Assembly
California Legislature

ASSEMBLY COMMITTEE ON
BUSINESS AND PROFESSIONS
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AGENDA

Tuesday, February 14, 2023
9:30 a.m. – 1021 O Street, Room 1100

ADOPTION OF COMMITTEE RULES

BILLS HEARD IN FILE ORDER

1. AB 269 Berman Public health: COVID-19 testing and dispensing sites. (Urgency)

Date of Hearing: February 14, 2023

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Marc Berman, Chair
AB 269 (Berman) – As Amended February 8, 2023

SUBJECT: Public health: COVID-19 testing and dispensing sites.

SUMMARY: Codifies two waivers granted by the Governor during the declared COVID-19 State of Emergency through an urgency measure to take effect prior to that declaration's anticipated termination on February 28, 2023.

EXISTING LAW:

1) Establishes the Board of Pharmacy (BOP) to administer and regulate the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000 *et seq.*)

2) Defines "pharmacy" as an area, place, or premises licensed by the BOP in which the profession of pharmacy is practiced and where prescriptions are compounded. (BPC § 4037)

3) Prohibits any person from conducting a pharmacy in the state unless they have obtained a license from the BOP. (BPC § 4110)

4) Defines "dispense" to include the furnishing of drugs or devices directly to a patient by a physician, nurse practitioner, dentist, optometrist, podiatrist, or veterinarian, or other health professional when acting within the scope of their practice. (BPC § 4024(b))

5) Requires labeling of all containers of prescription drugs stating information about the drug, directions for use, the names of the patient and the prescriber, and other information. (BPC § 4076)

6) Requires that all records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the BOP shall be retained on the licensed premises in a readily retrievable form for a period of three years. (BPC § 4105)

7) Prohibits a prescriber from dispensing drugs or dangerous devices to patients in the prescriber's office or place of practice unless specified conditions are met. (BPC § 4170)

8) Requires a prescriber who dispenses drugs to store all drugs to be dispensed in an area that is secure. (BPC § 4172)

9) Authorizes a registered nurse to dispense drugs or devices upon an order by a licensed physician and surgeon or other specified health professional if the registered nurse is functioning within a licensed primary care clinic. (BPC § 2725.1)

10) During a declared federal, state, or local emergency, authorizes the BOP to waive application of any provisions of the Pharmacy Law or the regulations adopted pursuant to it if, in the BOP's opinion, the waiver will aid in the protection of public health or the provision of patient care. (BPC § 4062)

11) Provides for the licensure, registration, and regulation of clinical laboratories and various clinical laboratory personnel by the California Department of Public Health (CDPH), with specified exceptions. (BPC §§ 1200 – 1327)

12) Defines "CLIA" as the federal Clinical Laboratory Improvement Amendments of 1988 (United States Code, title 42, § 263a; Public Law 100-578) and the regulations adopted by the federal Health Care Financing Administration (HFCA) that are effective on January 1, 1994, or later when adopted by the CDPH after being deemed equivalent to or more stringent than California laws or regulations, as specified. (BPC §§ 1202.5(a), 1208(b))

13) Defines "clinical laboratory" as any place used, or any establishment or institution organized or operated, for the performance of clinical laboratory tests or examinations or the practical application of the clinical laboratory sciences. (BPC § 1206(a)(8))

14) Defines "clinical laboratory test or examination" as the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of obtaining scientific data which may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual. (BPC § 1206(a)(5))

15) Prohibits any person from performing clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director and the test is performed by specified licensees or individuals enumerated in statute. (BPC § 1206.5)

16) Establishes the definition, duties, and qualifications of a "laboratory director" for purposes of clinical laboratories and testing. (BPC § 1209)

17) Includes in each specialized limited clinical laboratory scientist license specified specialties and subspecialties. (BPC § 1210)

18) Requires the local health department of a city or county to have available the services of a public health laboratory for the examination of specimens from suspected cases of infectious and environmental diseases. (Health and Safety Code (HSC) § 101150)

19) Provides that city or county public health laboratory and its personnel shall be approved by the State Department of Health Services (now the CDPH) and shall comply with the requirements of CLIA. (HSC § 101160)

20) Establishes the California Emergency Services Act to confer upon the Governor and upon the chief executives and governing bodies of political subdivisions of the state certain emergency powers. (Government Code (GOV) §§ 8550 *et seq.*)

21) Authorizes the Governor to make, amend, and rescind orders and regulations necessary to carry out the provisions of the California Emergency Services Act, which have the force and effect of law. (GOV § 8567)

THIS BILL:

1) Defines "COVID-19 oral therapeutics" as drugs that are approved or authorized by the United States Food and Drug Administration (FDA) for the treatment of COVID-19 and administered orally.

2) Authorizes an entity approved by the CDPH to operate a designated COVID-19 testing and dispensing site to acquire, dispense, and store COVID-19 oral therapeutics at or from a designated site.

