

Medical Aid in Dying in Washington State: A primer for participating physicians and pharmacists

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Summary

Medical Aid in Dying (MAID) is now legal in ten states and the District of Columbia. Though Washington patients have had access to this legal right since the passage of the Washington State Death with Dignity Act in 1998, physicians and pharmacists can find little published information about qualifications, protocols, or best practice parameters. Below, the most current drug regimen and practice recommendations are discussed.

Background

Medical Aid in Dying (MAID), also referred to Death with Dignity (DWD) or Physician Assisted Dying (PAD), was first approved by Oregon voters in 1997. Since that time, DWD has become law in Washington, Montana, Vermont, California, Colorado, Washington D.C., Hawaii, New Jersey, Maine and New Mexico. MAID is now available to 22 percent of US residents. All United States MAID laws require that **patients self-ingest the life-ending medications.***

In 2008, Washington State voters passed its Death with Dignity Act; the law was implemented in March 2009. By the end of 2020, prescriptions were dispensed to 2302 participants who had qualified under the act. There have been 1687 documented deaths from taking the MAID medications; the other 27 percent of the qualified participants died without taking the prescribed medications, or their status is unknown.¹

Physicians and pharmacists are not required to participate in DWD; they often decline for personal or religious convictions, or because of employer-imposed restrictions. Patients who pursue DWD are usually reasonably well informed and very determined. They (or their families) ask doctors or hospice personnel, or search the internet, for information and help. Patients often become anxious and discouraged when trying to navigate their way through this process.

Very little has been written on how medical aid in dying has actually been accomplished,^{2 3 4} partly because of concern that technical information might arm opponents or be used by persons seeking to commit suicide. However, in the interest of providing safe, consistent, quality options to patients who qualify for DWD and choose to use that option, we are presenting this information to interested physicians and pharmacists.

The Process of Qualifying⁵

The MAID laws in every legal jurisdiction in the US are very similar.⁶ In all states, a patient who is 'terminal' (i.e., has a medical diagnosis that is expected to lead to death within six months) is required to qualify in accord with the following criteria:

1. The patient must be a legal resident of the jurisdiction where MAID is available.
2. The patient must be of sound decision-making capacity. A psychiatric/psychological consult is required for any patient who the attending or consulting physician questions being of sound mind.[†]
3. Two independent, licensed, participating physicians must confirm that the patient is terminally ill. (Most jurisdictions require both doctors to complete a Physician Compliance form, which the

* In contrast, MAID has been available to terminally ill persons in Canada since 2016, allowing for either IV-administration or self-ingestion of the life-ending drugs. 99 percent of Canadian residents have chosen IV injection over self-ingestion*.

† New Jersey requires a psychological assessment completed on every MAID patient.

prescribing physician sends to the jurisdiction's department of health (DOH).[‡] The patient must also be able to self-administer/ingest the lethal medicine orally or by feeding or rectal tube.

4. The patient must make two 'oral requests' to a physician, at least 15 days apart, requesting the option to use MAID. The second oral request must be made to the Attending (prescribing) Physician. Oral requests must be documented in the patient's medical record. The timing between oral requests varies in other legal jurisdictions; clinicians in other states should check the law governing their state.[§]
5. After a face-to-face visit** with both physicians, the patient must sign a written Request for Medication which is witnessed by two individuals, at least one of whom is not related to the patient or entitled to any portion of the patient's estate.
6. The patient must be counseled about all end-of-life options and told that the request for MAID can be canceled at any time.

Once both oral requests have been made and the written request has been signed for at least 48 hours, the attending physician may write the prescription for life-ending medication and send it to a participating pharmacy. The prescription is valid for 6 months after it is written.^{††}

In 2020, 36 percent of Washington patients ingested their medications within the 30 days following the first request⁷; the median time between a patient's first request and death is noted to be 46 days in Oregon reports.⁸ If time is of the essence, the process of qualifying and obtaining prescriptions can be completed in as little as 15 days in all jurisdictions except Hawaii.

The Attending Physician is responsible for sending the Request for Life-ending Medication form, the two physician Compliance Forms, and the After-Death form to the state DOH by the Attending Physician, within 30 days of death. ^{††}

Non-Washington physicians should review their appropriate jurisdiction's laws.

