Fiscal Note: Proposed Amendment of
Rule 10A NCAC 26E .0406, *Disposal of Unused Controlled Substances from Nursing Home*

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Impact Summary:

State Government:	Yes
Local Government:	No
Substantial Economic Impact:	Yes

Authority: G.S. §§ 90-100; 143B-147

Necessity: The rule amendments are necessary to provide Long-Term Care pharmacies with viable, federally recognized options for disposing of and destroying unused controlled substances from nursing homes. Diversion and abuse of prescription drugs, particularly controlled substances, is a serious public health concern. This Rule helps ensure the safe, secure, and timely disposal and destruction of these drugs in North Carolina, thereby supporting ongoing efforts to reduce diversion risks.

I. Overview of Proposed Rule Amendments

Rule 10A NCAC 26E .0406 governs the disposal of unused controlled substances dispensed for administration to individuals residing in a licensed nursing home. The parties subject to this rule are Long-Term Care (LTC) pharmacies. Both the current rule and proposed rule require that controlled substances dispensed for inpatient administration to individuals residing in a licensed nursing home which, for any reason, are unused shall be returned to the pharmacy from which they were received. The pharmacist who receives these controlled substances shall return them to their stock or dispose of and destroy them in accordance with 21 CFR 1317.05(a).

Proposed amendments to this Rule will modernize and increase disposal options available to LTC pharmacies and enable their continued compliance with federal and state requirements to dispose of unused controlled substances so that they are "non-retrievable." This analysis presents two alternative versions of the proposed rule for consideration. One version ("**Alternative 1**") is substantively identical to the temporary version of the rule that went into effect on January 2, 2025. The second version ("**Alternative 2**") includes the options available in Alternative 1 plus an additional option for Collection Receptacles.

The proposed options for medication disposal are as follows:

1. **Witnessed destruction at an incinerator.** This option is already allowed under the existing permanent rule and is not proposed to change under either version of the proposed rule. Under this option, the LTC pharmacy contracts with the incinerator to collect, transport, and destroy the medications. When controlled substances are returned to the pharmacy, a representative from the

NCDHHS Drug Control Unit will conduct an audit. The controlled substances are subsequently secured and sealed in boxes. The boxes are then transported to a facility for incineration. This process is witnessed by a Drug Control Unit inspector. Because incineration is already allowed under the existing permanent rule, this analysis will focus on any additional costs for out-of-state incineration relative to costs for in-state incineration. These costs should be considered ongoing costs since in-state incineration is no longer a viable option in North Carolina.

2. **Reverse distributor.** Under this option, a LTC pharmacy that has controlled substances dispensed for inpatient administration returned to it from skilled nursing facilities may outsource destruction of such unused controlled substances to a reverse distributor that is registered with the federal Drug Enforcement Agency (DEA). If a pharmacy uses this option, they must provide written notification by email to one of the NCDHHS Drug Control Unit inspectors to indicate that they have elected to use a reverse distributor. Note that this option is included in the temporary version of this rule that went into effect on January 2, 2025 and in both "Alternative 1" and "Alternative 2" of the proposed rule.

3. **Collection receptacles.** Under this option, pharmacies that are authorized by the DEA as collectors may install, manage and maintain collection receptacles at nursing homes for the purpose of collection, disposal and destruction of unused controlled substances. Via a contract with the pharmacy, a third party registered with the DEA will periodically collect the medications stored in the Collection Receptacles and ensure their proper disposal. Note that this option was not included in the temporary version of this rule. It is included as an additional option in the "Alternative 2" version of the proposed rule.

   This option would have a direct impact on Licensed Nursing Homes. Stakeholder engagement from both the LTC Pharmacy and Licensed Nursing Home sectors, and research, have consistently shown that the use of Collection Receptacles creates a shared responsibility between LTC Pharmacies and the Licensed Nursing Homes they serve in terms of process, procedure and cost. The use of Collection Receptacles is approved at the federal level if they are fully compliant with 21 CFR 1317.05(c), and they are now recognized as an acceptable option for all affected sectors. Including Collection Receptacles as an option to the proposed rule will cover all current federally recognized disposal methods. This is common in other states, including Virginia and South Carolina, whose rules already allow this level of choice.

II. Rationale for Proposed Rule Action

The Department of Health and Human Services Division of Mental Health Developmental Disabilities and Substances Use Services (DMHDDSUS) is promulgating updates to Rule 10A NCAC 0406 in Permanent Rule to ensure timely, cost effective and secure disposal of controlled substances from licensed nursing homes, known informally as a witnessed destruction. Per G.S. § 90-100 and G.S. § 143B-147, the Commission has authority to adopt rules relating to the registration and control of the manufacture, distribution, security, and dispensing of controlled substances within this State.