3) Requires COVID-19 oral therapeutics to be stored at a designated site in a secure manner, as determined by the CDPH.

4) Expressly provides that a prescribing physician, or a registered nurse under the direction of such physician, may dispense COVID-19 oral therapeutics to patients at a designated site.

5) Requires COVID-19 oral therapeutics that are packaged by the manufacturer in a dispensable container to be dispensed in the original manufacturer's container and to comply with specified labeling requirements, including the address of the designated site where the therapeutic is dispensed.

6) Requires an entity approved to operate a designated site to maintain for three years records of acquisition and disposition for each site, including the kind and amounts of COVID-19 oral therapeutics dispensed at each site and for each patient, and requires those records shall be available for inspection by the CDPH and the BOP.

7) Provides that the above provisions shall remain in effect only until January 1, 2024.

8) Authorizes a person who meets the CLIA requirements for high complexity testing to perform an analysis of samples to test for SARS-CoV-2, the virus that causes COVID-19, in either a clinical laboratory or a city or county public health laboratory.

9) Declares the act to be an urgency statute that will take effect immediately in order to ensure the continued ability of nurses to dispense COVID-19 therapeutics as part of the Test to Treat Program and address the technical qualifications of laboratory workers allowing them to solely process COVID-19 tests.

FISCAL EFFECT: Unknown.

COMMENTS:

Purpose. This bill is sponsored by the author, who is the Chair of the Assembly Committee on Business and Professions. The Governor's press release announcing an anticipated February 28, 2023 termination date for the declared COVID-19 State of Emergency included the following: "To maintain California's COVID-19 laboratory testing and therapeutics treatment capacity, the Newsom Administration will be seeking two statutory changes immediately upon the Legislature's return: 1) The continued ability of nurses to dispense COVID-19 therapeutics; and 2) The continued ability of laboratory workers to solely process COVID-19 tests." This bill would fulfill the Governor's request by codifying both of the existing waivers identified in this press release.

Background.

COVID-19 Pandemic. On March 4, 2020, Governor Gavin Newsom proclaimed a State of Emergency as a result of the impacts of the COVID-19 public health crisis. On March 12, 2020, the Governor issued an executive order that directed residents to follow public health directives and guidance, including to cancel large non-essential gatherings that do not meet certain state criteria. On March 19, 2020, the Governor formally issued a statewide "stay at home order," directing Californians to only leave the house to provide or obtain specified essential services. Subsequent guidance from the State Public Health Officer expressly exempted from that order various professionals regulated by the Department of Consumer Affairs (DCA).

On March 30, 2020, Governor Newsom announced an initiative to "expand California's health care workforce and recruit health care professionals to address the COVID-19 surge" and signed Executive Order N-39-20. This executive order established a waiver request process under the DCA and included other provisions authorizing the waiver of licensing, certification, and credentialing requirements for health care providers. This waiver process constituted a delegation of the Governor's existing authority under the California Emergency Services Act (EMSA) to make, amend, and rescind orders and regulations necessary to respond to a declared emergency.

Approximately 74 further executive orders were issued to waive or revise various laws to advance the state's pandemic response. Over the course of the pandemic, approximately 596 EO provisions were effectuated, with 27 still in effect as of October 2022. Dozens of additional waivers have been issued for licensing programs under the DCA. The majority of these waivers have since expired, and a number were permanently codified through the enactment of legislation.

Clinical Laboratory Testing Requirements. Federal and state laws regulate clinical laboratory testing on human specimens for diagnostic or assessment purposes. The purpose of clinical laboratory regulation is to ensure patients who undergo diagnostic testing receive accurate and timely results. Inaccurate or delayed results may prevent a patient from receiving the proper level or type of care.

To that end, all clinical laboratories and tests must comply with requirements under CLIA. CLIA establishes the minimum standards under federal law but allows states to establish more stringent requirements. Under CLIA, laboratory tests are classified based on the complexity of the laboratory tests performed. In general, the more complicated the test, the stricter the requirements relating to the test, including the requirements for training and licensing of the laboratory personnel performing the test.

The federal FDA is the entity that determines the complexity of laboratory tests. Waived tests are simple tests with a low risk of incorrect results. They include tests listed in the CLIA regulations, tests cleared by the FDA for home use (such as pregnancy tests), and tests approved for a waiver by the FDA using the CLIA criteria. Tests not classified as waived are assigned a moderate or high complexity category based on seven criteria given in the CLIA regulations, including ease of use, the knowledge required, and types of materials tested. For commercially available FDA-cleared or approved tests, the test complexity is determined by the FDA during the pre-market approval process.

Under both federal and California law, any healthcare personnel providing direct patient care or any person as part of a nondiagnostic health assessment program may perform a waived test in a licensed laboratory. Various licensed professionals and scientists are enumerated through Section 1206.5 of the Business and Professions Code, with additional supervision requirements and testing scope limitations specified for certain licensees. High complexity testing requires more advanced licensure than moderate or waived tests. Generally speaking, California law is more restrictive than the federal requirements in terms of who may perform testing.

