March 21, 2021

The Honorable Richard Pan
Chair, California Senate Committee on Appropriations
State Capitol, Room 2114
Sacramento, CA 95814

Via E-mail only

Dear Senator Pan:

The California Health Benefits Review Program (CHBRP) was asked by the Senate Committee on Health on February 17, 2021, to analyze Senate Bill (SB) 510 (Pan) COVID-19 Cost-Sharing. In response, CHBRP is pleased to provide this letter.

SB 510, which would take effect immediately upon passage, includes benefit mandates related to COVID-19, as well as benefit mandates related to future pandemics. The mandates would affect the health benefit coverage of enrollees in health plans and health insurance policies regulated by the California Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI). Because the mandates related to COVID-19 would largely preserve the status quo beyond the current federally declared public health emergency, no measurable impact is expected. Because the other mandates would relate to an as-yet-unknown future pandemic, related impacts are unknown.

Further discussion of the COVID-19 related mandates and the future pandemic mandates follow.

COVID-19 Specific SB 510 Benefit Mandates

Sections 2 and 4 of SB 510 address COVID-19 related benefit coverage and refer to the federally declared COVID-19 public health emergency.

Bill Summary & Policy Context

For COVID-19 testing (and any related services and items), SB 510 would require

- Benefit coverage – whether accessed through an in-network provider or an out-of-network provider:
    - Without cost sharing to the enrollee; and
    - Without prior authorization requirements.
- Reimbursement for covered health care services:

    - To in-network providers with negotiated rates –
        - Reimbursement is to be based on rates negotiated prior to the federally declared public health emergency for as long as the current emergency lasts; and
        - Contract changes delegating financial risk (from the plan or insurer) are prohibited unless the parties have negotiated and agreed up on a new provision.
    - To out-of-network providers without a negotiated rate –
        - Reimbursement is to be based on prevailing rates in the provider's geographic area, and the provider is prohibited from seeking more reimbursement from the patient (i.e. no surprise billing).
    - In either case, the plan/insurer is to pay the provider what the provider would have received as cost sharing from the enrollee.
    - At the end of the federally declared public health emergency, these requirements regarding in-network providers remain in effect, but these requirements regarding out-of-network providers would end.

For any COVID-19 immunization (and any related services, such as office visits) with an "A" or "B" recommendation from the United States Preventive Services Task Force (USPSTF), or with a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the federal Centers for Disease Control and Prevention (CDC) – whether or not recommended for routine use – SB 510 would require

- Benefit coverage – whether accessed through an in-network provider or an out-of-network provider:
    - Within 15 days of the USPSTF or ACIP recommendation, whether the recommendation is adopted or granted emergency use authorization;
    - Without cost-sharing to the enrollee; and
    - Without prior authorization requirements.
- Reimbursement:
    - To in-network providers with negotiated rates –
        - Reimbursement is to be based on rates negotiated prior to the federally declared public health emergency for as long as the emergency lasts; and
        - Contract changes delegating financial risk are prohibited unless the parties have negotiated and agreed up on a new provision.
    - To out-of-network providers without a negotiated rate –
- Reimbursement is to be based on prevailing rates in the provider's geographic area and the provider is prohibited from seeking more reimbursement from the patient (i.e. no surprise billing).
    - In either case, the plan/insurer is to pay the provider what the provider would have received as cost sharing from the enrollee.
    - At the end of the federally declared public health emergency, these requirements regarding in-network providers remain in effect, but these requirements regarding out-of-network providers would end.

In several ways, SB 510 would extend the impact of current federal rules beyond the federally declared public health emergency.

For the duration of the federally declared public health emergency, FDA-approved COVID-19 testing must be covered without cost sharing[1] when delivered by in-network or out-of-network providers.[2] SB 510 would extend this mandate beyond the emergency period.

During the emergency period, the effective date of the federal requirement for coverage without cost sharing for recommended immunizations[3] is decreased from one year to 15 days for COVID-19 immunizations.[4] SB 510 would extend this mandate beyond the emergency period.

