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Paperwork, Paradox, and PRN: Psychotropic Medication Deficiencies in Assisted Living

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Abstract
Individual state approaches to assisted living/residential care (AL/RC) licensing and oversight in the United States result in different practice standards and requirements, including psychotropic medication use. We examined 170 psychotropic medication deficiency citations issued to 152 Oregon AL/RC settings from 2015-2019. Applied thematic analysis resulted in the following themes: 1) documentation issues are primarily responsible for noncompliance, 2) unclear parameters place direct care workers in a role paradox, and 3) there is a persistent disconnect about when to seek qualified expertise before requesting psychotropic medications. AL/RC-specific mechanisms for medication prescription and administration are necessary to improve the structure and processes of care. Policymakers might consider how regulations unintentionally incentivize task-oriented versus person-centered care practices.

What this paper adds
- Provides context for understanding state oversight and enforcement of psychotropic medication use in AL/RC settings.
- Highlights complexities of the unlicensed care worker roles in medication administration.
- Offers insight into how disconnects between prescriber instructions, processes of care, and regulatory expectations and enforcement can have consequences.

Applications of study findings
- Policymakers, AL/RC operators, and staff can identify (in)congruence between regulatory expectations and practical realities.
- Promote systems approaches to understand and prevent inappropriate psychotropic medication administration in AL/RC residents.
Introduction

A significant share of assisted living/residential care (AL/RC) settings residents have Alzheimer’s disease or related dementia (ADRD) (42%), and an estimated 26–90% have cognitive impairment (Sengupta et al., 2022; Zimmerman et al., 2014). Psychotropic medication used to manage symptoms and behaviors associated with ADRD, including AL/RC residents (Maust et al., 2018; Thomas et al., 2021), presents a significant health policy concern because of their associations with adverse events (e.g., falls, mortality) and care provision implications (Bangash et al., 2017; Beeber et al., 2021; Crystal et al., 2009).

Psychotropic medications—antipsychotic, antianxiety, antidepressant, sedatives, and hypnotics—are commonly used to respond to behavioral expressions associated with ADRD (Maust et al., 2017; Vaismoradi et al., 2019). Medication may be used if nonpharmacologic interventions (e.g., aroma, multisensory, reminiscence, music, validation therapies) do not alleviate an individual’s distress (Kales et al., 2015). The appropriateness of psychotropic medications to manage behavioral expressions associated with ADRD and cognitive impairment has received national and international attention from policymakers and clinicians (Mangin et al., 2018; Parsons, 2017; Ramsey et al., 2018).

Psychotropic Medication Deficiency Citations: What Can We Learn?

In nursing facilities, national regulatory standards and resident-level data collection have led to national quality metrics (e.g., Nursing Home Compare). Pursuing quality can theoretically lead to better care processes and outcomes (Konetzka et al., 2020). When defining “quality” in long-term care, one metric for evaluation is deficiency citations or measures of organizational non-compliance with regulations (Castle & Ferguson, 2010; June et al., 2020). Deficiencies have been associated with the quality of the physical environment, staff turnover, resident safety, and
resident-centered care (Lepore et al., 2020; Lerner et al., 2014). Compared to other medication-
related citations, the prevalence of psychotropic deficiencies is low and mainly consists of
documentation errors (Castle & Engberg, 2007; Young et al., 2008). Most deficiencies do not
describe severe risks to residents’ health and safety, and most medication errors are related to
documentation (June et al., 2020; Trinkoff et al., 2019; Young et al., 2008; Zimmerman et al.,
2011).

AL/RC settings are congregate environments that provide housing, social support,
medication management, and some health-related services to older adults and people with
disabilities. Unlike nursing facilities, AL/RC settings are not licensed health facilities and
typically rely on paraprofessional direct care staff. Oregon does not require AL/RC direct care
workers to have health certifications (e.g., certified nursing assistant, licensed professional nurse,
medication technician). Individual states oversee AL/RC regulations resulting in a wide variation
of licensing standards, staff training requirements, and admission/discharge criteria, limiting the
utility of measuring and comparing quality across states (Carder & O’Keeffe, 2016; Smith et al.,
2021; Trinkoff et al., 2020). States conduct periodic surveys to evaluate regulatory compliance,
issuing deficiencies to facilities that do not meet licensing standards (Trinkoff et al., 2020).

