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Report to Congressional Committees

April 2020

PREVENTING DRUG DIVERSION

Disposal of Controlled Substances in Home Hospice Settings

GAO-20-378

GAO Highlights

Highlights of GAO-20-378, a report to congressional requesters

April 2020

PREVENTING DRUG DIVERSION

Disposal of Controlled Substances in Home Hospice Settings

Why GAO Did This Study

Misuse of controlled substances continues to be a serious public health problem in the United States. Most commonly misused controlled substances include opioids (such as oxycodone), which are used to treat pain, and central nervous system depressants (such as diazepam), which are used to treat anxiety and sleep disorders. These types of drugs are commonly prescribed for patients in hospice care.

The SUPPORT Act included a provision for GAO to examine disposal of controlled substances in home hospice settings. This report describes selected home hospices' controlled substances disposal practices and the challenges they face in disposing of these substances.

GAO reviewed the SUPPORT Act and other related statutory and regulatory provisions. GAO also interviewed officials from the Centers for Medicare & Medicaid Services, the Drug Enforcement Administration, three national hospice trade associations, two national nurse trade associations, 11 state hospice associations, and seven hospices.

View GAO-20-378. For more information, contact James Cosgrove at (202) 512-7114 or CosgroveJ@gao.gov.

What GAO Found

Hospice care helps patients who are terminally ill maintain their quality of life. Most patients get hospice care at home, which typically includes use of controlled substances, including opioids such as oxycodone, to provide pain relief. When hospice patients die at home, they often leave behind unused controlled substances, which can be diverted and misused by anyone with access to them. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), enacted in 2018, allows employees of qualified hospice programs to dispose of unused controlled substances by collecting and destroying the drugs in patients' homes. In addition, some states had laws allowing hospice employees to dispose of patients' unused controlled substances prior to 2018.

Three of the seven hospices GAO contacted operate in states without such laws. Officials from two of these hospices told us their hospices began disposing of patients' controlled substances in their homes following the enactment of the SUPPORT Act in 2018. However, one hospice had not begun disposing of these medications because the state department of health directed it not to do so until a state law granting disposal authority to hospices had been enacted. An official from that hospice said that it continued the practice of leaving the controlled substances in the home and educating family members about how to dispose of the drugs themselves.

Hospice officials we spoke to identified best practices for preventing diversion and disposing of controlled substances. Best practices include prescription drug counts performed by hospice employees to determine if controlled substances are being used properly, use of lock boxes to limit access to controlled substances in situations where diversion is suspected to be a risk, and having a witness for the disposal of unused controlled substances.

The officials also identified challenges their hospice employees have faced when disposing of controlled substances in patients' homes. Challenges include the cost of certain disposal methods, a lack of a witness to the disposal process, and inconsistencies between state laws and federal law concerning which hospice employees may dispose of controlled substances.

The Departments of Justice and Health and Human Services provided technical comments on a draft of this report, which GAO incorporated as appropriate.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
DEA	Drug Enforcement Administration
EPA	Environmental Protection Agency
SUPPORT Act	Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act

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U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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April 14, 2020

Congressional Committees,

Misuse of controlled substances continues to be a serious public health problem in the United States.[1] National survey data from the Substance Abuse and Mental Health Services Administration show that in 2017, 53 percent of people 12 years of age and older in the United States who misused prescription pain relievers in the past year, obtained the drugs from friends and family.[2] The most commonly misused controlled substances include opioids (such as oxycodone), which are used to treat pain, and central nervous system depressants (such as diazepam), which are used to treat anxiety and sleep disorders. These types of drugs are prescribed for a large proportion of patients in hospice care. Patients select hospice care when they no longer want treatment for their terminal illness, but rather choose a hospice team to provide symptom management and control. In 2017, approximately 1.5 million Medicare beneficiaries received hospice services, and 56 percent of those patients received care in the patient's home. Medicare is the largest payer for hospice services.

When hospice patients die, any unused drugs left in the home create a potential for diversion.[3] One way to combat diversion of controlled

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[1]The National Institute on Drug Abuse defines misuse of prescription drugs, including controlled substances, as taking a medication in a manner or dose other than prescribed; taking someone else's prescription, even if for a legitimate medical complaint such as pain; or taking a medication to feel euphoria. See: National Institutes of Health, National Institute on Drug Abuse, *Misuse of Prescription Drugs*, (Updated December 2018).