Hospice participation

Most hospices have policies defining whether their physicians are permitted to participate as MAID providers. When hospice allows physician participation, it is usually as Consulting Physician, though an occasional hospice physician will serve as Attending Physician for DWD patients. Though many hospice employees (e.g., social workers, nurses, and chaplains) are personally supportive of DWD, hospice organizations can request that their employees do not attend DWD deaths.

* "**Attending Physician**" (AP) is the physician who agrees to write the prescriptions for DWDA. The AP also takes primary responsibility for counseling the patient, ensuring compliance with the law, and submitting physician documents to the DOH. The "**Consulting Physician**" (CP) examines the patient and makes a written confirmation of the patient's diagnosis, prognosis, ability to make an informed decision, and voluntary decision-making.

§ Hawaii requires that the two oral requests be 20 or more days apart.

Oregon and California offer an option to decrease the time between first and second oral requests if it is likely that the patient will not survive the 15 days required to qualify for medical aid in dying.

New Mexico was the first state to pass the aid-in-dying law with no mandatory (15- or 20-day) waiting period.

** "Patient visits, especially during the prolonged coronavirus pandemic, are often done via telemedicine. Attending and consulting physicians agree that the visual examinations and discussions during the clinical 'visit', combined with records and communications from treating physicians, are totally adequate to carefully evaluate, and qualify a patient for DWD.

†† In Hawaii, MAID prescriptions expire in 30 days of being written.

‡‡ Hawaii also requires patients to complete a Final Attestation Form 48 hours prior to taking the medication.

Aid in Dying Medications

Existing Death with Dignity laws do not specify what drugs physicians must prescribe for patient self-ingestion to peacefully end life, assuming physicians know best. Patients ask for the magic pill that has always been shown in old spy movies, but the FDA has worked diligently to make prescription drugs as non-toxic as possible.

When the first Death with Dignity law was passed in 1998 in Oregon, doctors searched to find FDA-approved drugs that would work. For the next 18 years, Oregon and Washington physicians prescribed short-acting barbiturates, since these drugs were rapidly absorbed, promptly resulted in sleep, and overdoses uniformly caused death. Secobarbital and pentobarbital remained the drugs of choice until the cost became prohibitive or they were no longer available to US patients. A combination of chloral hydrate, phenobarbital and morphine sulfate was also tried for a short time, but was deemed unacceptable. All of these choices depended on respiratory depression to cause death.

In 2016, the first attempt was made to design a drug regimen that included both respiratory- and cardiac-depressive components, which ushered in a new era in medical aid in dying. A group of Washington State physicians sought to find a combination of drugs which would produce quick sedation and coma, followed by a quick cessation of breathing and/or effective heart function. The drugs also needed to be affordable, available, predictable, comfortable, safe to non-medical helpers (as health care professionals are usually not present) and composed of FDA approved compounds. A pharmacist and a toxicologist were included in the design team. The first widely used regimen was called DDMP2 (digoxin 50 mg, diazepam 1 gram, morphine sulfate 15 grams, propranolol 2 grams). 68% of patients using this regimen died in less than 2 hours but, unfortunately, 5% of deaths took longer than 12 hours, with the maximum of 39 hours. All patients slept peacefully throughout.

The science of medical aid in dying took another leap as MAID became legal in California in 2016, with the introduction of physiologic monitoring. Dr. Lonny Shavelson not only prescribed MAID meds but also attended every patient's death, monitoring each patient throughout the entire process with ECG and pulse ox. Monitoring documented that faster MAID deaths (less than 1 hour) were primarily respiratory in origin, where those occurring after 1.5-2 hours confirmed significant cardiac causality.

Dr. Shavelson introduced changes in drug choice, dose and timing, resulting in D-DMA (requiring the digoxin 100 mg to be *ingested 30 minutes before* diazepam 1 gram, morphine sulfate 15 grams, amitriptyline 8 grams). Combined data from patients in Oregon and California showed that 85% of D-DMA patients died in less than 2 hours (n=104) with the longest death at 6 hours.^{§§} However, this drug regimen made the ingestion a 2-part process, with the potential for death from unsedated digoxin toxicity if the protocol was not followed correctly by an already anxious family.

Physicians working with End of Life Washington (EOLWA) modified the D-DMA regimen into DDMA for simplicity,^{***} ordering the powders in the same doses but dispensed together in one dark glass bottle as DDMA, to be ingested all at once, eliminating the possibility of digoxin toxicity without sedation.