In Oregon, state licensing agents conduct inspections at least once every 24 months in
AL/RC and memory care-endorsed (MC) settings (Endorsed Memory Care Communities, 2020;
Residential Care and Assisted Living Facilities, 2022). Surveyors inspect facility records,
including each resident’s medication administration record (MAR), which documents the orders
(e.g., dose, route, timing), whether the medication is scheduled or *pro re nata* (PRN; as needed),
and any pertinent side effects or interactions. Staff may administer medications, including
psychotropic classes, on a PRN basis to treat acute symptoms or supplement scheduled
medications. AL/RC staff must describe the parameters for PRN use, individualized to each resident. For example, the MAR for a resident with a PRN psychotropic medication order for “anxiety” or “aggression” must include a specific description of how that resident exhibits both “anxiety” and “aggression” and non-pharmacologic efforts that staff should attempt before administering medication (Carder, 2012; Vaismoradi et al., 2019).

Little is known about regulatory deficiencies in AL/RC settings, and even less about medication-related deficiencies. Within AL/RC contexts, direct care staff roles present an additional layer of complexity to understanding organizational compliance with medication administration regulations (Hrybyk et al., 2021; Kelly et al., 2020; Paudel et al., 2020). These staff are first-line responders to residents’ behavioral expressions but cannot formally assess or evaluate due to nursing scope of work standards (Carder, 2012; McKenzie et al., 2012; Sikma et al., 2014; Young et al., 2013). This study employs applied thematic analysis to examine patterns of setting-level noncompliance with psychotropic medication AL/RC rules in Oregon.

Methods

Data Sources

We use publicly available administrative documents from Oregon’s Long-Term Care Licensing website (https://ltclicensing.oregon.gov). This website hosts the last five years of routine inspection and complaint investigation reports containing deficiency citations. We downloaded psychotropic medication deficiency citations (C330 tags) issued from 2015-2019 into Microsoft Excel (n=170) and then imported them into ATLAS.ti, a qualitative analysis software (ATLAS.ti Scientific Software Development GmbH, 2018). Deficiency citations include three types of violations: abuse, licensing, and failure to self-report. Licensing violations
represent failures to substantially comply with licensing rules as determined by the survey team and include narratives that describe the nature of the violation.

Along with the deficiency citation, surveyors and AL/RC staff co-develop “plans of correction” describing the actions staff and management plan to take to both reconcile the deficiencies and prevent them from reoccurring. Plans of correction address the following questions: “What action will be taken to correct the rule violation?”, “How will the system be corrected so this violation will not happen?”, “how often will the area needing correction be evaluated? and “Who will be responsible to see that the correction area is completed/monitored?”

Setting characteristics include licensed capacity (number of beds), license type, whether the setting accepts Medicaid clients, urban/rural geography, and ownership status (profit/nonprofit). Other sources for setting characteristics include publicly available rosters of Oregon’s currently licensed AL/RC/MC settings, the Oregon Office of Rural Health geographic designations by zip code (Oregon Office of Rural Health, 2020), and the Oregon Secretary of State’s Business Registry.

Applied Thematic Analysis

The authors have publication records of qualitative inquiry of AL/RC within Oregon and across the United States. The authors are doctorally trained (research associate and professor) with gerontological specialization, including nationally recognized expertise in AL/RC policy and qualitative research methods. We used deductive and inductive coding approaches, reflective memos to describe emergent themes, and discussion among authors to determine interrater reliability. Applied thematic analysis lends itself to deductive and inductive coding procedures to contextualize and reflexively identify overarching patterns (Fereday & Muir-Cochrane, 2006;
were used to define the initial set of codes deductively. These codes parallel the reasons a setting could be cited for noncompliance: “lacking documentation of attempted nonpharmacologic interventions,” “lacking evaluation and service planning for nonpharmacologic interventions prior to requesting psychotropic medications,” “lacking documentation of resident-specific parameters for the use of psychotropic medication,” and “not consulting a health professional prior to requesting psychotropic medication.” Reading the deficiency citations revealed patterns beyond explicit regulatory noncompliance, leading to the formation of additional codes: types of psychotropic medications used, whether multiple psychotropic medications were ordered for the same resident, reasons medications were prescribed, staff roles implicated, and immediate and long-term strategies to reconcile the deficiency and prevent it from happening in the future.