There are two types of tests used to detect SARS-CoV-2, the virus that causes COVID-19. The first type is diagnostic tests, which will reveal if an individual has an active coronavirus infection; diagnostic tests include both antigen tests (which detect the presence of certain viral proteins) and molecular tests (which detect viral genetic material). The second type of COVID-19 test is antibody tests, which use a blood sample to detect antibodies that could reveal either an active or a previous infection. Tests for SARS-CoV-2 have been deemed CLIA-waived for the duration of the federal emergency declaration through the FDA's Emergency Use Authorization.

Emergency Waivers for COVID-19 Testing. Executive Order N-25-20, issued just days into the declared emergency on March 12, 2020, waived various statutes and regulations that were found to obstruct the state's nascent pandemic response efforts. Paragraph nine of the Order consisted of the following provision:

> "The certification and licensure requirements of California Code of Regulations, Title 17, section 1079 and Business and Professions Code section 1206.5 are suspended as to all persons who meet the requirements under the Clinical Laboratory Improvement Amendments of section 353 of the Public Health Service Act for high complexity testing and who are performing analysis of samples to test for SARS-CoV-2, the virus that causes COVID-19, in any certified public health laboratory or licensed clinical laboratory."

This executive order substantially broadened the available workforce for individuals to perform analysis of COVID-19 tests. Because California requirements are considered more restrictive than the federal regulations, laboratories utilizing the waiver have been able to utilize professionals who meet federal standards but who would not currently qualify under Section 1206.5. This increased capacity has been essential to California's robust response to the COVID-19 pandemic through the proliferation of testing options.

Because Executive Order N-25-20's authority relied on the active State of Emergency declared by the Governor, it will no longer have the force of law immediately upon the expiration of that declaration. The Governor has stated that the declaration will be terminated on February 28, 2023. However, the formal end of the declared emergency will not mean an end to the need for widely available COVID-19 testing. In his announcement regarding his timeline, the Governor requested statutory changes to ensure "the continued ability of laboratory workers to solely process COVID-19 tests." This bill would effectuate that request by continuing to waive state requirements for individuals analyzing COVID-19 tests who meet the federal requirements for high complexity testing.

COVID-19 Therapeutics. The FDA has authorized two oral antiviral pills for the treatment of mild-to-moderate COVID-19. Paxlovid, developed by Pfizer, is a combination formulation of two protease inhibitor medications: nirmatrelvir and ritonavirhas. Molnupiravir, developed by Merck & Co., is sold under the brand name Lagevrio. Both therapeutics have been shown to prevent hospitalization or death in high-risk patients with mild to moderate COVID-19.

As antiviral therapeutics for COVID-19 became available at the beginning of 2022, the CDPH and other public health entities have pushed to make those treatments accessible, particularly to high-risk patients. Therapeutics have been made free to all Californians, including the uninsured. COVID-19 therapeutics are most effective when taken within days of a patient developing symptoms, so beginning treatment immediately upon receipt of a positive test is the most efficacious way of prevent a patient's condition from becoming more severe.

Despite the effectiveness and wide availability of COVID-19 therapeutics, it was reported in 2022 that the antiviral medications were being underutilized, particularly within low-income communities and communities of color. The CDPH issued a health advisory for California healthcare providers urging a low threshold to prescribe COVID-19 therapeutics. The Governor repeatedly stated that his objective was to "remedy ongoing inequities in therapeutics access."

In May 2022, the CDPH announced that it was upgrading 146 existing testing sites to "Test to Treat" locations where individuals could be seen by a provider and receive a prescription for oral antiviral therapeutics immediately upon testing positive for COVID-19. This initiative was launched as a partnership with OptumServe, a company with existing contracts with the state to provide vaccination and testing site services. The state's program aligned with the Biden Administration's national Test to Treat initiative in the National COVID-19 Preparedness Plan.

Test to Treat sites are located in areas where access to insurance and health services is considered lower. Clinics traditionally serving these populations have not historically had the operational workflows required to coordinate access to therapeutics as part of their testing programs. The OptumServe sites offer antigen testing, telehealth prescribing for COVID-positive patients, and on-site Paxlovid and molnupiravir dispensing.

Pharmacy Waivers. In addition to the Governor's emergency powers under EMSA, the BOP has its own statutory authority to waive provisions of the Pharmacy Law and its implementing regulations. California law provides that "during a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care." This allowed the BOP to quickly waive laws that would have hindered the state's pandemic response independent of either EMSA or the waiver process established through the Governor's executive order.

