



Document #3459

The California End of Life Option Act

CMA Legal Counsel, January 2016

On October 5, 2015, California became the fifth state in the nation to allow physicians to prescribe terminally ill patients medication to end their lives. ABX2-15, the "End of Life Option Act," permits terminally ill adult patients with capacity to make medical decisions to be prescribed an aid-in-dying medication if certain conditions are met. (ABX2-15, Stats. 2015, Ch.1; Health & Safety Code §§443 *et seq.*) This document discusses the requirements of the End of Life Option Act.

EFFECTIVE DATE

1. When Does The End of Life Option Act Become Effective?

ABX2-15 was enacted during a special session of the California Legislature. Therefore, it will become effective on the 91st day after the special session ends, a date not yet determined but which will be between January 2016 and November 2016 (Effective Date).

Opponents of the Act have filed a referendum with the California Secretary of State to repeal the End of Life Option Act. The Act may go into effect while signatures are being gathered. However, if enough valid signatures are gathered and submitted to put the referendum on the ballot, the End of Life Option Act will be stayed until Election Day.

If the Act goes into effect, it will remain law until January 1, 2026, at which time it will be repealed by its own terms, unless further extended by the Legislature. (Health & Safety Code §443.215.)

REQUIREMENTS UNDER THE ACT

Form of Requests

2. Who Can Make An Aid-in-Dying Request Under The Act?

As set forth in Health & Safety Code §443.2(a), any adult (an individual eighteen (18) years of age or older (Health & Safety Code §443.1(a)) with the capacity to make medical decisions and with a terminal disease may make a request to receive a prescription for an aid-in-dying drug if all of the following conditions are satisfied:

- The individual's attending physician has diagnosed the individual with a terminal disease.
- The individual has voluntarily expressed the wish to receive a prescription for an aid-in-dying drug.
- The individual is a resident of California and is able to establish residency through one of the following:

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- ♦ Possession of a California driver license or other identification issued by the State of California.
- ♦ Registration to vote in California.
- ♦ Evidence that the person owns or leases property in California.
- ♦ Filing of a California tax return for the most recent tax year.
- The individual documents his or her request by submitting a Request form that is signed, dated, and witnessed pursuant to the Act's requirements.
- The individual has the physical and mental ability to self-administer the aid-in-dying drug.

A request for a prescription for an aid-in-dying drug cannot be made on behalf of patient through an agent under a power of attorney, an advance health care directive, a conservator, health care agent, surrogate, a legally recognized health care decisionmaker or any other person, regardless of relationship to the patient. Such a request must be made solely and directly by the individual diagnosed with the terminal disease. (Health & Safety Code §443.2(c).) Accordingly, a parent cannot request an aid-in-dying drug for his or her child and a spouse cannot request it for the other spouse.

3. How Does a Patient Make an Aid-in-Dying Request?

To make a request for a prescription for an aid-in-dying drug, an individual must submit to his or her attending physician two oral requests, made at least fifteen (15) days apart, and one written request in the statutory form. All three requests must be received directly by the attending physician, not a physician designee. (Health & Safety Code §443.3(a).) As explained below, requests can be made through the use of an interpreter if certain requirements are met. (Health & Safety Code §443.11(b)(2).)

4. Are There Documentation and Witness Requirements For Oral and Written Requests?

Yes. An attending physician who receives an oral or written request for an aid-in-dying drug must document each such request in the patient's medical record. (Health & Safety Code §§443.8(a); 443.8(b).) The law does not specify particular lan-

guage for oral requests or for documenting oral or written requests in the medical record. (Health & Safety Code §443.8.) However, a valid written request for an aid-in-dying drug must meet all of the following conditions:

- The written request must be made on the form "Request For An Aid-In-Dying Drug To End My Life In A Humane And Dignified Manner."
- The written request form must be signed and dated, in the presence of two witnesses, by the individual seeking the aid-in-dying drug.
- The written request must be witnessed by at least two other adults who, in the presence of the requesting individual, attest that to the best of their knowledge and belief the requesting individual is:
 - ♦ An individual who is personally known to them or has provided proof of identity;
 - ♦ An individual who voluntarily signed this request in their presence;
 - ♦ An individual whom they believe to be of sound mind and not under duress, fraud, or undue influence; and
 - ♦ Not an individual for whom either witness is the attending physician, consulting physician, or mental health specialist.

(Health & Safety Code §§443.3(b); 443.3(d); 443.11(a).) Also, only one witness may be related to the requesting individual by blood, marriage, registered domestic partnership, or adoption or be entitled to a portion of the requesting individual's estate upon death, or own, operate, or be employed at a health care facility where the patient is receiving medical treatment or resides. (Health & Safety Code §443.3(c).)

Required Documentation and Forms

5. Are There Additional Documentation Requirements?

Yes. Under this law, in addition to documenting all oral and all written requests for an aid-in-dying drug as described above, all of the following must also be documented in the requesting patient's medical record:

- The attending physician's diagnosis and prognosis, and the determination that a qualified individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision, or that the attending physician has determined that the individual is not a qualified individual.
- The consulting physician's diagnosis and prognosis, and confirmation that the qualified individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision, or that the consulting physician has determined that the individual is not a qualified individual.
- A report of the outcome and determinations made during a mental health specialist's assessment, if performed.
- The attending physician's offer to the qualified individual to withdraw or rescind his or her request at the time of the individual's second oral request.
- A note by the attending physician indicating that all requirements of the attending physician and of the consulting physician have been met and indicating the steps taken to carry out the request, including a notation of the aid-in-dying drug prescribed.
- All documentation required to be submitted to the California Department of Public Health (CDPH), as more fully described below, including a copy of the qualifying patient's written request, the attending physician checklist and compliance form, the consulting physician compliance form, and the attending physician follow up form.