We designated each citation as the unit of analysis and noted instances when multiple residents were discussed. For example, a citation could reflect deficiencies found within one resident’s medication records, among multiple residents’ records, or general staff practices (not specific to any resident). If a surveyor indicated they reviewed three residents’ records and found that two of those records lacked documentation of nonpharmacologic practices, those deficiencies would be coded separately for each resident. To support the validity of our approach, we individually coded the same ten deficiency citations and discussed coding decisions and additional considerations for interpreting surveyor comments. The first author maintained analytic memos to describe emergent themes while coding and discussed findings with the second author during biweekly meetings over a four-month period.
Findings

Setting Characteristics

Between 2015-2019 state surveyors issued 170 psychotropic-medication (C330) citations to 152 AL/RC settings (30% of all settings). Most settings that received C330 citations had an MC endorsement (54%), followed by 29% AL-only and 17% RC-only. Nearly all cited settings operated for-profit (96%), and over half were in urban counties (55%). Eighty percent of the cited settings accepted Medicaid payment. Capacity ranged from seven beds to 153 beds, and two-thirds of settings had a capacity of 54 beds or less.

Surveyors examined at least 292 residents’ records with PRN psychotropic medications among the 152 AL/RC settings that received a C330 deficiency citation. Surveyors found specific deficiencies in 251 (86%) of these records. The primary reasons for deficiency citations included a lack of documentation of attempted nonpharmacological interventions, resident-specific parameters indicating PRN psychotropic medication use, and lack of consultation with healthcare providers prior to requesting PRN psychotropic medications. Emergent themes and related subthemes are detailed below.

Theme 1: Documentation issues are primarily responsible for noncompliance.

Documentation errors comprised the vast majority of psychotropic medication deficiencies. Across the 170 citations, lacking documentation of attempted nonpharmacological interventions and resident-specific parameters were coded 188 and 130 times, respectively. The most frequently recorded scenario was that residents’ records lacked evidence that nonpharmacologic interventions were developed or attempted and failed to specify behavioral descriptions indicating the need for a PRN psychotropic medication. For example,

“There was no documentation [that] non-drug interventions had been attempted with ineffective results prior to administering the PRN psychotropic medication.”
Progress notes for the dates given showed inconsistent references to failed interventions, and no description of the behavior that required the medication.”

Sometimes nonpharmacologic interventions had been developed for staff to attempt but not documented on the administration record:

“Staff were to try at least three non-drug interventions prior to giving Ativan, which were listed beneath the Ativan order. During 2/2015, Resident 6 was given PRN Ativan on 18 occasions for "yelling" or "yelling and agitation." On 15 occasions, there were no documented non-drug interventions attempted prior to giving the Ativan. Results were not documented on most of the occasions. During 3/2015, Resident 6 was given PRN Ativan on 20 occasions for "yelling" or "yelling & agitation." No non-drug interventions were indicated on any of the occasions and results were not indicated on most of the occasions.”

Settings that documented available nonpharmacologic interventions for staff to attempt did not ensure these interventions were individualized to any particular resident:

“There was no documented evidence the facility had written resident-specific non-pharmacological interventions to be tried prior to administration. In an interview, 3/27/18 at 12:43 pm, Staff 7 [caregiver/medication aide] confirmed the facility used the form, "Behavior Interventions Before Using", for all residents who were prescribed PRN behavior medications. The form had a list of eight non-drug interventions to try prior to administration, however was not resident specific.”

Often PRN psychotropic medication parameters included a one-word rationale (e.g., anxiety or agitation). Surveyors noted that residents’ records were lacking descriptions of how residents expressed clinical indications such as “anxiety,” “agitation,” “restlessness,” or “paranoia.” For example:

“Resident had signed physician orders for the following PRN psychotropic medications to treat behaviors: Haloperidol 0.5 ml every 4 hours as needed for agitation or nausea. Lorazepam 0.5 mg tablet every 4 hours as needed for anxiety or breathing problems associated with anxiety. Resident 1’s MARs, reviewed between 4/1/18 and 6/10/18, revealed the following deficiencies: The MARs failed to include resident-specific parameters which described how Resident 1 exhibited "agitation" and "anxiety." As a result, staff were unclear as to when to administer each medication.”
Subtheme 1a. Plans of correction: Going through the motions or driving change?

