



September 4, 2020

Sent via email only

Mary Watanabe, Acting Director
California Department of Managed Health Care
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Sacramento, CA 95814-2724
Email: mary.watanabe@dmhc.ca.gov

Re: DMHC's Unlawful Emergency Regulation on COVID-19 Diagnostic Testing

Dear Ms. Watanabe,

We are writing to request that the Department of Managed Health Care (DMHC) rescind or amend its emergency regulation, codified at Section 1300.67.01 of Title 28 of the California Code of Regulations, and implemented through All Plan Letter 20-028, regarding the obligations of commercial health care service plans for covering COVID-19 diagnostic testing. The regulation, effective July 17, 2020, violates Section 6001 of the Families First Coronavirus Response ("Families First") Act and Section 3201 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act by allowing health plans in California to: (1) impose cost-sharing for testing despite a determination from a health care provider that testing is medically appropriate; and (2) impose their own utilization management procedures to approve and deny testing despite a determination from a health care provider that testing is medically appropriate.

I. The DMHC regulation violates federal law by allowing health plans to impose cost-sharing and utilization management procedures for COVID-19 diagnostic testing.

A. Under the Families First Act and CARES Act, health plans must cover testing at no-cost and without utilization management procedures when testing is determined to be medically appropriate by an attending health care provider.

The Families First Act clearly prohibits health plans from imposing cost-sharing or utilization management on COVID-19 diagnostic testing during the Public Health Emergency. Section 6001(a)(1) of the Families First Act (Pub. L. No. 116-127 (2020)) provides in pertinent part that "[a] group health plan and a health insurance issuer offering group or individual health insurance coverage (including a grandfathered health plan (as defined as section 1251(e) of the Patient Protection and Affordable Care Act) shall provide coverage" for COVID-19 diagnostic testing. Under this section, health plans also "shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or



other medical management requirements” for COVID-19 testing furnished during the emergency period. As of the date of this letter, we are still in the [Public Health Emergency](#) period as declared by U.S. Secretary of Health and Human Services on January 31, 2020, and extended on July 23, 2020.¹

As the [Congressional Research Service](#) has interpreted Section 6001: “The [testing] coverage must be provided without consumer cost-sharing, including deductibles, copayments, or coinsurance. Prior authorization or other utilization management requirements are prohibited.”²

Congress authorized the Secretary of Health and Human Services, Secretary of Labor, and Secretary of the Treasury to “implement the provisions of this section through sub-regulatory guidance, program instruction or otherwise.” Sec. 6001(c). Sub-regulatory guidance issued by these three federal agencies on April 11, 2020, instruct that testing “must be covered without cost sharing when medically appropriate for the individual, as determined by the individual’s attending healthcare provider in accordance with accepted standards of current medical practice.” [FAQs Pt. 42](#), p. 6, Question 6. Covered testing must be “primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition.” [FAQs Pt. 42](#), p. 6, Question 5. Thus,

[c]linical decisions about testing are made by the individual’s attending health care provider and may include testing of individuals with signs or symptoms compatible with COVID-19, as well as asymptomatic individuals with known or suspected recent exposure to SARS-CoV-2, that is determined to be medically appropriate by the individual’s health care provider, consulting CDC guidelines as appropriate.

[FAQs Pt. 42](#), p. 6, Question 5. The June 23, 2020 guidance [at Question 3](#) explicitly states that health plans and managed care organizations are not attending healthcare providers and, therefore, cannot deny testing against the opinion of a health care provider.³

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¹ U.S. Secretary of Health and Human Services Alex M. Azar II, Renewal of Determination that a Public Health Emergency Exists, July 23, 2020, *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-23June2020.aspx> (last accessed Sept. 4, 2020).

² Congressional Research Service, Health Care Provisions in Families First Coronavirus Response Act, P.L. 116-127, at 10, 11, April 17, 2020, <https://crsreports.congress.gov/product/pdf/R/R46316>

³ In addition to violating federal statutory provisions, explained in the sections below, the DMHC regulation may not be enforced to the extent it is preempted by federal law.



B. The DMHC regulation and subsequent guidance unlawfully allows health plans to charge enrollees for tests and deny tests on the health plans' own terms.