Phenobarbital was first added to both D-DMA and DDMA regimens in summer 2020, in an attempt to augment the respiratory deaths (by adding a 3rd class of sedative), hoping to pull in the long-death outliers. Data from the first 6 months of use the phenobarbital-containing regimens show a marked improvement in shortening times to death in the group of patients most at risk for longer death. In addition, the data profiles for D-DMA_{Ph} and DDMA_{Ph} were almost identical. At that point, DDMA_{Ph} became the only recommended

§§ Patients with gastroparesis or other significant risk factors may have been offered other modes of self-ingestion.

*** In, Washington, non-medical, experienced volunteers are usually present to support the patient and family at non-monitored DWD deaths.

drug regimen for all legal jurisdictions. Washington data (see Table 1) illustrate the improvement over all previous regimens: 81 percent of DDMAPh patients have died in less than 2 hours; 95 percent have died in less than 5 hours.

Table 1: Washington patient Time-to-Death by Life-Ending Medications (2009-2020)*

As of 1/1/22	# cases	Cost	Minutes to Sleep				Minutes to Death				% < 2 hr
			Med	Avg	Min	Max	Med	Avg	Min	Max	
Pentobarbital (up to 2017)	180	\$500	5	5	1	20	20	66	2	2490	
Secobarbital (up to 2019)	380	\$3,000	5	6	1	130	25	76	4	2400	
Secobarbital + Propranolol (up to 2019)	32	\$3,000	5	1	1	20	26	55	5	510	
Chloral Hydrate Mixture	77	\$500	7	7			51	205	8	4280	
DDMP (diazepam, dig, MS, propranolol)	71	\$600	8	9	2	30	67	185	9	1860	
DDMP2 (Higher dose)	342	\$700-850	7	9	2	123	60	207	5	3710	67%
DDMA (dig, diaz, MS, amitriptyline)	105	\$700	5	6	1	28	51	104	10	956	78%
DDMA (higher dose)	101	\$750-900	5	7	1	31	54	112	6	802	70%
DDMAPh (dig, diaz, MS, ami, phenobarb)	252	\$550-1400	5	6	1	30	45	92	5	1569	81%

Unexpected occurrences: Over the years there have been rare patients who have not died for 10 or more hours (max 60 hours in 2015). The most common cause is severe preexisting gastroparesis, especially with pancreatic cancer.

- Vomiting: In the over 1600 patients who have taken legal life-ending medications in Washington State over the first 12 years, less 1 percent have regurgitated some of the life-ending medication; all of these patients died within 10 hours post regurgitation.
- Surgically-Isolated rectal mucosa epithelialization (occurs progressively over time in an unused rectum): One patient, with a total bowel obstruction and a previous surgically-isolated rectum, self-administered DDMP2 rectally. After delayed time to sleep, he awoke 17 hours later, and was admitted to in-patient hospice for support. He died suddenly 3 days later, presumably from delayed absorption of the digoxin.

DDMAPh (digoxin 100 mg [10x the always-lethal dose], diazepam 1 gram, morphine sulfate 15 grams, amitriptyline 8 grams), phenobarbital 5 grams) is currently the recommended life-ending medication regimen for use in Washington State, as well as in every other legal US jurisdiction.

Prophylactic antiemetics are always recommended an hour prior to the life-ending medication unless life-ending meds will be administered by jejunal feeding tube or rectal catheter. In Washington, recommended antiemetics are metoclopramide 20 mg and haloperidol 2 mg, as haloperidol often works in patients with ondansetron failures and promotes additional relaxation in an anxious patient on the day of death.^{9 10} *Ondansetron 8 mg can be used as an alternative to the haloperidol, especially in a very weak or somnolent patient.*

The Challenging Patient and Red Flags: factors recognized to prolong time to death

Sometimes a patient can take a significantly longer to die than expected, and this has been shown for every life-ending drug regimen ever utilized. (Table 1)

The most important factor in prolonged time-to-death is impaired gut motility and/or absorptive capacity:

Life-ending medications are absorbed primarily in the small intestine, not the stomach.^{11 12 13 14}, though there is some absorption of phenobarbital by gastric mucosa.^{+++ 15 16} The rate of drug absorption is influenced by the solution in which the powdered drugs are mixed, how quickly the drugs travel through the stomach and reach the numerous small intestine absorptive compartments, available surface area, blood flow, and the patient's specific disease processes.¹⁷

+++ Barbiturates and aspirin are some of the few drugs absorbed in the acidic pH of the stomach.