To prevent future deficiencies, setting staff must propose a system change. For example, some AL/RC settings provide care staff with a visual cue in the form of an order note, “All residents with orders for PRN psychotropic medications will have non-pharmacological interventions added to their MARS as an ‘attempt first order.’” Plans of correction varied in level of detail and specificity across settings.

Another common proposed plan of correction includes in-service training on medication management, administration, documentation, and regulations for care staff, medication technicians, and management staff (e.g., executive director, administrator, registered nurses). Surveyors described in-house (e.g., registered nurse) and external (e.g., consultant pharmacist) trainers. Plans of correction did not detail the content or frequency of training. Some settings described interdisciplinary plans of correction that included multiple types of staff within the setting, residents’ families, pharmacists, and physicians. One setting planned to implement daily PRN medication order checks,

“Resident Coordinators will check daily through all given PRN medications and check documentation of their staff to ensure all prior non-pharmacological interventions had been attempted and documented before administering the medication. Resident Coordinators will report monthly, to nursing, if any PRN medications are being used 3 or more times in a month. This will ensure accurate tracking by the nurses or nurse practitioners of the frequency of PRNs given. During the end of the month medication cycle fill, the Resident Coordinators will double check each medication order to ensure that reasons for use are added and parameters/steps are clear. While training new staff all supervisors will teach required residential care rules around using PRN psychotropic medications and proper non-pharmacological interventions and documentation for each resident in their home.”
Theme 2: Unclear parameters place direct care workers in a role paradox.

In some circumstances, the prescriber’s instructions for medication administration left room for interpretation, placing unlicensed direct care staff in a position to overstep their defined roles. Staff who administer PRN medications were left to decide how to do so if MARs did not describe residents’ behaviors or medication indications. For example, one resident had a medication order for a PRN antipsychotic medication with multiple dosages,

“The current MAR indicated PRN Haloperidol Lactate Concentrate 2 mg/ml for delirium or nausea - give 0.25 every 4 hours, or give .5 every 4 hours. Non-licensed staff were left to decide which dose of Haloperidol to administer and what behavioral symptoms the resident might exhibit indicating a need for the medication.”

Another resident had multiple PRN orders for psychotropic medications for “anxiety,” “sleep,” and “agitation.” However, the lack of specific parameters left room for unlicensed care staff to interpret when to give which medication,

“The current MAR included lorazepam (anti-anxiety), one to two tablets every four hours as needed for "anxiety or sleep" and haloperidol (antipsychotic) 2 mg/ml concentrate 0.5 ml by mouth or under tongue every 6 hours as needed for "agitation." Non-licensed staff were left to decide how many tablets of lorazepam to administer and what behavioral symptoms the resident might exhibit indicating a need for the medication. Staff were also left to decide how Resident 3 might exhibit agitation, indicating a need for PRN haloperidol.”

Sometimes residents receive PRN psychotropic medications for reasons not prescribed or indicated as a parameter. One resident had a PRN benzodiazepine order for “anxiety or shortness of breath.” The surveyor noted the following deficiency:

“Resident was administered Lorazepam for "agitation and aggression." There was no documented evidence that Resident 1 was displaying anxiety or shortness of breath when the medication was administered. On 11/18/18, she was administered Lorazepam for "agitation and inappropriate behaviors," and there was no documentation that non-pharmacological interventions were tried and ineffective before the medication was given.”
Theme 3: Persistent disconnect about when to seek qualified expertise before requesting psychotropic medications.

AL/RC operators and staff must consult a licensed healthcare professional before requesting psychotropic medications to determine appropriateness and rule out other potential concerns. Surveyors issued deficiency citations when unlicensed AL/RC staff requested psychotropic medications before consulting with the facility RN. For example,

“Resident’s progress notes and interviews with staff revealed unlicensed staff contacted the physician on multiple occasions to request routine and PRN psychotropic medications to treat behavioral symptoms. There was no documented evidence Staff 3 (RN Consultant) was consulted or directed staff to contact the physician.”