The DMHC regulation, Section 1300.67.01(c)(3), violates the express prohibitions in Section 6001 of the Families First Act and its implementing guidance by allowing for cost-sharing in situations where testing has been recommended by an enrollee's health care provider, regardless of whether the enrollee has symptoms or known or suspected exposure to the virus. This DMHC regulation does contain the generic qualification "unless otherwise specified by . . . federal law." But the subsequent DMHC guidance in All Plan Letter 20-028 erases any doubt about the meaning of this regulation and impermissibly allows health plans to subject enrollees to cost-sharing amounts. This All-Plan Letter sets forth the following standard for cost-sharing:

[H]ealth plans must continue to impose no cost-sharing for COVID-19 testing for enrollees with symptoms of or known/suspected exposure to COVID-19. . . . *For all other enrollees (i.e., enrollees without symptoms of or known/suspected exposure to COVID-19), health plans may impose ordinary cost-sharing for COVID-19 testing.*

APL 20-028, p. 3 (emphasis added). Both this provision of the DMHC regulation and APL 20-028 impermissibly contravene Section 6001 of the Families First Act and its implementing guidance.

It should be noted that the state, including the California Department of Public Health, guarantees the public on its centralized COVID-19 website that "[t]here are no out-of-pocket costs for medically-necessary testing."⁴ The California Department of Insurance similarly continues to require its health plans to provide all medically necessary COVID-19 diagnostic testing without cost-sharing.⁵ Yet the California Department of Managed Health Care disagrees with these two other agencies as Section 1300.67.01(c)(3) and All Plan Letter 20-028 state otherwise about cost-sharing allowances by health plans.

To make matters worse, Section 1300.67.01(c)(2) also allows health plans "to impose ordinary utilization management procedures allowed by the Knox-Keene Act" to determine when a COVID-19 test is covered for enrollees who are asymptomatic, without known or suspected exposure, and are not essential workers. Here, too, the regulation violates Section 6001 of the Families First Act and its implementing guidance. Health plans are prohibited from imposing any

⁴ California All, Testing and Treatment, <https://covid19.ca.gov/testing-and-treatment/> (last accessed Sept. 4, 2020).

⁵ California Insurance Commissioner, Bulletin to All Health Insurers, March 5, 2020, <http://www.insurance.ca.gov/0250-insurers/0300-insurers/0200-bulletins/bulletin-notices-commiss-opinion/upload/COVID-19-Screening-and-Testing.pdf>; see also Department of Insurance, Coronavirus Home Page, <http://www.insurance.ca.gov/01-consumers/140-catastrophes/Coronavirus.cfm> (containing March 5 Bulletin as current policy) (last accessed Aug. 31, 2020). While the Department of Insurance "strongly" encourages" plans to "waive prior authorization" for services related to COVID-19, the agency continues to allow utilization management for COVID-19 diagnostic testing; this may also violate federal testing requirements.



utilization management procedures in situations where testing has been recommended by an enrollee's health care provider, regardless of the employment of an enrollee and regardless of whether the enrollee has symptoms or known or suspected exposure.

Under the DMHC regulation and guidance, plans could charge a co-payment or deny tests for asymptomatic patients awaiting surgery unrelated to COVID-19, for individuals with comorbidities,⁶ for childcare givers who are currently not identified as essential workers in the regulation, and for individuals living and working in COVID-19 hot spots. Yet health care providers could recommend testing for these individuals based on their own clinical knowledge and CDC, state, and local public health guidelines. By allowing health plans to impose cost-sharing and utilization management in certain situations and to override the determination of health care providers, the DMHC regulation violates federal statute.

II. In addition to violating federal law, the DMHC regulation violates public health guidance and undermines efforts to stop the spread of COVID-19.

Health plans must cover the cost of testing whenever it is determined to be medically appropriate by an enrollee's attending health care provider. FAQs Pt. 42, p. 6. Testing guidance for COVID-19 is changing as new research emerges on the virus. Medically appropriate criteria for testing should, therefore, be left to the determination by medical providers who are in the best position to understand individual medical needs and make informed clinical decisions.

