ENATE JUDICIARY COMMITTEE
Senator Thomas Umberg, Chair
2025-2026 Regular Session

AB 1103 (Ward)
Version: June 27, 2025
Hearing Date: July 8, 2025
Fiscal: Yes
Urgency: No
AM

SUBJECT

Controlled substances: research

DIGEST

This bill expands the sunset date on the authorization for the Research Advisory Panel of California (RAPC) to meet in closed session and be considered an advisory body under the Bagley-Keene Open Meeting Act (Bagley-Keene) by one year to January 1, 2028. The bill authorizes expedited review of research projects, as specified, and provides that panel members assigned to conduct such expedited review are not a state body for purposes of Bagley-Keene. The bill makes other changes to how RAPC reviews and approves research projects in the state, including the authority to withdraw approval for reasonable cause.

EXECUTIVE SUMMARY

RAPC authorizes applications for research projects concerning cannabis or hallucinogenic drugs, or the treatment of the abuse of controlled substances in the state. In August of 2023, RAPC identified an alleged conflict in existing law—mainly that they are subject to the Bagley-Keene Open Meeting Act (Bagley-Keene)—which they asserted they could not comply with without violating other existing statutes relating to confidential and proprietary information. Prior to August of 2023, RAPC had solely met in closed session. As a consequence of RAPC refusing to meet, research in the state was plunged into chaos, and a major backlog of applications for research projects sat pending approval. As a result of this, the Legislature authorized RAPC to meet in closed session to review and approve research applications until January 1, 2027. During this chaos, stakeholders raised several issues and concerns with the current process of RAPC approval to the Legislature. This bill seeks to make changes to the process in which RAPC reviews and approves research projects. The provisions of the bill in this Committee's jurisdiction relate to the limitation on the access to open meetings under Bagley-Keene. The bill is sponsored by Veterans Exploring Treatment Solutions and supported by several other organizations, including the California

Medical Association, the California Pharmacists Association, and advocates for veterans. No timely opposition was received by the Committee. The bill passed the Senate Health Committee on a vote of 11 to 0.

PROPOSED CHANGES TO THE LAW

Existing law:

1) Provides, pursuant to the California Constitution, that the people have the right of access to information concerning the conduct of the people's business, and, therefore, the meetings of public bodies and the writings of public officials and agencies are required to be open to public scrutiny. (Cal. const. art. I, § 3(b)(1).)
    a) Requires a statute to be broadly construed if it furthers the people's right of access, and narrowly construed if it limits the right of access. (Cal. const. art. I, § 3(b)(1).)
    b) Requires a statute that limits the public's right of access to be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest. (Cal. const. art. I, § 3(b)(1).)

2) Establishes the Bagley-Keene Act, which requires state bodies to conduct their business in open public meetings, except as provided by the Act, and establishes requirements and procedures for such meetings. (Gov. Code §§ 11120 et seq.)[1]
    a) "State bodies" covered by Bagley-Keene include: every state board; commission or body created by statute or required by law to conduct official meetings; every commission created by executive order; any board or body exercising the authority of a state body by delegation; any advisory body created by formal action of a state body; any state body that is supported by public funds and on which a member of a state body serves in their official capacity; and the State Bar of California. (Gov. Code § 11121.)
    b) "State bodies" do not include specified legislative agencies, agencies subject to the Brown Act, and certain educational and health-related agencies. (Gov. Code § 11121.1.)

3) Authorizes state advisory boards and similar advisory bodies to hold a meeting via teleconference, without posting a member's remote location on the agenda or having the location that the member is participating from accessible by the public, if it complies with specified requirements. (Gov. Code § 11123.5)

4) Establishes the Research Advisory Panel of California (RAPC) as an independent panel to encourage further research into the nature and effects of cannabis and hallucinogenic drugs and to coordinate research efforts on such subjects.

[1] All further references are to the Government Code unless specified otherwise.

a) Authorizes RAPC to approve research projects, which have been registered by the Attorney General (AG), concerning cannabis or hallucinogenic drugs, or the treatment of abuse of controlled substances in the state. Authorizes RAPC to withdraw approval of a research project at any time.
b) Authorizes RAPC to hold hearings on, and in other ways study, research projects concerning cannabis or hallucinogenic drugs and the treatment of abuse of controlled substances. (Health & Saf. Code §11480 & 11481.)