During the emergency period, balance billing by providers for COVID-19 testing and immunization is prohibited.[5] SB 510 would extend this prohibition beyond the emergency period.

Background

COVID-19 is an infectious disease caused by a new strain of coronavirus that is responsible for a worldwide pandemic (WHO, 2021). On March 13, 2020, a national emergency was declared to help states and healthcare systems prevent the spread of COVID-19 in the United States (CMS, 2020). Despite these efforts, as of March 16, 2021, there have been 29,319,457 confirmed cases and 533,057 deaths from COVID-19 in the U.S. (CDC, 2021a) and 3,530,055 confirmed cases and 55,372 deaths from COVID-19 in California (COVID19.CA.GOV, 2021c). By October 2020, COVID-19 became the third leading cause of death in the U.S. for adults aged 45 to 84 years old and the second leading cause of death for adults aged 85 years or older (Woolf et al., 2020). Estimated life expectancy in the U.S. has declined by about 1 year as a result of the COVID-19 pandemic (Andrasfay and Goldman, 2021). Reductions in life expectancy are greater for Black (about 2 years) and Latino (about 3 years) populations as compared to White (about 0.6 years) population (Andrasfay and Goldman, 2021). Total cases and deaths are projected to continue to rise until there is adequate vaccination coverage in the population.

Early in the pandemic, testing for COVID-19 was not readily available. Over the last year, several tests to detect COVID-19 have been developed; they are widely utilized throughout California and the U.S. to identify people with symptomatic and asymptomatic COVID-19. There are testing sites organized by the state of California through OptumServe, at the county level, and by healthcare providers and clinics (COVID19.CA.GOV, 2021b). Currently, COVID-19 tests are provided to insured individuals at no cost, as described in the *Policy Context* section.

Since December 2020, COVID-19 vaccines have been available in limited supplies, which are gradually expanding. The goal of vaccination is to slow the spread of disease and reduce hospitalizations and mortality related to COVID-19 infection (CDC, 2021c). Currently, all vaccines have been purchased by the federal government and will be provided at no cost for all Californians (DHCS, 2020). Vaccine administration fees will apply, and providers should be reimbursed by insurance.

Medical Effectiveness

The SARS-CoV-2 virus responsible for the COVID-19 pandemic was identified in 2019. Efforts to develop effective tests, treatments, and vaccinations have progressed very rapidly, but the short time frame and fluid circumstances of the pandemic mean that the science continues to evolve. Under these circumstances, CHBRP accepts FDA emergency use authorization or approval, in combination with CDC recommendations, as establishing the standard of care.

Several different tests have been developed to diagnose COVID-19 or detect recent infection of COVID-19. The viral PCR nucleic acid amplification diagnostic tests (NAATS) and rapid antigen tests for viral

[1] 2020 Families First Coronavirus Response Act (FFCRA).
[2] 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act
[3] 2012 Affordable Care Act
[4] 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act
[5] 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act

proteins detects current infection (CDC, 2021b). Both tests utilize samples from the nose or mouth. The NAATS are more accurate and more sensitive for detecting asymptomatic COVID-19 infections compared to the antigen tests, which are simpler to perform (CDC, 2021b). On March 12, 2021, the FDA issued a warning that false positive results can occur with the Roche Molecular Systems, Inc. (Roche) cobas® SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas® Liat® System, and it is recommended that users of this test should monitor for clusters of positive Flu B results, repeat tests when two or three tests are positive, and stop using the cobas® Liat® System if false positives are suspected (FDA, 2021). The COVID-19 antibody test utilizes blood samples to detect antibodies to identify past COVID-19 infections. The antibody test is not used to diagnose current infections because the body may not develop antibodies to COVID-19 for 1-3 weeks after the infection (CDC, 2021e). Rapid, point-of-care tests include combination flu/COVID-19 tests, saliva tests, and at-home collection tests (FDA, 2020). The FDA has approved over-the-counter and prescription at home COVID-19 tests (COVID19.CA.GOV, 2021b). These recently approved tests are not yet widely available. Other home tests require self-collected nasal swab or saliva samples to be shipped to a lab for analysis (CDPH, 2020).