The Centers for Disease Control and Prevention (CDC) currently recommends testing for individuals who: (a) have symptoms of COVID-19 when advised by a health care provider; or (b) live in a high COVID-19 transmission area and have attended a public or private gathering of more than 10 people without proper precautions, when recommended by a health care provider or local public health officials.⁷ At all times, the CDC refers individuals to follow the advice of state and local public officials to determine whether they should be tested.⁸

In contrast, under the DMHC regulation, health plans are allowed to deny testing or impose cost-sharing even when testing is medically appropriate according to CDC guidelines or an individual's health care provider. However, the federal guidance specifically narrowed its definition of who is an attending health care provider to exclude plans, and nowhere under

⁶ Reference ID. MN20-33164, DMHC Independent Medical Review Database, <https://wpso.dmhc.ca.gov/imr/> (upholding plan denial of COVID-19 testing without discussion of recommendation from attending health care provider, as required by federal law) (last accessed Aug. 31, 2020).

⁷ Center for Disease Control and Prevention, Overview of Testing for SARS-CoV-2 (COVID-19), <https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html> (last accessed Aug. 31, 2020).

⁸ Center for Disease Control and Prevention, Overview of Testing for SARS-CoV-2 (COVID-19) ("State and local public health officials may advise specific people, or groups of people, to be tested. You should follow this advice.").



federal testing standards are health plans given the authority to set testing criteria or priorities. FAQs Pt. 43, p. 6, Question 3, fn. 11.

Importantly, while CDC guidance is instructive, it advises providers to refer to local public health guidance to determine when testing is medically appropriate. The California Department of Public Health issued statewide guidance on how to prioritize testing. Amongst the Department of Public Health's testing priorities are individuals who are asymptomatic and not essential workers, such as patients requiring pre-operative admission screening and patients being discharged from hospitals to lower levels of care.⁹ Across the state, county health departments have issued their own testing priorities and guidelines to respond to local needs. Under the DMHC regulation, health plans are allowed to impose cost-sharing or deny testing for the very groups prioritized by public health agencies.

DMHC should rescind or amend Section 1300.67.01 because it is impeding the state's two-fold goal of preventing the spread of COVID-19 and providing widespread testing at the lowest cost to taxpayers.

III. DMHC's regulation is forcing state taxpayers to pay for COVID-19 testing while allowing health plans to profit in the billions.

State and local governments are bearing the brunt of testing costs throughout California. Yet the DMHC regulation allows health plans to shift the cost burden to taxpayers and shields the plans from costs they are required to pay.

As the Governor noted on August 26, the state is trying to expand its testing capacity "to fight COVID-19 and protect essential workers and those most at risk of infection."¹⁰ While operating state-run testing sites, the Governor expects "to recoup costs from health insurance companies or other payers" so this program will be at the lowest cost to taxpayers.¹¹ The state will be unable to achieve this goal of recouping costs from health plans if DMHC allows plans to refuse to cover testing when required to do so.

Anecdotally, we have heard about more individuals receiving tests at publicly funded testing sites than directly from providers. Both patients and providers are uncertain about whether health plans will cover or reimburse them for the costs of tests. Providers are also determining where to

⁹ California Department of Public Health, Updated COVID-19 Testing Guidance (last updated Aug. 3, 2020), <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Updated-COVID-19-Testing-Guidance.aspx> (last accessed Aug. 31, 2020).

¹⁰ Office of Governor Gavin Newsom, Governor Newsom Announces Major Plan to More than Double State's Testing Capacity, Reduce Turnaround Time, Aug. 26, 2020, <https://www.gov.ca.gov/2020/08/26/governor-newsom-announces-major-plan-to-more-than-double-states-testing-capacity-reduce-turnaround-time/> (last accessed Aug. 31, 2020).

¹¹ Office of Governor Gavin Newsom, Aug. 26, 2020.



send tests based on turnaround time and quality and accuracy of labs, rather than standards and networks set by the numerous health plans that cover their patients. By taking away decision-making authority from providers, the DMHC regulation complicates and delays the decision-making process for quick and nimble testing.

It would be consistent with existing medical necessity criteria under the Knox-Keene Act for DMHC to require plans to defer to the opinion of attending health care providers in covering COVID-19 testing. The Knox-Keene Act already requires medical decisions made by plans in the usual utilization management process to be based on clinical principles and practices. Health and Safety Code Section 1367.01(b) provides that health plans’ “policies and procedures shall ensure that decisions based on the medical necessity of proposed health care services are consistent with criteria or guidelines that are supported by clinical principles and processes.” Health and Safety Code Section 1363.5 in turn states that at a minimum, criteria used by plans for utilization management must “[b]e consistent with sound clinical principles and processes.” Current federal testing guidelines require health plans to step away from their utilization management role and instead, to allow health care providers to exercise their clinical judgment.