Drugs are classified as controlled substances and placed into one of five schedules based on their currently accepted medical use, potential for abuse, and risk of dependence. Controlled substances are regulated under the Controlled Substances Act. Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (codified, as amended, at 21 U.S.C. § 801 et seq.). See also 21 C.F.R. Chp. II (2019).

[2]Misusers were given, bought, or stole the prescription pain relievers from family and friends. See: Substance Abuse and Mental Health Services Administration, *Behavioral Health Barometer United States, Volume 5: Indicators as measured through the 2017 National Survey on Drug Use and Health and the National Survey of Substance Abuse Treatment Services*, Department of Health and Human Services Publication No. SMA-19-Baro-17-US, (Rockville, Md.: 2019).

[3]Diversion of a controlled substance is taking it from a legitimate entity, such as a patient, and putting it into an illicit channel, such as the community.

substances in home hospice settings is to ensure they are properly disposed of when no longer needed by the patient.[4] The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), enacted in October 2018, amended prior law to allow licensed medical and nursing employees of qualified hospices to handle patients' controlled substances for the purpose of disposal as long as the disposal occurs onsite in accordance with all applicable laws.[5] The SUPPORT Act included a provision for GAO to review the disposal of unused controlled substances in home hospice, including federal oversight and the experiences of home hospices.[6] In this report, we describe selected hospices' experiences disposing of and preventing the diversion of controlled substances in home settings.

To describe what is known about the selected hospices' experiences disposing of and preventing the diversion of controlled substances in home settings, we interviewed officials from 11 selected state hospice associations and seven selected hospices. Of the 11 selected state hospice associations, we interviewed officials from five operating in states with laws on the disposal of controlled substances in home hospices and six operating in states without such laws.[7] The information obtained from these interviews is not generalizable, but provided us with valuable examples of hospices' experiences with the disposal of controlled substances. The 11 states were chosen for this review because they had state hospice associations that were involved in disposal discussions with national hospice associations or they had higher opioid-related death

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[4]We use the term "home hospice" in this report because our report was limited to the disposal of controlled substances in hospice patients' homes. The Centers for Medicare & Medicaid Services (CMS) does not differentiate between inpatient hospice services and home hospice services.

Disposal of controlled substances is the collection and destruction of these drugs.

[5]Pub. L. No. 115-271, § 3222, 132 Stat. 3894, 3948 (2018) (codified at 21 U.S.C. § 822(g)(5)). The disposal of controlled substances may also be subject to other federal, state, tribal, and local laws.

Under prior law, home hospice personnel could not dispose of a deceased patient's controlled substances unless authorized to dispose of the patient's property by a state or local law.

[6]Pub. L No. 115-271, § 3223, 132 Stat. 3894, 3949 (2018).

[7]The five states with laws on the disposal of controlled substances in home hospice settings are Delaware, Florida, Maryland, Ohio, and South Carolina. The six states without such laws are California, Illinois, Indiana, Massachusetts, Tennessee, and West Virginia.

rates than most states.[8] The seven selected hospices whose officials we interviewed were located in six of the 11 states.[9] We interviewed officials from four hospices in three of the selected states with disposal laws and officials from three hospices in three of the selected states without disposal laws. The hospices were chosen based on recommendations from the national or state hospice associations with which we spoke. All seven hospices are Medicare certified. We also spoke with officials from the Centers for Medicare & Medicaid Services (CMS); the Drug Enforcement Administration (DEA); the National Association for Home Care and Hospice; the National Hospice and Palliative Care Organization; the National Partnership for Hospice Innovation; the Hospice and Palliative Nurses Association; and the Visiting Nurses Association of America. We also reviewed the SUPPORT Act and other related statutory and regulatory provisions.

We conducted this performance audit from April 2019 to April 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[8]Data on opioid-related death rates came from the National Institute of Health/National Institute of Drug Abuse, "Opioid Summaries by State." *2017 Opioid-Involved Overdose Death Rates (per 100,000 people)*, accessed July 16, 2019, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state.