Three vaccines have received Emergency Use Authorization from the FDA for use in adults. Two are mRNA vaccines: the Pfizer-BioNTech COVID-19 vaccine and the Moderna COVID-19 vaccine. Both are administered in a series of two shots: three weeks apart for the Pfizer vaccine and four weeks apart for the Moderna vaccine. The recently approved Johnson & Johnson Janssen COVID-19 vaccine is based on a modified adenovirus and is given as a single injection (CDC, 2021c). Evidence from clinical trials showed 94-95% effectiveness at preventing symptomatic COVID-19 for the Pfizer and Moderna vaccines; the Johnson & Johnson Janssen COVID-19 vaccine was 66% effective at preventing symptomatic COVID infection overall and 85% effective at preventing severe disease, hospitalizations, and death 28 days after vaccination (Johnson & Johnson, 2021).

Tests and immunizations for COVID-19 that are approved (or granted emergency use authorization) by the Federal Food and Drug Administration (FDA) are the standard of care. The FDA's recommendations and CDC guidelines present *clear and convincing* evidence that the recommended tests and treatments effectively manage COVID-19; that unmanaged COVID-19 can lead to serious health complications; and that management of COVID-19 reduces transmission.

Benefit Coverage, Utilization, and Cost Impacts

SB 510 would mandate benefit coverage for tests and vaccinations for COVID-19 with no cost sharing imposed on the enrollee, for all DMHC-regulated plans and CDI-regulated policies. Additionally, coverage of vaccinations extends only to vaccines that have been approved for use by the Federal Drug Administration (FDA), most commonly under emergency use authorization. According to language in the bill, SB 510 would immediately become effective upon signing.

According to the survey of California's eight largest (by enrollment) DMHC- and CDI-regulated plans and insurers, 100% of enrollees currently have coverage for COVID-19 tests and vaccinations with no cost sharing for the enrollee and no balance billing, in compliance with federal regulations that require this benefit coverage. Although not required by current law, all enrollees in DMHC-regulated plans and CDI-regulated policies also have coverage for COVID-19 tests and vaccinations with no prior authorization requirements. Because the current declaration of a federal public health emergency is expected to continue (as of late January 2021, expected to extend through the end of the year[6]), SB 510 would have no measurable postmandate impact on benefit coverage of COVD-19 tests or vaccinations.[7] CHBRP also

[6] Letter from Acting Health and Human Services Secretary Norris Cochran to all governors, dated 1/22/2021, accessed at: https://ccf.georgetown.edu/wp-content/uploads/2021/01/Public-Health-Emergency-Message-to-Governors.pdf on March 7, 2021.

[7] CHBRP is aware that there is the remote possibility that the federal public health emergency declaration could end prior to the enactment of SB 510, but whether insurance carriers would then cease to offer COVID-19 tests and vaccinations with no cost sharing and no balance billing is unknowable. CHBRP is therefore unable to project the impact of this unlikely event.

cannot determine a baseline annual utilization of COVID-19 testing, as there is no available insurance claims data to model distribution of tests over the course of a projected year, or to determine the baseline for reimbursement at in-network rates as mandated under SB 510. CHBRP is also unable to determine utilization of COVID-19 vaccinations at baseline, since the distribution of vaccinations is dependent on FDA authorization of vaccines and manufactured supply. At the time of this writing, the Johnson & Johnson vaccine had been approved within the prior month (see *Background* for more information), and vaccinations of most adults in California is projected to be done by Summer 2021.[8] The baseline utilization of vaccinations is therefore rapidly changing, and depending on when SB 510 would be enacted, vaccination of nearly all adults in California may be largely accomplished prior to the bill taking effect. Although it is possible that COVID-19 vaccine booster shots will be necessary in the long term, CHBRP is unable to project the impact of that possibility. CHBRP also cannot determine whether in-network or out-of-network providers are currently performing the provision of COVID-19 tests and vaccinations for enrollees in plans or policies subject to SB 510. Therefore, with no measurable change in benefit coverage and no ability to determine current utilization, CHBRP cannot determine any impact on postmandate utilization or costs due to SB 510.