5) Requires RAPC to, annually and in a manner it determines, report to the Legislature and the Governor those research projects it approved, the nature of each research project, and the conclusions of the research project, where available. (Health & Saf. Code §§ 11480(g) & 11481.)

6) Provides that RAPC is considered a multimember advisory body solely for the purposes of 3), above. Repeals this provision on January 1, 2027. (Health & Saf. Code § 11480.5.)

7) Requires RAPC to provide a report to the Legislature on or before January 1, 2026, that provides an update on the backlog of applications that includes, at minimum, the number of backlog applications that have been reviewed and how many are still pending review. (*Ibid*.)

8) Authorizes, until January 1, 2027, RAPC to hold a closed session meeting for purposes of discussing, reviewing, and approving research projects, including applications and amendment applications, that contain sensitive and confidential information, including, but not limited to, trade secrets, intellectual property, or proprietary information in its possession, the public disclosure of which is prohibited by law. (Gov. Code § 11126(a)(20).

This bill:

1) Revises the duties and responsibilities of RAPC to require RAPC to review, and authorizes RAPC to approve, research projects to be conducted in this state that require the administration of Schedule I or Schedule II controlled substances, or both, to human and animal research subjects. Authorizes the panel to withdraw approval from a research project for reasonable cause, as provided.
    a) Requires RAPC to inform the Attorney General of the head of the approved research projects that are entitled to receive quantities of cannabis, as specified.
    b) Requires the Attorney General, in order to ensure continuity, to continue to employ an Executive Officer of the panel and necessary employees, whose duties shall include, but not be limited to, coordinating with the panel's

Chairperson to assign incoming research project applications for review or approval by individual panel members with relevant core competencies.

2) Authorizes RAPC to expedite the review of completed and timely applications that include both of the following:
    a) Proof of independent peer review of the study for scientific merit and rigor by the National Institutes of Health, the United States Department of Defense, the Heffter Research Institute, the United States National Science Foundation, or a comparable group within an institutional setting that has previous experience with research or grant review.
    b) For research projects involving human subjects, an approval letter from an institutional review board established in accordance with federal law demonstrating that the board's evaluation of the underlying research protocol has considered relevant federal and state laws regarding the use of human subjects. For research projects involving animal subjects, an approval letter from an institutional animal care and use committee (IACUC) established pursuant to federal law demonstrating that the IACUC has considered relevant federal and state laws regarding the use of live, vertebrate animals in the research project, and their humane treatment.

3) Specifies that research projects that do not satisfy the criteria set forth 2), above, must be reviewed pursuant to the standard review process, as provided.
    a) Provides that the panel's process for conducting expedited review and its criteria for approving research projects described in subdivision 2), above, is to be published on the RAPC's website.
    b) Requires any rules or regulations related to the panel to be formulated by the Attorney General in collaboration with the Chairperson of RAPC.
    c) Requires information on whether or not a research projects was approved under this expedited review to be included in an existing annual report to the Legislature.

4) Authorizes the Chairperson of RAPC, in consultation with the Executive Director, to assign two or more individual members of RAPC to conduct an expedited review of eligible research applications and deputize those members to approve those applications on behalf of the panel without the need for a full panel vote at a regularly scheduled meeting of RAPC.
    a) Assigned panel members have the authority to approve research project applications eligible for expedited review that also satisfy the criteria for approval published on the panel's website.
    b) Individual panel members are authorized to communicate and consult asynchronously with other individual panel members with complementary core competencies outside of panel meetings in order to conduct their individual reviews.

c) Panel members assigned to conduct an expedited review pursuant to these provisions are not a state body under Bagley-Keene.
d) Panel members must notify the Chairperson and Executive Officer of RAPC of their decision to approve or withhold approval of the eligible research applications assigned for their review.

5) Repeals the provisions in 2) through 4), above, on January 1, 2028.

6) Extends the sunset date on the provision that provides RAPC is to be considered a multimember advisory body solely for the purposes of Bagley-Keene to January 1, 2028.

