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The End of Life Option Act – The Pharmacist's Role

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The Act

On June 9, 2016, terminally ill individuals in California acquired the legal means to end his or her own life provided certain conditions are met. Specifically, the End of Life Option Act (the "Act") added section 443, et seq. to the California Health & Safety Code ("HSC"). The Act allows California residents diagnosed with a terminal illness and a survival prognosis of six months or less, to receive an "aid-in-dying drug" to end his or her own life in a nonpublic place.

Under the Act, the pharmacist's role is limited, since the process for receiving a drug order for an aid-in-dying drug differs considerably than ordinary practice. However, while the Act is silent on the pharmacist's legal responsibility to provide patient consultation, it clearly contemplates that an aid-in-dying drug be dispensed by a pharmacist in a community or outpatient setting. Given the irreversible finality of dispensing such drugs, the pharmacist should be assured that voluntary participation in the Act is in full compliance with its provisions, and the pharmacist will not be subject to retaliation, termination, or litigation. For these reasons, the pharmacist must understand the Act's rigorous vetting requirements imposed on the attending physician to be able to ascertain whether any particular terminally ill individual is, or may be, qualified to receive an aid-in-dying-drug, and to also appreciate the rigors imposed on the individual patient seeking to become qualified to legally receive a drug to end his or her own life.

What is an Aid-In-Dying Drug?

HSC § 443.1(b) 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." This definition, at first blush, may appear benign and somewhat unremarkable. However, it is important to view it through the prism of another definition offered by the Act: the meaning of "self-administer."

Under HSC § 443.1(p), "Self-administer" means a qualified individual's affirmative, conscious, and physical act of administering and ingesting the aid-in-dying drug to bring about his or her own death." The choice of aid-in-dying drug is decided by the attending physician based upon its determined effectiveness (for lack of a better description) and likelihood of achieving the desired outcome of death. However, the choice is equally based upon dosage form considerations, which may ensure that the qualified individual will be able to "affirmative[ly], conscious[ly], and physical[ly]" take the drug orally and "ingest[ing]" it. The "affirmative[ly], conscious[ly], and physical[ly]" requirements immediately rule out anyone other than the qualified individual from physically handling the aid-in-dying drug or administering it. Further, the "ingest[ing]" requirement dictates the dosage form, ruling out any drugs administered intravenously, subcutaneously, intrathecally, transdermally, rectally, or any other dosage form other than that taken through oral ingestion. Profound obstructions to employ the rights afforded under the Act are created by the very definition of what the Act considers an "aid-in-dying drug."

Individuals who endure a terminal illness that renders him or her unable to use his or her arms, hands, and fingers (or feet and toes, as the case may be) will likely be unable to "self-administer" an aid-in-dying drug. A strict interpretation of the language in HSC § 443.1(p) disqualifies individuals with such physical limitations from receiving an aid-in-dying drug. Arguably, patients who are unable to swallow would also be barred from qualifying under the Act. Still further, patients with gastrointestinal disorders that prevent drug absorption to the extent required for the chosen drug to have its intended life-terminating effect are also disqualified.

In the event that a pharmacist knows that an otherwise qualified

individual is unable to physically self-administer the aid-in-dying drug consistent with the Act, the pharmacist should not furnish the aid-in-dying drug, because doing so in this context would fail to comply with technical requirements of the Act and could be construed as assisted suicide, which is unlawful in California. Accordingly, where the pharmacist has knowledge of any physical limitation that prevents the patient from self-administering the aid-in-dying-drug, the pharmacist should confer with the attending physician and qualified individual.

How to Become a "Qualified Individual"

The Act allows an individual with a terminal disease to request and obtain a prescription for a drug that the individual can self-administer to end his life only if pursuant to an informed patient decision after the attending physician fully informs the patient of all the following:

1. The individual's medical diagnosis and prognosis.
2. The potential risks associated with taking the drug to be prescribed.
3. The probable result of taking the drug to be prescribed.
4. The possibility that the individual may choose not to obtain the drug or may obtain the drug but may decide not to ingest it.
5. The feasible alternatives or additional treatment opportunities, including, but not limited to, comfort care, hospice care, palliative care, and pain control.