Public Health Impacts

COVID-19 has impacted the health of individuals throughout California, and the current state of emergency supports continued efforts to test and vaccinate as many Californians as possible. As of March 16, 2021, 55,372 COVID-19 deaths were reported in California (COVID19.CA.GOV, 2021c). The COVID-19 death rate in California was143 reported deaths per 100,000 people as of March 15, 2021 (JHU, 2021). An analysis completed in California from March 1 through August 22, 2020 reported 19,806 deaths in excess from predicated historical trends (Chen et al., 2020). “Excess mortality was highest among people aged 65 years and older, men, Black and Latino residents, and those without college degree” (Chen et al., 2020). Older adults and people with severe underlying health conditions such as heart or lung disease or diabetes are at highest risk of developing complications related to COVID-19 (CDC, 2021d). However, anyone can develop mild to severe symptoms of COVID-19.

Most people experience mild symptoms of COVID-19 and recover, but some patients have symptoms that persist for weeks to months after infection (CDC, 2020). The more serious long-term health outcomes of COVID-19 among survivors include inflammation of the heart, lung function abnormalities, acute kidney injury, hair loss, rash, smell and taste problems, sleep issues, memory problems, depression, anxiety, and mood changes (CDC, 2020). The long-term impacts of these more serious complications of COVID-19 are not fully understood and investigation continues. The public health emergency due to COVID-19 has impacted Californians throughout the state. Testing, physical distancing, mask use, and vaccines are necessary to slow the spread of disease. It is unclear how long testing and vaccination will be needed due to the unpredictability of the disease and the unknown impact of the emerging coronavirus variants of COVID-19. Booster vaccinations may also be needed to sustain immunity.

California’s racial/ethnic communities and low-income groups have been disproportionately impacted by COVID-19 illness and death (Azar et al., 2020; COVID19.CA.GOV, 2021a). The pandemic has exacerbated the existing inequities in health and healthcare systems and efforts have been made to increase access to testing, treatment, and vaccines (COVID19.CA.GOV, 2021a). SB 510 would prevent financial burden associated with cost sharing for COVID-19 testing, vaccines, and vaccine administration, should the current federal regulations be removed. Without eliminating the cost barriers for testing and vaccination, COVID-19 illness and death may be further exacerbated especially among racial/ethnic and low-income groups within the California insured population.

As discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, 100% of enrollees plans and policies regulated by DMHC and CDI currently have coverage for COVID-19 testing and vaccinations, and for these enrollees, the passage of SB 510 would not result in a change in benefit coverage. The

[8] Timeline expectation from the California Department of Public Health at https://covid19.ca.gov/vaccines/, accessed on March 7, 2021.

requirements of SB 510 will prevent increased financial barriers to testing and vaccinations should the federal emergency requirements be lifted. For this reason, CHBRP concludes that SB 510 would have no measurable impact on disparities in health outcomes by race/ethnicity, as Californians covered by SB 510 should have no financial barriers to testing and vaccinations under the federal emergency requirements.

Future Pandemic SB 510 Benefit Mandates

SB 510 would also mandate benefit coverage for tests and vaccinations for future pandemics, as defined by the declaration of a public health emergency. Although it is commonly accepted that another global pandemic will occur, it is unclear what the nature of that pandemic will be in terms of potential mortality, testing costs, spread through the community, and need for vaccination. CHBRP is therefore unable to determine any estimates for the impacts of a future global pandemic in the long term.

Thank you for the opportunity to have CHBRP assist. We are happy to answer any questions.

Sincerely,

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