Because a key aspect of the CDPH's Test to Treat program involves the dispensation of COVID-19 therapeutics, the BOP waived provisions of the Pharmacy Law that would have prohibited those drugs from being stored and dispensed outside of a clinical setting or pharmacy. On April 19, 2022, the BOP issued a limited waiver to the CDPH waiving any statutory restrictions on entities operating a testing site approved by the CDPH to dispense COVID-19 oral therapeutics from state supplies, under the following specified conditions:

1. The Approved Site complies with all conditions of the FDA approval or authorization of the COVID-19 Oral Therapeutic issued under an EUA, guidance of the federal Health and Human Services Agency and the FDA, and applicable federal dispensing laws.

2. The Approved Site complies with all of the required conditions of any agreement or attestation required to be signed by organizations participating in the federal Program.

3. The Approved Site also complies with all guidance and requirements established by CDPH.

The BOP's waiver also required Test to Treat sites to comply with a series of additional requirements relating to drug container labeling, storage, and recordkeeping. The original waiver was scheduled to expire at the end of 2022; the waiver was subsequently extended on December 5, 2022. However, because the BOP's waiver authority remains dependent on an actively declared state of emergency, the authority granted by the board to the CDPH is currently set to expire on February 28, 2023 when the State of Emergency is terminated.

The expiry of the BOP's waiver would mean that patients who receive positive COVID-19 tests at a Test to Treat site would have to be directed to pick up their therapeutics at a nearby pharmacy or through a mail order, which could delay treatment and exacerbate inequities. In light of this, the Governor called in his press release announcing the end of the COVID-19 State of Emergency for statutory changes to preserve "the continued ability of nurses to dispense COVID-19 therapeutics" at Test to Treat sites.

This bill would codify the BOP waiver for purposes of allowing COVID-19 therapeutics such as Paxlovid and molnupiravir to be stored and dispensed at Test to Treat locations. The bill would place into statute the same patient safety requirements as the BOP's waiver. The provision of the bill related to COVID-19 therapeutic dispending would also be subjected to repeal on January 1, 2024, allowing for the Test to Treat program to continue operating under their existing model through the end of the year.

Prior Related Legislation. AB 2107 (Flora, Chapter 956, Statutes of 2022) authorized a person licensed as a clinical genetic molecular biologist scientist to use molecular biology techniques to perform a clinical laboratory test or examination for the detection of any human disease.

SB 1267 (Pan, Chapter 473, Statutes of 2022), added clinical laboratory geneticist scientists and clinical reproductive biologist scientists to the types of clinical laboratory personnel that are licensed and regulated by the CDPH.

AB 526 (Wood, Chapter 653, Statutes of 2021) authorized both dentists and doctors of podiatric medicine to independently prescribe and administer influenza and COVID-19 vaccines and provided additional authority for dentists to administer rapid point-of-care tests for COVID-19.

ARGUMENTS IN SUPPORT:

Quest Diagnostics supports this bill, writing that the Governor's executive order relating to clinical laboratory requirements "was critical to the state's response to the COVID-19 pandemic and enabled the lab community to ensure enough resources were available to support testing demand. Without the flexibility granted by the Executive Order, COVID-19 testing demand would have surpassed lab resources, potentially leaving Californians without timely results to COVID-19 tests which have been key to managing the spread of the virus. Further, there have been no adverse implications to test quality since the Executive Order."

The **California Association of Public Health Laboratory Directors** (CAPHLD) also supports this bill. CAPHLD has suggested that the bill be "broadened to include additional outbreaks that may occur in this time period and beyond" through amendments to allow for similar waivers of state requirements for lab analysis of any "communicable disease that is declared a Public Health Emergency" by the CDPH. However, CAPHLD supports this bill regardless of whether that suggested amendment is made to the bill.

ARGUMENTS IN OPPOSITION:

The **California Association for Medical Laboratory Technology** (CAMLT) opposes this bill. CAMLT writes: "For over 80 years, CAMLT's professional members and the entire clinical laboratory community have and will continue to work to protect the health and welfare of all Californians. Patient safety has always been our highest priority and lowering laboratory standards would be an unsafe and unsound practice."

REGISTERED SUPPORT:

California Association of Public Health Laboratory Directors
California Clinical Laboratory Association
Quest Diagnostics

REGISTERED OPPOSITION:

California Association for Medical Laboratory Technology

Analysis Prepared by: Robert Sumner / B. & P. / (916) 319-3301

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2023 – 2024 COMMITTEE RULES

The Committee shall operate under the most recently adopted Joint Rules of the Senate and Assembly and the Standing Rules of the Assembly. The following Committee procedures and guidelines are designed to further expedite the conduct of Committee business.

Committee hearings are held on Tuesdays at 9:00 a.m. in Room 1100 of 1021 O Street, subject to the discretion of the Speaker. A majority of the Committee membership shall constitute a quorum.

1. WORKSHEET

When a bill (or constitutional amendment or resolution) is referred to the Committee, Committee staff shall forward to the author a worksheet ("Background Information Request") to be completed as part of the preparation of the Committee analysis. To allow Committee staff adequate time to analyze the bill, the completed Committee worksheet and all relevant background information, including updated support and opposition letters, must be provided to the Committee no later than seven (7) calendar days after receipt of the worksheet, and also at least ten (10) calendar days prior to the proposed hearing date. The Committee Chair may decline to set the bill for hearing unless and until the completed worksheet and background materials are provided to the Committee in a timely manner.

