amount the plan reimbursed the provider.

Note that after the federal public health emergency ends, SB 510 requires plans to continue to cover SB 510 Services delivered to enrollees by out-of-network providers. However, SB 510 allows enrollees to be charged applicable cost-sharing amounts if the enrollees receive SB 510 Services from an out-of-network provider after the federal public health emergency ends.[13]

V. "Lost" cost sharing

SB 510 requires plans to reimburse providers for the "lost" cost sharing the provider would have been entitled to receive but for SB 510.[14] For purposes of SB 510, cost sharing is lost and must be reimbursed to the provider in those instances where the terms of the enrollee's health plan product would have required the enrollee to pay the provider a cost share (e.g., a copayment) to receive the SB 510 Services. If the provider improperly collected cost-sharing from the enrollee, the plan shall reimburse the enrollee for the cost-sharing amount improperly charged and seek reimbursement from the provider.

For those COVID-19 testing and related services (e.g., office visit to collect the specimen) that both the CARES Act and SB 510 require plans to cover (e.g., testing of a symptomatic enrollee during the federal public health emergency), the plan shall reimburse the provider for the lost cost sharing per the terms of SB 510.

If an enrollee receives non-SB 510 Services during a visit, the enrollee may be subject to cost sharing for such services per the terms of the enrollee's health plan product.

VI. At-home testing

Federal guidance issued on January 10, 2022, requires commercial full-service plans to cover at-home over-the-counter COVID-19 tests (OTC COVID tests) authorized by the U.S. Food and Drug Administration.[15] Commercial plans must cover at least eight (8)

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[13] Health and Safety Code section 1342.2, subdivisions (a)(3)(B) and (b)(3)(E)(ii).

[14] Health and Safety Code section 1342.2, subdivisions (a)(1) and (b)(3)(B)

[15] *FAQs About Affordable Care Act Implementation Part 51, Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act, Implementation* issued by the federal Departments of Labor, Health and Human Services, and Treasury on January 10, 2022. These FAQs hereinafter reviewed to as the "Jan. 10, 2022 FAQs Part 51" and are available at this link Jan 10, 2022 FAQs Part 51 (last accessed 3/7/2022).

OTC COVID tests per enrollee per month. The federal requirements took effect on January 15, 2022, and will continue through the end of the federal public health emergency. Further information regarding the federal requirements can be found in APL 22-005, which the DMHC issued on January 25, 2022. During the federal public health emergency, commercial full-service health plans must follow the federal guidance when determining the provider reimbursement amount for OTC COVID tests.

The DMHC interprets SB 510 as also requiring commercial full-service health plans to cover at least eight (8) OTC COVID tests per month. However, this coverage requirement is not additive—i.e. plans *do not* need to cover at least 16 OTC COVID tests per month while the federal guidance is in place. Rather, they must cover at least eight (8) OTC COVID tests per month.

A. Direct coverage of OTC COVID tests

The tri-agency federal guidance issued on January 10, 2022, explained that under federal law, health plans may elect to provide direct coverage of OTC COVID tests to their enrollees, but cannot limit coverage to only those tests provided via the direct coverage network.[16] However, the guidance also set up a "safe harbor" provision, which states that if a health plan establishes a system through which it provides OTC COVID tests directly to its enrollees, the health plan may limit reimbursement for other OTC COVID tests to the actual cost of the test, or $12 per test (whichever is lower), instead of having to pay the cash price as otherwise required under federal law.

The Department is incorporating this federal direct coverage safe harbor provision for OTC COVID tests in California. If a health plan establishes a direct coverage system through which it provides OTC COVID tests directly to enrollees, the health plan may limit its reimbursement of OTC COVID tests purchased by the enrollee to the actual cost of the test, or $12 per test (whichever is lower).

B. Reimbursement rates for OTC COVID tests when no "safe harbor" exists

If the health plan does not establish a direct-to-consumer system which qualifies for the federal safe harbor provision, the health plan must follow the requirements of federal (e.g., CARES Act, FFCRA) and state law (e.g., SB 510) in determining the appropriate reimbursement rate of the OTC COVID tests.