On July 26, 2024, Stericycle, the owners of the only incinerator in North Carolina that was capable of destroying controlled substances to the point that they are non-retrievable, notified long-term care pharmacies in North Carolina that they will no longer accept bookings for witnessed destruction of controlled substances. Stericycle's business decision to no longer provide long-term care pharmacies the option of destruction of unused controlled substances from nursing homes by an incinerator within the State was not foreseen by the Department. Rule 10A NCAC 26E .0406 was amended via emergency procedures, effective September 25, 2024, and via temporary procedures, effective January 2, 2025. Those amendments were intended to provide immediate clarity regarding the use of federally recognized

options for disposing of and destroying unused controlled substances from nursing homes, including outsourcing the destruction to reverse distributors, to help ensure safe, secure, and timely disposal and destruction of unused controlled substances in North Carolina. A temporary rule expires as specified in G.S. 150B-21.1(d). The Commission proposes to amend the Rule via permanent rulemaking procedures.

III. Analysis of Fiscal Impact

The parties regulated by this rule are LTC pharmacies. Other parties affected by this rule include the State of North Carolina government (DMHDDSUS), nursing homes, and the general public. This section will assess the impact of the proposed rule changes on State funds, Long-Term Care (LTC) pharmacies, licensed nursing homes, and the general public. No impacts are expected on local government entities.

Regulatory Baseline

This analysis presents the estimated impacts of the proposed rule changes compared to the regulatory baseline. The regulatory baseline is comprised of the existing permanent version of Rule 10A NCAC 26E .0406 and federal regulations in 21 CFR 1317. The temporary rule that is currently in effect is not considered part of the regulatory baseline. Under the existing permanent rule, the only viable method by which LTC pharmacies can comply with the requirement to dispose of unused controlled substances so that they are "non-retrievable" is incineration with witnessed destruction. Until recently, LTC pharmacies in North Carolina have used an in-state incinerator. As such, costs of the various disposal options in the proposed rules will be compared to costs of in-state incineration for purposes of this analysis. However, because in-state incineration is no longer an option, costs associated with the proposed rules should be considered ongoing costs.

Costs to Long-Term Care (LTC) Pharmacy Sector

LTC pharmacies have primary responsibility for ensuring the chain of custody and ultimate destruction of unused controlled substances from nursing homes. There are currently **26 LTC pharmacies** affected by this change in North Carolina of varied size and scale, including small local enterprises and large multi-state providers. As compared to the regulatory baseline, the proposed rules will result in added costs to these LTC pharmacies for disposal of unused medications. The magnitude of new costs will vary by pharmacy and will depend primarily on the method of disposal they choose: 1) cross-state witnessed destruction; 2) reverse distribution; or 3) Collection Receptacle.

Key stakeholders from the LTC pharmacy sector provided DMHDDSUS with estimated costs. These estimated costs varied but were generally consistent. These stakeholder estimates were used to produce the cost tables in this report. Determining actual, versus estimated, cost for this rule change is impossible due to the number of variables involved, including the purchasing power of the provider organizations to negotiate contracts, the size of the facilities being served, and variabilities in the frequency of unused controlled substances.

The direct costs associated with the disposal of controlled substances by LTC pharmacies are included in their logistics contracts. Because disposal is an essential aspect of managing controlled substances, related staff expenses – such as full-time equivalents (FTEs), travel, and overhead – are likely to be incorporated into new work processes. Since mid-2024, the closest incinerator accepting witnessed destruction of controlled substances is in Fairfax, Virginia. Mileage for LTC Pharmacy travel to the incinerator was included in the calculations based on the current reimbursement rate of $.70 per mile[1]. LTC Pharmacy

[1] Privately owned vehicle (POV) mileage reimbursement rates | GSA

staff time and mileage to retrieve unused controlled substances from Nursing Homes has not been included in this analysis since these costs will not change as a result of the proposed rules.

Table 1 provides estimates for costs per LTC pharmacy for each of the three disposal options: incineration, reverse distributor, and Collection Receptacle.

Table 1: Estimated costs per LTC pharmacy under each of the disposal options.

Description	Estimate	Calculation	Assumptions
In-state Incineration (baseline)			
Incineration Burn Cost	$1,600 per burn		
Total Costs per LTC pharmacy	$1,600 per year		Assumes one burn per LTC pharmacy
Out-of-state Incineration			
Incineration Burn Cost	$1,600 per burn		
Travel costs for out-of-state witnessed destruction	$894 per trip		
Total Costs per LTC pharmacy	$2,494 per year		
Reverse Distributor			
Total Costs per LTC pharmacy	$37,596 per year		Averaged two estimates provided by pharmacy stakeholders.
Collection Receptacle			
Collection Receptacle Setup Cost	$2,500 one off cost		This is an upper range estimate. Some pharmacies reported costs as low as $2,000 per box.
Collection Receptacle inner liner (box) ongoing fees for liner removal and transport	$200 per month		Assumes liner collection and transport occurs 6x/yr on average. Actual frequency could be more or less.
Total Costs per LTC pharmacy	$59,200 first year	$40,000 one off installation cost + 1 year collection fees at $19,200	
	$19,200 subsequent years for collection fees		

Alternative #1: Out-of-state incineration + Reverse Distributor

This proposed version of amended Rule 10A NCAC 26E.0406 contains two options for an LTC Pharmacy to destroy controlled substances returned from a licensed nursing home. Projected costs are

based on the percentage of LTC Pharmacies that have chosen each of the two options while the emergency and temporary rules have been effect.

