STATE OF WASHINGTON
DEPARTMENT OF SOCIAL AND HEALTH SERVICES
Home and Community Living Administration
P.O. Box 45600 • Olympia, Washington 98504

October 16, 2025

HCLA: NH #2025-053
UPDATED GUIDANCE FOR MELATONIN USE IN NURSING HOMES (NHs)

Dear Nursing Facility/Home Administrator:

This letter is to inform you of the Centers for Medicare and Medicaid Services (CMS) updated guidance concerning the use of Melatonin in NHs, issued in May 2025.

Melatonin is a naturally occurring hormone that regulates the body's sleep-wake cycle. The U.S. Food and Drug Administration (FDA) classifies Melatonin as a dietary supplement, a category defined by CMS as “herbal and alternative products that are not regulated by the FDA and their composition is not standardized.”

The guidance from CMS, outlined in Appendix PP of the State Operations Manual (SOM) concerning Melatonin use in NHs, is as follows:

- **Classification:** Melatonin is not classified as a hypnotic medication. As such, it is not subject to the psychotropic medication requirements, including the gradual dosage reduction (GDR) requirements in F605 at §483.10(e)(1).

- **Resident Rights and Consent:** In accordance with the requirements at §483.10(c), residents have the right to be informed of and participate in their treatment. Prior to initiating or increasing a medication, the resident and/or resident representative must be informed of the benefits, risks, and alternatives for the medication, in advance of such initiation or increase.

- **Comprehensive Assessment:** Melatonin is not considered a hypnotic; however, factors such as age, co-occurring medications, and individual health status impact medication and supplement interactions. NHs must ensure use of Melatonin is based on the resident assessment – specifically the resident’s condition and therapeutic goals and any treatments that may be “safer” must have been deemed clinically contraindicated. .§483.20

- **Documentation:** NHs must document adequate indication for the use, dosage, intake, and duration of all dietary supplements - including Melatonin - in the clinical record. §483.45(d)(1).

- **Monitoring for Adverse Consequences:** When a resident is taking Melatonin, NH staff, prescriber(s), and consulting pharmacist(s), must be aware of, monitor for, and document any potentially dangerous, unintended, or unwanted effects that may impair or cause decline in the resident’s medical condition, functional status, or psychosocial status – to include interactions between medications, nutritional supplements, and dietary supplements that a resident is receiving. §483.45.

- ***Please note***: The monitoring protocols and regulatory requirements for hypnotic (psychotropic medications) do not apply to melatonin, and routine shift-by-shift monitoring of sleep or side effects is not required.

If you have any questions, please contact RCSpolicy@dshs.wa.gov.

Sincerely,

Amy Abbott, Director
Residential Care Services

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Related References:

- SOM Appendix PP
- §483.10(c)
- §483.10(e)(1)
- §483.20
- §483.45
- §483.45(d)(1)
- QSO-25-14-NH
- CMS-20082 Unnecessary Medications
- SOM Appendix PP
- QSO-25-14-NH
- CMS-20082 Unnecessary Medications