(Health & Safety Code §§443.9; 443.9(a); 443.9(b); Health & Safety Code §443.19.)

6. Are Particular Forms Required by the Act?

Yes. As mentioned above, the End of Life Option Act requires five new forms to be used with patients electing the aid-in-dying drug option made available by this law. The forms include:

1. "Request For An Aid-In-Dying Drug To End My Life In A Humane And Dignified Manner" (Health & Safety Code §443.11(a));

2. "Final Attestation For An Aid-In-Dying Drug To End My Life In A Humane And Dignified Manner" (Health & Safety Code §443.11(c));
3. "Attending Physician Checklist & Compliance Form" (Health & Safety Code §443.22(b));
4. "Consulting Physician Compliance Form" (Health & Safety Code §443.22(b)); and
5. "Attending Physician Follow-Up Form" (Health & Safety Code §443.22(b)).

The exact language of these forms is set forth in statute and must be utilized word for word. The law expressly states that the Medical Board of California (MBC) is permitted to update three of the five forms ("Attending Physician Checklist & Compliance Form," "Consulting Physician Compliance Form," and "Attending Physician Follow-Up Form") and that any such updates be published on the CDPH website (Health & Safety Code §443.22(a).) Physicians should use those three forms and should not create their own.

The MBC has indicated its position is that it has statutory authority over all five forms but it is currently unclear whether the MBC or CDPH will create and publish the other two forms ("Request For An Aid-In-Dying Drug To End My Life In A Humane And Dignified Manner" (Request) and "Final Attestation For An Aid-In-Dying Drug To End My Life In A Humane And Dignified Manner" (Final Attestation).)

7. Can An Interpreter Be Used?

Yes. If an interpreter is used, the written Request form signed by the requesting patient must be written in the same language as any conversations, consultations, or interpreted conversations or consultations between a patient and his or her attending or consulting physicians. (Health & Safety Code §443.11(b)(1).) However, even when the conversations or consultations or interpreted conversations or consultations were conducted in a language other than English, the written Request form may be prepared in English if the English language form includes an attached interpreter's declaration that is signed under penalty of perjury. (Health & Safety Code §443.11(b)(2).) The interpreter's declaration must be substantially similar to language set forth in the statute. (Health & Safety Code §443.11(b)(2).) Currently, it is not known whether the MBC or

CDPH will produce a standard form interpreter's declaration.

If a request or communication or consultation related to a request for an aid-in-dying drug is made with the use of an interpreter, the interpreter must not be related to the patient by blood, marriage, registered domestic partnership, or adoption or be entitled to a portion of the patient's estate upon death. (Health & Safety Code §443.11(b)(3).) The interpreter must also meet the standards promulgated by the California Healthcare Interpreting Association (<http://chia-online.org/CHIA-Standards>) or the National Council on Interpreting in Health Care (www.ncihc.org/ethics-and-standards-of-practice) or other standards deemed acceptable by CDPH for health care providers in California. (Health & Safety Code §443.11(b)(3).)

Health Care Provider Defined

8. Who Is A "Health Care Provider" Under The End Of Life Option Act?

For purposes of this law, "health care provider" or "provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code (physicians, nurses, psychologists, physician assistants, pharmacists, and other professionals); any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code (emergency medical technicians and paramedics); and any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code (general acute care hospitals, acute psychiatric hospitals, special hospitals, skilled nursing facilities, intermediate care facilities, and other facilities). (Health & Safety Code §443.1(h).)

Requests for Aid-in-Dying Drug

9. Can Any Physician Receive A Request For An Aid-In-Dying Drug?

No. Only a patient's attending physician may receive a request for an aid-in-dying drug. Under the law, a patient's "attending physician" is the physician who has primary responsibility for the health care of a requesting patient and treatment of the patient's terminal disease. (Health & Safety Code §443.1(c).) The attending phy-

sician may not serve as a witness to a written Request (Health & Safety Code §443.11(a), cannot be related to the requesting patient by blood, marriage, registered domestic partnership, or adoption, or be entitled to a portion of the patient's estate upon death. (Health & Safety Code §443.17(d).)

10. What Are The Obligations Of The Attending Physician Who Receives A Request?

Before prescribing an aid-in-dying drug, the attending physician must fulfill numerous requirements. Specifically, the attending physician must:

- Make the initial determination of whether the patient is "qualified" to receive an aid-in-dying drug under the End of Life Option Act;
- Confirm that the patient is making an informed decision;
- Refer the patient to a consulting physician;
- Confirm that the patient's request does not arise from coercion or undue influence;
- Counsel the patient;
- Inform the patient that he or she may withdraw or rescind the request for an aid-in-dying drug at any time and in any manner;
- Offer the patient an opportunity to withdraw or rescind the request for an aid-in-dying drug before prescribing the drug;
- Verify, immediately before writing the prescription for an aid-in-dying drug, that the patient is making an informed decision;
- Confirm that all requirements are met and all appropriate steps are carried out in accordance with the law before writing a prescription for an aid-in-dying drug;
- Fulfill all documentation requirements;
- Complete the "Attending Physician Checklist & Compliance Form," place it and the "Consulting Physician Compliance Form" in the patient's medical record, then submit both forms to CDPH; and
- Give the requesting patient the Final Attestation Form and instruct the patient about completing it.

