



MIKE ROHRKASTE

STATE REPRESENTATIVE • 55TH ASSEMBLY DISTRICT

Assembly Bill 791
Testimony of State Representative Mike Rohrkaste
Assembly Committee on Mental Health Reform
January 25, 2016

Thank you, Chair Tittl, and members of the Committee on Mental Health Reform for holding this public hearing.

Assembly Bill 791 requires informed consent for psychotropic medications in community-based residential facilities (CBRFs). Currently, the U.S. Food and Drug Administration (FDA) has issued black box warnings for all psychotropic medications stating that these drugs are not approved for treating dementia patients because of an increased risk of death.

Right now, nursing homes are already required to obtain written informed consent before administering a psychotropic medication with a black box warning to a resident with a degenerative brain disorder like dementia. This legislation would require CBRFs to obtain a signed acknowledgement form for administration of psychotropic medications similar to what nursing homes do now.

The goal of this bill is to protect those with Alzheimer's or other dementia who live in a CBRF and are being administered a psychotropic medication. The intent is to ensure that families are informed of the black box warning before psychotropic drugs are administered. This legislation does not prohibit the use of a psychotropic medication for residents with Alzheimer's or other dementia in a CBRF, as long as the family is notified of the risk.

A CBRF is the appropriate setting to require this signed acknowledgement form. Unlike what is currently required of nursing homes, this legislation treats CBRFs differently by requiring that they only obtain a signed form acknowledging the information has been provided instead of a consent form. The CBRF will be providing the resident's guardian with a prepared acknowledgment form which shouldn't require any specialized medical training.

This legislation is supported by both the Alzheimer's Association and the Alzheimer's and Dementia Alliance of Wisconsin (ADAW). It was requested by the ADAW in conjunction with a constituent of my district who had a psychotropic medication given to his mother without his knowledge.

Thank you for your time and I'm happy to answer any questions.



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January 25, 2016

Alzheimer's and Dementia Alliance of Wisconsin testimony in support of AB 791

Good morning Chair Tittl and members of the committee. Thank you for the opportunity to speak today. I'm Rob Gundermann, the Public Policy Director for the ADAW and I'm speaking in favor of AB 791.

In 2009 the Legislature passed a bill requiring nursing homes to inform the family or guardian about the Black Box Warning for psychotropic or antipsychotic medications and to obtain a signature on a form before administering the drugs.

Since 2009 Wisconsin has gone from being one of the highest prescribing states to the fifth lowest. There were several factors that led to the decline in the use of these drugs in nursing homes but we believe that legislation was a contributing factor.

At the time we weren't seeing these drugs being administered in Community Based Residential Facilities but now we're seeing problems there too, likely because people are staying in CBRFs longer than in years past.

I understand that there have been suggestions made that the prescribing physician should be the individual required to obtain the black box warning acknowledgement form rather than the Community Based Residential Facility (CBRF). We believe this would be problematic.

- A physician may not have any knowledge of a patient's guardianship or health care power of attorney while a CBRF would have a copy of a resident's activated guardianship or HCPOA and would probably have a relationship with the guardian or HCPOA.
- A physician may not know that someone lives in a CBRF.
- A physician may not be aware of a black box warning on a particular medication because the physician may never see the packaging.

The ADAW continues to believe that the CBRF administering the medication should be the entity required to obtain the acknowledgement form. When a doctor prescribes a medication it's our responsibility to read the materials and understand the risks, dosage and side effects

but when someone takes possession of our medication, packaging, warnings and instructions and administers it to us we no longer have the ability to be informed consumers. Since the CBRF is in possession of the packaging with that black box warning and performs the actual administration of the medication it is logical that they would also be the entity to obtain the signed acknowledgement form.

The bill recognizes that CBRFs are not based on a medical model and treats them differently than nursing homes by requiring CBRFs only to obtain a signed form acknowledging information has been provided rather than the consent form nursing homes are required to obtain. Providing prepared materials explaining the black box warning for dementia and obtaining a form acknowledging receipt of those materials by the guardian or HCPOA shouldn't require any specialized medical training. If a more detailed conversation needs to take place the bill does instruct the CBRF to provide contact information for the prescriber.

For these reasons we urge the committee to support AB 791 as written. With me today is Wayne Nitz who would like to share the experience his family had with these medications and then we would be happy to try to answer any questions.



WHCA / WiCAL

Wisconsin Health Care Association

Wisconsin Center for Assisted Living

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WISCONSIN ASSISTED LIVING PROVIDERS OPPOSE AB 791 AS DRAFTED

Good morning, Chairman Tittl, and members of the Assembly Committee on Mental Health Reform. Thank you for the opportunity to testify today. At the outset, we would like to recognize and applaud the efforts of Representative Rohrkaste and the other members of the Speaker's Task Force on Alzheimer's and Dementia for their hard work and willingness to address this difficult condition that too many Americans face. The final work product of the Task Force is an important compliment to the ongoing dementia care redesign efforts of the Department of Health Services. As advocates, providers, regulators and legislators combine their forces to tackle the crucial issues facing our state related to individuals facing Alzheimer's and related dementias, we support this kind of collaboration which is essential if we are to succeed in this battle.

As representatives of the Wisconsin Health Care Association (WHCA), Wisconsin Center for Assisted Living (WiCAL), LeadingAge Wisconsin, Wisconsin Assisted Living Association (WALA), and Residential Services Association of Wisconsin (RSA) – all of the state's assisted living provider associations – we would like to register our joint **opposition to Assembly Bill 791, as drafted**.