2. SETTING BILLS

(a) *Initial Referral to Committee.* No bill may be set, nor file notice published, until it has been referred to the Committee. Once referred, the Committee may set the bill for any available hearing date, at its discretion. [Assembly Rule 56]

(b) *30-Day Waiting Period.* No bill may be heard or acted upon until, after its introduction, it has been in print for 30 days. This rule may be suspended concurrently with the suspension of the requirement of Section 8(a) of Article IV of the California Constitution. [California Constitution Article IV, Section 8(a); Joint Rule 55]

(c) *Notice.* A bill of first reference being heard in the Committee must be published in the Daily File at least four (4) days prior to a hearing. Otherwise, notice shall be published in the Daily File two days prior to the hearing. This requirement can be waived by a majority vote of the Assembly. [Joint Rule 62(a)]

(d) *Three Set Limit.* A bill may be set for hearing in a Committee only three times. A bill is considered "set" when it has been published in the Daily File for one or more days. If the author postpones the hearing of a bill, or submits amendments in violation of Rule 6 below causing the hearing to be rescheduled, such action may count as a set. If the Committee postpones the hearing on the bill for its own reasons, such action shall not count as a set. If the Daily File indicates "testimony only," the hearing does not count as a set. This requirement may be suspended by approval of the Rules Committee and a two-thirds (2/3) vote of the Assembly. [Joint Rule 62(a)]

(e) Setting of Bills by Subject Matter. When, in the judgment of the Chair, more than one bill before the Committee deals with like subject matter, the Chair may schedule such bills to be heard together. [Assembly Rule 56]

3. COMMITTEE ANALYSES

A Committee analysis is required for every bill. Analyses shall be made available to the public at least one working day prior to the hearing, with a working day being defined as any day on which the Assembly Daily File is published. In the case of special meetings, analyses shall be made available to the public at the beginning of the hearing. [Assembly Rule 56.5]

4. ORDER OF AGENDA

(a) *Priority of Authors.* Bills of the Committee members shall be taken up after all other authors present have taken up their measures.

(b) *Consent Calendar.* The Committee consent calendar may be taken up as determined by the Chair.

(c) *Special Orders of Business*. When the Chair finds that another order of business would be more expedient, measures may be taken up out of order or set as a special order of business.

(d) *Author's Representative.* If a bill is to be presented by someone other than the author, it will be taken up after all present authors (including those temporarily "passed over" and Committee members) have been accommodated. The representative must be an Assemblymember or Senator, a member of the author's staff, or staff of an Assembly or Senate committee. No lobbyist, sponsor or supporter of the bill may present the bill before the Committee. Staff or members other than the author will be permitted to present the bill only after the Committee has received written confirmation from the author.

5. CONSENT CALENDAR

(a) *Chair's Recommendation.* The Chair may, prior to a hearing, recommend bills for consideration on the Committee's consent calendar. The proposed consent calendar shall be made available to the public at the same time as the Committee analyses. [Assembly Rule 56.7]

(b) *Removal.* Any member of the Committee may request that a bill be removed from the Committee's consent calendar. Upon such request, the Chair shall remove the bill from

the consent calendar, direct that the author be notified of the change, and place the bill on the Committee's regular calendar.

6. AMENDING BILLS

(a) *Sharing Amendment Requests with the Committee.* When submitting amendments to Legislative Counsel for a bill in the possession of the Committee, or such a bill in the subsequent possession of the Senate or Assembly Floors, the author's office shall provide a copy to the Committee as a courtesy.

(b) *Providing Amendments to the Committee*. Author's amendments in secured Legislative Counsel form, including the "in-context" version of the amendments and background materials, shall be submitted to the Committee electronically no later than 12:00 p.m. noon eight (8) calendar days preceding the scheduled hearing of the bill.

If substantive author's amendments are submitted to the Committee after 12:00 p.m. noon eight (8) calendar days preceding the scheduled hearing of the bill, the bill may be put over, rescheduled for a subsequent hearing and a "set" may be counted against the bill for purposes of Rule 2(d), unless this requirement is waived by the Chair. The Chair shall determine whether or not an amendment is substantive. [Assembly Rule 68]

(c) *Amendments Offered in Committee*. If an author or Committee member offers amendments at the hearing, and the amendments are substantive, the Chair may put the bill over to allow adequate time for Committee staff to reanalyze the bill and provide an updated analysis to the Committee members. The Chair shall determine whether or not an amendment is substantive. Otherwise, the Chair shall generally characterize the amendments being voted upon prior to the roll being called. Committee staff shall be responsible for preparing any amendments adopted in Committee. [Assembly Rules 67 and 68.5]

(d) *Amended Bills in Print.* Except as otherwise provided, a vote on passage of any bill shall be taken only when the bill is in print, including any previously adopted amendments to the bill. When a bill is amended and the amended version is not in print, the Committee may act on the bill only if the Chair determines that the effect of the amendment can be readily understood by all of the members and audience present at the hearing. [Assembly Rule 68.5]

(e) *Amendments to a Two-year Bill*. Author's amendments in Legislative Counsel form should be submitted to the Committee no later than 12:00 p.m. noon on the first Monday in December of the odd-numbered year in order for the bill to be set for hearing, unless this requirement is waived by the Chair.