Further, the qualified individual must be afforded ample opportunity to change his or her decision at any point before receiving, and even after receiving, an aid-in-dying drug. Specifically, the Act requires the qualified individual to submit at least two verbal requests to the attending physician at least 15 days apart and a written request for the aid-in-dying drug to the attending physician personally, and the patient may not delegate this responsibility to any other person.

Moreover, this written request must be made on a form described in detail within HSC § 443.11, and must be signed and dated by the qualified individual in the physical presence of two witnesses. Each of these two witnesses must attest in writing that, to the best of his or her knowledge and belief, the qualified individual is personally known to him or her (or the qualified individual has at least provided proof of identity to him or her), that the qualified individual has voluntarily signed the request for the aid-in-dying drug in his or her presence, that the qualified individual is of sound mind and not under duress, fraud, or undue influence, and that the witnesses are not the attending physician, consulting physician, or a mental health specialist. And lastly, no more than one of the two witnesses may be related to the qualified individual, nor entitled to a portion of that qualified individual's estate upon his or her death, nor may the witness be an owner, operator, or employee at the healthcare facility where the qualified individuals is a resident or receiving medical treatment.

The Act also requires the attending physician to privately discuss with the individual whether he is feeling coerced or unduly influenced by any others before prescribing an aid-in-dying drug. By definition, this would mean if the patient is in the presence of any other person, then the attending physician must insist or require a private one-on-one conversation with the patient outside the presence of others, even if the patient protests.

Clearly, these arduous requirements are intended to protect the qualified individual from being pressured into a decision to obtain an aid-in-dying drug and terminate his or her life by anyone who stands to receive any personal financial benefit upon the death of the individual or by anyone who simply wants to avoid the expense of routine care and palliative treatment during the patient's last days.

How to Transact and Dispense the Aid-In-Dying Drug

Medications used for aid-in-dying purposes may include secobarbital and pentobarbital, both Schedule II controlled substances. As such, the pharmacist receiving these prescriptions must ensure that the prescription order is submitted on a secure tamper-resistant prescription form with the required security features and that it has been executed by the attending physician in accordance with the law. The Act permits the pharmacist to receive such prescriptions via hard copy by mail or personally delivered by the attending physician, or via properly authenticated e-prescribing. However, there is a distinct procedural difference between processing an aid-in-dying prescription order and a typical outpatient/community C-II prescription. An aid-in-dying drug prescription order must be delivered directly via those specified means from the attending physician to the pharmacist. An aid-in-dying prescription itself will never be handed to the qualified individual himself (nor his agent). In other words, the pharmacist should never be presented with prescription orders for aid-in-dying drugs by the qualified individual or his or her agent.

According to the Act, the pharmacist may dispense an aid-in-dying drug directly to the qualified individual, or deliver the completed prescription order for an aid-in-dying drug to the attending physician or a person expressly predesignated by the qualified individual to the pharmacist via a written or verbal authorization. Alternatively, the completed prescription order may be delivered via messenger service or mail/commercial carrier (signature required) to the attending physician, the

qualified individual, or to any person predesignated by the qualified individual.

Interestingly, a conflict of law exists between the Act, which is a California state law, and the Drug Enforcement Agency's interpretation of "constructive transfer" under the federal Controlled Substance Act ("CSA"). The DEA suggests that a pharmacist delivering a completed prescription order for an aid-in-dying drug to the attending physician's office for subsequent delivery to the qualified individual violates the CSA because of its explicit definitions for the terms "dispense," "deliver," and "ultimate user," as follows:

- Under § 11010, the term "dispense" means "to deliver a controlled substance to an ultimate user…pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery."
- Under § 11009, the term "deliver" means "the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship."
- Under § 11030, the term "ultimate user" means "a person who lawfully possesses a controlled substance for his own use or for the use of a member of his household or for administering to an animal owned by him or by a member of his household."