The two most likely scenarios are presented in Tables 2 and 3 below. Table 1 shows the estimated costs under the scenario where an out-of-state incinerator (e.g., Virginia) remains available as an option for NC LTC pharmacies. The likelihood of the Virginia facility choosing to no longer accept materials from NC is unknown. As of the date of this fiscal note, 35% of LTC Pharmacies have used the out-of-state incinerator option and 65% have used a Reverse Distributor.

Table 2: Estimated costs to LTC pharmacies under "Alternative 1" which allows incineration with witnessed destruction and Reverse Distribution. This scenario assumes an out-of-state incinerator will continue to be a viable option.

Description	Estimate	Calculation	Assumptions
Out-of-State Incineration Costs	$22,446 per year	$2,494 per yr x 9 pharmacies	Assumes 9 of 26 of LTC pharmacies will use an out-of-state incinerator to conduct one burn per year.
Reverse Distributor Costs	$639,132 per year	$37,596 per yr x 17 pharmacies	Assumes 17 of 26 LTC pharmacies will use a reverse distributor.
Total cost to LTC Pharmacies per year for Alternative 1, mixed disposal option scenario	**$619,978***	$661,578 new costs *minus* $41,600 baseline costs	

**Estimated total cost excludes baseline costs. In other words, this estimate subtracts out baseline costs incurred by LTC pharmacies for complying with existing controlled substances destruction requirements. For the purposes of this analysis, baseline costs are costs for in-state incineration.*

Table 3 shows the estimated costs to LTC pharmacies under the scenario where an out-of-state incinerator is no longer an option. In this scenario, using a Reverse Distributor would be the only viable option.

Table 3: Estimated costs to LTC pharmacies under "Alternative 1" which allows incineration with witnessed destruction and Reverse Distribution. This scenario assumes Reverse Distribution is the only viable option.

Description	Estimate	Calculation	Assumptions
Reverse Distributor Costs	$977,496 per year	$37,596 per yr x 26 pharmacies	Assumes all 26 LTC pharmacies will use a reverse distributor.
Total cost to LTC Pharmacies per year for Alternative 1, Reverse Distributor only scenario	**$935,896***	$977,496 new costs *minus* $41,600 baseline costs	

**Estimated total cost excludes baseline costs. In other words, this estimate subtracts out baseline costs incurred by LTC pharmacies for complying with existing controlled substances destruction requirements. For the purposes of this analysis, baseline costs are costs for in-state incineration.*

Alternative #2: Out-of-state incineration + Reverse Distributor + Collection Receptacles

This proposed alternative version of amended Rule 10A NCAC 26E.0406 contains three options for an LTC Pharmacy to destroy controlled substances returned from a licensed nursing home. Projected costs have been calculated with the assumption that, although Collection Receptacles involve higher initial expenses, they are expected to be an appealing option. Specifically, our analysis indicates that Collection Receptacles are likely to be more cost-effective over time compared to utilizing a reverse distributor, making them a more attractive long-term solution.

The use of Collection Receptacles located at the Licensed Nursing Facility carries no greater risk of diversion than returning the controlled substances to the pharmacy. As a result of stakeholder engagement, the following costs associated with the use of Collection Receptacles were provided for informational purposes. It must be assumed that there will be variances based on unpredictable market factors. There is a one-time cost to purchasing the Collection Receptacle and installing it in the nursing home which ranges between $2,000 and $2,500. This initial cost may be entirely on the pharmacy or it could be shared with the nursing home, as occurs in other states. This would be a business decision made between the pharmacy and the nursing home on a case-by-case basis. After year one, the cost for using the Collection Receptacles will be limited to ongoing monthly costs to contract for pick up and safe removal of the inner liners. For purposes of our analysis, we assumed that all 421 nursing homes currently licensed would have one of these collection receptacles. Further, we assumed that the costs for the 421 boxes would be evenly distributed across all 26 pharmacies (16 receptacles per pharmacy). In reality the distribution will vary from zero to many more.

Table 4 shows the estimated costs to LTC pharmacies under the scenario where all federally recognized options are viable options in North Carolina.