Any patient who has **gastroparesis** (from pancreatic or other upper GI cancers, diabetes, etc.) or **significant obstruction of the upper GI tract** will be at risk for delayed gastric emptying. The meds cannot work until they get into the intestine where they are absorbed.

In addition, for the medications to be absorbed, the intestinal villi must be functioning well, with good blood supply. Patients who are **status-post small bowel resection** or who have **malabsorptive syndromes** will have a longer time-to-death. Any patient with gastroparesis, bowel obstruction or malabsorption should be considered candidates for rectal self-administration of life-ending medication (unless the rectum has been surgically isolated months to years previously).

Other factors influencing prolonged time-to-death: these have been identified as potential outliers through data analysis

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- Patients who are very tolerant or **addicted to opiates/sedative drugs/alcohol** should be considered to have a cross-tolerance to the morphine-diazepam-phenobarbital components of the life-ending drug regimens.
 - Patients with intractable pain or who require **IV pain pumps**
 - **Young and healthy** patients (especially athletes)
 - **Large patients** (over 300 lb. regardless of BMI)
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These patients and their helpers should be counseled that the time-to-death might be longer than for most other MAID patients. The use of a phenobarbital-containing drug regimen is also recommended for these known challenging patients in order to potentially shorten the time-to-death.

Seizures:

Rarely, a patient may exhibit seizures after being asleep for several hours. Terminal seizures are more likely in patients with a history of brain insult (tumor, trauma or stroke) or history of seizure disorder, but can also occur from hypoxia immediately preceding death. The incidence of seizures is not statistically increased in patients who choose to ingest DDMAPh. However, persons attending the death of a patient should be advised of the possibility of terminal seizure (as it is often upsetting when witnessed) and be assured that, if a seizure does occur, it will not awaken the patient or cause him any discomfort.

Writing the prescription

The most recent updates on recommendations for life-ending medications are available on:

End of Life Washington's Website: <https://endoflifewa.org> OR

End of Life WA Providers' Network: <https://endoflifewa.ning.com/?xgi=wHU1wwSPRBVWg1>

Attending and Consulting Physicians information packets, a list of participating compounding pharmacies, and family information documents are available for download from EOLWA. Instructions for feeding tube and rectal catheter self-administration are also available for patients and families.^{†††}

Though not required, it is helpful for the attending physician to call the pharmacist to introduce him or herself and to let the pharmacist know that the prescription is coming. Pharmacists often have specific questions or suggestions. Because the medications are not always in sufficient stock, and prescriptions must be individually 'built' for each patient, one or two days of lead time is recommended when requesting that prescriptions be filled. Written prescriptions are valid for six months; if a patient survives longer than six

^{†††} EOLWA has also specifically developed instructions during periods when volunteers cannot be present with terminal patients for education, hand-holding, or even preparing the final cocktail, during the time of the COVID 19 restrictions.

months, prescribing physicians can simply reissue the expired prescription without having to restart the qualifying process.

When writing the prescription, the name of the person(s) who will be picking up the medication should be included on the prescription. Including this information allows the pharmacist to dispense the medications to family members or a designee, since it is rare that a dying patient is able to pick up his own medications.

In Washington State, prescriptions may be faxed to the compounding pharmacy for HOSPICE PATIENTS^{§§§} and those in long-term care facilities only. For all other Washington patients, the original MAID prescription must be hand delivered to the pharmacist by the prescribing doctor or courier, or received by mail before it can be filled.