These terms of the Controlled Substances Act had not been interpreted judicially nor explained by the DEA until the case of Wedgewood Village Pharmacy v. DEA, which resulted in a 2010 stipulated settlement between the DEA and the Wedgewood Village Pharmacy ("Wedgewood"). In the DEA's "Administrative Memorandum of Agreement" ("Agreement") with Wedgewood, the agency clearly opined on the intended meaning of the term "constructive transfer" and how it applies to whether a pharmacy is permitted to deliver a completed controlled substance prescription order to a prescriber, even where that prescriber is the ultimate user's (i.e., the patient's) physician. DEA terms and conditions in that agreement stated:

> *"The DEA's core legal position has been and remains that the transfer of a controlled substance to anyone (including the prescribing practitioner) other than an 'ultimate user' as that term is defined in the CSA [Controlled Substances Act] constitutes the distribution of a controlled substance…[and drug distribution is not allowed by pharmacies – only dispensing]."*
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> **(Wedgewood v. DEA, 509 F.3d 541: See DEA Administrative Memorandum of Agreement, page 3, Paragraph II)**

Based on the principles outline by the DEA in the Wedgewood case, a pharmacist choosing to participate within the parameters of the Act should explain to the attending physician the specific options for delivery of the aid-in-dying drug to the qualified individual permitted under the Act and emphasize that the DEA's definition for "constructive transfer" would not allow delivery of completed prescription orders for aid-in-dying drugs (to the extent they are controlled substances) directly to the attending physician.

Even after a qualified individual has completed the requirements under the Act, another substantial hurdle must be overcome to obtain the aid-in-dying drug, and that is the potentially prohibitive cost of these medications. Lexicomp™ estimates the cash price of Seconal™ 100 mg #90 at $3,329.16, an expense that many patients may have to pay out of pocket.[12] While Medi-Cal, California's state Medicaid program, covers aid-in-dying drugs when all of the Act's requirements are met,[13] private insurers are not legally compelled to offer the same. This noteworthy financial burden may therefore prevent individuals who may be legally qualified to obtain aid-in-dying drugs from doing so.

Separately, pharmacists who contemplate compounding aid-in-dying drugs pursuant to patient-specific prescriptions would be well advised to prepare for the newly created rigors imposed on hazardous compounding under the United States Pharmacopeia (USP), Chapter 800 in its new General Chapter 800 ("USP 800"), as well as all of the new California State Board of Pharmacy hazardous compounding regulations that took effect January 1, 2017.

Consultation with Qualified Individuals for Aid-In-Dying Drugs

The Act does not impose any affirmative duty on pharmacists to provide any special patient consultation when dispensing aid-in-dying drugs to qualified individuals. In fact, because the Act is completely silent on pharmacist consultation, pharmacists should refer to the standard requirements set forth in California Code of Regulations § 1707.2(a)[14] and § 1707.2(c)[15]. However, pharmacists should understand and appreciate the rigorous mandatory consultation required by the Act by attending physicians before any prescription orders for aid-in-dying drugs are written. Specifically, an individual seeking aid-in-dying drugs must be personally counseled by the attending physician on all of the following:[16]

1. Arranging to have another person present when ingesting the aid-in-dying drug;
2. Making sure not to ingest the aid-in-dying drug in a public place;[17]
3. Considering notifying next of kin, but that eligibility to receive the aid-in-dying drug does not depend on such notification;
4. Considering participating in a hospice program;
5. Ensuring storage of the aid-in-dying drug in a safe and secure location until the time of ingestion, if ever; and

6. Understanding that he may withdraw or rescind his request for an aid-in-dying drug at any time and in any manner.

Since the attending physician must cover the above subject matter with the qualified individual through an in-person consultation prior to ordering an aid-in-dying drug, pharmacists should avoid redundant patient consultation at the point of dispensing and, rather, counsel the qualified individual about the mechanics and anticipated side effects that the individual may encounter. The role of the pharmacist when interacting with the patient at this point should be to provide clear instructions and guidance on how to properly self-administer the Aid-in-dying drug and what to reasonably expect. For example, patient instructions could include:

1. How to carefully open each capsule and pour out the capsule's entire contents without spillage or waste;
2. Which beverages may be considered, as well as which should be avoided;
3. What the proper sequence and timing are for ingestion of the aid-in-dying drugs;
4. Within what optimal period of time must full ingestion of the entire dose be completed;
5. What the relevant side effects are of not only the aid-in-dying drug, but also any previously ingested antinausea and/or antiemetic pretreatment(s);
6. What to do if the patient changes his mind in the middle of or immediately after the process of ingesting the aid-in-dying drug;
7. What the patient should do if the aid-in-dying drug does not work; and
8. How to properly destroy unused drugs if, at any time, the patient aborts the process because he changed his mind or died before the aid-in-dying drug was ever used.

Compliance, Liability, and Discretion to Not Participate in the Act

It is equally important for the pharmacist to have a high degree of confidence that the attending physician completed all procedural requirements under the Act. To provide some measure of assurance, the pharmacist should request a copy of the patient's completed and executed request for the aid-in-dying drug[18] document from the attending physician, and then keep that copy on file with the original prescription order. The pharmacist in charge should implement clear and unambiguous policies and procedures to avoid violating the Act and corresponding new sections of the California Health and Safety Code, and also to provide for some measure of consistency in pharmacist consultations with a qualified individual.

Participation in the Act by any healthcare provider, whether that provider is an attending physician or a pharmacist, is purely optional, discretionary, and arbitrary. No language prohibits or requires any healthcare provider to participate in any aspect of the Act. In fact, the Act itself provides absolute immunity for healthcare providers from any form of retaliation and liability. Specifically, healthcare providers are given immunity from any civil, criminal, administrative, disciplinary, employment, or credentialing proceedings as well as from any contractual liability.[19] In addition, the Act prohibits a healthcare provider or professional organization from subjecting a provider to censure, discipline, suspension, loss of license, loss of privileges, loss of membership, or any other penalty for participating in good faith compliance or for refusing to participate in an End of Life Option Act request.[20] In summary, a healthcare provider has the freedom to choose whether or not to participate in the Act, and as long as the provider complies with all of the regulations set forth, the law provides full protection from any liability, discipline, and other negative consequences.

However, the robust shield from liability described for a provider's good faith compliance does not apply in the case of a provider who chooses to participate and fails to comply with the strict terms of the Act. That is precisely why pharmacists must have a high degree of confidence in the attending physician, as well as his or her working knowledge of the Act, and ensure that all of the technical requirements of the Act have been indisputably satisfied.

Conclusion

The End of Life Option Act permits pharmacists to work with attending physicians to provide aid-in-dying drugs for the purpose of allowing qualified individuals an option and a means to end his or her own life on his or her own terms. In return, the Act unambiguously provides blanket immunity from any retaliation in any form, and even affords immunity to those who choose not participate. Pharmacists who choose to participate should do so only after fully understanding the requirements of the Act, appreciating the plight of the would-be qualified individual, and considering other laws and governmental agencies that speak to dispensing controlled substances.

About the Author

Laura Petrillo, MD, is a Palliative Care Physician at the San Francisco Veterans Affairs Medical Center and in the Division of Geriatrics at the University of California, San Francisco. She provided expert testimony in the California State Assembly hearing on the End of Life Option Act and has been a leading physician voice on safe implementation of the law. Dr. Petrillo has no conflicts of interest to report.