Table 4: Estimated costs to LTC pharmacies under "Alternative 2" which includes all federally approved options (Incineration, Reverse Distributor, and Collection Receptacles) and assumes out-of-state incineration remains a viable option.

Description	Estimate	Calculation	Assumptions
Out-of-State Incineration Costs	$17,458 per year	$2,494 per yr x 7 pharmacies	Assumes 7 of 26 of LTC pharmacies will use an out-of-state incinerator to conduct one burn per year.
Reverse Distributor Costs	$112,788 per year	$37,596 per yr x 3 pharmacies	Assumes 3 of 26 LTC pharmacies will use a reverse distributor.
Collection Receptacle Costs	$947,200 in first year	$59,200 per yr x 16 pharmacies	Assumes 16 of 26 LTC pharmacies will use Collection Receptacles.
	$307,200 in each subsequent year	$19,200 per yr x 16 pharmacies	
Total cost to LTC Pharmacies per year for Alternative 2	**$1,035,846* in first year**	$1,077,446 new costs *minus* $41,600 baseline costs	
	$395,846* in each subsequent year	$437,446 new costs *minus* $41,600 baseline costs	

**Estimated total cost excludes baseline costs. In other words, this estimate subtracts out baseline costs incurred by LTC pharmacies for complying with existing controlled substances destruction requirements. For the purposes of this analysis, baseline costs are costs for in-state incineration.*

Table 5 shows the estimated costs to LTC pharmacies under the scenario where all federally recognized options are allowed under North Carolina's rule, but the only two viable options are reverse distribution and collection receptacles. This is perhaps the most likely scenario in the long term, considering there is a significant possibility that out-of-state incinerators will also stop accepting these medications for incineration.

Table 5: Estimated costs to LTC pharmacies under "Alternative 2" which includes all federally approved options (Incineration, Reverse Distributor, and Collection Receptacles) but assumes out-of-state incineration is no longer a viable option.

Description	Estimate	Calculation	Assumptions
Reverse Distributor Costs	$150,384 per year	$37,596 per yr x 4 pharmacies	Assumes 4 of 26 LTC pharmacies will use a reverse distributor.
Collection Receptacle Costs	$1,302,400 in first year	$59,200 per yr x 22 pharmacies	Assumes 22 of 26 LTC pharmacies will use Collection Receptacles.
	$422,400 in each subsequent year	$19,200 per yr x 22 pharmacies	
Total cost to LTC Pharmacies per year for Alternative 2	**$1,411,184* in first year**	$1,452,784 new costs *minus* $41,600 baseline costs	
	$531,184* in each subsequent year	$572,784 new costs *minus* $41,600 baseline costs	

**Estimated total cost excludes baseline costs. In other words, this estimate subtracts out baseline costs incurred by LTC pharmacies for complying with existing controlled substances destruction requirements. For the purposes of this analysis, baseline costs are costs for in-state incineration.*

Costs to State Government

DMHDDSUS has responsibility for ensuring compliance with controlled substance disposal regulations under this rule, including oversight of pharmacy compliance. The proposed rule changes will not increase costs to DMHDDSUS.

Alternative #1: Out-of-state incineration + Reverse Distributor

Table 6 shows the estimated costs to State government under the scenario where an out-of-state incinerator (e.g., Virginia) remains available as an option for NC LTC pharmacies. As compared to the regulatory baseline, the only additional costs the State will incur is related to traveling to the out-of-state incinerator to participate in the witnessed destruction.

Table 6: Estimated costs to State government (DHHS) under "Alternative 1." Assumes an out-of-state incinerator is a viable option in addition to using a Reverse Distributor.

Description	Cost	Calculation	Assumptions
Mileage costs for out-of-state witnessed destruction	$379 per trip	542 miles x $0.70 per mile	Assumes round-trip of 542 miles (Raleigh to Fairfax)
Staff time costs (opportunity costs) for out-of-state witnessed destruction	$844 per trip	$52.78 per hr x 16 hrs x 1 staff	Avg DHHS staff compensation of $52.78/hr calculated using OSHR total compensation calculator
Lodging and meal costs	$ 178 per trip	$110 pn lodging & $68 per diem meal costs	
Total cost per trip per person	$1,402	$379 mileage + $844 time + $178 lodging/meals	
Total cost to DHHS per year for out-of-state witnessed destructions*	**$12,617**	9 trips x $1,402 per trip	Assumes 9 of the 26 LTC pharmacies will choose to use an out-of-state incinerator once per year.