Pharmacists have a vital role in the preparation, dispensing and use of the medication:¹⁸

A compounding pharmacist must prepare DDMPH mixtures. **Concentrated powder forms** of these component drugs should be used, instead of grinding tablets.^{****} The compounded mixture should be **dispensed in powdered form, in an amber colored glass bottle.**⁺⁺⁺⁺ Immediately before ingesting, the **powdered mixture can easily be mixed with 2-3 oz. water or clear juice.** Mixing the powdered mixture with a favorite clear drinking alcohol is not recommended: the powders are no more soluble in alcohol and will cause the favorite liquor to taste horrible, and the liquor may increase the incidence of a burning sensation on ingestion. Mixing the medication in soft food, particulate juices or fatty or dairy products can result in delayed gastric emptying and will prolong the time to death. **Shelf-life of the unsuspended/dissolved powdered life-ending medication is considered to be 6 months; once the powders have been mixed with a liquid of choice, the medications must be used within 2 weeks.** Cost to the patient is \$700-\$850, as these are rarely covered by insurance.

Additional considerations for providing the best patient care:

If a patient has a functioning pacemaker there is no need to do anything, but if the patient has a AICD (pacemaker/defibrillator), the patient should arrange with his cardiologist to have the defibrillator function turned off shortly before ingestion.

If not already enrolled, patients should be encouraged to **enroll in hospice**, as soon as they bring up the option of physician assisted dying. Hospice provides additional medical, physical, emotional, and spiritual support to the patient and his family, in the last days, weeks, and months of the patient's life. **Enrollment in hospice also facilitates disposition of the body after death, as emergency services, coroners and medical examiners will not be involved** and this often matters to the family.

Counseling the patient and family

Written instructions are invaluable to the patients and families. Family members often become anxious as the day of death approaches, and really appreciate written instructions for reference. This material should confirm the information that they hear during the counseling session with the attending physician, and cover mixing the medication, positioning the patient, and what to expect after the meds are ingested. **Instruction documents are available through End-of-Life Washington.**

There is a limited 'window of opportunity' for terminally ill patients to use the DWD laws. Because of the decline of dying persons, some may suddenly (e.g., those with brain tumors) lose competence and become

§§§ "HOSPICE PATIENT" must be clearly noted on the faxed prescriptions.

**** When pills are pulverized, the filler from the tablets adds a large volume of inert powder, which has been shown to result in longer deaths.

++++ Diazepam is absorbed into plastic and degraded in light; thus, it should only be dispensed in amber glass bottles.

ineligible to use the law. The 'window' concept should be reviewed in advance with the patient and family, as it may influence the timing of the patient's decision on whether to use life-ending medicine.

One in four qualified patients dies without using available MAID medications. **Physicians should advise patients to leave the prescription on file at the pharmacy until they decide that the time has come to use the medication and fill it shortly before expected use.** This saves on the significant cost of filling a never-used prescription and eliminates the need for disposal of a lethal substance.

Family information: Oral self-ingestion

The life-ending medications should be taken on a fairly empty stomach.

- Pain medications should be continued as needed just before the life-ending medicine. Laxatives or stomach-coating medications (e.g., Pepto-Bismol, Sucrafrate, Maalox) are not recommended.
- **The patient should not eat solid food or dairy products or drink particulate (non-clear) juices for 5 hours** before the medications are planned. He may have a light meal the night before, or up to five hours before the chosen time, and then just some clear juice or water. Carbonated beverages and stomach coating medicines (e.g., Pepto-Bismol, Sucralfate) are not recommended.

On the day chosen to take the medications, a patient may choose to be surrounded by friends and family, or to be alone with just one person in attendance. It is usually easiest for everyone concerned if the patient plans to take the medications in mid-to-late morning, as the dying process may take a number of hours. At least one person should be present to mix the medications, to help position the patient, and to gather the information required by the attending physician for the state compliance forms.

The patient must have the ability to drink 2-3 ounces of volume within a minute or two, so that she ingests the entire amount of drug before becoming unconscious. An additional cup of clear juice or water, a popsicle, or spoonfuls of sorbet (which contains no dairy) should be immediately available before and after ingesting the medication. These options clear the bitter taste from the mouth and throat and, more importantly, stimulate gastric emptying¹⁹ and hasten movement of the medication into the small intestine where it is absorbed. A final glass of wine or clear liquor is fine for patients who still have a taste for it. Patients fall asleep in about 5-15 minutes, and sleep very comfortably thereafter, peacefully and without pain, until they die. It's helpful to have a DWD experienced provider or volunteer present to oversee the process, and coach the patient to swallow quickly; and if swallowing is impaired the patient should practice quickly swallowing 2-3 ounces of liquid a day or so ahead of the 'final act'.