[9]We talked to officials from the following home hospices: Delaware Hospice, Hospice of the Panhandle (West Virginia), Sutter Care at Home (California), Hospice of Wyandot County (Ohio), Heartland Hospice (Ohio), Calvert Hospice (Maryland), and Good Shepherd Community Care (Massachusetts).

Background

Hospice Services

Hospice care helps patients who are terminally ill—as well as the families of those patients—maintain their quality of life. Hospice care focuses on the comfort of patients (palliative care), not curing the illness. Patients are eligible for hospice care under Medicare if they have a life expectancy of six months or less.[10] Most patients get hospice care at home, which typically includes use of controlled substances, including opioids such as oxycodone, to provide pain relief.[11] According to CMS, hospice teams are required to include a physician, nurse, social worker, and pastoral or other counselor; and may also include hospice aides, trained volunteers, and speech, physical, and occupational therapists. The patient selects a primary caregiver when first admitted into home hospice, and this person becomes a member of the home hospice team. The primary caregiver, often a family member, provides most of the care for the patient in home hospice, including most of the physical care for the patient, keeping records of symptoms and other problems, and communicating with the hospice team.[12]

Disposal of Controlled Substances in Home Hospice

The Controlled Substances Act regulates the manufacture, distribution, use, and disposal of controlled substances.[13] In general, the Controlled Substances Act was enacted to facilitate the use of controlled substances for legitimate medical, scientific, research, and industrial purposes while preventing them from being diverted for illegal uses. DEA is the primary agency with responsibility for administering and enforcing the law, and DEA provides oversight of all persons or entities required to register with

[10]See 42 C.F.R. §§ 418.20 and 418.3 (2019).

[11]Home hospice care can also be provided in other locations, such as nursing homes and residential facilities. See: *National Hospice and Palliative Care Organization, Facts and Figures, 2018 Edition (Revised July 2, 2019)* (Alexandria VA.: July 2019).

[12]There can be multiple caregivers, such as more than one family member, friends, and neighbors.

[13]Pub. L. No. 91-513, tit. II, 84 Stat. 1236, 1242-84 (1970) (codified, as amended, at 21 U.S.C. § 801 et seq.).

DEA.[14] The Controlled Substances Act has been amended twice to clarify federal requirements for patient disposal of controlled substances.

- **2010.** The Secure and Responsible Drug Disposal Act of 2010 amended the Controlled Substances Act to allow a patient who has lawfully obtained a controlled substance to deliver the controlled substance to another person for the purpose of disposal, without being registered with DEA.[15] Any person lawfully entitled to dispose of a deceased patient's property may also deliver the patient's controlled substances to another person for the purpose of disposal. The person receiving the controlled substances must be legally authorized to do so and the disposal has to take place in accordance with DEA regulations, which DEA issued in 2014. Among other things, the DEA rulemaking clarified that home hospice personnel could not dispose of a deceased patient's controlled substances unless authorized to dispose of the patient's property by a state or local law.[16] Instead, the rulemaking encouraged home hospice personnel to assist patients and their families in disposing of controlled substances in accordance with the Controlled Substances Act, and partner with authorized collectors to promote or jointly conduct mail-back programs.[17]
- **2018.** The SUPPORT Act amended the Controlled Substances Act to allow employees of qualified hospices, whether or not registered with DEA, to dispose of a patient's unused controlled substances onsite and in accordance with all applicable laws after the patient's death or the controlled substance expires.[18] The employee must be a physician, physician assistant, nurse, or other person who is:
    - employed by a qualified hospice;

[14]Under the Controlled Substances Act, all persons or entities that manufacture, distribute, or dispense controlled substances are required to register with DEA, unless specifically exempted. For example, pharmaceutical companies that manufacture controlled substances and pharmacies that dispense controlled substances are required to register with DEA. DEA registration is a closed system, and it allows DEA to monitor the flow of controlled substances in the United States.

[15]Pub. L. No. 111-273, § 3(a), 124 Stat. 2858, 2859-60 (2010) (codified at 21 U.S.C. § 822(g)).

[16]See 79 Fed. Reg. 53,520, 53,546 (Sept. 9, 2014).

