Analysis and Commentary on California's End-of-Life Option Act, in two versions

SB 128, End-of-Life Options Act, introduced to the California Senate in January 2015, mirrored the Oregon and Washington "Death with Dignity" statutes closely, with some additional specificity relevant to California's legal landscape and to pre-emptively respond to common critiques. ABX2 15, submitted in the special session after SB 128 failed to advance in the regular session, is nearly identical to SB 128, with a few important changes and amendments, detailed below. Notably, it included all the necessary compliance forms and regulatory requirements to expedite implementation without requiring a rule-making process in the Department of Health. If passed through both chambers and signed, the bill will go into effect January 1, 2016. In a late amendment, the law will sunset automatically, unless some other law is passed to extend it, on January 2, 2026.

General Summary of the Bills' Provisions

In general outline, the bills propose to create a process whereby physicians are protected from liability for prescribing life-ending medications to adult residents of California with mental capacity and a terminal condition ("qualified individuals" or QI).

In this process, the QI must:

- Be 18, a resident of the state of California, and mentally and physically capable of self-administering the medication;
- Have mental capacity to make healthcare decisions;
- Have a medically confirmed terminal disease which will likely cause death within 6 months;
- Make two oral requests, at least 15 days apart, and one written, witnessed request for life-ending medication directly to their attending physician;
- Be seen by a consulting physician and, if needed to rule out mental disorder impairing judgement, a qualified mental health provider;
- Complete and sign a final attestation form within 48 hours of ingesting the medications.

The QI's attending physician must:

- Make the terminal diagnosis;
- Determine that the QI has mental capacity, is making the request voluntarily, and is not suffering from impaired judgement due to a mental disorder;
- Communicate to the QI the diagnosis, expected prognosis of less than 6 months, risks and probable results of taking the life-ending medications, possibility that the QI may choose not to take the drugs and may rescind request at any time, feasible alternatives or additional treatment options including hospice and palliative care and pain control;
- Confirm residency of the QI in the state by specified means;
- Confirm that QI is acting voluntarily by talking with them outside presence of any other persons other than qualified interpreter if needed;
- Provide a professional interpreter if needed;
- Refer the QI to a consulting physician and, if there are any indications of mental disorder, to a qualified mental health professional;
- Receive and document two oral requests for the life-ending medications, at least 15 days apart, and one written, witnessed request no less than 48 hours prior to writing the prescription, and a

final attestation from the QI as to voluntariness of the request and informed consent within 48 hours of the QI's ingesting the medications;
- Document all process steps in QI's medical record, complete and submit compliance forms to the state within 30 days of writing the prescription and another follow-up form within 30 days of the QI's death from any cause.

The consulting physician must:
- Physically examine QI and QI's medical records;
- Confirm terminal diagnosis and prognosis;
- Confirm absence of mental disorder impairing judgement (or, if present, refer QI to mental health professional);
- Verify QI has mental capacity and is acting voluntarily;
- Submit compliance forms to the state.

The mental health professional, if consulted, must:
- Confirm that QI does not have a mental disorder impairing judgement. If QI does have a mental disorder impairing judgment, no prescription for life-ending medication can be written until mental disorder resolved.

Witnesses (2) to the written request must attest that they believe QI has voluntarily signed request, is "of sound mind and not under duress, fraud, or undue influence." Only one of the witnesses is required to NOT be related to the patient by blood, marriage, registered domestic partnership, or adoption, or entitled to any portion of QI's estate; or own, operate, or be employed at a healthcare facility where the QI is receiving care or residing. Neither witness can be the attending physician, consulting physician, or mental health professional involved in the process, and none of these persons can be related to the QI by blood, marriage, etc. or entitled to any portion of their estate.

The prescription may be delivered directly to the QI by the attending physician or may be filled by a pharmacist and delivered (in person or by mail) to the QI or someone the QI designates. There is no requirement that the medications be ingested at all or within any timeframe once the prescription is filled. If the QI dies without taking the drugs, the person who has custody of the medications "shall" dispose of the drugs according to processes and regulations set by the California Board of Pharmacy.

Assuming all these steps in the process are completed and documented, physicians are immune from civil or criminal liability in the death of the QI and from professional sanction for participating in the process. Other persons, too, are immune from civil or criminal prosecution for participation in any of the steps of the process including helping to prepare the drugs and being present in the room when they are ingested. However, it is a felony for any person to assist the QI with the actual ingestion or to cause ingestion without the QI's knowledge. It is also a felony to knowingly alter or forge a request for life-ending medications, to conceal or destroy a withdrawal or recission of a request for the drugs, or to knowingly coerce or exert undue influence on a person to request a drug or to destroy a withdrawal or recission of a request.

No physician/mental health provider is required to participate in the process. Employers or entities contracting with physicians/mental health providers may prohibit them from participating at the place of employment, on premises owned by the employer or entity, or within the context of their contracted

responsibilities. However, employers or entities contracting with physicians/mental health providers cannot prohibit them from participating off-premises or outside the scope of their contracts or duties as employees. (Diagnosing terminal condition, assessing mental capacity, and informing patients of their disease, prognosis, options including life-ending medications, and providing a referral to a prescribing physician are not considered "participation" in the process and cannot be prohibited.)

Contracts, wills, other agreements and provision of life, health, or annuity policies or benefit plans or rates charged therefore cannot be conditioned on or affected by the request for life-ending medications. Insurance companies cannot inform patients, in the same communication, of the denial of coverage for treatment and of the availability of aid-in-dying drug coverage.

