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Legal requirements for pharmacists to destroy unused medications in skilled nursing facilities. – A 50 state review and insights based on the Covid-19 pandemic

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ABSTRACT

A novel challenge presents itself when the law requires a pharmacist be on site to perform their required duties, such as destroying unused medications, however a skilled nursing facility is not allowing them to enter the property due to a pandemic. Current laws regarding drug destruction are unclear and vastly differ among the states. At times, there is even conflict between skilled nursing facility laws and regulations with pharmacy laws and regulations. This legal analysis reveals that the states are divided into 4 general groupings. 1) Where a pharmacist is physically required on site to destroy medications, 2) a pharmacist is not needed on site to destroy medications, 3) a pharmacist is likely not needed on site to destroy medications; however, the terms “witness” and “presence” are not defined, and 4) it is unknown based on the states laws whether a pharmacist is required on site to destroy medications. States would benefit from amending their laws and regulations to explicitly allow pharmacists to either destroy medications themselves when onsite or delegate the drug destruction to a trusted, responsible member of the healthcare field so long as the pharmacist is able to virtually witness said destruction.

1. Background

The healthcare industry has proven to be one of the most adaptable fields with the onset of severe acute respiratory syndrome Coronavirus 2 or SARS-COV2 (“Covid-19”). Healthcare, being a highly regulated field, often is guided by statutes and regulations that are prescriptive as to what a member of the healthcare industry can’t do and oftentimes, lays out in great detail as to what they can do, along with how to do it. This serves especially true in the area of pharmacy practice, which in most states have not adopted a pharmacist standard of care and over-regulates every aspect of the profession.

1.1. Compliance challenges due to Covid-19

So, what happens when a professional must comply with certain laws and regulations, but they are forced into non-compliance due to a global pandemic? This was especially the case in the skilled nursing setting, where a large proportion of patients are older, sicker, and more vulnerable. Skilled Nursing Facilities (“SNFs”) were at one point turning away outside visitors altogether, whether by policy or mandated by law as a result of various executive orders pursuant to Covid-19. A novel challenge presents itself when the law requires a pharmacist be on site to perform their required duties, such as destroying unused medications, however the SNF is not allowing them to enter the property.

1.2. Analysis overview of drug destruction laws and regulations

This analysis looks at each state’s pharmacy practice act and corresponding regulations as well as those statutes and regulations pertaining to SNFs to determine which states mandate a pharmacist to be physically present in the SNF to perform drug destruction functions in any manner. Alternatively, this analysis looks at those states that require a pharmacist to “witness” or be “present” for said destruction, in the absence of definition of what those terms mean. Additionally, some states have separate requirements for controlled medications and non-controlled substances (“legend drugs”), which present a scenario where the requirements differ based on the type of drug as how it is scheduled Federally or by the State. Finally, either don’t address the topic or leave drug destruction up to the policies and procedures established by the pharmacist. This allows for the pharmacist to build a process and utilize

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technology to oversee said process while using other healthcare professionals to carry out the process for them. Pharmacists are a critical component of the healthcare system. However, current laws regarding drug destruction are unclear and vastly differ among the states. At times, there is even conflict between SNF laws and regulations with pharmacy laws and regulations. The focus of this paper is to provide an overview of the legal landscape on the topic of pharmacist drug destruction in a SNF and to provide recommendations to give a pharmacist flexibility to perform these functions virtually.

As Covid-19 has moved schools and the workforce to a virtual environment, so too did it move the practice of pharmacy in that direction. Going forward, laws and regulations should recognize situations whereby providing remote or virtual functions may be a necessity, such as the Covid-19 pandemic.

