

Legal Issues



By William C. Wilson, Esq.

Informed Prescribers Should Obtain Informed Consent

Mrs. S, age 96, resides in a skilled nursing facility and has moderate dementia with severe anxiety and agitation. She did not grant a durable power of attorney for her health care or other responsibilities while she still had decisional capacity. Her attending physician prescribes lorazepam as needed for anxiety, and the facility administers it with apparent good effect.

Mrs. S's medical record contains no documentation that informed consent was obtained from anyone for the administration of the drug. Are Mrs. S's resident rights being violated, despite the fact that the lorazepam has significantly calmed her down and is apparently improving her quality of life? Even though staff followed physician's orders, the answer may be yes, depending on state law and the culture of surveyors locally. The action may expose the facility and the prescriber to liability.

The notion of informed consent is in any list of patients' rights. And while it should, ideally, be obtained for any medical order or intervention, in reality it is often not done or not documented. Use of medications for "off-label" indications, especially ones with black-box warnings (such as antipsychotics), should prompt the prudent clinician to ensure that appropriate consent is obtained and documented. Some states, including California and Illinois, already have requirements for informed consent of nursing home residents who receive antipsychotic (or other psychotropic) medications, and there is strong consumer advocacy and even proposed federal legislation to expand this requirement.

According to the Centers for Medicare & Medicaid Services (CMS), antipsychotic medications are frequently prescribed improperly for residents with dementia who have only behavioral or psychological symptoms of dementia, commonly called BPSD. When antipsychotic medications are used without a clear medical indication or for the purpose of limiting or controlling disruptive behavior, it is unlikely that the medication will be effective, according to the agency. Consequently, elders' advocacy groups, CMS, and provider associations, such as AMDA, are making every effort to reduce the administration of these drugs in nursing homes.

Ironically, a cottage industry has emerged among attorneys as a result of these efforts. In California, for example, plaintiffs' attorneys are using Health & Safety Code Section 1430(b) as a means to recovering millions of dollars for perceived abuses of psychotropic

medications in the elderly. The advantage for plaintiffs is that they do not have to prove liability or even any actual harm to a resident in order to recover statutory damages. Plaintiffs only have to prove that the resident's right to informed consent was violated. Then, he or she is entitled to a statutory penalty of up to \$500 – plus attorneys' fees and costs. Obviously, the attorneys' fees are what can run up to high six-figure judgments against a facility.

California facilities are required by the Department of Public Health to verify that a resident's medical record documents the informed consent, yet there is no concrete procedure the prescriber has to follow in obtaining it. Ultimately, liability for improper administration of psychotropic medications is falling more and more upon the facilities, although physicians and other prescribers will no doubt share in some of the liability if they, too, fail in this obligation.

Verify Informed Consent

Informed consent means that a patient or surrogate has been given all the information necessary to make a decision about getting therapy from a health care practitioner acting within the scope of his or her professional licensure. In the context of skilled nursing facilities, it is clear that psychotropic medications have often been prescribed and administered without this step. Various facilities and practitioners have fallen down in several ways.

Under current interpretation of California law, for example, facility staff, including nurses, cannot obtain informed consent because it is outside the scope of their licensure. Physicians in California and beyond need to know whether informed consent must be obtained by them or the nurse practitioner or physician's assistant whom they supervise. Even where this is not required, it is advisable for physicians to confirm that a resident or surrogate has truly been informed; understands the risks, benefits and alternatives to treatment; and has agreed to it – especially with a potentially dangerous drug for an off-label indication. Generally, physicians are immune to civil liability exposure for this issue because laws governing informed consent for prescriptions do not apply to physicians. Usually a plaintiff's counsel will not file cases against physicians due to the causation and damages challenges, and the lack of statutory basis to do so. The standard of care and the law require physicians to work as a team with the skilled nursing facility to ensure that informed consent is obtained and

documented prior to administering psychotropic drugs.

Practical Challenges

A special challenge presents when a resident comes into a nursing facility in the evening with orders for psychotropic medication and the staff cannot verify informed consent. Under current interpretation of California law, the medication cannot be administered in this situation, despite the order in effect. This may place the resident in jeopardy. One example would be the paranoid schizophrenic who has a history of violence, but has been stable and hallucination-free on olanzapine for 10 years. The facility must have policies and procedures set in place to address this event.

California regulations do not require any particular form of documentation to indicate how informed consent was obtained. Therefore, state surveyors will accept almost any documentation that shows written or verbal informed consent was obtained by the prescribing physician or nonphysician practitioner acting within his or her scope of professional licensure.

The documentation must conform to the facility's norms regarding how such information will be recorded in the medical record. Therefore, facilities should review their policies and procedures to determine whether they verify informed consent in a resident's medical chart and whether there are procedures in place for unexpected contingencies, such as when consent cannot be immediately verified. Physicians need to be aware of these policies and conform their practices to them.

CMS expects nursing facilities to document attempts to include a resident's family and any representative in the decision whether or not to consent to the administration of psychotropic drugs. If a family member or representative is unable to participate in person, then the facility needs to document what further attempts were made by telephone or electronic means to include this person in the discussions and development of a care plan.

The following are suggested best practices for facilities and physicians regarding informed consent and administration of psychotropic medications:

- ▶ Do not prescribe psychotropic medications if they are not medically necessary or if nonpharmacologic measures have been shown to help, except in an emergency.
- ▶ Physicians, nurse practitioners, or physician assistants should confirm informed consent for any psychotropic medication

prior to prescribing it, especially an antipsychotic for a dementia patient.

▶ If the psychotropic medication is prescribed in an acute care setting and the patient is subsequently transferred to a skilled nursing facility, the transfer paperwork should include documentation of informed consent.

▶ Each facility should implement a rigorous dose-reduction program for all residents on psychotropic medications, with a focus on the residents' needs.

▶ If a resident is on psychotropic medications, this should be discussed in depth at care-planning conferences with the family, and anytime there is a change in drug or dosage so all risks, benefits, alternatives, and expected duration of the medications are fully addressed.

▶ When facility staff receive an order for psychotropic medications, they should always check the chart to see if the prescribing clinician obtained informed consent. In California, the state that most specifically addresses the issue of informed consent in the long-term care setting, if the chart does not contain documentation that consent was obtained, the medication cannot be administered. If this situation arises, the facility must follow its policy and procedure for dealing with inability to verify informed consent. This may consist of transferring the resident back to an acute care facility.

▶ Every nursing facility should consider implementing a policy for staff to confirm that a resident or responsible party has spoken with the physician/prescriber and consented to the use of a psychotropic medication prior its administration.

Many psychotropic medications are appropriate and beneficial. But the bottom line is that before prescribing psychotropic medications, proper informed consent should be obtained, and adequate documentation should be placed in the resident's medical chart for the facility and any agency to verify. Failure to do this, especially in some jurisdictions, will place physicians and facilities at risk of regulatory action and civil liability.

This column is not to be substituted for legal advice. WILLIAM C. WILSON is a partner in the law firm Wilson Getty LLP, which is devoted to representing health care providers, including all types of long-term care facilities, against civil claims of elder abuse and neglect, professional negligence, wrongful death, and violation of patient's rights. He also represents facilities in administrative hearings and advises long-term care clients on risk management and corporate compliance.