** These estimates do not exclude costs that would have been incurred by DHHS for travel to the in-state incinerator in Haw River under the existing permanent rule. As such, the per trip costs shown in Table 5 are likely slightly overestimated.*

Alternative #2: Out-of-state incineration + Reverse Distributor + Collection Receptacles

There would be no additional costs to State government over baseline associated with either the Reverse Distributor or Collection Receptacle options. Table 7 shows the estimated costs to State government under the scenario where an out-of-state incinerator (e.g., Virginia) remains available as an option for NC LTC pharmacies. As compared to the regulatory baseline, the only additional costs the State will incur is related to traveling to the out-of-state incinerator to participate in the witnessed destruction. Under this scenario, it was assumed that fewer pharmacies would choose to use an out-of-state incinerator when there is the Collection Receptacle option.

Table 7: Estimated costs to State government (DHHS) under "Alternative 2" which includes all federally approved options (Incineration, Reverse Distributor, and Collection Receptacles) and assumes out-of-state incineration remains a viable option

Description	Cost	Calculation	Assumptions
Mileage costs for out-of-state witnessed destruction	$379 per trip	542 miles x $0.70 per mile	Assumes round-trip of 542 miles (Raleigh to Fairfax)
Staff time costs (opportunity costs) for out-of-state witnessed destruction	$844 per trip	$52.78 per hr x 16 hrs x 1 staff	Avg DHHS staff compensation of $52.78/hr calculated using OSHR total compensation calculator
Lodging and meal costs	$ 178 per trip	$110 pn lodging & $68 per diem meal costs	
Total cost per trip	$1,402	$379 mileage + $844 time + $178 lodging/meals	
Total cost to DHHS per year for out-of-state witnessed destructions*	**$9,813**	7 trips x $1,402 per trip	Assumes 7 of 26 of LTC pharmacies will use an out-of-state incinerator to conduct one burn per year.

** These estimates do not exclude costs that would have been incurred by DHHS for travel to the in-state incinerator in Haw River under the existing permanent rule. As such, the per trip costs shown in Table 6 are likely slightly overestimated.*

Costs to Licensed Nursing Homes

Licensed nursing homes are required to return unused controlled substances to dispensing pharmacies under both the existing and proposed rules. There are **421 licensed nursing homes** in North Carolina. These private businesses are varied in size and scale with a combination of small local enterprises and large multi-state providers. Although they will not necessarily have to adjust their operations or incur additional costs as a result of the proposed rule changes, it is likely that some nursing homes will be impacted if they agree to cost share collection receptables ("Collection Receptacles") on site. Either way, these facilities remain central to ensuring compliance and preventing on-site diversion risks and they are, therefore, integral to decision-making regarding this rule.

Key stakeholders from the licensed nursing home sector provided estimated costs that varied but were generally consistent. These were used to produce the cost tables in this report.

Alternative #1: Out-of-state incineration + Reverse Distributor

Nursing homes would not incur any costs or savings due to this option as compared to the regulatory baseline.

Alternative #2: Out-of-state incineration + Reverse Distributor + Collection Receptacles

There is a one-time cost to purchasing the Collection Receptacle and installing it in the nursing home which ranges between $2,000 and $2,500. This initial cost may be entirely on the pharmacy or it could be shared with the nursing home. This would be a business decision made between the pharmacy and the nursing home on a case-by-case basis.

If a nursing home chooses to share costs, there costs would presumably be highest in the first year, then decrease in Year 2 and beyond. Based on information gathered in the stakeholder engagement period, the most common cost-sharing scenario is for the licensed nursing home to cover the one-off cost of buying and installing the metal collection receptacle and for pharmacies to cover the annual costs of the liners including collection. The potential costs across all 421 licensed nursing homes would range from $0 to $1,052,500 in the first year, and $0 in subsequent years. On a per nursing home basis, this equates to $0 to $2,500 in the first year, assuming one Collection Receptacle per facility. These costs would not necessarily be a result of the proposed rules; rather, they would agree to share costs with the LTC pharmacies. Since the metal collection receptacles must be physically installed in the licensed nursing home, there are many practical considerations relating to position, building regulations and upkeep that may inform the decision to share cost.

Benefits

The primary benefit to the amendment of Rule 10A NCAC 26E.0406 is that it improves options to safely destroy controlled substances and prevents drug diversion, including improved logistic management that reverse distribution is known to create. The rule in place until September 2024 did not include all federally approved options, and whilst it was the least costly, the events of 2024 demonstrated that limiting options creates significantly more risk and cost. Reverse Distributors are certified by the federal Drug Enforcement Agency, ensuring compliance with security and inventory measures known to prevent diversion.

Drug diversion is costly to the North Carolina population through preventable overburdening of the judicial, health and social service systems estimated in billions of dollars. Multiple legislative mechanisms are required to fully prevent diversion, the full itemization of these costs' benefits are relevant outside the scope of this Rule Amendment.

The proposed rule changes are designed to address an unforeseen medication disposal gap. If the rule changes fail to get adopted, all Long Term Care Pharmacies may cease to be compliant with federal regulations, resulting in fines, loss of license and ability to practice in the state. This in turn would have a detrimental impact on the licensed nursing homes to which they provide critical medications.