[17]Mail-back programs generally provide postage-paid envelopes that patients can use to mail unused drugs to DEA-registered collectors for destruction.

[18]Pub. L. No. 115-271, § 3222, 132 Stat. 3894, 3948 (2018) (codified at 21 U.S.C. § 822(g)(5)).

- licensed to perform medical or nursing services by the jurisdiction in which the patient is receiving hospice care;
- acting within the scope of their employment in accordance with applicable state law; and
- trained on the disposal of controlled substances by the qualified hospice.

If the hospice patient no longer requires the controlled substances because of a change in his or her care plan, only the patient's DEA-registered physician may dispose of the patient's unused controlled substances. The authority to dispose of unused controlled substances under the SUPPORT Act applies only to qualified hospices. Such hospices must have written policies and procedures for assisting in the disposal of controlled substances after the patient's death, and must document that they provided and discussed these policies and procedures in an understandable manner with the patient and family. In addition, the hospice must document the type of controlled substance, dosage, route of administration, and quantity disposed, as well as the time, date, and manner in which the disposal occurred. The SUPPORT Act also allows the Attorney General to issue guidance to hospices regarding the disposal of controlled substances in patients' homes.

Federal Oversight

According to DEA officials, DEA's oversight of the disposal of controlled substances in home hospices is limited to instances of suspected or actual diversion. This is because the SUPPORT Act allows employees of qualified home hospices to dispose of unused controlled substances in patients' homes without registering with DEA.

CMS regulates Medicare-certified home hospices through the Hospice Conditions of Participation, which are intended to protect the health and safety of individuals under hospice care. Hospices must be in compliance with the Hospice Conditions of Participation to participate in the Medicare program.[19] CMS oversees compliance with the Hospice Conditions of Participation primarily through inspections, which are conducted by state survey agencies contracted by CMS or CMS-approved national private accrediting organizations. Among other things, the Hospice Conditions of Participation require hospices to have written policies and procedures for the management and disposal of controlled substances in the patient's

[19]See 42 U.S.C. § 1395x(dd)(2) and 42 C.F.R. Part 418 (2019). Hospices also must be licensed under state law to provide patient care.

home, discuss the hospice policies and procedures for managing the safe use and disposal of controlled substances with the patient and family in a manner that they understand, and document that the written policies and procedures for managing controlled substances were provided and discussed. CMS does not oversee the disposal process.

Selected Home Hospices' Experiences, Best Practices, and Challenges in Disposing of Controlled Substances

Selected Home Hospices' Experiences Disposing of Controlled Substances

According to a national hospice association official, each hospice had a different approach to disposal prior to the DEA rulemaking in 2014. Some hospices asked their employees to dispose of controlled substances to prevent diversion and others did not. After the DEA rulemaking, some states enacted laws granting authority to hospice employees to dispose of patients' unused controlled substances when the medications were no longer needed, upon death of the patient, or both. Requirements under states' laws vary (see appendix I).

Hospices in some states without laws on the disposal of controlled substances in home hospice began, or resumed, disposing controlled substances in patients' homes following the enactment of the SUPPORT Act in 2018.[20] Officials from six selected home hospices expressed support for the authority to dispose of controlled substances granted by the SUPPORT Act, and officials we interviewed from two hospices operating in states without disposal laws told us their hospices had resumed disposing of controlled substances in patients' homes under the authority granted by the SUPPORT Act. In contrast, an official from one hospice told us that their hospice had not begun disposing of these

[20]Those hospices that resumed disposing of patients' controlled substances had stopped doing so in 2014 when DEA rulemaking clarified that home hospice personnel could not dispose of a deceased patient's controlled substances unless authorized to dispose of the patient's property by a state or local law.

medications with the enactment of the SUPPORT Act because the state department of health directed it not to do so until a state law granting disposal authority to hospices had been enacted. For now, the hospice has continued with its practice of educating patients' family members on how to dispose of controlled substances themselves.