(Health & Safety Code §443.5(a).) Each of these steps is described more fully below.

11. What Is Required For An Initial Determination That A Patient Is "Qualified" To Request An Aid-In-Dying Drug?

In order to make an initial determination that a patient is "qualified" under the Act to receive an aid-in-dying drug, the attending physician must determine all of the following:

- Whether the patient has the capacity to make medical decisions, meaning the patient has the ability to:
 - ♦ Understand the nature and consequences of a health care decision;
 - ♦ Understand its significant benefits, risks, and alternatives; and
 - ♦ Make and communicate an informed decision to health care providers. (Health & Safety Code §§443.1(e); 443.5(a)(1)(A)(i).)
- Whether the patient has a terminal disease, defined as an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, result in death within six (6) months. (Health & Safety Code §§443.5(a)(1)(B); 443.1(q).)
 - ♦ Only a patient with a terminal disease may be prescribed an aid-in-dying drug. (Health & Safety Code §443.2(a)(1).)
 - ♦ "Medically confirmed" means the medical diagnosis and prognosis of the attending physician has been confirmed by a consulting physician who has examined the individual and the individual's relevant medical records. (Health & Safety Code §443.1(j).)
- Whether the patient has voluntarily made the request for an aid-in-dying drug in a manner that satisfies the requirements of the Act, including witness attestations that the patient is of sound mind and not under fraud, duress or undue influence. (Health & Safety Code §§443.5(a)(1)(C); 443.2(a)(2); 443.3(b)(3)(B); (b)(3)(C).)
- Whether the patient is a "qualified" individual, defined as an adult who has the capacity to make medical decisions, is a resident of California, and has satisfied the requirements of the Act in order to obtain a prescription for a drug

to end his or her life. (Health & Safety Code §§443.5(a)(1)(D); 443.1(o).)

An individual cannot be deemed "qualified" based solely on age or disability. (Health & Safety Code §443.2(b).)

12. Can A Terminally Ill Patient With A Mental Disorder Be "Qualified" To Request An Aid-In-Dying Drug?

Yes, but only under specific circumstances. If the attending physician determines that the patient has indications of a mental disorder, the attending physician must refer the patient for an assessment by a mental health specialist. When a referral for a mental health specialist assessment is made, no aid-in-dying drugs may be prescribed until the mental health specialist determines that the individual has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder. (Health & Safety Code §§443.5(a)(1)(A)(ii); 443.5(a)(1)(A)(iii).)

13. Does A Patient's Request For An Aid-In-Dying Drug Mean The Patient Needs Someone Else To Make Decisions For Them?

No. A request by a qualified individual to an attending physician for an aid-in-dying drug in good faith compliance with the provisions of the Act does not, by itself, indicate that the patient cannot make informed decisions for themselves. In fact, the Act specifically states that such a request cannot provide the sole basis for the appointment of a guardian or conservator of the person. (Health & Safety Code §443.14(d)(1).)

14. Are There Specific Requirements To Ensure That The Patient Is Making An Informed Decision?

Yes. The attending physician is required to confirm that the patient is making an informed decision by discussing with him or her all of the following:

- His or her medical diagnosis and prognosis.
- The potential risks associated with ingesting the requested aid-in-dying drug.
- The probable result of ingesting the aid-in-dying drug.

- The possibility that he or she may choose to obtain the aid-in-dying drug but not take it.
- The feasible alternatives or additional treatment options, including, but not limited to, comfort care, hospice care, palliative care, and pain control.

Then, after all other requirements are met and immediately before writing the prescription for an aid-in-dying drug, the attending physician must again verify that the patient is making an informed decision.

(Health & Safety Code §§443.5(a)(2); 443.5(a)(8); 443.10.)

15. Is A Referral To A Consulting Physician Required For Every Patient?

Yes. The attending physician must refer a patient who requests an aid-in-dying drug to a consulting physician for medical confirmation of the diagnosis and prognosis, and for a determination that the individual has the capacity to make medical decisions and has complied with the requirements of the Act. (Health & Safety Code §443.5(a)(3).)

16. Does The Act Contain Safeguards Against Coercion And Undue Influence?

Yes. The attending physician must confirm that the patient's request does not arise from coercion or undue influence by another person by discussing with the patient, outside of the presence of any other persons, except an interpreter, whether or not the patient is feeling coerced or unduly influenced by another person. (Health & Safety Code §443.5(a)(4).)

17. Will The Patient Be Counseled About Taking An Aid-In-Dying Drug?

Yes. The attending physician must counsel the patient about the importance of all of the following:

- Having another person present when he or she ingests the aid-in-dying drug.
- Not ingesting the aid-in-dying drug in a public place, defined as any street, alley, park, public building, any place of business or assembly open to or frequented by the public, and any other place that is open to the public view, or to which the public has access.

- Notifying the next of kin of his or her request for an aid-in-dying drug. A request for an aid-in-dying drug cannot be denied because a patient declines or is unable to notify next of kin.
- Participating in a hospice program.
- Maintaining the aid-in-dying drug in a safe and secure location until the patient self administers the drug.

(Health & Safety Code §§443.5(a)(5); 443.1(n).)