2. Research results and discussion

Based on the analysis of both pharmacy and SNF laws and regulations outlining drug destruction in skilled nursing homes, the results of the analysis allowed for the states to be divided into general groupings. Table 1 summarizes the results and the groupings consist of the following:

- A pharmacist is physically required on site to destroy medications (Group A)
- A pharmacist is not needed on site to destroy medications (Group B)
- A pharmacist is likely not needed on site to destroy medications; however, the terms “witness” and “presence” are not defined (Group C)
- It is unknown based on the states laws whether a pharmacist is required on site to destroy medications (Group D)

By grouping states into these broader categories, it allowed for a better juxtaposition of state laws and regulations while condensing those state laws and regulations that essentially say the same thing, with slightly different language. For instance, Kansas regulations K.A.R. 28-39-156(f) (3)\(^7\) state that the licensed pharmacist shall destroy, if appropriate, any deteriorated, outdated, unused, or discontinued drugs and biologicals at the nursing facility and in the presence of one witness who is a licensed nurse employed by the facility. This is compared to Arkansas regulations Ark. Admin. Code 007.39.5-05-00-0003(a) (5),\(^4\) which states that the consultant pharmacist(s) shall spend sufficient time to evaluate discontinued or other unused medication for destruction or donation and destroy unused medication not intended for donation.

2.1. States that require a pharmacist to be physically present on site at a SNF to destroy medications (group A)

The 11 states included in Group A contain statutory or regulatory language that requires a pharmacist to destroy medications or to be physically on-site at the SNF in order to destroy medications. This language does draw a distinction in 4 states, where the requirements only apply to controlled substances, but not legend drugs. Those states include Florida, Michigan, Mississippi and Oklahoma,\(^10,23,25,37\) Additionally, the conclusions reached at times were based on inference rather than black letter law. Table 2 provides additional detail on the conclusions reached in Group A.

2.2. States where it is not clear whether the pharmacist is required to be on site for drug destruction to occur or whether they can virtually witness the destruction (group C)

The ambiguity exists in group C where it is not clear whether the pharmacist is required to be on site in order for drug destruction to occur, whether they can virtually witness the destruction, or if they can develop policies and procedures outlining drug destruction based on a variety of cofactors including the facility, staff, patient population, geography, etc. This variability in statutes and regulations makes it unclear for the pharmacist to maintain compliance while accommodating COVID-19 precautions by not physically entering SNFs in several states.

States in Group C commonly use statutory or regulatory language such as “witness” and “presence” in their laws when determining whether a pharmacist is required to be on site for drug destruction. These words are undefined by the law and it could be inferred that a virtual witnessing or a virtual presence is sufficient for someone else to destroy the medications on the pharmacist’s behalf so long as the pharmacist can virtually be there to sign off on the destruction. Table 3 provides additional detail on the conclusions reached in Group C.

At issue is the degree and variability of interpretation in this language that a pharmacist could implore to reach a conclusion on how they could comply with the law. One person may interpret the laws to allow them to witness the destruction virtually whereas a second person may interpret the same law and require the pharmacist to physically be present to witness the destruction. In addition to generally causing confusion, a pharmacist may be concerned about potential discipline by their regulatory authority due to their interpretation of the law.

2.3. States that allow the pharmacist to decide who can destroy medication, who can witness the destruction, and what methods of destruction are acceptable. (Group D)

The states in Group D generally leave the destruction up to the pharmacist. The pharmacist decides who can destroy medication, who can witness the destruction, and what methods of destruction are acceptable. By allowing the pharmacist to outline these methods, the states are allowing them to use their judgement as the drug experts to decide who is responsible enough to destroy the medication, but also allowing the pharmacist to utilize different forms of technology to