AB 791 would require CBRFs to obtain a signed acknowledgement form from a CBRF resident, or their legal decision-maker, before administering to that resident a psychotropic medication that has a federally-designated "black box" warning to a resident with a degenerative brain disorder. The intent of the bill, according to its co-sponsorship memo, is "to ensure that families are informed of the black box warning before psychotropic drugs are administered."

While the bill attempts to create a distinction between the "informed consent" form to be used by nursing facilities, and the "acknowledgement" form to be used by CBRFs, the distinction is lost, particularly when the sections refer to the withdrawal of the acknowledgment form. The blurring of this distinction essentially creates the expectation that a CBRF obtain what is the equal of informed consent, a role that is beyond the scope of such facilities. The members of our associations believe informed consent of the use of psychotropic medications is vital but would argue that the consent or acknowledgement required under AB 791 is not truly "informed" because:

- CBRFs do not prescribe medications – any medications, psychotropic or otherwise. Only physicians and certain other medical professionals may prescribe medications.
- CBRF resident care is primarily provided by non-licensed/certified personnel. While regulations establishing training requirements must be met, most personnel are not medically trained and they certainly are not qualified to discuss the risk and benefits of psychotropic medications with their residents or family members. Yet in many cases, these are the individuals that would be required to obtain the signed acknowledgement form under Section 3 of AB 791.
- A CBRF is a social-model, not a medical-model facility, and, unlike nursing homes, is not required by code or statute to have a medical director, mandated physician visits, or professional nursing staff on site at all times.

As indicated above, our members are opposed to AB 791 as drafted and feel that any effort towards improving and assuring additional information be targeted towards the relationship between the prescriber and the resident/patient. Discussions on the use of psychotropic medications should be held by the professional who is qualified and has been properly trained to offer this kind of advice – the prescriber. This is already an obligation for physicians, as Wis. Stat. 448.30 requires "any physician who treats a patient shall inform the patient about the availability of reasonable alternate medical modes of treatment and about the benefits and risks of these treatments." To the extent there is a belief that the completion of a consent/authorization form will create a

benefit, it should be obtained at the time it is prescribed, as part of the discussion or the risks and benefits of such medications.

S. 50.08 (3)(bh)2 of AB 791 would seem to concur with our belief that the prescriber is the more appropriate participant in an informed consent discussion. The provision states that if a CBRF resident with Alzheimer's disease and/or their legal representative wants more information on the psychotropic medication and its use, the CBRF must provide them with the prescriber's contact information. In other words, the bill would seem to acknowledge the shortcomings of a CBRF in these informed consent discussions. If the goal of the bill is informed consent that truly is informative, it should be a discussion between the resident and the medication's prescriber.

As the co-sponsorship memo to this legislation correctly pointed out, there are concerns with the use of psychotropic medications, which is why existing statutes and regulations treat these medications differently than many others. In the context of CBRFs, expectations already exist on the CBRF found at Wis. Admin. Code DHS 83.37 regarding scheduled and prn (as needed) use of psychotropic medications. While certainly attention must remain, it should be noted that there has been dramatic reductions in the use of antipsychotic and psychotropic medications in the elderly that have occurred in the past two years due to collaborative efforts of providers, regulators and advocates, without prescriptive and misplaced mandates.

Passage of AB 791 as currently drafted may also have other unintended consequences, including that the placing the informed consent expectations outside of the dialog between the patient and physician/prescriber may create a condition in which the prescriber erroneously or inappropriately abdicates the responsibility to assure a meaningful risk/benefit discussion about the medication. If both the CBRF and the prescriber assume that the other will engage in the detailed risk/benefit discussion, the bill could actually represent a step backwards towards the goal of assuring full understanding of such risks and benefits. Further this legislation references the use of several state forms, and requires the CBRF to search and identify information from the FDA regarding medications that must be (a) identified, and (b) shared with the resident. As mentioned, CBRFs do not have physicians or pharmacists on staff, and the expectation for CBRF personnel to identify the relevant FDA or related information invites paperwork errors by non-medical staff could result in less than current information being shared, and will further put facilities at risk of state citations and/or forfeitures and potentially expose facilities and staff at risk of legal action.

In addition to placing the written informed consent expectation to the most appropriate relationship, that being between the patient and prescriber, there are several other changes to AB 791 we believe would improve the bill:

- **HOSPICE:** Some CBRFs serve residents that have elected to bring in hospice care providers, where the use of psychotropic medications might be more appropriate. A hospice exemption under AB 791 might be appropriate.
- **CLARIFY SCOPE:** Black box warnings apply to other medications beyond the scope of this bill. We would suggest clarifying that AB 791 applies to the use of psychotropic medications with black box warnings by individuals with Alzheimer's disease or a related dementia.
- **EFFECTIVE DATE:** Without any discussion of an effective date included in the legislation, the bill will go into effect 24 hours after publication. The Wisconsin Department of Health Services should be afforded appropriate time to make changes to forms required under this bill.

While well intentioned, AB 791 as drafted would fail to meet its stated goals. On behalf of Wisconsin's hard-working assisted living providers and the residents with Alzheimer's disease they serve, we urge you to amend Assembly Bill 791 as recommended.

If you have any questions regarding our position on this legislation, please contact:

- Brian Purtell, Wisconsin Center for Assisted Living/Wisconsin Health Care Association – (608) 257-0125; Dale Kelm, Council Chair, WiCAL Council.
- Forbes McIntosh, Wisconsin Assisted Living Association – (608) 332-5205
- Dan Drury, Residential Services Association of Wisconsin – (414) 276-9273
- John Sauer, LeadingAge Wisconsin – (608) 255-7060