18. What Are The Final Steps Before An Aid-In-Dying Drug Can Be Prescribed?

Before writing a prescription for an aid-in-dying drug, the attending physician must actively confirm that all requirements of the Act are met and that all appropriate steps have been carried out in accordance with the Act. The attending physician must also complete all documentation requirements, including completion of the Attending Physician Checklist and Compliance form. Finally, the attending physician must give the patient the "Final Attestation for an Aid-in-Dying Drug to End My Life in a Humane and Dignified Manner" form with the instruction that the form be filled out and executed by the patient within 48 hours prior to self-administering the aid-in-dying drug. (Health & Safety Code §§443.5(a)(9); 443.5(a)(10); 443.5(a)(11); 443.5(a)(12).)

Obtaining Aid-in-Dying Drug

19. How Does A Qualified Patient Obtain The Aid-In-Dying Drug?

If the attending physician has fulfilled the requirements of the Act, the attending physician may provide the aid-in-dying drug in any of the following ways:

- Dispensing Directly To The Patient: If the attending physician is authorized to dispense medicine under California law, has a current United States Drug Enforcement Administration (USDEA) certificate and complies with any applicable administrative rule or regulation, he or she may dispense the aid-in-dying drug directly to the patient, including any ancillary medication intended to minimize the patient's discomfort.

- **Delivering Prescription To The Pharmacist:** With the patient's written consent, the attending physician may contact a pharmacist, inform the pharmacist of the prescriptions, and deliver the written prescriptions personally, by mail, or electronically to the pharmacist. The pharmacist may then dispense the drug to the patient, the attending physician, or a person expressly designated by the patient if the designation is delivered to the pharmacist either verbally or in writing. The Act does not specifically state who must deliver the verbal or written designation to the pharmacist although it is best to have the patient do so. Delivery of the dispensed drug to the patient, the attending physician, or a person expressly designated by the patient may be made by personal delivery, or, with a signature required on delivery, by United Parcel Service, United States Postal Service, Federal Express, or by messenger service.

Handing the patient a written script to take to the pharmacy is not an authorized method of delivering an aid-in-dying prescription and therefore, is not permitted. (Health & Safety Code §§443.5(b)(1); 443.5(b)(2); 443.5(c).)

Consulting Physician

20. Who Can Be A Consulting Physician And What Are Their Responsibilities?

Before a patient obtains an aid-in-dying drug from his or her attending physician, the patient must be seen by a "consulting physician," defined as a physician who is "independent" from the attending physician and who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding the patient's terminal disease. The law does not define "independent." (Health & Safety Code §443.1(f).)

The consulting physician may not be a witness to the patient's written request for an aid-in-dying drug and may not be related to the patient by blood, marriage, registered domestic partnership, or adoption, or be entitled to a portion of the patient's estate upon death. (Health & Safety Code §§443.3(b)(3)(D); 443.17(d).)

Under the End of Life Option Act, a consulting physician must do all of the following:

- Examine the referred patient and his or her relevant medical records.
- Confirm in writing the attending physician's diagnosis and prognosis.
- Determine that the individual has the capacity to make medical decisions, is acting voluntarily, and has made an informed decision.
- If there are indications of a mental disorder, the consulting physician must refer the patient to a mental health specialist for an assessment.
 - Although the Act does not explicitly so state, it is feasible that a patient who has indications of a mental disorder would be referred twice to a mental health specialist for an assessment because that referral is an affirmative obligation of both the attending and consulting physician.
- Fulfill the record documentation required by the Act.
- Complete and submit the "Consulting Physician Compliance Form" to the attending physician.

(Health & Safety Code §§443.5(a)(3); 443.6.)

Mental Health Specialist Assessment

21. Is a Mental Health Specialist Assessment Required For Every Patient Who Requests An Aid-In-Dying Drug?

No. A mental health specialist assessment is only required if a patient's attending or consulting physician determines that the patient has indications of a mental disorder. In such a case, a prescription for an aid-in-dying drug cannot be provided unless and until the attending or consulting physician refers the patient to a mental health specialist for an assessment and that specialist fulfills his or her requirements under the Act. (Health & Safety Code §§443.5(a)(1)(A)(ii); 443.5(a)(1)(A) (iii); 443.6(d).)

The mental health specialist assessment shall consist of one or more consultations between the referred patient and the mental health specialist for the purpose of determining that the patient has the capacity to make medical decisions and is not suffering from impaired judgment due to a mental disorder. (Health & Safety Code §443.1(k).)

22. Who Can Serve As A Mental Health Specialist Under The Act And What Are Their Responsibilities?

Under the Act, a "mental health specialist" is defined as a psychiatrist or a licensed psychologist. The mental health specialist may not be a witness to the requesting patient's written request for an aid-in-dying drug and cannot be related to the patient by blood, marriage, registered domestic partnership, or adoption, or be entitled to a portion of the patient's estate upon death. (Health & Safety Code §§443.1(l); 443.3(b)(3)(D); 443.3(d); 443.17(d).)

A psychiatrist or psychologist who sees a patient for a mental health specialist assessment pursuant to the Act must do all of the following:

- Examine the patient and his or her relevant medical records.
- Determine that the patient has the mental capacity to make medical decisions, act voluntarily, and make an informed decision.
- Determine that the individual is not suffering from impaired judgment due to a mental disorder.
- Fulfill the documentation requirements of the Act.

(Health & Safety Code §443.7.)

