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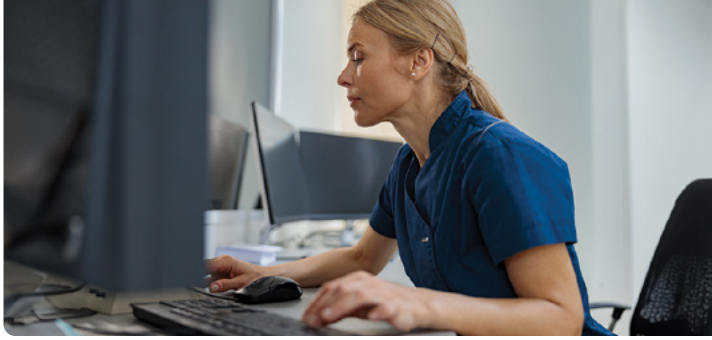

CMS – Informed Consent for Psychotropic Drugs

Tuesday, August 12 2025

Revised CMS guidance on informed consent for psychotropic medications emphasizes the resident's right to be fully informed and the right to accept or decline a medication. Here are some questions and answers related to informed consent for psychotropic drugs.

When is informed consent required?

Informed consent is required before initiating or increasing a psychotropic medication, says CMS.

Can a resident refuse a psychotropic drug?

Yes, by CMS guidance, the resident, family, and/or resident representative has the right to refuse a drug treatment.

What should be included in an informed consent?

Informed consent begins with a conversation. A discussion with the resident, their representative, and/or family member should address key elements:

- The physician or nurse practitioner should name the medication.
- The practitioner should identify the relevant diagnosis. (There are additional requirements that address documenting a diagnosis, per F658.)
- The practitioner should describe how the team arrived at the recommendation, including attempts using non-pharmacological interventions and outcomes of those attempts.
- The practitioner should also explain what the alternatives are.
- The practitioner should describe the indications for use and explain the anticipated benefits and risks. An example of a benefit might be easing distress or increasing safety. An example of a risk might be dizziness or a risk of falls—potential side effects of the proposed medication.

This information should be communicated in a way that is understandable to the resident or representative, notes CMS. A practitioner can take the time to discuss a proposed treatment and answer questions.

How should informed consent be documented?

The above elements should all be documented in the medical record. The outcome of the discussion, i.e., consent or refusal, should also be documented.

Do we need a form?

This is not required, but using an informed consent form helps guide team members through the required elements of informed consent. It also provides consistent documentation and helps organize information for reference by surveyors.

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CMS – Informed Consent for Psychotropic Drugs *continued*

Why is risk-benefit thinking important?

It is unlikely that a medication recommendation will come with a guarantee of success. Individual variations in response to any drug can be expected. Deciding to use a psychotropic drug for treatment of BPSDs is a risk-benefit decision, suggests Elizabeth Crocco, MD in her video, Pharmacological Management of Agitation & Aggression in Alzheimer's and Related Dementias. In her community-based experience, she says, "A success is 50% reduction in the intensity and frequency of these symptoms." In many situations, that can represent a major benefit, she adds.

Do we need a policy about informed consent?

Using a written policy/procedure to detail and standardize informed consent practices in your nursing home organization is a sound idea. It communicates expectations to staff and can also be used as a training tool. As CMS informed consent standards related to psychotropic drugs have been strengthened, be sure to review any legacy policies and procedures to ensure they reflect current standards.

More resources

If you are looking for support in meeting CMS nursing home guidance and managing behavioral concerns in dementia care, feel free to reach out to the experts at GuideStar Eldercare.

To learn more about revised CMS guidance, see the blog, New CMS Guidance: Prevent Unnecessary Psychotropic Medications. For more questions and answers about CMS compliance for nursing homes, visit cms.guidestareldercare.com.

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