Interpreting and Operationalizing Regulations Worksheet

This material was prepared by Stratis Health under contract with The Minnesota Department of Health (MDH). Use of this tool is not mandated by MDH, nor does its completion ensure regulatory compliance.

This worksheet helps you read regulations, understand their meaning, and determine what actions your organization must take. Use it when reviewing rules, regulations, guidance, or payer requirements.

When should you use this worksheet?
Use this worksheet whenever a regulation needs clearer interpretation, for example, when reviewing new or updated regulations or when requirements are unclear on first read. Existing providers should focus on upcoming or revised requirements, while new providers can work through regulations tied to their planned license type to build compliant systems from the start.

Additional Resources
Guide to Reading Regulations
Guide to Interpreting and Operationalizing Regulations
Terms You Should Know
Acronyms

Use the Minnesota Administrative Rules Chapter 4659 is a further interpret statue.

Regulation being reviewed:	
Date reviewed:	

Step 1: What is the regulation asking?	
Find the regulation and read the full text.	
Requirement Component	**Notes/Response**
What does the regulation say? Quote or summarize it.	
Why was this regulation created? What problem is it trying to prevent or fix?	
Does this regulation apply to my setting, staff, residents/clients, services, or building?	
Which terms do I need to look up? (Examples: provider, staff, manager, facility, abuse, neglect)	
Is this regulation active now, changing soon, or in a transition period?	
What is unclear about this regulation?	
How do I interpret the unclear part, and why do I interpret it that way? Minnesota Administrative Rules Chapter 4659 is a valuable resource to further interpret Assisted Living laws.	

This may serve as documentation for surveyors to explain your interpretation. Include definitions, cross references, purpose, and any expert input. ***It does not guarantee that you will not be cited.***	
How does this interpretation change our policies, workflows, or training?	

Step 2: Break down the requirement.

Figure out what the regulation is asking you to do.

Requirement Component	**Notes/Response**
What must I do? *Look for key words like "must" or "shall."*	
What is optional? *Look for key words like "may."*	
Are there any exceptions?	
Does this regulation refer to other regulations?	

Step 3: What does this mean in practice?

Think about what this looks like in day-to-day work.	
Operational Area	**What needs to happen?**
Daily practice/workflow.	
Who is responsible?	
Documentation, training, or environmental changes.	
What barriers do I anticipate in implementation?	
What evidence will a surveyor look for? *Use surveyor forms to help understand what the Minnesota Department of Health (MDH) will inspect:* *Assisted Living Survey Forms* *Home Care Survey Forms*	

Step 4: Identify risk.	
Check all that apply:	
What could happen if we got this wrong?	**Notes**

☐ Resident/client safety risk	
☐ Regulatory risk (citations, penalties)	
☐ Operational or staffing risk	
☐ Privacy or financial risk	

Step 5: Plan to stay compliant.

Plan how you will keep this requirement on track.

Tip: Use the Action Planning Worksheet [18_Action Plan] to identify required steps, assign responsibility, and track compliance tasks.

Reminder: *Build monitoring and audit processes that are realistic and sustainable over time. Expectations should be operationally feasible for staff to maintain consistently (e.g., weekly reviews rather than every two hours unless required).*

Compliance Area	**Plan/Actions**
Monitoring (spot checks, logs, audits). Make sure frequency is realistic and sustainable.	

Keeping documents up to date.	
Ongoing staff training.	
Review often and make changes to stay on track. Adjust processes if they are not practical to maintain long term.	

Example Worksheet

DISCLAIMER: This worksheet is provided as an educational example only. It is intended to help users practice reading and understanding regulatory requirements, not to serve as legal advice or a definitive interpretation of the law. Laws, regulations, and guidance may change, and their application can vary by setting. Organizations should consult official sources and, when needed, legal or regulatory professionals to determine their specific compliance obligations.

Regulation being reviewed:	**Prescription Drugs** Minnesota Statute § 144G.71, Subd. 20 (Assisted Living) https://www.revisor.mn.gov/statutes/cite/144G.71#stat.144G.71.20 Minnesota Statute § 144A.4792, Subd. 20 (Home Care) https://www.revisor.mn.gov/statutes/cite/144A.4792#stat.144A.4792.20

Step 1: What is the regulation asking?