(f) *Urgency Clauses*. A bill may not be amended to add an urgency clause unless the author of the amendment has secured the prior approval of the Assembly Rules Committee. Adoption of an urgency clause amendment requires a majority vote by the Committee. [Joint Rule 58]

(g) *Germaneness*. An amendment or substitute must relate to the same subject as the original bill. [Joint Rule 9]

7. MEETINGS

(a) *Open Meetings*. All Committee meetings, except for an authorized closed session, shall be open and public, and all persons shall be allowed to attend the meetings. [Assembly Rule 11.3(a)]

(b) *Time and Place*. The Committee shall meet at its regularly scheduled time, unless otherwise permitted by the Speaker. [Assembly Rule 56]

(c) *Special Meetings*. A special meeting shall be held in an area readily accessible to the public and not in the Assembly Chamber during Floor Session, and the Committee shall take care that every effort is made to inform the public that a meeting has been called. [Assembly Rule 56]

(d) *Direction of Discussion*. The Chair shall direct the discussion of matters under consideration by the Committee.

i. The Chair may permit questions to be asked by the members of the Committee in an orderly and efficient fashion and in keeping with proper decorum.

ii. A member who desires to address the Committee or ask questions of a witness shall first signal or respectfully address the Chair. Upon being recognized by the Chair, the member may speak, confining any remarks or questions to the merits of the matter under consideration by the Committee.

(e) *Limits on Testimony*. When it is necessary, due to the number or complexity of the bills on the agenda at a hearing, to limit testimony on one or more of the bills in order to ensure that all of the bills on the agenda have a fair and reasonable opportunity to be presented by the author and heard and discussed by the Committee, the Chair may do any or all of the following:

i. limit duplicative testimony;

ii. limit the number of witnesses appearing in support or opposition to a bill; and

iii. limit the time allotted to the presentation of testimony on a bill provided that both support and opposition receive equal time for their presentation.

(f) *Restrictions on Chair*. The Chair shall not preside at a hearing on a bill if the Chair is the sole author or the lead author of the bill. [Assembly Rule 60]

(g) *Role of Vice-Chair*. If, at a hearing commenced by the Chair, the Chair is not present or otherwise is presenting a bill to the Committee, the Vice-Chair shall temporarily preside. If the Vice-Chair is absent when the Chair must also be absent, the Chair may designate another Committee member to temporarily assume duties.

8. VOTING

(a) *Quorum*. A majority of the Committee membership constitutes a quorum. A quorum is necessary to take action or to adopt amendments. [Assembly Rule 57, Joint Rule 62(c)]

(b) *Vacancies & Disqualification*. Any vacancy on the Committee shall not reduce the number of votes required to take action on a bill. If a member is disqualified from voting, there shall be no change in the quorum requirements or the number of affirmative votes required to report a bill out of Committee. A disqualified member shall advise the Chair of the disqualification, and the Chair shall announce which members are so disqualified at the commencement of the hearing of the bill. [Assembly Rule 57, Joint Rule 44]

(c) *Call of the Committee*. The Chair may, at any time, order a call of the Committee. If requested by any member of the Committee or the author of the bill under consideration, the Chair shall order a call. In such a case, the Chair shall send the Sergeant-at-Arms for those members who are absent and not excused by the Assembly. A quorum call or a call of the Committee with respect to a particular bill may be dispensed with by the Chair without objection by any member of the Committee, or by a majority of the members present. The Chair may adjourn the hearing after a previously announced period of time has elapsed without the arrival of a member of the Committee or the author of a bill on the agenda. [Joint Rule 62(d)]

(d) *Operation as a Subcommittee*. If a quorum is not present, the Chair may commence the hearing as a subcommittee and receive testimony on any scheduled bill.

(e) *Voting on Bills*. A majority of the Committee membership is required to report a bill out of Committee. Committee action on bills, including reconsideration, shall be by roll call vote, and shall show all votes for and against, all members absent, and all members not voting. In the case of a tie vote, a motion fails. The final action of the Committee shall be announced by the Chair. [Assembly Rules 57, 58.5 and 107]

(f) *Voting on Amendments*. A quorum is required for there to be a vote on amendments. A roll call vote is required to adopt amendments in Committee. Amendments shall be approved by a majority of those present and voting. [Assembly Rules 57 and 67]

(g) *Substitution of Prior Roll Call*. The Committee may, upon unanimous consent of the members present, substitute a prior roll call, provided that the members whose votes are substituted are present at the time of the substitution. [Joint Rule 62(c)]

(h) *Making of Motions*. A member who desires to make a motion shall first obtain recognition by the Chair. The member shall then open by stating the motion, and may not speak to the merits of the motion at that time, but shall confine any remarks to those necessary to explain the motion. If the motion is in order and is seconded, the Chair shall state such to the Committee. If the motion is debated, the Member who made the motion shall be recognized to open debate on the motion.