These citations included evidence of direct care staff or administrators contacting physicians’ offices directly through fax and requesting medications by name or asking for medications to treat specific behaviors:

“A fax was sent to the resident's physician from caregiving staff. The fax indicated ‘Can we have an order for Lorazepam PRN for [resident name]. [They have] an order for Lorazepam 0.5 mg- 1/2 tab before showers. Res seems very anxious, aggitated [sic]. Screaming and yelling. Thank you.’ The physician responded with the order as requested. There was no documented RN assessment of the need for an increase in the resident's Lorazepam order.”

Working with third-party hospice services and staff introduced complexity and confusion about responsibility. Oregon rules require clinical consultation before requesting psychotropic medications except for hospice recipients, though other PRN psychotropic requirements remain. One setting received a citation for lacking resident-specific parameters and evidence of nonpharmacologic interventions for a resident receiving hospice services,

“Resident 2 had orders for Lorazepam PRN for anxiety or insomnia and Haldol PRN for agitation and/or hallucinations. A description of the behaviors that warranted the medications was lacking and there was no documented evidence other factors had been ruled out for the resident's behaviors including pain, and lack of bowel management. Non-medication approaches to attempt were not

...
identified and per the 3/1-3/31 and 4/1-4/30/19 MAR noted "not applicable-Hospice." There was no order from Hospice to not attempt non-medication approaches.”

Discussion

To our knowledge, this is the first qualitative analysis investigating the scope of psychotropic medication deficiency citations in AL/RC settings. This study provides context for understanding state oversight and enforcement of this important quality of care topic. Over half of the settings that received a psychotropic medication citation had an MC endorsement. This is expected, given higher psychotropic medication use among individuals with an ADRD diagnosis (Bangash et al., 2017; Mueller et al., 2021). A seven-state study of 250 AL/RC communities prescribing and administration of PRN psychotropic medications found that prescribing was higher among residents with a dementia diagnosis and in settings that were larger and had more dementia care beds (Carder et al., 2022).

Most citations addressed the lack of documentation of attempted nonpharmacologic practices or resident-specific descriptions of behaviors that warrant the administration of PRN psychotropic medications. This echoes findings of other studies suggesting the majority of deficiency citations issued in long-term care settings do not present imminent danger to residents (June et al., 2020; Wesson et al., 2020). A recent study showed that nursing facilities with residents using antipsychotic medications were more likely to have citations associated with inappropriate management of behaviors (Yoon et al., 2022). Lack of documentation might not mean that staff did not attempt a nonpharmacologic intervention before administering a PRN psychotropic medication. However, AL/RC operators’ documented reasons for attempted nonpharmacologic interventions provide one level of evidence to state surveyors that required
practices actually occurred. Documentation also provides an information source for care staff to make decisions about resident care (Bowman & Rogers, 2016).

An in-depth ethnographic study of technology use in AL/RC reported that staff are “overwhelmed by paperwork [...] they feel draws them away from focusing on working with clients” (Procter et al., 2018). Perhaps most importantly, direct care workers in long-term care are underpaid and under-resourced for the care they are expected to provide to residents, forcing staff to prioritize (Spetz et al., 2019; Stone & Harahan, 2010). It is possible that other tasks such as documentation and charting, though necessary, become a lower priority to meet residents’ needs and perform caregiving tasks. Future studies could investigate whether and to what extent regulations unintentionally incentivize documenting tasks at the expense of person-centered care and if any existing regulatory approaches strike a balance.