Find the regulation and read the full text.	
Question	**Notes/Response**
Why was this regulation created? What problem is it trying to prevent or fix?	• Prevent medication errors by making sure drugs stay in the original labeled container. • Ensure staff know the correct drug, dose, instructions, and expiration date. • Reduce the risk of mix-ups, contamination, or outdated medications.
Does this regulation apply to my setting, staff, residents/clients, services, or building?	Applies to: • Assisted Living (AL) and Home Care (HC) providers. • Anyone who handles, stores, or sets up medications (licensed nurses, unlicensed personnel allowed under delegation, medication aides). • Any location within the setting where medications are stored or prepared.
Which terms do I need to look up? (Examples: provider, staff, manager, facility, abuse, neglect)	**144G (Assisted Living):** https://www.revisor.mn.gov/statutes/cite/144G.08 Medication Medication administration Medication reconciliation Medication setup Pharmacist Prescriber Prescription

	Unlicensed personnel **144A (Home Care):** does not specifically define medication-related terms. https://www.revisor.mn.gov/statutes/cite/144A.01
Is this regulation active now, changing soon, or in a transition period?	Assisted Living: 08/1/2021 Home Care: 07/01/2013
What is unclear about this regulation?	• Are there any exceptions to keeping medications in their original labeled containers? • What constitutes as "original labeled container" when medications are repackaged by a pharmacy?
How do I interpret the unclear part, and why do I interpret it that way?	• Medications should stay in their original labeled container so staff can verify the correct drug, dose, and instructions. • Pharmacy-prepared packaging (like blister packs or unit-dose packaging) can count as the original labeled container if it has all the needed label information. • Pill organizers can be used, but they do not replace the original container. Staff should still be able to check the original label when needed. • This approach helps make sure medications are clearly identified and reduces the chance of errors.
How does this interpretation change our policies, workflows, or training?	• Update policies to explain which types of packaging are allowed (like blister packs). • Make clear when and how medications can be placed into pill organizers and who is allowed to do it.

	• Ensure staff can always access the original labeled container (or pharmacy-labeled packaging) for verification. • Train staff to check labels carefully and understand safe medication handling. • Do regular checks to make sure medications are stored and labeled correctly.

Step 2: Break down the requirement.	
Figure out what the regulation is asking you to do.	
Requirement Component	**Notes**
What must I do? *(look for "must" or "shall")*	• Keep all prescription medications in the original pharmacy-dispensed container until they are set up for administration. • Ensure the pharmacy label is legible and includes the expiration or beyond-use date if required. • Follow this regulation for both immediate and later administration of the medication.
What is optional? *(look for "may")*	Providers *may* use their own internal procedures for how medications are organized, if original containers and labels are maintained.

Are there any exceptions?	• No explicit exceptions in the statute. • Blister packs, punch cards, and multi-dose packaging still count as "original containers" *if* they were dispensed and labeled by the pharmacy.
Does this regulation refer to other regulations?	Yes. Medication management requirements in statute. Delegation and storage regulations are in related subdivisions. 144G.71 (AL medication management) • https://www.revisor.mn.gov/statutes/cite/144G.71 144A.4792 (HC medication management) • https://www.revisor.mn.gov/statutes/cite/144A.4792

Step 3: What does this mean in practice?

Think about what this looks like in day-to-day work.

Operational Area	**What needs to happen?**
Daily practice/workflow	Staff must store medications only in the pharmacy's original container until they set them up. Do not repackage medications or move them into unlabeled containers.
Who is responsible?	Nurses, trained unlicensed assistive personnel, med techs, clinical supervisors, and managers overseeing medication services.

Documentation, training, or environmental changes	• Train all staff on proper medication storage. • Make sure lighting and storage areas allow labels to be readable. • Replace any damaged, illegible, or missing labels through the pharmacy.
What evidence will a surveyor look for?	Medications stored correctly in original containers. • Labels are intact and legible. • Staff able to explain the process correctly. • Policies reflect the statutory requirements.

Step 4: Identify risk.	
Check all that apply:	
What could happen if we got this wrong?	**Notes**
☐ Resident/client safety risk	Wrong medication or wrong doses could be given.
☐ Regulatory risk (citations, penalties)	Citations under 144G or 144A medication management standards.
☐ Operational or staffing risk	Increased errors Retraining required

	Staff discipline.
☐ Privacy or financial risk	Need to destroy/replace medications. Complaints or liability.

Step 5: Plan to stay compliant.

Plan how you will keep this requirement on track.

Tip: Use the Action Planning Worksheet [18_Action Plan] to identify required steps, assign responsibility, and track compliance tasks.

Compliance Area	Plan/Actions
Monitoring (spot checks, logs, audits).	Weekly or monthly audits of the medication cart and/or medication storage to make sure original containers are used and labels are legible.
Keeping documents up to date.	Update medication management policies to include statutory language. Make sure pharmacy partners provide compliant labeling.
Ongoing staff training.	Train new staff during onboarding and give refreshers annually or after any medication error event.

Review often and make changes to stay on track.	Revise procedures if survey findings or incident reports identify gaps. Collaborate with the pharmacy to improve labeling or packaging.