Selected Home Hospices' Policies and Best Practices for Disposing of Controlled Substances and Reducing the Risk of Diversion

Medicare-certified hospices, including the seven we selected for our review, are required by CMS's Hospice Conditions of Participation to have written policies and procedures for the safe disposal of controlled substances in a patient's home. The policies and procedures may include best practices, such as measures for assessing and mitigating the risk of diversion in a patient's home, and if and how the hospice will conduct controlled substance disposal. According to officials we interviewed from the selected hospices and state hospice associations, hospices utilize various strategies or best practices to attempt to mitigate diversion risks, including, but not limited to, the following:

- **Education on controlled substance use and disposal.** Hospice policies may include disposal education for patients and their caregivers. Specifically, officials from five hospices and five state hospice associations said that patient and family member education on controlled substances and their disposal begins or should begin upon the patient's admission into hospice care or as soon as possible thereafter. According to officials from three hospices, their staff may use written agreements or acknowledgements that must be signed by the patient or their caregiver. An official from one hospice association told us the association made an agreement template available to their hospice members that can be used to ensure patients understand how to properly use prescribed controlled substances, agree to use them properly, and will not give them to anyone else.
- **Prescription drug counts.** Officials from four hospices and two state hospice associations told us that, in general, nurses conduct prescription drug counts at every visit to check if the proper amounts of medications remain. Officials from two of these hospices said that drug counts should require the family's acknowledgement or be witnessed. Officials from three other state hospice associations mentioned that their members use drug counts as well but did not specify if this occurred at every visit. These counts can be used to recognize possible drug misuse or diversion. If there is an indication that diversion may be the cause of an incorrect count, hospices can put additional drug diversion risk reduction practices in place.

- **Lockboxes.** If diversion is suspected to be a risk or if there are children present in the patient's home, a hospice may choose to use a lockbox to store the patient's medications and limit access to only an alert patient or their caregivers. Officials from five hospices and five state hospice associations mentioned that their employees and members use lockboxes for such purposes. One hospice official explained that lockboxes may also be used as an accountability tool so that those with access cannot accuse others of stealing if drugs are unaccounted for.
- **Pharmacy cooperation.** A hospice may choose to have the pharmacy mail a prescribed controlled substance in smaller quantities and with greater frequency. For example, an official from one of the selected hospices explained that the pharmacy they use will deliver medications as often as daily if needed to reduce the risk of controlled substances being diverted. Similarly, an official from a state hospice association explained that some pharmacy managers and benefits managers note when a refill for a prescription is requested sooner than it should have been and alert the hospice.
- **Witnessed disposal or assisted disposal.** Pursuant to some state disposal laws and according to officials from five hospices and four state hospice associations, controlled substance disposal and assisted disposal must or should be performed with a witness present. The state disposal laws may specify who the witness must be. For example, according to two state laws, a family member or a second hospice employee may witness disposal.
- **In-home disposal products.** Hospices may have varying preferences for how they dispose of controlled substances; officials from four of the selected hospices mentioned using in-home disposal products, and two specifically explained they believed these to be the safest disposal method, even though, according to the officials, it can be costly.[21] Officials from another hospice told us they receive their in-home disposal products through a grant program.
- **Documentation.** Officials from four selected hospices told us their employees document the completion of certain tasks, such as diversion risk assessments, drug counts, drug disposal, and the refusal of drug disposal. An official from one of these hospices told us their staff perform and document a diversion risk assessment of the patient's home. While officials from four hospices told us their

[21]For information about in-home disposal products, see GAO, *Prescription Opioids: Patient Options for Safe and Effective Disposal of Unused Opioids*, GAO-19-650 (Washington, D.C.: Sep. 3, 2019), 15.

employees perform drug counts, only one official specified that employees from their hospice document the drug counts. Another hospice official explained that disposal documentation includes the name, dosage, form, and administration method of the medication. One hospice official told us that if a patient's family members refuse disposal, they must sign a form stating they declined to allow the nurse to dispose of the patient's remaining drugs.