(i) *A Second to a Motion*. Except as otherwise provided, a motion shall require a second.

(j) *"Without Objection" Motions*. A second is not required where the Chair makes a motion that begins with the words "without objection." If any member objects, the motion is automatically withdrawn.

(k) *Keeping the Roll Open*. The roll shall be kept open at the request of an author or any member of the Committee until adjournment of the Committee hearing. In the absence of objection, the roll shall be kept open at the request of an author or any member of the Committee until adjournment of the committee hearing. [Assembly Rule 58.5]

(l) *Vote Adds and Changes*. Once the roll is closed and the final vote on a motion is announced, any member of the Committee may change or add a vote to the roll prior to adjournment of the hearing, unless the change or addition would affect the outcome of the motion. [Assembly Rule 55, Assembly Rule 106]

9. RECONSIDERATION

(a) *Single Opportunity*. Reconsideration of a bill may be granted only one time. [Joint Rule 62(a)]

(b) *Motion Requirements*. A motion to reconsider can be made only under the following circumstances:

i. At the same meeting at which the bill is passed or defeated and the author is present; or,

ii. Within 15 legislative days of the meeting at which the bill was defeated or prior to the interim study joint recess, whichever occurs first, in which case the same file notice is required as for setting a bill. [Joint Rule 62(a)]

(c) *Notice of Reconsideration*. Authors seeking reconsideration under Rule 9(b)(ii) above shall notify the Committee secretary in writing in order that notice of reconsideration may be published in the Daily File.

(d) *Vote Required for Reconsideration.* A majority vote of the Committee is required to grant reconsideration (same as a quorum). These requirements may be suspended with the approval of the Assembly Rules Committee and two-thirds (2/3) vote of the Assembly. [Assembly Rule 57.1, Joint Rules 62(a) and 62(c)]

(e) If there is no objection, reconsideration can be granted by unanimous consent; however, if any Member objects, a roll call vote shall be recorded. [Assembly Rule 57.1, Joint Rule 62(a), Mason's Manual section 39]

10. INTERIM STUDY & INFORMATIONAL HEARINGS

(a) *Interim Study*. The Committee may refer the subject matter of any bill not given a do pass recommendation to the Rules Committee for interim study. The Committee may, however, subsequently reconsider and act on the bill. [Assembly Rule 59]

(b) *Informational Hearings*. The Chair may call the Committee to sit during interim or recess to conduct public hearings, gather information, discuss proposed legislation, or for any other proper purpose, conditioned on the approval of the Speaker and publication of the appropriate four-day file notice. [Assembly Rule 59; Joint Rule 60(b)]

(c) *Geographic Restriction*. Informational and oversight hearings outside of Sacramento are permitted during recesses, but the Committee may not act on a bill outside of Sacramento. [Joint Rule 60]

11. LETTERS OF SUPPORT AND OPPOSITION

(a) *Letter Deadline*. Letters communicating a formal position on a bill (support, opposition, concerns, etc.) must be received by the Committee by 5:00 p.m. seven (7) calendar days preceding the scheduled hearing of the bill in order for the position to be referenced in some form in the analysis. Letters received after that time may be referenced at the discretion of the Committee.

(b) *Letter Requirements*. Position letters must be signed, on organizational letterhead where possible, and include the name and mailing address for the organization or individual expressing the position. Letters may be submitted to the Committee via online portal/committee website, by hand, via regular mail or email attachment, provided that the other requirements of this Rule are met. Additional requirements for the submission of letters regarding a specified bill may be instituted at the discretion of the Chair.

(c) *Updated Letters*. Position letters must reference the most current version of the bill being heard before the Committee. Individuals and organizations wishing to withdraw or update a previous position letter must communicate that information to the Committee in writing at least seven (7) days prior to the hearing. Letters in the possession of the Committee which are not addressed to the Committee, or which reference a prior version of a bill and have not been otherwise withdrawn, may be included at the discretion of the Committee if it deems the letter to have continuing relevance.

(d) *Conditional Letters.* Letters indicating that an organization or individual is "opposed unless amended" to a bill will result in the organization or individual being listed as opposed to the bill. Letters indicating that an organization or individual has taken a "support if amended" position on a bill and neutral letters reflecting concerns or suggested amendments will not result in an organization or individual being listed in the analysis unless the Committee determines that there would be substantial value in doing so. Any letters submitted to the Committee may be referenced in the body of the analysis of the bill at the Committee's discretion.