Patient Right to Withdraw or Rescind Request

23. Can A Patient Change His Or Her Mind To Use An Aid-In-Dying Drug?

Yes. At any time and without regard to the patient's mental state, a patient may withdraw or rescind his or her request and may decide not to ingest an aid-in-dying drug. In fact, the attending physician has an affirmative obligation to inform the patient that he or she can withdraw or rescind his or her request for an aid-in-dying drug at any time and in any manner. The attending physician also has an affirmative, non-delegable obligation to offer the patient the opportunity to withdraw or rescind the request before a prescription for an aid-in-dying drug is written. (Health & Safety Code §§443.4(a); 443.4(b); 443.5(a)(6); 443.5(a)(7).) According to the documentation requirement of the Act, that "offer" must be made at the time of the patient's second oral

request and must be documented in the patient's medical record. (Health & Safety Code §443.8(f).)

Final Attestation Form

24. Does The Patient Have Any Additional Obligations Once The Aid-In-Dying Prescription Is Written?

Yes. Within forty-eight (48) hours prior to the patient self-administering the aid-in-dying drug, the patient is required to complete the "Final Attestation for an Aid-in-Dying Drug to End My Life in a Humane and Dignified Manner" form that the attending physician is required to provide to the patient and instruct the patient about completing. If the aid-in-dying drug prescribed is not later returned or relinquished upon the patient's death as required by the law, the completed Final Attestation Form must be delivered by the individual's health care provider, family member, or other representative to the attending physician who must include it in the patient's medical record. (Health & Safety Code §§443.5(a)(12); 443.11(c)(1); 443.11(c)(2).)

It is unclear what the attending physician's obligations are, if any, if the Final Attestation Form is not received. Under the law, unused aid-in-dying drugs must be relinquished after the requesting patient's death to qualified facilities that properly dispose of controlled substances. (Health & Safety Code §443.20.) Thus, the attending physician may not know if such unused drugs are turned in and if a Final Attestation Form should be forthcoming, if the requesting patient died a natural death without ingesting the aid-in-dying drug or decided not to take it. Presumably, the attending physician does not have any affirmative obligation to seek out completion or collection of the Final Attestation Form beyond providing it to the requesting patient and instruct them on its completion and submission.

Aid-In-Dying Drug

25. Does The Act Specify What Aid-In-Dying Drug Can Be Prescribed?

No. While the law defines an aid-in-dying drug as a drug determined and prescribed by a physician for a qualified individual, which the qualified individual may choose to self-administer to bring about his or her death due to a terminal disease (Health & Safety Code §443.1(b)), the law is silent as to which medi-

cation(s) can be used as the aid-in-dying drug prescribed.

Death Certificate

26. What Should Be Stated As The Official Cause Of Death On The Death Certificate?

The Act is silent as to the cause of death that should be identified on the death certificate of a patient who died as a direct result of self-administering an aid-in-dying drug prescribed by an attending physician. The Act provides that death caused by the self-administration of an aid-in-dying drug shall not constitute suicide. (Health & Safety Code §443.18.) Thus, physicians should not list suicide as the cause of death of the patient. Physicians can list the cause(s) of death that they feel is the most accurate. The Act does not preclude physicians from listing the underlying terminal illness and/or pursuant to the End of Life Option Act.

Reporting and Data Collection Requirements

27. What Are The Attending Physician's Reporting Requirements?

Within thirty (30) calendar days of writing a prescription for an aid-in-dying drug, the attending physician must submit to CDPH:

- A copy of the qualifying patient's written "Request For An Aid-In-Dying Drug To End My Life In A Humane And Dignified Manner";
- The "Attending Physician Checklist And Compliance Form"; and
- The "Consulting Physician Compliance Form."

(Health & Safety Code §443.9(a).)

Within thirty (30) calendar days following the qualified individual's death from ingesting the aid-in-dying drug, or any other cause, the attending physician must submit to CDPH the "Attending Physician Followup Form." (Health & Safety Code §443.9(b).) This assumes that the attending physician will be notified of or otherwise be aware of the patient's death. The law is silent as to what the attending physician's obligation is when he or she is not notified or aware of the patient's death.

The acceptable method(s) and address for submission of these documents to CDPH has not yet been announced. Because the law requires the attending physician to submit these documents to CDPH, such disclosure is allowed by HIPAA. (45 C.F.R. §165.512.) However, physicians must ensure that they submit the required information in compliance with the HIPAA Privacy and Security Rules.

28. What Are The Aid-In-Dying Data Collection And Publication Requirements?

Under the Act, CDPH is required to collect and review the information submitted by attending physicians. The information collected by CDPH is confidential and must be collected in a manner that protects the privacy of the patient, the patient's family, and any medical provider or pharmacist involved with the patient under the Act. The information collected cannot be disclosed, is not discoverable, and cannot be compelled to be produced in any civil, criminal, administrative, or other proceeding. (Health & Safety Code §443.19(a).)

Beginning in 2017, and each year thereafter, based on the information collected in the previous year from the Attending Physician Followup Form and vital statistics, CDPH must post on its website on or before July 1 a report that includes the following:

- The number of people for whom an aid-in-dying prescription was written.
- The number of known individuals who died each year for whom aid-in-dying prescriptions were written, and the cause of death of those individuals.
- For the period commencing January 1, 2016, to and including the previous year, cumulatively, the total number of aid-in-dying prescriptions written, the number of people who died due to use of aid-in-dying drugs, and the number of those people who died who were enrolled in hospice or other palliative care programs at the time of death.
- The number of known deaths in California from using aid-in-dying drugs per 10,000 deaths in California.
- The number of physicians who wrote prescriptions for aid-in-dying drugs.