When it is time to take the medications, the patient should position herself sitting comfortably in an adjustable bed or recliner, or prop himself up in bed with pillows, as it is easiest to swallow the meds quickly in the sitting position. A volunteer from EOLWA, a family member or a friend should pour 2-3 ounces of water or clear juice into the bottle of powdered meds, recap it, and shake vigorously for 30 seconds. The medication should be ingested immediately: chugged from right the bottle, or poured into a small glass, or sipped through a straw.

No matter which drug regimen the patient has been prescribed, or what liquid it is mixed in, the life-ending medication which the patient orally ingests has a distinctly BITTER taste that cannot be blocked. In addition, about half of DDMAPH patients notice some burning upon ingestion (similar to a shot of whiskey), but this is usually eliminated by drinking a pre-prepared glass of water, or eating a popsicle or sorbet immediately after swallowing the medication. It is a good idea to discuss these issues beforehand. Weak or debilitated patients should practice drinking 3 ounces of liquid as quickly as possible for several days before the planned death. A prepared patient does a much better job of getting all the medication comfortably ingested in the suggested time frame.

If a patient has been on oxygen for comfort, it should be discontinued after the patient falls asleep. Let the family know this in advance, as it seems cruel to some.

Family information: *Rectal or feeding tube self-ingestion/administration*

In US jurisdictions that permit MAID, patients must self-administer the life-ending medication, but not all terminally ill persons in the process of dying retain the ability to ingest in the usual way. Some patients develop progressive weakness (e.g., those with neuromuscular diseases) or obstruction (e.g., from esophageal cancer) making them unable to swallow the required amount. Intractable nausea and vomiting may make it impossible for the patient to keep the life-ending medications down. Legal opinion defines 'ingestion' to include self-administration of food or medications anywhere within the alimentary canal. For patients who eat or take their medications through a feeding tube, the medication can be **self-administered into the feeding tube by the patient**. When no upper GI feeding tube is present, patients who are unable to swallow or keep food down may rectally self-administer any of the available agents by means of a rectal tube. For tube self-ingestion, the patient must either push the plunger on 1-2 syringe(s) containing the suspended medicine for ingestion, or open a clamp or valve to allow the medicine to flow from a gravity bag into the feeding tube or rectal catheter.

Patient positioning after sleep ensues

Patient positioning has been a long-discussed issue. The **patient should be sitting to take the medication and remain in that position for at least the next twenty minutes** for optimal gastric emptying. After 20-30 minutes, patients may be left in a sitting position or lowered to a semi-recumbent position. Some physicians believe that the patient should then be placed in right lateral decubitus (RLD) position to enhance gastric emptying. However, unless the patient is very small or the family/friends present are well-muscled, positioning the sleeping patient in the RLD position can cause injury to the positioner. Basically, any position will result in death, and all these factors must be considered before moving sleeping patients to a more favorable position.

Reviewing the literature concerning the influence of different body positions (sitting, supine, right lateral decubitus, and left lateral decubitus) on gastric emptying in healthy volunteers, two studies have shown no statistically significant difference between positions;^{20 21} others have found gastric emptying to occur faster in sitting position than supine.^{22 23} Sanka et al. found that 100 ml of plain water flowed passively (without peristalsis) into the small bowel faster when the patient was positioned in RLD,²⁴ but no thicker liquids were studied. In their excellent review of the effect of postural influence on the physiology and pharmacokinetics of drug absorption, Quackenberry and Fuhr summarize "... because for most of the drug's total [exposure in the patient] is not affected by posture, the clinical impact for mobile patients would seem to be quite limited. In bedridden patients, particularly those with severe illness and/or those taking drugs with a narrow therapeutic range, the situation may be different: to position a patient in right lateral posture may accelerate the onset of therapeutic effects."²⁵ A study in children found that delayed gastric emptying shows significant improvement with change of position.²⁶ Interestingly, it is not uncommon for us to get reports from friends or family witnessing a Death with Dignity that the patient died within a short time after position change.

As death occurs...

After the patient has ceased breathing (no breaths in 10 minutes) and no longer has a pulse, hospice should be called. NOTE: For patients not enrolled in hospice, the medical examiner or the funeral parlor should be called. In addition, the prescribing physician can sometimes preemptively arrange with the local medical examiner or coroner that emergency response protocols not be activated for a planned DWD death.

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