During the ongoing COVID-19 pandemic, health plans are experiencing soaring profits. For the first two quarters of this year, Kaiser Foundation Health Plan and Hospitals reported \$3.3 billion in revenue compared to \$2.7 billion last year at this time,¹² Anthem, Inc. reported \$5.6 billion compared to \$3.4 billion last year,¹³ and Centene (Health Net) reported \$3.7 billion, representing 3.1 times in net earnings¹⁴. DMHC should hold health plans accountable to spend more on the requisite COVID-19 testing for Californians. Health plans are capable of doing so.

IV. DMHC should rescind or amend the regulation to comply with federal law.

DMHC should immediately rescind or amend the emergency regulation. Expansive access to testing is critical to controlling the spread of COVID-19 and informing our local governments about reopening decisions. To bring the regulation into compliance with federal law, all COVID-19 testing deemed medically appropriate by an individual’s attending health care provider should be provided at no-cost and without utilization management by the individual’s health plan. This is a similar standard used for COVID-19 testing in the Medi-Cal program, which requires only a showing of medical necessity using CDC guidance and other credible sources as determined by a

¹² Kaiser Foundation Health Plan and Hospitals Q2 2020 Financial Update, Aug. 7, 2020, <https://about.kaiserpermanente.org/our-story/news/announcements/kaiser-foundation-health-plan-and-hospitals-q2-2020-financial-update> (last accessed Sept. 4, 2020).

¹³ Anthem Reports Second Quarter Results, Reaffirms Commitment to Stakeholders During COVID-19 Pandemic, Jul. 29, 2020, [https://ir.antheminc.com/news-releases/news-release-details/anthem-reports-second-quarter-results-reaffirms-commitment?field_nir_news_date_value\[min\]=](https://ir.antheminc.com/news-releases/news-release-details/anthem-reports-second-quarter-results-reaffirms-commitment?field_nir_news_date_value[min]=) (last accessed Sept. 4, 2020).

¹⁴ <https://investors.centene.com/news-releases/news-release-details/centene-corporation-reports-second-quarter-2020-results>



treating physician.¹⁵ This is also the same standard used by the state of Washington: health plans must cover COVID-19 testing with no-cost sharing “for enrollees who meet the CDC criteria for testing, as determined by the enrollee’s health care provider” and must suspend “any prior authorization requirements that apply to covered diagnostic testing.” [Emergency Order No. 20-01](#), Directives B & C, March 5, 2020 (extended to August 28, 2020).

DMHC’s concern in enacting the emergency regulation was, in part, to manage the scarcity of testing. DMHC can still address this reality without running afoul of federal requirements that have been enacted to ensure widespread testing and control of a pandemic. DMHC could still allow individual providers to adjust to fluctuating testing supplies by prioritizing who gets tested. DMHC should make the clear that health plans are required to pay for COVID-19 diagnostic testing as a basic health care service and must cover all testing at no-cost when it is determined to be medically appropriate by an attending health care provider. Guidance is available from the California Department of Public Health and local public health agencies to inform providers on testing priorities.

Given the urgency of this public health matter, we request that, no later than next Friday, September 11, 2020, you confirm DMHC’s regulation and guidance on COVID-19 diagnostic testing have been withdrawn and you will issue new guidance to health plans in a manner consistent with the language of the Families First Act, CARES Act, and related federal guidance. If not, we will take appropriate legal action seeking relief on behalf of California plan enrollees. I can be reached at (213) 235-2638 and htran@wclp.org.

Sincerely,

Helen Tran
Staff Attorney

Cc: Sarah Ream, Acting Deputy Counsel, Acting Deputy Director
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¹⁵ Department of Health Care Services, COVID-19 Virus and Antibody Testing, Aug. 7, 2020, <https://www.dhcs.ca.gov/Documents/COVID-19/COVID-19-Antibody-Testing.pdf> (“DHCS covers both COVID-19 viral and serologic (antibody) tests, at no cost to Medi-Cal beneficiaries. This includes all medically necessary viral and serologic testing as well as serologic (antibody) tests ordered for infection control purposes (e.g. pre-operative screening or planned hospitalizations). We recommend that all Medi-Cal providers follow the testing guidance provided by the California Department of Public Health (CDPH), the Centers for Disease Control and Prevention (CDC), and other governmental and professional organizations with expertise on COVID-19 testing.”).