COMMENTS

1. Stated need for the bill

The author writes:

> AB 1103 would expedite State review and approval (performed pursuant to existing law by the Research Advisory Panel of California in the Attorney General's office ("RAP-C") since 1968) of federally-sanctioned drug trials and other clinical research projects that study the potential medical uses of Schedule I and II controlled substances conducted at California institutions.
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> This includes clinical trials administering psychedelic compounds to treat opioid use disorders, other substance use disorders, traumatic brain injury, post-traumatic stress disorder, major depressive disorder, generalized anxiety disorder and other mental health conditions fueling the disproportionate incidence of suicide among California veterans and daily rates of suicide among Californians generally. According to a January 2025 report by the California Department of Public Health Office of Suicide Prevention, suicide is "the leading cause of violent death" in the state, and a "major preventable public health concern in CA that can have both immediate- and long-term emotional and economic impacts on individuals, families, and entire communities."
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> As these clinical trials are prerequisites to developing new and more effective Food and Drug Administration (FDA)-approved treatments for these conditions, eliminating all unnecessary delays in commencing such clinical research in California will expedite the availability of these treatments, and save lives that could otherwise be lost due to effective treatments arriving too late.

2. Background on RAPC

Research entities seeking to conduct research projects concerning cannabis or hallucinogenic drugs or regarding the treatment of abuse of controlled substances in California are required to submit their research proposals or applications to RAPC prior to receiving a federal Drug Enforcement Agency (DEA) license to use controlled substances in the research project. These research projects may be affiliated with public and private research universities, as well as private pharmaceutical companies, drug manufacturers, or other private entities. RAPC evaluates the scientific validity of each proposed project, and is authorized to reject proposals if the panel decides the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of human subjects in California to the risk of the proposed controlled substance exposure.

RAPC was created by the Legislature in 1972. Members of the panel are required to have expertise in certain fields, and are appointed by various appointing authorities including: the Governor, the Department of Public Health, the State Board of Pharmacy, the University of California, a statewide professional medical society, a private university, and the Attorney General. The Department of Justice (DOJ) provides administrative and legal support to the RAPC. (Health & Saf. Code § 11480.) The Senate Health Committee analysis of this bill states that "RAPC's work complements a regulatory approval process that includes Institutional Review Boards (IRBs), the Federal Drug Administration (FDA), and DEA review of controlled substance research studies using Schedule I and II controlled substances, or that involve new treatments for misuse of substances, such as fentanyl and other opioids. While the FDA and DEA are government institutions, IRBs are institutional entities registered with the FDA and charged with providing ethical oversight of research involving human subjects."

In August of 2023 RAPC ceased meeting to approve research proposals. RAPC's refusal to meet created havoc in the research community, with repercussions including loss of grant funds and the trickledown effects of this on staffing at research entities, and important research being stymied. Additionally, it created a backlog of research applications pending approval.

The exact facts of what lead to RAPC choosing to no longer meet was not and is still not entirely clear to Committee staff. The situation was presented to staff as a purported conflict in existing law that was realized in late 2023. Specifically, the conflict is that RAPC is likely subject to Bagley-Keene, and therefore is required to meet openly when meeting to approve research projects, which it had never done in the entirety of its existence. However, RAPC was arguing that it could not meet publically due to other laws related to protection of proprietary and confidential information, specifically pointing to provisions in the Evidence Code. A Los Angeles Times article in May of 2024 reported:

> The panel had long met behind closed doors to make its decisions, but concerns arose last year that it was supposed to fall under the Bagley-Keene Act, a state law requiring open meetings. Holding those meetings in public, however, raised alarm about exposing trade secrets and other sensitive information. So the panel stopped meeting at all. It has not convened since August. Meetings ordinarily scheduled for every other month have been canceled since October. The result has been a ballooning backlog: As of early May, there were 42 new studies and 28 amendments to existing projects awaiting approval, according to state officials.[2]

Committee staff analyzed the statutes under Bagley-Keene and recently enacted legislation and concluded that there had been no recent change to Bagley-Keene that created the purported conflict. In 2001 Bagley-Keene was overhauled and expanded what state entities were required to meet under its provisions through AB 192 (Canciamilla, Ch. 243, Stats. 2001). It is conceivable that prior to AB 192, RAPC would not have met the definition of state body under Bagley-Keene in Section 11121 of the Government Code. However, since 2001 the only substantive change made to that section was to include the California State Bar under the definition of a state body. Committee staff ultimately concluded that if RAPC was required to meet under Bagley-Keene it has been required to do so since at least 2002 when AB 192 would have become operative. If there was indeed, a conflict under existing law preventing RAPC from meeting it has existed for over 20 years.