Resources for Healthcare Providers and Patients

The California Department of Public Health provides, on its website, valuable resources, including the text of the law itself, a number of provider forms, and a number of patient forms.[21]

- Physician Forms
  - » Attending Physician's Checklist & Compliance Form
  - » Consulting Physician's Compliance Form
  - » Attending Physician's Follow-up Form
  - » What Forms Does the Attending Physician Have to Submit to CDPH?
- Patient Forms
  - » Patient's Request for Aid-In-Dying Drug
  - » Final Attestation for Aid-In-Dying Drug
  - » Interpreter's Declaration

References

1. https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520162AB15
2. It is this author's professional opinion that self-administration of an aid-in-dying drug through the use of one's feeding tube will likely pass muster under the Act's definition of "self-administer."
3. As defined in the Act as "an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, result in death within six months." [Emphasis added]. HSC § 443.1(q).
4. HSC § 443.1(i)
5. HSC § 443.3(a)
6. HSC § 443.3(a) - (d)
7. HSC § 443.5(a)
8. In Oregon: Secobarbital (60%), Pentobarbital (39%) 2014: N = 105. https://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Documents/year17.pdf
9. HSC §11162.1
10. HSC § 443.5(b)-(c)
11. Wedgewood v. DEA, 509 F.3d 541.
12. Secobarbital. Lexi-Drugs. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Available at: http://online.lexi.com. Accessed October 31, 2016.
13. "End of Life Option Act Services." September 2016. www.medi-cal.cal.gov.
14. (a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings: (1) upon request; or (2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment. (b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present: (A) whenever the prescription drug has not previously been dispensed to a patient; or (B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions is dispensed by the pharmacy.
15. (c) When oral consultation is provided, it shall include at least the following: (1) directions for use and storage and the importance of compliance with directions; and (2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.
16. HSC § 443.5(a)
17. HSC § 443.1(n): "'Public place' means 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."
18. HSC § 443.11; please see enclosed form marked "Request For An Aid-In-Dying Drug To End My Life In A Humane And Dignified Manner," also downloadable from The Medical Board of California at: http://www.mbc.ca.gov/Forms/Licensees/aid-in-dying_request.pdf.
19. HSC § 443.14(c)
20. HSC § 443.14(b), § 443.14(e)(2)
21. https://www.cdph.ca.gov/Pages/EndofLifeOptionAct.aspx

REQUEST FOR AN AID-IN-DYING DRUG TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER

I, _____,
am an adult of sound mind and a resident of the State of California.

I am suffering from _____,
which my attending physician has determined is in its terminal phase and which has been medically confirmed.

I have been fully informed of my diagnosis and prognosis, the nature of the aid-in-dying drug to be prescribed and potential associated risks, the expected result, and the feasible alternatives or additional treatment options, including comfort care, hospice care, palliative care, and pain control.

I request that my attending physician prescribe an aid-in-dying drug that will end my life in a humane and dignified manner if I choose to take it, and I authorize my attending physician to contact any pharmacist about my request.

INITIAL ONE:

_____ I have informed one or more members of my family of my decision and taken their opinions into consideration.

_____ I have decided not to inform my family of my decision.

_____ I have no family to inform of my decision.

I understand that I have the right to withdraw or rescind this request at any time.

I understand the full import of this request and I expect to die if I take the aid-in-dying drug to be prescribed. My attending physician has counseled me about the possibility that my death may not be immediately upon the consumption of the drug.

I make this request voluntarily, without reservation, and without being coerced.

Signed:_____ **Dated:**_____

DECLARATION OF WITNESSES

We declare that the person signing this request:

(a) is personally known to us or has provided proof of identity;
(b) voluntarily signed this request in our presence;
(c) is an individual whom we believe to be of sound mind and not under duress, fraud, or undue influence; and
(d) is not an individual for whom either of us is the attending physician, consulting physician, or mental health specialist.

Witness 1:_____ **Date:**_____

Witness 2:_____ **Date:**_____

NOTE: Only one of the two witnesses may be a relative (by blood, marriage, registered domestic partnership, or adoption) of the person signing this request or be entitled to a portion of the person's estate upon death. Only one of the two witnesses may own, operate, or be employed at a health care facility where the person is a patient or resident.