Health plans are not required to provide reimbursement for OTC COVID tests which were purchased by a third party—such as the enrollee's school or place of employment— for use by the enrollee. Moreover, federal guidance applies regarding reimbursement of OTC COVID tests if an enrollee has a health flexible spending arrangement (FSA) or health reimbursement arrangement (HRA).[17]

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[16] Jan. 10, 2022 FAQs Part 51, Q2.

[17] See, Q5 of *FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 52* issued by the federal

C. Coverage of OTC COVID tests outside the parameters of the federal guidance

The federal guidance took effect January 15, 2022, and remains in effect for the duration of the federal public health emergency. As discussed above, until the federal public health emergency ends, health plans must cover at least eight (8) OTC COVID tests per enrollee per month; SB 510 does not require plans to cover additional OTC COVID tests (beyond the eight tests required to be covered by federal guidance) during the federal public health emergency.

For OTC COVID tests purchased by an enrollee *before* January 15, 2022, commercial plans must cover at least eight (8) OTC COVID tests per month and must reimburse enrollees for such tests at the actual price the enrollee paid for the tests, including taxes and shipping costs (if any).

After the federal public health emergency ends, commercial plans must continue to cover at least eight (8) OTC COVID tests per month. At that time, if the plan has established a direct coverage system through which it provides OTC COVID tests directly to enrollees, the health plan may limit its reimbursement of OTC COVID tests purchased by the enrollee to the actual cost of the test, or $12 per test (whichever is lower). If the plan has not established a direct coverage system, the plan must reimburse the enrollee for the actual amount the enrollee paid for the OTC COVID tests, including taxes and shipping costs (if any).

Health plans may request reasonable documentation from enrollees as evidence that the enrollee purchased the tests and the tests were for personal use only. Health plans shall reimburse enrollees within the timeframes stated in Health and Safety Code section 1371.

D. OTC COVID tests used by schools or employers

Notwithstanding the limits described above, when a school or employer is required by a federal, state, or local public health order to conduct COVID-19 screening testing, health plans shall cover the costs of OTC COVID tests used by the school or business to screen its enrollees. When a school or business purchases OTC COVID tests to conduct its mandated screening testing, the school or business shall submit requests for reimbursement to the relevant health plan for tests administered to an enrollee of the health plan. The health plan shall not require the enrollee to submit a request for reimbursement; the health plan shall reimburse the school or business directly. Health plans and schools or business may agree to a negotiated rate for which the health plan shall reimburse the school or business for COVID-19 testing of the plan's enrollees. Tests administered or provided to enrollees by a school or business shall not count toward the eight OTC COVID tests per month the health plan must cover for the enrollee.

Departments of Labor, Health and Human Services, and Treasury on February 4, 2022, available at this link Q5 of FAQs (last accessed 3/7/2022).

VII. Applicability of federal guidance

Health plans shall look to federal guidance regarding coverage requirements for COVID-19 testing and immunizations for any specific issue on which SB 510 is silent.[18] Federal guidance shall control when it would be impossible for a plan to comply with both federal guidance and SB 510. However, where federal guidance creates a "floor," and it is possible for a plan to comply with both the federal guidance and SB 510, plans shall comply with both.[19]

VIII. Payments for SB 510 Services rendered between March 4, 2020, and December 31, 2021

Health and Safety Code section 1342.2, subdivision (d), as added by SB 510, states that section 1342.2 applies "retroactively beginning from the Governor's declared State of Emergency related to the SARS-CoV-2 (COVID-19) pandemic on March 4, 2020." Accordingly, a health plan shall reimburse a provider for SB 510 Services the provider delivered between March 4, 2020, and December 31, 2021, if the health plan has not already reimbursed the provider for those services at either a specifically negotiated rate or at a rate that is at least 125% of Medicare.[20] When a plan and provider do not have a specifically negotiated reimbursement rate for COVID-19 testing and/or vaccine administration, the plan shall not consider the plan's general capitation payment to include costs for SB 510 Services.