Selected Home Hospices' Challenges with Disposing of Controlled Substances

Officials from selected hospices and state hospice associations in our review described various challenges associated with disposing of controlled substances in patients' homes. The challenges described by the selected hospices and state hospice associations include but are not limited to the following:

- **Certain disposal methods may be too costly.** An official from one state hospice association said that most of its members do not use a drug disposal process, which may include a mail-back program or in-home disposal product, because it is an extra expense, and an official from one hospice said that after pricing an in-home disposal product, their hospice decided it was cost prohibitive. One state hospice association official explained that although most of its in-home hospice members use an in-home disposal product, in instances when the hospice employee is disposing of 40 to 50 vials, the expense of this disposal method can be burdensome. The official told us the product costs approximately $6 each and fits four to five vials of pills in each.
- **Disposal can be time consuming.** One hospice official said that disposal can sometimes be a time-consuming and resource-intensive activity. According to two state hospice association officials, sometimes a patient's family will ask the disposing hospice employee to dispose of all of the patient's unused prescription drugs that remain in the home, not only controlled substances or drugs prescribed under hospice care. Officials from two of our selected hospices and two state hospice associations told us that it is not atypical for a hospice patient to have bags or boxes full of unused medications, though the officials did not describe this as a disposal challenge for hospices.
- **Lack of a witness.** One hospice official told us that it is a challenge when a witness is not available or is unwilling to participate in a drug count or disposal. Another hospice official indicated that the patient's primary caregiver is not always the family member present at the time of a drug count or disposal. This can create a challenge, as the hospice employee must either wait for the patient's primary caregiver

to arrive, or for that person to agree to witness a count, disposal, or both.

- **Family members and caregivers sometimes refuse to dispose of controlled substances.** Officials from two hospices and three state hospice associations indicated that a family's refusal to dispose of a patient's remaining medications can be a challenge, though one hospice official said it occurs infrequently. An official from another hospice said that if a family initially refuses disposal, hospice staff return after two weeks to complete the disposal process.
- **Inconsistencies between state laws and federal law.** Hospices must comply with applicable federal and state laws governing controlled substances, and to the extent state law is inconsistent with the Controlled Substances Act, hospices must follow federal law.[22] Hospice officials told us that inconsistencies between state laws and federal law can cause challenges. For example, the SUPPORT Act limits disposal to only physicians, physician assistants, nurses, or other hospice employees who are licensed to provide medical or nursing services. An official from one hospice stated that the hospice used the help of social workers and volunteers to dispose of controlled substances. Regulations in this state do not specify which types of hospice employees are permitted to assist with disposal. According to the official, social workers and volunteers helped dispose of patients' controlled substances when disposal occurred at a later time, rather than immediately following a patient's death. Since the SUPPORT Act limits disposal to home hospice personnel with specific qualifications, it is unclear whether hospices are able to allow social workers and volunteers to help in that capacity.

  As another example, under the SUPPORT Act, only a hospice patient's DEA-registered physician can dispose of the patient's controlled substances if the plan of care has been modified.[23] However, some state laws allow other types of hospice employees to perform disposal in this circumstance. Officials from two hospices in these states indicated it will be a challenge for disposal to be limited to physicians when a patient's plan of care is modified. Similarly, officials from two other selected hospices in states without disposal laws also stated that this would be a challenge. For example, one hospice

[22]See 21 U.S.C. § 903.

[23]An example of a modification in the plan of care is when a patient no longer needs a prescribed controlled substance.

official explained that their hospice does not have many physicians, and it would be unlikely for a physician to be able to visit a patient's home solely to handle disposal.

Agency Comments

We provided a draft of this report to the Departments of Justice and Health and Human Services for review. The Departments of Justice and Health and Human Services provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Attorney General of Justice, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at CosgroveJ@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix II.

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Director, Health Care

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Appendix I: Summary of Five States' Controlled Substances Disposal Laws for Hospices

To describe what is known about selected hospices' experiences disposing of and preventing the diversion of controlled substances in home settings, we selected five states with laws on the disposal of controlled substances in home hospices and six states without such laws.[1] The five states with disposal laws were chosen for this review because they had state hospice associations that were involved in disposal discussions with a national hospice association or they had higher opioid-related death rates than most states.[2] The summaries in Table 1 below reflect our reviews of the five states' laws.

[1]The five states with laws on the disposal of controlled substances in home hospice settings are Delaware, Florida, Maryland, Ohio, and South Carolina. The six states without such laws are California, Illinois, Indiana, Massachusetts, Tennessee, and West Virginia.