Table 1

| Research Groupings | States |
|--------------------|--------|
| A pharmacist is physically required on site to destroy medications (Group A) | Alabama, Kansas, Florida, Georgia, Kansas, Michigan, California, Mississippi, Nebraska, New York, New Jersey, Rhode Island, Utah, Arizona, Colorado, Connecticut, Arkansas, Delaware, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Minnesota, Missouri, New Hampshire, New Jersey, New York, North Dakota, Ohio, Oregon, South Carolina, Tennessee, Virginia, Washington, Wisconsin, Wyoming, Maine, South Dakota, Utah |
| A pharmacist is not needed on site to destroy medications (Group B) | Arizona, Arkansas, Colorado, Connecticut, Delaware, Indiana, Iowa, Kentucky, Louisiana, Maine, Maryland, Minnesota, Missouri, New Hampshire, New Jersey, New York, North Dakota, Ohio, Oregon, South Carolina, Tennessee, Virginia, Washington, Wisconsin, Wyoming, Maine, South Dakota, Utah |
| A pharmacist is likely not needed on site to destroy medications; however, the terms ‘witness’ and ‘presence’ are not defined (Group C) | California, Nevada, New Mexico, North Carolina, Alaska, District of Columbia, Hawaii, Idaho, Illinois, Massachusetts, Montana, Pennsylvania, Rhode Island, Vermont |
| It is unknown based on the states laws whether a pharmacist is required on site to destroy medications (Group D) | Alaska, District of Colombia, Hawaii, Idaho, Illinois |

\(^{1,2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51}\)
oversee this process. For instance, they may virtually witness the destruction to prevent excess people entering the SNF while maintaining patient safety and drug accountability, they may utilize other responsible healthcare professionals who are already onsite, to perform this duty under the pharmacist’s general supervision. This is a common theme among group D states and allows for efficient methods to be established that vary based on the needs of the institution and pharmacist.

### 2.4. Conflicts between pharmacy and SNF laws/regulations and the distinction between controlled substances and legend drugs

There were a few instances of conflicting laws in some states regarding the pharmacy practice laws/regulations and the SNF laws/regulations. These conflicts inevitably make it impossible for the pharmacist to know how to apply the law and places a pharmacist at risk of non-compliance with one of the conflicting laws. For example, West Virginia pharmacy regulations state that the destruction must be performed by a pharmacist in the presence of a registered nurse. In contrast, the West Virginia residential care community regulations state that the destruction must be performed by the residential community in the presence of a pharmacist and registered nurse. This conflict causes confusion as to who must destroy medications.

The final discrepancy to mention is the contrasting laws/regulations between destroying controlled substances and legend drugs. Many states would explicitly say who was able to destroy and witness the destruction of certain schedules of medications and would not address non-scheduled medications. Mostly this would occur with controlled substances being more direct and legend drugs not being addressed, however that was not always the case. There were 17 states where there was a distinction made between controlled substances and legend drugs.

### Table 2

| State      | Is the physical presence of a pharmacist required for drug destruction in skilled nursing facilities per State statutes or regulations? |
|------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Alabama    | Likely Yes. (Controlled and Legend) Because the Pharmacist WITH a Registered Nurse must carry out the drug destruction. |
| Arkansas   | Yes. (Controlled and Legend) Consultant pharmacist shall destroy unused medication. |
| Florida    | Likely Yes. (Controlled) Because, as it pertains to controlled substances, the method of destruction must be conducted by a prescription department manager or the consultant pharmacist of record, along with another health care professional. |
| Georgia    | Yes. (Legend) Because non-controlled drugs can be destroyed at the facility by the consultant pharmacist and another pharmacist, nurse, or licensed practical nurse designated by the facility. |
| Kansas     | The licensed pharmacist shall destroy in the presence of one witness who is a licensed nurse employed by the facility. |
| Michigan   | Yes. (Legend) A pharmacist shall personally supervise the destruction of unused portions of prescription medication, other than controlled substances. “Personal Supervision” likely refers to physical presence, as used in other areas of MI law and rule. |
| Mississippi| Yes. (Controlled) The consulting pharmacist must both supervise and assist in the disposal of all discontinued, expired or otherwise unneeded controlled substance medications. |
| Nebraska   | Yes. (Controlled and Legend) Although Nebraska state statute does not signify which individuals may destroy controlled substances, skilled nursing facility regulations specify a pharmacist and a licensed nurse must dispose of all medications. |
| Oklahoma   | Yes. (Controlled) Controlled medication shall be destroyed by a licensed pharmacist and the Director of Nursing. |
| Texas      | Yes. (Controlled and Legend) A licensed nurse may destroy legend drugs in place of a pharmacist. |
| West Virginia | The consultant pharmacist is specifically authorized to destroy dispensed drugs, |