- Of people who died due to using an aid-in-dying drug, demographic percentages organized by the following characteristics:
 - ♦ Age at death;
 - ♦ Education level;
 - ♦ Race;
 - ♦ Sex;
 - ♦ Type of insurance, including whether or not they had insurance;
 - ♦ Underlying illness.

(Health & Safety Code §443.19(b).)

Unused Aid-in-Dying Drugs

29. What Happens To Unused Or Excess Aid-in-Dying Drugs?

Any person who has custody or control of any unused aid-in-dying drug prescribed under the Act after the death of the patient must personally deliver for disposal the unused or excess aid-in-dying drugs to the nearest qualified facility that properly disposes of controlled substances. If none is available, the person must dispose of the drugs by lawful means in accordance with guidelines promulgated by the California State Board of Pharmacy or a federal Drug Enforcement Administration approved take-back program. (Health & Safety Code §443.20.) Because many patients and their families may not know which facilities are qualified to dispose of controlled substances, the attending physician may wish to provide that information before or at the time that an aid-in-dying drug is prescribed.

PARTICIPATION IN END OF LIFE OPTION ACT

30. Are Physicians Required To Participate In The End Of Life Option Act?

No. The Act expressly states, "Participation in activities authorized [by this Act] shall be voluntary. (Health & Safety Code §443.14(e)(1).) Thus, physicians are free to choose whether to participate in the End of Life Option Act or not. California Health and Safety Code section 442.5 requires a health care provider who diagnoses a patient with a terminal illness to notify the patient of his or her right to comprehensive information and counseling regarding legal

end-of-life options and, upon the request of the patient, to provide that comprehensive information and counseling. (Health & Safety Code §442.5(a)(1), (a)(2).) However, the End of Life Option Act contains an express exemption to those obligations. Specifically, the Act provides that, "Notwithstanding Sections 442 to 442.7, inclusive, a person or entity that elects, for reasons of conscience, morality, or ethics, not to engage in activities [authorized by this Act] is not required to take any action in support of an individual's decision under this [law]." (emphasis added) (Health & Safety Code §443.14(e)(1).) In other words, any participation in the End of Life Option Act is completely voluntary despite other provisions of California law that require certain health care providers to notify certain patients of their legal end-of-life options. Thus, while receiving an aid-in-dying drug will be a legal end-of-life option for qualified terminally ill patients in California once the Act becomes effective, the Act's specific conscience exemption means that physicians do not have to advise or counsel patients regarding or participate in any aid-in-dying activities if they are opposed thereto by reasons of conscience, morality or ethics.

31. Are There Legal Protections If A Physician Chooses Not To Participate?

Yes, the Act contains express immunity for refusing to inform or participate and for refusing to refer to a provider who does participate. Specially, the Act states that a health care provider is not subject to civil, criminal, administrative, disciplinary, employment, credentialing, professional discipline, contractual liability, or medical staff action, sanction, or penalty or other liability for refusing to participate in activities authorized under the Act, including, but not limited to, refusing to inform a patient regarding his or her rights under the Act, and not referring an individual to a physician who participates in activities authorized under this law. (Health & Safety Code §443.14(e)(2).) This language is further assurance that a physician with a conscience, morality or ethical objection to physician aid-in-dying has no obligation to participate in the activities of the Act or even to notify a patient whom they diagnose with a terminal illness about aid-in-dying as an end-of-life option. However, if a physician is unable or unwilling to carry out a qualified patient's request for an aid-in-dying drug and the qualified

patient transfers care to a new health care provider, the patient may request a copy of his or her medical records pursuant to law. (Health & Safety Code §443.14(e)(3).)

Similarly, a health care provider who refuses to participate in activities under the Act on the basis of conscience, morality or ethics cannot be subject to censure, discipline, suspension, loss of license, loss of privileges, loss of membership, or other penalty by a health care provider, professional association or organization. (Health & Safety Code §443.14(b).)

32. Can Medical Staff Members, Employees, And Others Be Prohibited From Participating?

Yes. If certain steps are taken, an employer or health care provider may prohibit its employees, independent contractors, or other persons or entities, including other health care providers, from participating in activities under the Act while such persons are on premises owned or under the management or direct control of that prohibiting employer or health care provider or while acting within the course and scope of any employment by, or contract with, the prohibiting employer or health care provider. (Health & Safety Code §443.15(a).)

33. What Is Considered "Participation" In Activities Authorized By The Act?

As defined in the Act, participating, or entering into an agreement to participate, in activities under this law, means doing or entering into an agreement to do any one or more of the following:

- Performing the duties of an "attending physician" as defined in the Act.
- Performing the duties of a "consulting physician" as defined in the Act.
- Performing the duties of a "mental health specialist" as defined in the Act, when a referral to such a specialist is made.
- Delivering the prescription for, dispensing, or delivering the dispensed aid-in-dying drug.
- Being present when the qualified individual takes the aid-in-dying drug.

(Health & Safety Code §443.15(f)(2).) A prohibiting employer or health care provider cannot prohibit a health care provider from providing any

health care services that are not specifically included in the definition of "participating, or entering into an agreement to participate, in activities under" the Act. (Health & Safety Code §443.15(h).) Further, the following activities are expressly excluded from that definition and thus, cannot constitute "participating, or entering into an agreement to participate, in activities under" this law:

- Diagnosing whether a patient has a terminal disease.
- Informing a patient of the medical prognosis.
- Determining whether a patient has the capacity to make decisions.
- Providing information to a patient about the End of Life Option Act.
- Providing a patient, upon the patient's request, with a referral to another health care provider for the purposes of participating in the activities authorized by the Act.