[2]Data on opioid-related death rates came from the National Institute of Health/National Institute of Drug Abuse, "Opioid Summaries by State." *2017 Opioid-Involved Overdose Death Rates (per 100,000 people)*, accessed July 16, 2019, https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state.

Table 1: Summary of Five States' Controlled Substances Disposal Laws for Hospices

State	Effective Date	Description
Delaware	August 11, 2014	Under Delaware regulations, every in-home hospice must have policies and procedures that address medication disposal following the death of a patient. Specifically, the policies and procedures must, among other things: • Designate hospice staff that will assist the patient's family member or primary caregiver with disposal of prescription medications, in accordance with Food and Drug Administration guidelines; • Define the time frame in which disposal must occur; • Prohibit hospice staff from removing prescription medications from the patient's home; • Describe the actions hospice staff must take when there is evidence of missing prescription medications; and • Indicate that diversion or retention of a patient's prescription medications could result in criminal offenses. Delaware regulations also require in-home hospice agencies to have policies and procedures regarding patient record documentation. For example, the policies and procedures must address, among other things, documentation of an inventory of all disposed prescription medications or documentation of a refusal to dispose of prescription medications.[a]
Florida	July 1, 2017	Under Florida statute, a hospice physician, nurse, or social worker may assist in the disposal of prescription medications at the time of the patient's death, either in accordance with the Drug Enforcement Administration's (DEA) regulations or, with the permission of the patient's family member or caregiver, in accordance with the hospice agency's written policies and procedures. Any hospice that chooses to assist in the disposal of prescribed controlled substances must establish policies, procedures, and systems for acceptable disposal methods. Disposal must occur in the patient's home.[b]
Maryland	October 1, 2018	Under Maryland statute, a hospice employee must collect and dispose of a patient's prescription medications upon the patient's death or upon the prescriber's termination of a prescription, but only with written authorization from the patient or the patient's family member or representative. If authorized, the hospice employee must dispose of the patient's prescription medication at the site of care, in accordance with Environmental Protection Agency (EPA) and DEA guidelines and in the presence of a witness. The disposal must be documented in the patient's medical record. Every in-home hospice must have written policies and procedures for the collection and disposal of unused prescription medications. Upon refusal to authorize disposal of the patient's prescription medication, the hospice employee must advise the patient or the patient's family member or representative to dispose of the medication in a safe and legal manner in accordance with EPA and DEA guidelines. The hospice employee must document the refusal in the patient's medical record, including the name and quantity of each unused prescription medication not surrendered.[c]

State	Effective Date	Description
Ohio	September 17, 2014	Under Ohio statute, every in-home hospice, before providing hospice care and services, must inform the patient and the patient's family that the hospice will dispose of the patient's unused prescription opioids. When prescription opioids are no longer needed by the patient, including after the patient's death, the hospice must send a written request for any remaining prescription opioids. Any person who receives a written request to relinquish prescription opioids must relinquish them. If the patient or patient's family does not do so, the hospice must report the quantity and type of remaining opioids to local law enforcement. Every in-home hospice must have written policies and procedures to prevent the diversion of opioid prescriptions, including procedures for the disposal of opioids that are relinquished to the program. The policies and procedures require that disposal be documented and occur in the presence of a witness.[d]
South Carolina	May 19, 2017	Under South Carolina statute, ownership of a patient's prescription medications transfers to the hospice agency upon the patient's death. A hospice nurse must, in the presence of a witness, document the name and quantity of each prescription medication and conduct immediate disposal at the site of care in accordance with EPA and DEA guidelines. Every hospice agency must have written procedures to ensure safe disposal. Hospice employees may not remove medications from the site of care unless they are conducting immediate mail-back to a registered collector.[e]

Source: GAO summary of state laws. | GAO-20-378

[a]See 16 Del. Admin. Code § 4468, Appendix A

[b]See Fla. Stat. § 400.6096.

[c]See Md. Code, Health-General § 19-914.

[d]See Ohio Rev. Code Ann. § 3712.062.

[e]See S.C. Code Ann. § 44-71-85.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact name above, Martin T. Gahart (Assistant Director), Deborah J. Miller (Analyst in Charge), Samuel G. Amrhein, Kaitlin M. Farquharson, and Christina C. Murphy made key contributions to this report.

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