### Table 3

| State      | Is the physical presence of a pharmacist required for drug destruction in skilled nursing facilities per State statutes or regulations? |
|------------|-----------------------------------------------------------------------------------------------------------------------------------|
| California | Likely No. (Schedule II, III and IV) Because “Presence” is not defined and arguably may be a virtual presence. |
| Nevada     | Likely No. (Controlled) A pharmacist may witness controlled substance destruction as long as the director (or a licensed nurse in their place) destroys the controlled substance on the premises of the facility. The pharmacist could presumably virtually witness this destruction. Likely No. (Legend) |
| New Mexico | Likely No. (Controlled and Legend) The destruction of the drug must be “witnessed” by the consultant pharmacist, however the method of being a witness is not defined and presumably may be done virtually. They are also responsible for “verifying” the inventory of the drugs being destroyed. |
| South Dakota | No. (Legend) Legend drugs shall be destroyed or disposed of by a nurse and another witness. |
| South Dakota | Likely No. (Controlled and Legend) Controlled substance destruction shall be witnessed by two persons, both of whom are a nurse or pharmacist, as designated by facility policy. However, the method of being a witness is not defined and presumably may be done virtually. |
| Utah       | Likely No. (Controlled and Legend) Authorized destruction of all prescription drugs shall be witnessed by the medical or nursing director or a designated physician, registered nurse or other licensed person employed in the facility and the consulting pharmacist or licensed pharmacy technician. However, the method of being a witness is not defined and presumably may be done virtually. |

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Some of the states had the same result for both controlled substances and legend drugs, but still made a distinction. In Michigan, their laws contrast this by ruling that a pharmacist needs to personally supervise the destruction of legend drugs, but still made a distinction. In Michigan, their laws regarding the role of the pharmacist pertaining to drug destruction in skilled nursing facilities. Covid-19 has changed the entire healthcare system, precluded pharmacists from having personal access into these facilities and presented new compliance challenges, which have not regularly been questioned.

States which fall into group A and C would benefit from amending their laws and regulations to explicitly allow pharmacists to either destroy medications themselves when onsite or delegate the drug destruction to a trusted, responsible member of the healthcare field so long as the pharmacist is able to virtually witness said destruction. This will not only enhance the understanding of the laws but also allow for healthcare professionals who are already working at these sites to act on the pharmacists behalf on destroying medications with their virtual presence, but instead force the pharmacist to enter the nursing home facility, which was not often possible during the Covid-19 pandemic.

3. Recommendations and conclusions

This analysis clearly shows that there is area for improvement in clarifying laws and regulations regarding the role of the pharmacist pertaining to drug destruction in skilled nursing facilities. Covid-19 has changed the entire healthcare system, precluded pharmacists from having personal access into these facilities and presented new compliance challenges, which have not regularly been questioned.

States which fall into group A and C would benefit from amending their laws and regulations to explicitly allow pharmacists to either destroy medications themselves when onsite or delegate the drug destruction to a trusted, responsible member of the healthcare field so long as the pharmacist is able to virtually witness said destruction. This will not only enhance the understanding of the laws but also allow for healthcare professionals who are already working at these sites to act on the pharmacists behalf on destroying medications with their virtual presence, but instead force the pharmacist to enter the nursing home facility, which was not often possible during the Covid-19 pandemic.

Disclaimer

The views expressed in this manuscript are those of the authors alone, and do not necessarily reflect those of their respective employers or universities.

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