(Health & Safety Code §443.15(f)(3).)

Given these exclusions, any health care provider can, without limitation, make the initial medical determinations for a patient who requests an aid-in-dying drug under the Act (diagnosis, prognosis, capacity) and can provide information to a patient about or, upon request, refer a patient to another health care provider for services under the Act. This is true even if the employer or entity has a policy prohibiting health care providers from participating in activities under the Act. (Health & Safety Code §443.15(f)(3).)

Thus, while a health care provider may, on the basis of conscience, morality or ethics, decline to provide information to a patient about the Act or provide a patient with a referral to another health care provider for participation in activities under the Act, a prohibiting employer or health care provider may not prohibit willing employees, independent contractors, or other persons or entities, including other health care providers, from doing so. (Health & Safety Code §§443.14(e)(1); 443.14(e)(2); 443.15(f)(3).)

34. Does The Act Require Notice Of A Prohibiting Employer Or Health Care Provider's Policy Prohibiting Participation In Activities Under The Act?

Yes. If an employer or health care provider is going to prohibit its employees, independent contractors, or other persons or entities from participating in activities under the Act, the employer or health care provider must first give notice of such policy to the individual or entity. Notice is defined as a separate statement in writing advising of the prohibiting employer or health care provider's policy with respect to participating in activities under the Act. (Health & Safety Code §443.15(f)(1).) An employer or health care provider that fails to provide such notice to an individual or entity cannot enforce such a policy against that individual or entity. (Health & Safety Code §443.15(b).)

35. Are There Limits On A Prohibiting Employer or Health Care Provider's Ability To Prohibit Participation In Activities Under The Act?

Yes. A prohibiting employer or health care provider's ability to restrict participation is not without limits. The Act expressly states that a prohibiting employer or health care provider cannot:

- Prohibit any other health care provider, employee, independent contractor, or other person or entity from participating, or entering into an agreement to participate, in activities under the Act while on premises that are not owned or under the management or direct control of the prohibiting employer or provider or while acting outside the course and scope of the participant's duties as an employee of, or an independent contractor for, the prohibiting employer or health care provider (Health & Safety Code §443.15(d)(1));
- Prohibit any other health care provider, employee, independent contractor, or other person or entity from participating, or entering into an agreement to participate, in activities under the Act as an attending physician or consulting physician while on premises that are not owned or under the management or direct control of the prohibiting employer or provider (Health & Safety Code §443.15(d)(2)); or

- Sanction an individual health care provider for contracting with a qualified patient to engage in activities authorized by the Act if the individual health care provider is acting outside of the course and scope of his or her capacity as an employee or independent contractor of the prohibiting employer or health care provider. (Health & Safety Code §443.16(b).) It is unclear whether this protection requires both the contract to be made and the services to be rendered at a time that the individual health care provider is acting outside the course and scope of his or her capacity as an employee or independent contractor of the prohibiting employer or health care provider or if only the services must be rendered at such time.

36. Can A Physician Be Disciplined For Violation Of A Prohibiting Employer or Health Care Provider's Policy Prohibiting Participation In The Act?

Yes. A prohibiting employer or health care provider that provides appropriate notice, meaning a separate statement in writing advising the recipient of the prohibiting employer or health care provider's policy with respect to participating in activities under the Act (Health & Safety Code §443.15(f)(1),) may take action against any individual or entity that violates the policy. Permissible actions in the event of such a violation include, but are not limited to:

- Loss of privileges, loss of membership, or other action authorized by the bylaws or rules and regulations of the medical staff.
- Suspension, loss of employment, or other action authorized by the policies and practices of the prohibiting employer or health care provider.
- Termination of any lease or other contract between the prohibiting employer or provider and the individual or entity that violates the policy.
- Imposition of any other non-monetary remedy provided for in any lease or contract between the prohibiting employer or provider and the individual or entity in violation of the policy.

However, regardless of the prohibiting employer or health care provider's policy, an individual health care provider may not be sanctioned for any of the following:

- Making an initial determination pursuant to the standard of care that an individual has a terminal disease and informing him or her of the medical prognosis.
- Providing information about the End of Life Option Act to a patient upon the request of the individual.
- Providing an individual, upon request, with a referral to another physician.

(Health & Safety Code §443.16(a).) These activities are not by definition considered "participation in the activities authorized by the Act." (Health & Safety Code §443.15(f)(2), (f)(3).)

37. Can A Physician Be Reported To The Medical Board Solely For Violation Of A Policy Prohibiting Participation Under The Act?

No. The fact that a health care provider participates in activities under the Act cannot be the sole basis for a complaint or report by another health care provider of unprofessional or dishonorable conduct under Business and Professions Code Sections 800 to 809.9. (Health & Safety Code §443.15(g).) Similarly, if a prohibiting employer or health care provider takes any action for violation of a prohibiting employer or health care provider's policy prohibiting participation in activities under the Act, such action is not reportable under Business & Professions Code Sections 800 to 809.9. (Health & Safety Code §443.15(g).)

38. Are There Protections And Immunities For Physicians Who Choose To Participate?

Yes. There are several protections and immunities for health care providers who choose to provide a qualified patient with services authorized by the Act.