12. SUNRISE QUESTIONNAIRE

(a) *New Agency or License Plan Requirements*. Prior to hearing any bill or other measure that proposes to create a new state board or a new category of licensed or regulated professional, the Chair may require the author or sponsor of the legislation to develop a plan for the establishment and operation of the board or category in accordance with the requirements of Government Code Section 9148, *et seq*.

(b) *Sunrise Questionnaire*. In addition, for any legislative proposal to create a new board, category or professional subject to state regulation, the Chair may require the author of the legislation to complete and return the Committee's occupational regulation proposal questionnaire ("Sunrise Questionnaire").

(c) *Questionnaire Deadline*. The Chair may require the author of the legislation to return the plan and completed questionnaire to the Committee at least seven (7) days prior to the proposed hearing of the bill, and also to provide copies to any state agency in which the new regulatory program or category would be located, and any known interested parties that would be affected by the proposal.

(d) *Incomplete or Untimely Questionnaires*. If, in the opinion of the Chair, any of these requirements have not been met, the hearing of the bill may be rescheduled or canceled.

13. FEE QUESTIONNAIRE

(a) For any legislative proposal to increase licensing fees or to raise statutory fee caps for licensing entities, the Chair may require the author of the legislation to complete and return the Committee's "Fee Questionnaire."

(b) *Questionnaire Deadline*. The Chair may require the author of the legislation to return the questionnaire to the Committee no fewer than seven (7) days prior to the proposed hearing of the bill, and also provide copies to any state entity or interested parties that would be affected by the proposal to increase fees or raise statutory fee caps.

14. PUBLIC RECORDS

(a) *Public Records*. The Secretary is the custodian of the Committee's legislative records. The Secretary shall preserve the Committee's current legislative records and may store the Committee's past legislative records with the State Archives. The legislative records contained in an official Committee file that are in the possession of the Secretary are open to inspection and reproduction by the public in the Committee office by appointment during normal working hours, subject to Assembly requirements. The records held in the State Archives are open to inspection and reproduction pursuant to the procedures established by the Secretary of State.

15. REVIEW OF ADMINISTRATIVE REGULATIONS

(a) *Review of Regulations Within Jurisdiction.* At the discretion of the Speaker, the Chair may direct Committee staff to review any proposed administrative rules and regulations

which are contained in the California Regulatory Notice Register and which pertain to agencies and programs within the scope of the Committee's jurisdiction. [Joint Rules 37.7 and 40.1]

(b) *Taking Action*. If so directed, Committee staff shall review each such rule or regulation for conformity with the enabling statute and with legislative intent. Rules or regulations which do not appear to be based on statutory authority or which do not appear to be consistent with legislative intent may be placed on the Committee's agenda for appropriate action, including but not limited to the request of a priority review by the Office of Administrative Law pursuant to Government Code Section 11340.5.

16. COMMITTEE BILLS

(a) *Requirements.* The Committee may introduce a bill germane to any subject within the proper consideration of the Committee in the same manner as any member. A majority of the members of the Committee, including the Chair, must provide written confirmation of intent to author a committee bill. [Assembly Rule 47(f)]

(b) *Naming of Authors.* If all members of the Committee agree to author a bill, at the option of the Chair, the committee members' name need not appear as authors in the heading of the printed bill.

(c) *Consolidation.* The Committee, at the discretion of the Chair, may consolidate related subject matter into a single legislative proposal whenever appropriate.

17. OMNIBUS BILLS

(a) *Requirements.* The Committee may introduce one or more omnibus bills germane to any subject within the proper jurisdiction of the Committee. Any such omnibus bill shall include only provisions determined by the Committee to be technical, non-substantive, or otherwise non-controversial. In the event that a provision included in the bill is later deemed by the Chair to be controversial, or upon the request of any member of the Committee, it shall be deleted from the bill.

(b) *Naming of Authors.* If all the members of the Committee agree to author a bill, at the option of the Chair, the Committee members' names need not appear as authors in the heading of the printed bill.

18. PILOT PROJECTS

(a) *Requirements*. Any bill that proposes the creation of a pilot project shall, if so requested by the Chair, include with the background materials information to the following effect, as a condition of being set for hearing:

i. A statement of purpose of the proposed pilot project which specifies the goals or objectives, and the length of time of the project;

ii. Precise cost projections and methods by which savings, if any, may be calculated; and

iii. A definitive mechanism by which the value and success, if any, of the project may be quantified. This mechanism shall include specific numerical objectives that must be met or exceeded, if a project is to be judged successful, and a suggested timeline.

19. RULES

(a) *Amendment of the Rules*. These rules may be suspended or changed, or additional rules adopted, by a majority vote of the Committee consistent with the Joint Rules and the Rules of the Assembly.

(b) *Mason's Manual*. In all cases not provided for by these rules, the most recently adopted Assembly or Joint Rules, or by statute, the authority shall be the most recent edition of Mason's Manual. [Joint Rule 31]

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