Notwithstanding section 1300.71(g) of title 28 of the California Code of Regulations, upon receipt of a complete claim, commercial health plans subject to SB 510 shall reimburse providers for SB 510 Services rendered between March 4, 2020, and December 31, 2021, by **July 1, 2022**, or within 45 days of receipt of the claim, whichever is later.

If a plan fails to pay a complete claim within the timeframes outlined here, the provider shall be entitled to interest and penalties as described in California Code of Regulations, title 28, section 1300.71, subdivisions (i) and (j). If a plan fails to pay a complete claim

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[18] Feb. 26, 2021 FAQs*; FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act, Implementation of Part 43*, issued by the federal Departments of Labor, Health and Human Services, and Treasury on June 23, 2020 (available at this link, last accessed 11-19-2021); and *FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act, Implementation of Part 42*, issued by the federal Departments of Labor, Health and Human Services, and Treasury on April 11, 2020 (available at this link, last accessed 11-19-2021).

[19] Medi-Cal managed care plans should refer to section III.A., above, for guidance regarding reimbursement of out-of-network providers.

[20] Costs associated with vaccine administration have been carved out of the Medi-Cal managed care delivery system and are reimbursed through Medi-Cal fee-for-service. Medi-Cal managed care plans should refer to DHCS All Plan Letter 20-022 for more information.

within the timeframes described above, interest and penalties will begin to accrue on the later of July 1, 2022, or within 45 days of the plan's receipt of the claim. If a health plan fails to comply with this section, the DMHC may impose administrative and/or civil penalties on the plan.

IX. Delegation between health plans, including restricted or limited licensees

SB 510 and this APL apply to health plans with "restricted" or "limited" licenses ("restricted/limited plan") under the Act only to the extent the contract between the fully licensed plan and the restricted/limited plan delegates the financial responsibility for covering SB 510 Services to the restricted/limited plan.[21]

The DMHC acknowledges that in some instances a fully licensed plan may believe its contract with a restricted/limited plan, or with another fully licensed plan, delegates financial risk for SB 510 Services to the downstream plan. However, the downstream plan may disagree and believe the contract did not delegate financial responsibility for SB 510 Services to the downstream plan.

In such instances, the two plans should negotiate and attempt to reach a resolution. During the pendency of those negotiations, if providers who are contracted with the restricted/limited plan seek reimbursement for SB 510 Services, the restricted/limited plan must reimburse the providers to the extent required by SB 510 and this APL. The restricted/limited plan can then seek reimbursement from the fully licensed plan as appropriate.

X. Compliance and filing requirements

Health plans subject to this APL shall submit by **May 27, 2022**, one filing affirming compliance with the requirements discussed in this APL. Submit the filing via eFiling as an Amendment titled "Affirmation of Compliance with SB 510."

- In the Affirmation of Compliance with SB 510 filing, include an Exhibit E-1 (the "Compliance E-1") affirming the following:
    - That until the federal public health emergency expires, the health plan will cover SB 510 Services without cost-sharing, prior authorization, or utilization management, regardless of whether the services are provided by an in-network or out-of-network provider. After the expiration of the federal public health emergency, plans shall continue to cover SB 510 Services without prior authorization or utilization management, regardless of whether the services are provided by an in-network or out-of-network

[21] Because Health and Safety Code section 1342.2(a) applies "Notwithstanding any other law," the Department interprets SB 510, including the requirement to cover OTC COVID tests as described in this APL, as applying to Mexican prepaid health plans licensed under Health and Safety Code section 1351.2. Applicable plans should contact their licensing counsel with any questions.

provider; however, at that time enrollees who received SB 510 Services out-of-network may be subject to applicable cost-sharing.

- That the health plan will reimburse providers, to the extent a provider would have been entitled to receive cost sharing for these services, in the amount of the lost cost sharing.
- That the health plan will negotiate and agree upon a new contract provision pursuant to Health and Safety Code section 1375.7 with its contracted provider prior to delegating financial risk to the contracted provider for diagnostic and screening testing related to the public health emergency.
- That the health plan will cover at least eight (8) OTC COVID tests per enrollee per month.

If you have questions regarding the applicable timelines for filing or other questions about the requirements of this APL, please contact your health plan's assigned reviewer in the OPL.