Unlicensed care staff administer medications to AL/RC residents in most states (Carder, 2012; Carder & O’Keeffe, 2016; Spellbring & Ryan, 2003). Oregon’s Board of Nursing rules permit registered nurses to delegate nursing tasks to unlicensed care staff, which is associated with levels of services provided and qualifications of staff handling medications (Beeber et al., 2018). In addition to documentation errors, the way prescribers order PRN medications places direct care staff in a complicated position regarding the scope of their role in medication administration. Regulations do not permit unlicensed care staff to evaluate or make decisions regarding treatments for residents; these staff must deliver treatment and medications as ordered by prescribers. The citations included in this study did not capture the scenario of resident requests related to PRN medications. Residents may request certain as-needed medications from caregivers, who then decide whether to facilitate the administration (Carder, 2012; Carder et al., 2009). In citations where the surveyor listed relevant medication orders for an individual
resident, there was frequent co-prescription of PRN antipsychotic and benzodiazepine medications. In some cases, a PRN benzodiazepine was ordered for a resident’s “agitation,” and a PRN antipsychotic order was in place for “severe agitation.” These multiple medication orders and vague parameters put direct care staff in a position where they can and do make these decisions that exceed their scope of practice.

Nonspecific descriptions of residents’ behaviors assigned, combined with polypharmacy, increase the risk of medication administration errors, most commonly consisting of documentation inconsistencies (Young et al., 2008). Additionally, unless an AL/RC setting is working directly with a consultant pharmacist or nurse, pharmacy technician staff typically process prescription refills and communicate with physician offices, presenting a potential barrier to oversight (Witry & Doucette, 2014). Explicit study of prescribing and deprescribing practices, assessment for inappropriate medications, staff interpretation of prescriber parameters, and communication strategies among AL/RC staff and prescribers are needed to more comprehensively understand how these citations are associated with care delivery in these settings (Cross et al., 2021).

Licensing regulations define psychotropic and PRN medication use in Oregon AL/RC. In some states, like Alabama, AL/RC settings are not allowed to use psychotropic medication to respond to residents’ behavioral symptoms under any circumstances. Other states, such as Idaho, provide explicit guidelines for the circumstances, conditions, and staff training related to psychotropic medication use. Disconnection between prescriber instructions, processes of care, and regulatory expectations have consequences. Studies that have examined the relationship between regulatory oversight and antipsychotic medication use suggest public reporting and stringency do influence medication use rates (Bowblis et al., 2012, 2015). The number and
severity of deficiency citations can indicate “quality,” though these reported relationships are nuanced and complex (Davila & Johnson, 2021; June et al., 2020; Konetzka et al., 2020; Siegel & Young, 2020). Future studies may examine both deficiencies and written orders to identify AL/RC-specific mechanisms for medication prescription and administration necessary to improve the structure and processes of care (Lapane, 2018; Zimmerman et al., 2015).

Limitations

This study has several limitations. First, the level of detail documented in state surveyor inspections facilitates or inhibits our ability to evaluate the qualitative context of deficiency citations, beyond presence or absence. Future research could incorporate interviews with surveyors, facility staff, and residents to contextualize and improve understanding of quantitative and qualitative findings related to deficiency citations and conceptualizations of quality and safety in long-term care. Second, this study examined AL/RC regulatory requirements in a single state and may not apply to the regulatory and practice environments of psychotropic medication use among AL/RC residents in other states. Psychotropic medication use and regulatory requirements may differ based on the licensing and classification within states. Variation in AL/RC regulations and resident populations across the U.S. merit comparison of psychotropic medication use between and within states to inform relevant policy action. Third, this study focused on psychotropic medication deficiency citations and cannot speak to the greater context of organizational practices or compliance with licensing regulations, which may relate to psychotropic medication use. Relatedly, the extent to which AL/RC settings implement the proposed plans of correction or whether these plans are effective at reducing deficiencies are not reflected in these data. Fourth, examining psychotropic medication deficiency citations does not provide a comprehensive perspective of medication administration decision-making.
Understanding the context of these practices requires review of resident MARs to assess the prevalence and frequency of psychotropic medication prescription and administration within AL/RC settings.

Conclusions & Implications

Documentation errors comprised the majority of psychotropic medication deficiency citations issued to Oregon AL/RC settings. By examining deficiency citations, policymakers, operators, and staff can identify (in)congruence between regulatory expectation and practical reality. Policymakers and practitioners can consider how regulations may unintentionally incentivize task-oriented versus person-centered care practices and incorporate AL/RC staff perspectives in policy development. Citations do not fully capture the upstream circumstances that may lead to organizational non-compliance including physician prescribing practices, staff resources and support, and industry influences (e.g., revenue, pharmaceutical culture, perceptions of behavioral expressions associated with ADRD/cognitive impairment).


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