Risks

The necessity to change the rule through emergency procedures resulting from an unforeseen circumstance meant that the amendments made were specific to the sector most affected, LTC Pharmacies. Since the approval of the Emergency and Temporary Rules, review of stakeholder input and eye-witness accounts from the DHHS Inspectors supporting the LTC Pharmacy Sector has raised two key risks to the Rule as it currently stands:

1) The LTC Pharmacy Sector experiencing significant cost increases to this activity,

2) LTC Pharmacies and the DHHS Inspectors are recounting difficulties implementing unplanned contracts with Reverse Distributors and with the Virginia based facility. The risk of the Virginia site to cease to be an option should difficulties remain, or if business or Virginia legislation changes, is deemed "likely" where it was unlikely before. Expectations are that this option may not be available within the next two years.

IV. Alternatives analysis

Option 1: Maintain the status quo. Allow the temporary rule to expire and revert to enforcing the existing permanent rule.

Due to the change in business model of Stericycle, the instate facility, this is no longer a viable option. If the rule is not revised to allow for reverse distribution and/or collection receptacles (Collection Receptacles),the only option would be to use out of state facilities. The North Carolina is not the first state to see these incinerator sites discontinue this function, increasing the likelihood that out of state options will cease to exist. In this scenario Long Term Care Pharmacies may become out of compliance with federal regulations and be subject to fines and loss of business. Licensed nursing homes would no longer be able to receive critical medications.

Option 2: Adopt draft rule version "Alternative 1." This would limit drug disposal options to out-of-state incineration and reverse distribution.

This option is in line with the temporary rule that is currently in effect. To do this, the State accepts the assumption that business practices will recover from the initial implementation problems, the cost to the LTC Pharmacies is acceptable and that the risk of the Virginia site to cease to be an option is an acceptable risk.

Option 3: Adopt draft rule version "Alternative 2". This would expand drug disposal options to include all federally recognized options (incineration + reverse distribution + Collection Receptacles).

This option provides additional flexibility for pharmacies, allowed continued compliance with federal and state controlled substance disposal laws. Compared to the rule option which would not allow Collection Receptacles, this option is very likely to result in lower costs to pharmacies, nursing homes, and State government. Further, the use of Collection Receptacles located at the Licensed Nursing Facility carries no greater risk of diversion than returning the controlled substances to the pharmacy.

V. Summary

These rule changes will allow pharmacies to continue to comply with federal and state requirements to dispose of controlled substances so that they are "non-retrievable." This enables the pharmacies and nursing homes, by extension, to continue to provide this critical service that greatly reduces the risk of diversion of these harmful substances into the community. Further, giving the regulated community more options will allow them to make decisions that better serve their specific needs and goals while providing an equivalent level of diversion risk reduction.

The Temporary Rule being promulgated for Permanent status, and the proposed alternative we've developed to improve available options to LTC Pharmacies, both modernize the State's approach to this function by reflecting current federal regulations, and with significant consideration for the financial and

operational impact these amendments have on those directly and indirectly affected. Those considerations continued after the initial promulgation of the Emergency and Temporary rules to ensure the Agency remains open and flexible to the needs of those we serve.

This analysis shows that both Alternative #1 and Alternative #2 provide the same level of diversion risk reduction, at least in the near term. However, Alternative #2 -- which introduces the use of collection receptacles -- is likely to be more cost-effective beginning in Year 2, especially considering the uncertain future viability of the out-of-state incinerator as a disposal option. This cost-effectiveness alone could lead to incremental yet meaningful improvements in diversion risk reduction by making it easier for regulated entities to comply with requirements. Stakeholder engagement indicates that acceptability of options is not necessarily contained to lowest price but includes assessments of which process in each situation will reduce diversion, increase shared responsibility, and improve logistic management.

Summaries of the costs for both Alternatives are shown in Tables 8 and 9.

Table 8: Summary of Annual Costs for Alternative #1 which allows incineration with witnessed destruction and Reverse Distribution

Entity	Year 1 (2026)	Year 2 (2027)	Year 3 (2028) & beyond	Notes
26 LTC Pharmacies	$620,000 to $936,000	$620,000 to $936,000	$620,000 to $936,000	Costs would be on the higher end if reverse distribution is the only viable option.
DHHS – State Government	$0 to $13,000	$0 to $13,000	$0 to $13,000	Costs related to traveling out of state for witnessed destructions. Total costs would be $0 if no out-of-state incinerations occur in a given year.
421 Nursing homes	$0	$0	$0	No change from baseline.