The state will collect all the compliance forms and create a summarizing report annually on specific features of utilization of the law. All original compliance forms and patient-level detail, however, will be kept confidential and will not be available for public inspection, disclosed, subject to discovery, or produced in any civil, criminal, administrative, or other proceeding.

Commentary

While the process outlined appears comprehensive, even complex, and the safeguards abundant, it fails to include significant features that would ensure true compliance and any real enforcement:

- No requirement that the "attending" physician have any or current knowledge of capacity or mental health assessment, pain and symptom management, or available hospice and palliative services
- No requirement that family members be informed of the QI's intention or assessed for caregiver burden or undue influence on the QI
- No requirement for assessment of mental illness other than that which might "impair judgement"; any assessment for mental illness is entirely at the attending physician's discretion
- No mention of the role of the coroner in investigating or confirming the circumstances of the death, or what cause of death is to be listed on the QI's death certificate
- No follow up to retrieve or ensure safe disposal of any unused lethal medications
- All data on compliance with the law and presence/absence of abuse or misuse of the law or adverse patient/family effects is derived from the attending physician compliance forms and follow-up questionnaire. No data is requested from Qis directly or from family members.
- No requirement for objective, third-party review of physician's compliance forms or medical records to ensure that steps documented actually took place; no stated sanction or follow-up if compliance forms are not filed or are incomplete.
- As the attending physician is not required – and is highly unlikely – to be present at the death, data concerning time of ingestion and death will be incomplete. As well, there is no way to ensure that QI actually did self-administer drugs or was not aided or influenced in the process.
- All data regarding motivation for request is reported by the physician in the follow-up questionnaire, which is likely to be completed weeks if not months after the request was made. Notably, the California questionnaire leaves out two options historically included in the Oregon data: concern over burden on family members or caregivers and financial concerns. This means the CA data will be incomplete and not directly comparable to the data collected in other states.

Comparison of SB 128 and ABX2 15

ABX2 15 is nearly identical to SB 128, with a few notable changes at introduction and additional amendments:

Changes at Introduction

Requirements for the two witnesses to the written request have been much changed and considerably (IMHO) weakened. SB 128 required the witnesses to attest that the QI "has the capacity to make medical decisions, [is] acting voluntarily [and is] not being coerced to make or sign the request." In ABX2 15, witnesses must attest that the QI "voluntarily signed this request in their presence, [is] an individual whom they believe to be of sound mind and not under duress, fraud, or undue influence." *Comment:* "Sound mind" is a far cry from having "capacity to make medical decisions"; "voluntarily signing" a form is meaningfully different from "acting voluntarily" in making the request; and "believe to be" is a much lower standard than "is."

Reporting requirements have been simultaneously strengthened and made less accessible. The attending and consulting physicians must complete extensive forms indicating that all the various procedural and substantive requirements have been met and then must not only include the forms in the individual's medical record, but submit them to the Department of Health (the latter requirement being new) within 30 days of writing the prescription. Within 30 days of the QI's death, *by any means*, another extensive follow-up form must be completed by the physician and submitted to the Department (also new). These forms will form the basis of the Department's annual review of the practice, but there is no indication that the forms will be checked for compliance or that any regulatory or legal follow-up will ensue if they are out of compliance. ABX2 15 contains quite a bit more information on what will go in to the annual report, which looks pretty much like what has been reported out of Oregon. (These features are not dissimilar from what has been required in other states; the difference in CA is that the requirements and the forms are included in the statute rather than addressed in administrative rules.)

The compliance forms themselves are included in ABX2 15, and while extensive, they are also problematic, especially the post-death follow-up. This form requires the physician to report a lot of specificity about the time of ingestion, time to death, circumstances of the death, etc. that are very likely not going to be known by the physician, as physicians are not obliged to be present at assisted deaths and almost never are. Notably, in the report as to what motivated the assisted death request by the individual in the first place, only these choices are offered:

- His or her terminal condition representing a steady loss of autonomy
- The decreasing ability to participate in activities that made life enjoyable
- The loss of control of bodily functions
- Persistent and uncontrollable pain and suffering
- A loss of dignity
- Other concerns

NOT included are two additional reasons collected by Oregon and Washington: feeling of being a burden on caregivers or family and financial concerns. (Of note, in the 2014 WA report, 59% of assisted death

patients were reported to have concern over burden on family/caregivers, which is significantly higher than the percentage in OR.)

Also new to ABX2 15 is the statement that the forms themselves "shall not be disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative or other proceeding." So if any kind of dispute arose from a death by aided dying – a family member questioning the voluntariness of the request, or some question about the diagnosis/prognosis, for instance – the physician's reports could not be introduced into evidence.

September 3 Amendments:

- In the definition of capacity, SB 128 allowed for communication of the request for lethal medications "through a person familiar with the individual's manner of communicating, if that person is available." This clause was deleted.
- Physician required to give to the patient, and the patient to complete and sign, a "final attestation form" (attesting to voluntariness of ingestion and informed consent) within 48 hours of self-administering the drug. The wording of the form is included in the bill. If the drugs are ingested and the patient dies, the patient's "healthcare provider, family member, or other representative" must return the form to the attending physician for inclusion in the medical record.
- Makes it a felony for any person to administer the drugs to the patient without the patient's knowledge and modifies immunities from civil or criminal prosecution to solely for being present when the drug is ingested; immunity is not granted to persons assisting with the ingestion.
- Requirement that attending and consulting physicians and any mental health providers involved in the process "shall not be related to the individual by blood, marriage, registered domestic partnership, or adoption, or be entitled to a portion of the individual's estate upon death."
- **Sunset provision: Shall be automatically repealed January 1, 2026 unless a new law is specifically passed to extend the law.**