

MEMORANDUM

A.1461-A (Paulin)/S.893-A (Sepulveda)

AN ACT to amend the public health law, in relation to the use of psychotropic medications in nursing homes and adult care facilities

LeadingAge New York must oppose this bill because its requirement of *written* informed consent prior to the initiation of an antipsychotic medication for a resident is likely to impede access to needed medication and cause unnecessary distress for residents and their families. LeadingAge New York supports the goal of this legislation – to further reduce the inappropriate use of antipsychotic medications in nursing homes. However, the strategy this bill would deploy – enhanced consent in writing – is misguided. To be clear, we do not oppose informed consent to these medications – we oppose the requirement that nursing home residents or their authorized representatives consent in writing.

Generally, residents (or if they lack decision-making capacity, their authorized representatives) provide oral consent to treatment, after discussing treatment options with the nursing home’s clinical team. Their oral consent is then documented by the clinical team in the medical record. Requiring residents or their representatives to sign a written consent document will present unnecessary barriers to care for residents whose representatives do not visit the facility frequently or are unable to manage digital signature documents. Importantly, the prior version of this bill (A.1461) did not require the informed consent to be in writing, and LeadingAge New York did not oppose it. To promote the bill’s goal of further mitigating the use of unnecessary antipsychotics, while ensuring access to effective treatment for certain individuals, LeadingAge New York recommends that the bill be amended (i) to remove the requirement that consent be provided in writing, and (ii) to eliminate the requirement that consent be renewed every 12 months.

Specifically, the bill requires an enhanced level of written informed consent from nursing home residents or the resident’s “lawful representative” before initiating an antipsychotic medication. The legislation specifies that this enhanced consent *will not* be required for: residents who have been prescribed an antipsychotic medication prior to admission/readmission to the nursing home; residents who have previously provided informed consent within the last 12 months; residents receiving hospice care or admitted to certified behavioral intervention units; or residents with a primary diagnosis of Huntington’s disease. The bill also authorizes nursing homes and health care professionals to issue an order for an antipsychotic medication without prior informed consent in the case of an emergency that could cause an immediate threat to the life, health or safety of the resident or another person.

The medical and emergency exemptions from the informed consent requirements strive to support access to appropriate treatment and resident safety, while also protecting resident autonomy. The requirement that informed consent be in writing, however, will only disrupt access to appropriate care without providing any additional support for resident autonomy.

Nursing home residents in need of antipsychotic medications often lack the capacity to make health care decisions. Unfortunately, their authorized representatives may live far from the nursing home and visit infrequently. If a resident is in need of an antipsychotic medication, it may be infeasible to obtain written consent within a reasonable timeframe. Executing a consent form digitally may also be infeasible. The authorized representatives of nursing home residents are often older adults themselves – e.g., the 85-year-old sister of a 90-year-old resident – who struggle with digital technology. Further, for some families, there are language barriers that can be addressed relatively easily through telephone-based oral interpretation; but requiring a written translation of a resident-specific written consent document in the decision-maker’s primary language, and in response to the time-sensitive needs of the resident, would be infeasible in many cases. In situations where antipsychotic medication is needed, a delay or failure to provide the medication can cause needless suffering for the resident and distress for the family.

LeadingAge New York is also concerned that the bill’s requirement to renew informed consent every 12 months for certain residents will disrupt medication regimens and lead to adverse outcomes. LeadingAge New York believes that requiring nursing homes to renew a resident’s consent every 12 months is unnecessary given the many other measures in place to prevent inappropriate use of these medications.

There are already ample federal and state guardrails in place to safeguard against the unnecessary use of antipsychotics. Federal regulations (42 CFR §483.45(e)) require nursing homes to ensure that psychotropic drugs are not dispensed unless they are necessary, based on an assessment of the resident, to treat a specific condition diagnosed and documented in the clinical record. Residents who use psychotropic drugs must receive gradual dose reductions (GDRs) and non-pharmacological interventions, unless clinically contraindicated, aimed at discontinuing these drugs.¹ *Pro re nata* (PRN or as needed) orders for psychotropic drugs are limited to 14 days unless the attending physician or prescribing practitioner documents the rationale in the resident’s medical record. Additionally, such medication must only be used to treat the resident’s medical symptoms and must never be used for discipline or staff convenience, which would be deemed a chemical restraint. These requirements are enforced through state and federal inspections (surveys). Depending on the scope and severity, non-compliance is penalized with monetary fines, CMS star rating reductions, possible loss of authority to operate a nurse aide training program, denial of payment for new admissions, and ultimately exclusion from Medicaid and Medicare and loss of authority to operate.

Notably, the Centers for Medicare and Medicaid Services (CMS) updated its State Operations Manual (SOM) last year to materially strengthen the severity of (and thereby penalties for) findings of non-compliance with restrictions on administration of antipsychotic medications in nursing homes. Under the updated SOM, which governs the enforcement of federal regulations by state and federal surveyors (i.e., inspectors), the administration of unnecessary psychotropic medications will be deemed *resident abuse*.² **However, even though CMS chose to implement new, stronger provisions to prevent the unnecessary administration of psychotropic medications, it did *not* elect to require *written* consent.** Presumably, CMS understood that requiring written informed consent would present a significant and unnecessary barrier to access.

In addition to the possibility of regulatory penalties, nursing homes have other incentives to limit the use of antipsychotic medications. There are two CMS quality measures related to the percentage of residents who receive an antipsychotic (one measure for long-stay residents and one for short-stay residents). **New York**

¹ Gradual dose reduction refers to the stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose, or if the dose or medication can be discontinued.

² The new provisions are scheduled to take effect this month.

State facilities perform better than the national average on both measures – the most recent data indicates that in New York State nursing homes, 12.7% of long-stay residents have received antipsychotic medications, compared to 14.6% nationwide, and 1.2% of short-stay residents have newly received antipsychotic medications, compared to 1.7% nationwide (the short-stay and long-stay measures have different definitions). To further target unnecessary antipsychotic use, CMS began auditing nursing homes to validate schizophrenia diagnoses beginning in 2023.

New York nursing homes are also incentivized through the State’s Nursing Home Quality Initiative (NHQI) to minimize utilization of antipsychotic medications. Under the NHQI, the State annually reduces Medicaid nursing home reimbursement by \$50 million, which it redistributes to nursing homes based on measures of compliance, quality and avoidable hospital use. Among the measures used to determine NHQI funding distributions is the *percent of long stay residents with dementia who received an antipsychotic medication*. The poor performers (i.e., those with higher utilization rates based on this measure) do not receive funding back through the NHQI and instead see an overall reduction in funding.

By imposing an infeasible written consent requirement, this bill will impede nursing home residents’ access to necessary medications and cause distress for residents and their families.

For the above reasons, LeadingAge NY opposes A.1461-A (Paulin)/S.893-A (Sepulveda).

LeadingAge New York represents over 350 not-for-profit and public long term care providers, including nursing homes, home care agencies, senior housing, retirement communities, assisted living, adult care facilities, adult day health care and managed long term care.

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