- All cost estimates in Table 8 are compared to the ongoing regulatory baseline costs.
- Total amounts are rounded and have not been adjusted for inflation.
- Data is presented for Years 2026-2028, but costs will be ongoing in subsequent years.
- For the 3-year period from 2026-2028, the estimated Present Value (PV) of costs to LTC pharmacies, DHHS, and nursing homes ranges from $1.6M to $2.5M (7% discount rate, 2025 dollars). PV is the current value of a future sum of money or stream of benefits and costs, calculated by discounting those future amounts using a specific rate of return. This calculation is based on the principle that money or impacts received today are worth more than the same amount received in the future due to the time value of money. If this analysis had quantifiable benefits, a calculation of the Net Present Value (NPV) would have been done instead of PV.

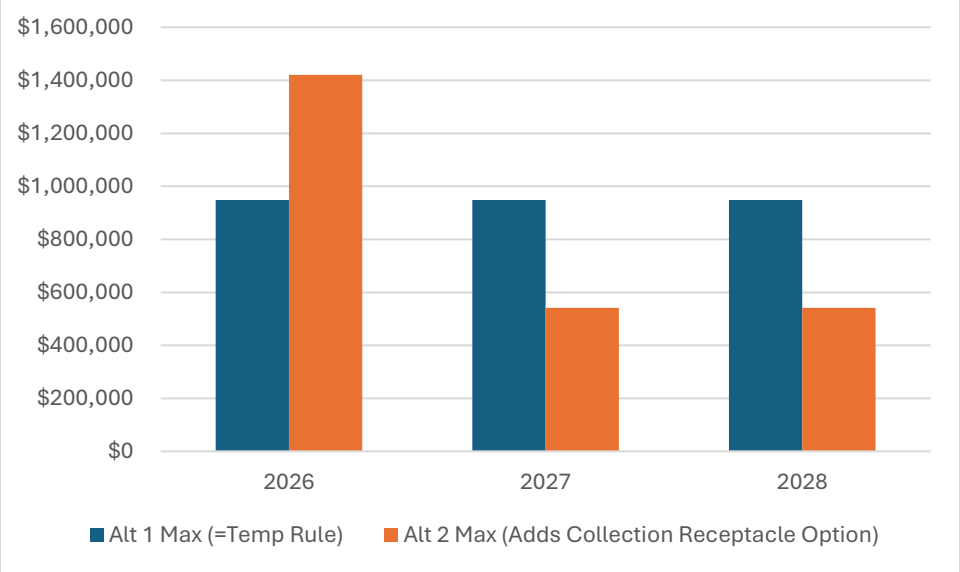
Table 9: Summary of Annual Costs for <u>Alternative #2</u> which allows incineration with witnessed destruction, Reverse Distribution, and Collection Receptacles

Entity	Year 1 (2026)	Year 2 (2027)	Year 3 (2028) & beyond	Notes
26 LTC Pharmacies	$1,036,000 to $1,411,000*	$396,000 to $531,000*	$396,000 to $531,000*	Higher first year costs are driven by initial purchase and setup costs for Collection Receptacles. Costs would be on the higher end under this alternative if out-of-state incineration is no longer a viable option. *Some portion of these costs are likely to be shared with nursing homes.
DHHS – State Government	$0 to $10,000	$0 to $10,000	$0 to $10,000	Costs related to traveling out of state for witnessed destructions. Total costs would be $0 if no out-of-state incinerations occur in a given year.
421 Nursing homes	$0*	$0*	$0*	*The rules will not necessarily result in costs to nursing homes. It is expected, however, that a portion of nursing homes will choose to share costs for Collection Receptacles with the pharmacies.

- All cost estimates in Table 9 are compared to the ongoing regulatory baseline costs.
- Total amounts are rounded and have not been adjusted for inflation.
- Data is presented for Years 2026-2028, but costs will be ongoing in subsequent years.
- For the 3-year period from 2026-2028, the estimated Present Value (PV) of costs to LTC pharmacies, DHHS, and nursing homes ranges from $1.6M to $2.2M (7% discount rate, 2025 dollars). PV is the current value of a future sum of money or stream of benefits and costs, calculated by discounting those future amounts using a specific rate of return. This calculation is based on the principle that money or impacts received today are worth more than the same amount received in the future due to the time value of money. If this analysis had quantifiable benefits, a calculation of the Net Present Value (NPV) would have been done instead of PV.

Chart 1 presents a comparison of the annual maximum costs for Alternatives #1 and #2. While Alternative #2 is projected to have higher costs in the first year, it is expected to result in substantially lower costs than Alternative #1 in the following years -- potentially offering annual savings of up to $400,000.

Chart 1: Annual Maximum Cost Comparison (2026-2028): Alternative 1 vs. Preferred Alternative w/ Collection Receptacles



While these projected costs are based on reasonable assumptions and estimates, there remains significant uncertainty and expected variability, particularly regarding the projected uptake of each disposal option. The volume of medications requiring disposal can fluctuate greatly from month to month and year to year, which can substantially impact overall costs for pharmacies. Additionally, the continued availability of out-of-state incineration as a disposal method is uncertain. Although the analysis provides minimum and maximum cost ranges to account for some of this variability, actual costs may fall outside these estimates. It is also important to note that these projections do not include the unquantifiable benefits associated with the proposed rules.