First, a person is not subject to civil or criminal liability solely because the person was present when a qualified individual self-administers the prescribed aid-in-dying drug. A person who is present may, without civil or criminal liability, assist the qualified individual by preparing the aid-in-dying drug so long as the person does not assist the qualified person in ingesting the aid-in-dying drug. (Health & Safety Code §443.14(a).) Nothing in the law indicates that health care providers are excluded from these protections.

Second, a health care provider or professional organization or association cannot subject an individual to censure, discipline, suspension, loss of license, loss of privileges, loss of membership, or other penalty for participating in good faith compliance with the Act. (Health & Safety Code §443.14(b).)

Third, a health care provider is not subject to civil, criminal, administrative, disciplinary, employment, credentialing, professional discipline, contractual liability, or medical staff action, sanction, or penalty or other liability for participating in activities pursuant to the Act, including, but not limited to, determining the diagnosis or prognosis of an individual, determining the capacity of an individual for purposes of qualifying under the Act, providing information to an individual regarding the Act, or providing a referral to a physician who participates in activities authorized by the Act. (Health & Safety Code §443.14(c).) Notably, for purposes of these immunity protections provided by the Act for health care providers who participate in activities pursuant to the Act and notwithstanding the more narrow definition of "participating" provided in section 443.15(f)(3) of the Act, "participating" includes determining the diagnosis or prognosis of an individual, determining the capacity of an individual for purposes of qualifying under the Act, providing information to an individual regarding the Act, or providing a referral to a physician who participates in activities authorized by the Act. (Health & Safety Code §§443.14(c); 443.15(f)(3).)

Fourth, the law specifically states that actions taken in accordance with the Act shall not, for any purposes, constitute suicide, assisted suicide, homicide, or elder abuse under the law. (Health & Safety Code §443.18.) However, neither the activities authorized under the Act nor the protections provided by the Act for participating therein may be construed to authorize or allow a physician or any other person to end an individual's life by lethal injection, mercy killing, or active euthanasia. (Health & Safety Code §443.18.)

Finally, the law expressly states that no actions taken in compliance with the provisions of the Act may constitute or provide the basis for any claim of neglect or elder abuse for any purpose of law. (Health & Safety Code §443.14(d)(2).)

The immunities and prohibitions on sanctions of a health care provider apply solely to actions of a health care provider taken pursuant to the End of Life Option Act. Health care providers may be sanctioned by their licensing board or agency for conduct and actions constituting unprofessional conduct, including failure to comply in good faith with the Act. (Health & Safety Code §§443.14(c); 443.16(c).)

CRIMINAL PENALTIES

39. What Is Considered Criminal Conduct Under The Act?

The Act expressly states that it is a felony to knowingly:

- Alter or forge a request for an aid-in-dying drug to end an individual's life without his or her authorization if the act is done with the intent or effect of causing the individual's death.
- Conceal or destroy a withdrawal or rescission of a request for an aid-in-dying drug if the act is done with the intent or effect of causing the individual's death.
- Coerce or exert undue influence on an individual to request or ingest an aid-in-dying drug for the purpose of ending his or her life.
- Destroy a withdrawal or rescission of a request for an aid-in-dying drug.
- Administer an aid-in-dying drug to an individual without his or her knowledge or consent.

(Health & Safety Code §443.17(a)-(d); Penal Code §7.) These criminal violations and resulting penalties are in addition to any civil liability and other criminal penalties. (Health & Safety Code §443.17(e), (f).)

INSURANCE POLICIES AND CONTRACTS

40. How Does The Act Impact Insurance Policies and Contracts?

The Act specifically provides that death resulting from the self-administration of an aid-in-dying drug pursuant to the Act is not suicide. (Health & Safety Code §443.13(a)(2).) Broadly, the Act expressly states that the sale, procurement, or issuance of a life, health, or annuity policy, health care service plan contract, or health benefit plan, or the rate charged

for a policy or plan contract may not be conditioned upon or affected by a person making or rescinding a request for an aid-in-dying drug. (Health & Safety Code §443.13(a)(1).)

For qualified individuals who have policies of insurance, the Act expressly prohibits health and insurance coverage from being exempted on the basis of death brought about by self-administration of an aid-in-dying drug. (Health & Safety Code §443.13(a)(2).) Similarly, a qualified individual's act of self-administering an aid-in-dying drug cannot affect a life, health, or annuity policy other than by having the same impact as a natural death from the underlying disease. (Health & Safety Code §443.13(b).)

The Act forbids health insurance carriers and health care service plans from providing any information in communications made to an individual about the availability of an aid-in-dying drug unless there is a request by the individual or his or her attending physician at the behest of the individual. Further, no communication may include both the denial of treatment and information as to the availability of aid-in-dying drug coverage. (Health & Safety Code §443.13(c).)

Similar to the prohibitions on insurance policies, a provision in a contract, will, or other agreement executed on or after January 1, 2016, whether written or oral, to the extent that it would affect whether a person may make, withdraw, or rescind a request for an aid-in-dying drug is not valid. (Health & Safety Code §443.12(a).) In other words, that portion of any agreement that purports to require or prohibit a person to request, withdraw or rescind a request for an aid-in-dying drug is not enforceable to the extent of that requirement although the remaining provisions of the agreement may be. Further, any obligation owing under any contract executed on or after January 1, 2016, cannot be conditioned upon or affected by a qualified individual making, withdrawing, or rescinding a request for an aid-in-dying drug. (Health & Safety Code §443.12(b).)

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