To address the issues raised by RAPC refusing to meet, AB 2841 (Waldron, Ch. 156, Stats. 2024) was enacted by the Legislature. AB 2841 did several things, specifically it:

- authorized RAPC to hold closed session meetings to discuss, review, and approve research projects, including applications and amendment applications, that contain sensitive and confidential information, including, but not limited to, trade secrets, intellectual property, or proprietary information in its possession, the public disclosure of which is prohibited by law;
- authorized RAPC to meet as an advisory body under Bagley-Keene, which has less stringent meeting requirement than those for state bodies;
- required RAPC to provide a report to the Legislature, on or before January 1, 2026, that provides an update on the backlog of applications that includes, at minimum, the number of backlog applications that have been reviewed and how many are still pending review; and
- repeals these provisions on January 1, 2027.

The purported purpose of the authorization to meet as an advisory body was to assist RAPC in addressing the backlog of applications that arose from its refusal to meet.

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[2] Emily Alpert Reyes, *Bill could end holdup for California research on psychedelics and addiction treatment*, L.A. Times (May 7, 2024), available at https://www.latimes.com/science/story/2024-05-07/california-bill-could-end-holdup-for-studies-on-psychedelics-and-addiction-treatment.

3. Public access to the open meetings is a constitutional and statutory right

In 2004, the right of public access was enshrined in the California Constitution with the passage of Proposition 59 (Nov. 3, 2004, statewide gen. elec.),[3] which amended the California Constitution to specifically protect the right of the public to access and obtain government records: "The people have the right of access to information concerning the conduct of the people's business, and therefore the meetings of public bodies and the writings of public officials and agencies shall be open to public scrutiny." (Cal. Const., art. I, sec. 3 (b)(1).) The California Constitution requires a statute to be broadly construed if it furthers the people's right of access and narrowly construed if it limits the right of access, and requires a statute that limits the public's right of access to be adopted with findings demonstrating the interest protected by the limitation and the need for protecting that interest. (Cal. const. art. I, § 3(b)(1).)

Bagley-Keene generally requires state bodies to conduct their meetings openly and make them accessible to the public. The first section of Bagley-Keene lays out the public policy of the act, stating:

> It is the public policy of this state that public agencies exist to aid in the conduct of the people's business and the proceedings of public agencies be conducted openly so that the public may remain informed. In enacting this article the Legislature finds and declares that it is the intent of the law that actions of state agencies be taken openly and that their deliberation be conducted openly.
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> The people of this state do not yield their sovereignty to the agencies which serve them. The people, in delegating authority, do not give their public servants the right to decide what is good for the people to know and what is not good for them to know. The people insist on remaining informed so that they may retain control over the instruments they have created. (§ 11120.)

A state body includes boards, commissions, committees, councils, and any other public agencies created by state statute or executive order, with some exceptions, and the State Bar. (§ 11121.) The law does not apply to individual officials, advisory committees with no decision-making authority, or the California State Legislature. The law also requires state bodies to provide advance notice of their meetings and agendas and to allow public comments on matters under consideration. (Gov. Code § 11125.) Bagley-Keene allows state bodies to meet in closed sessions for the purposes of discussing personnel issues, pending litigation, or real estate purchases. (§ 11126.) Additionally, there are several authorizations to meet in closed session granted to specific state bodies for certain reasons or purposes, such as to protect the information being discussed. (*Id.*)

[3] Prop. 59 was placed on the ballot by a unanimous vote of both houses of the Legislature. (SCA 1 (Burton, Ch. 1, Stats. 2004))