Despite these uncertainties, the agency expects that the benefits of reducing diversion risks by ensuring the proper disposal of controlled substances from nursing homes will continue to far outweigh the associated costs, even in light of the recent loss of the in-state incinerator option.

Alternative #1 proposal for amendment of Rule 10A NCAC 26E .0406 via permanent procedures.

10A NCAC 26E .0406 DISPOSAL OF UNUSED CONTROLLED SUBSTANCES FROM NURSING HOME

Controlled substances dispensed for inpatient administration to individuals residing in ~~to~~ a licensed nursing home which for any reason are unused shall be returned to the pharmacy from which they were received. The ~~pharmacist who~~ pharmacy that receives these controlled substances shall return them to ~~his~~its stock or dispose of and destroy them in accordance with ~~the procedure outlined by the director and~~21 CFR 1317.05(a). The pharmacy shall keep a record of ~~this~~the disposal and destruction of unused controlled substances available for a minimum of two years. This record of disposal and destruction shall be kept on the Division of Mental Health, Developmental Disabilities, and Substance Use Services (Division) form entitled ~~"Controlled~~ "Record of Controlled Substances Destroyed".~~Destruction Record Nursing Homes."~~ Pursuant to Rule 10A NCAC 26E .0406". This form is available upon request at Drug Control Unit 3008 Mail Service Center Raleigh, NC 27699-3008 or nccsareg@dhhs.nc.gov. Controlled substances returned to stock must be in a hermetically sealed container or in ~~an otherwise~~ a pure uncontaminated condition and be identifiable. A pharmacy may outsource destruction of the unused controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the pharmacist must first verify the vendor is registered with the Federal Drug Enforcement Agency (DEA) as a reverse distributor and maintains compliance with all applicable federal and State laws and regulations governing reverse distributors and destruction of unused controlled substances per 21 CFR 1317.15. Compliance with this rule is subject to audit by the Division Director or their designated representative.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. June 30, 1978;
Amended Eff. September 15, 1980; May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Emergency Amendment Eff. September 25, 2024;
Temporary Amendment Eff. January 2, 2025;
Eff. _____.

Alternative #2 proposal for amendment of Rule 10A NCAC 26E .0406 via permanent procedures.

10A NCAC 26E .0406 DISPOSAL OF UNUSED CONTROLLED SUBSTANCES FROM NURSING HOME

A pharmacy that has provided controlled substances for inpatient administration to individuals residing in a licensed nursing home shall be responsible for either returning unused controlled substances to its stock, or disposing of and destroying any unused controlled substances in accordance with 21 CFR 1317.05(a) or (c), and other applicable federal regulations governing U.S. Drug Enforcement Administration registrant collection, disposal, and destruction of unused controlled substances in licensed nursing homes. The pharmacy shall keep a record of ~~this~~the disposal and destruction of unused controlled substances available for a minimum of two years. This record of disposal and destruction shall be kept on the Division of Mental Health, Developmental Disabilities, and Substance Use Services (Division) form entitled ~~"Controlled~~ "Record of Controlled Substances Destroyed".~~Destruction Record Nursing Homes."~~ Pursuant to Rule 10A NCAC 26E .0406". This form is available upon request at Drug Control Unit 3008 Mail Service Center Raleigh, NC 27699-3008 or nccsareg@dhhs.nc.gov. Controlled substances returned to stock must be in a hermetically sealed container or in ~~an otherwise~~ a pure uncontaminated condition and be identifiable. A pharmacy may outsource destruction of the unused controlled substances to a reverse distributor in accordance with 21 CFR 1317.05(a)(2), provided the pharmacist must first verify the vendor is registered with the Federal Drug Enforcement Agency (DEA) as a reverse distributor and maintains compliance with all applicable federal and State laws and regulations governing reverse distributors and destruction of unused controlled substances per 21 CFR 1317.15. Pharmacies that are authorized by the U.S. Drug Enforcement Administration as collectors may install, manage and maintain collection receptacles at nursing homes for the purpose of collection, disposal and destruction of unused controlled substances from nursing homes, in accordance with 21 CFR 1317.05(c), 21 CFR 1317.40 and other applicable federal regulations governing the use of collection receptacles by authorized pharmacy collectors in nursing homes. Compliance with this rule is subject to audit by the Division Director or their designated representative.

History Note: *Authority G.S. 90-100; 143B-147;*
Eff. June 30, 1978;
Amended Eff. September 15, 1980; May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;
Emergency Amendment Eff. September 25, 2024;
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