State bodies must provide at least ten days' notice before a meeting, specifying the time and location, and post an agenda containing a brief description of each item to be discussed or acted upon. (§ 11125.) The agenda must be made available to the public, and state bodies cannot discuss or take action on items not listed on the agenda, with limited exceptions for emergency situations. (§ 11125.) State bodies must conduct their meetings openly, ensuring that members of the public can attend and participate without any restrictions based on race, gender, disability, or other discriminatory factors. (§ 11123.) Bagley-Keene also requires state bodies to provide reasonable accommodations for individuals with disabilities, ensuring accessibility to meetings and materials. (§ 11123.1.) The public has the right to address state bodies on any agenda item before or during the meeting. (§ 11125.7.) State bodies must provide opportunities for public comment and cannot prohibit criticism of their policies, procedures, or actions. (*Id.)* They may, however, impose reasonable time limits on public comments to maintain order and facilitate the conduct of business. (*Id*. at subd. (b).)

4. This bill limits access to public meetings

This bill seeks to extend the sunset date from January 1, 2027, to January 1, 2028 for both the authorization for RAPC to hold closed session meetings to approve research applications and the authorization to meet as an advisory body under Bagley-Keene. The bill also provides that RAPC members assigned by the Chairperson to conduct expedited review of applications are not a state body for purposes of Bagley-Keene. Under the bill, certain research projects would be eligible for expedited review for approval of their applications. The review and approval of these projects would not need to be noticed to the public or agenized on any meeting of RAPC, nor would public comment be required to be taken. The author argues this is necessary to eliminate delays in commencing such clinical research in California. The bill states that the limitation on access to public meetings is necessary to: allow RAPC to conduct its review and approval of research studies in a quick manner; protect the privacy of subjects; and maintain the confidentiality of proprietary data, trade secrets, potential intellectual property, or other information, the public disclosure of which is prohibited by state or federal laws, or both, and regulations.

The backlog in applications at RAPC is largely due to the refusal of RAPC to meet, as described above. The Committee may wish to consider whether granting further exemptions for RAPC to Bagley-Keene to allow for "quick review and approval" of research applications when the delay was largely self-inflicted by RAPC, is warranted.

5. Amendment

The author has agreed to take the following clarifying amendment to ensure that the provision in Section 11121.1 of the Government Code that exempts RAPC members conducting expedited review from Bagley-Keene becomes inoperative on the same date that the authority for expedited review sunsets, which is January 1, 2028.

6. Statements in support

The California Medical Association writes in support, stating:

> […] This bill would expedite State review and approval of federally sanctioned drug trials and other clinical research projects that study the potential medical uses of Schedule I and II controlled substances conducted at California institutions. AB 1103 also extends the sunset date for the Bagley-Keene Open Meetings Act exemption to 2028 for the Research Advisory Panel of California.
> As clinical trials are prerequisites to developing FDA-approved psychedelic treatments for conditions such as post-traumatic stress disorder and major depressive disorder, eliminating unnecessary delays in commencing such clinical research in California will help expedite the availability of these treatments and save lives that might otherwise be lost while waiting for access to effective therapies. CMA fully supports the further study of the therapeutic application of psilocybin/psilocin and related psychedelic substances, and supports efforts to decrease regulatory burdens that delay clinical research on the therapeutic use of these substances. […]

SUPPORT

California Civil Liberties Advocacy
California Medical Association (CMA)
California NORML
California Pharmacists Association
Compassionate Veterans
Courage California
Heroic Hearts Project
Navy Seal Foundation
Smart Justice California, a Project of Tides Advocacy
The American Legion

OPPOSITION

None received

RELATED LEGISLATION

Pending Legislation: None known.

Prior Legislation: AB 2841 (Waldron, Ch. 156, Stats. 2024), among other things authorized RAPC to hold closed session meetings to discuss, review, and approve research until January 1, 2027.

PRIOR VOTES

Senate Health Committee (Ayes 11, Noes 0)
Assembly Floor (Ayes 75, Noes 0)
Assembly Appropriations Committee (Ayes 15, Noes 0)
Assembly Health Committee (Ayes 16, Noes 0)
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