



The
NEW
Nursing
Home
Regulations

Antipsychotic Drugs, Psychotropic Drugs & Pharmacy Services

Presented by Richard Mollot, Long Term Care Community Coalition

www.nursinghome411.org

This program is made possible by the generous support of the NY State Health Foundation

+ What is the Long Term Care Community Coalition?

- **LTCCC:** Nonprofit organization dedicated to improving care & quality of life for the elderly & adult disabled in long-term care (LTC).
- **Our focus:** People who live in nursing homes & assisted living.
- **What we do:**
 - Policy analysis and systems advocacy in NYS & nationally;
 - Education of consumers and families, LTC Ombudsmen and other stakeholders.
- **Coalition members** include several LTC Ombudsman Programs, the Center for Independence of the Disabled, AARP NY, several Alzheimer's Association Chapters, other senior and disabled organizations. Also individuals, including ombudsmen, who join in our mission to protect residents.
- **Richard Mollot:** Joined LTCCC in 2002. Executive director since 2005.



+ What Will We Be Talking About TODAY?

■ BRIEF BACKGROUND

- Overview of the Nursing Home System
- The Federal Nursing Home Law & Why it is Important

■ PSYCHOTROPIC DRUGS, PHARMACY SERVICES & DEMENTIA CARE

- A Persistent & Wide-Spread Problem: Dementia Care & the Inappropriate Use of Antipsychotics & Other Psychotropics
- Standards for Dementia Care & Drugging
- New Requirements for Pharmacy Services
- Where Do We Go From Here?: Resident-Centered Advocacy in Challenging Times



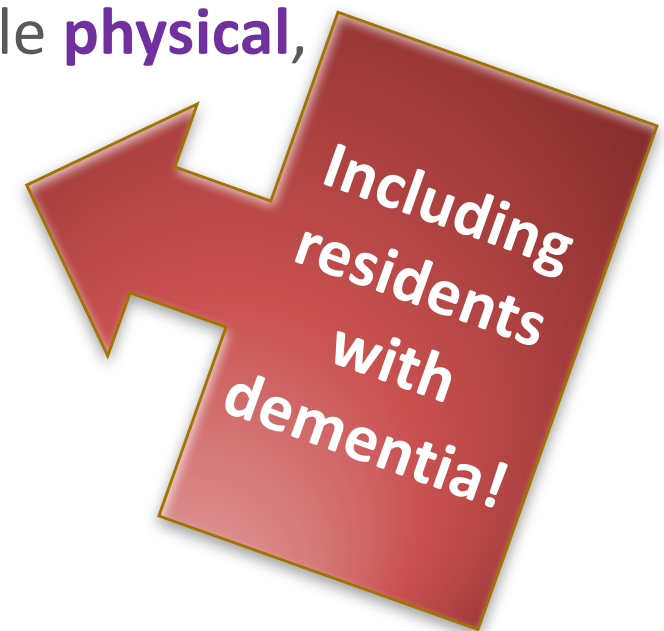
+ The Nursing Home System in a Nutshell

- Almost all nursing homes participate in Medicaid and/or Medicare.
- In order to participate in Medicaid/Medicare, a facility agrees to meet the standards provided for in federal law.
- States may have additional protections, but no state can have less protections.
- Federal ***protections are for all the residents*** in a facility, whether their care is paid for by Medicare, Medicaid or private pay.



+ The Nursing Home Reform Law

- The Nursing Home Reform Law (aka OBRA 87) requires nursing homes receiving federal funding to conform to specific standards of care.
- Federal law requires that **every** nursing home resident is provided the care and quality of life sufficient for them to attain and maintain their highest practicable **physical**, **emotional** and **social** well-being.
- This is what we pay for.
- This is what providers agree to provide.
- This is what every resident deserves.



+ Why are the laws & regs important?

- The 1987 Nursing Home Reform Law proscribes the use of psychotropic drugs as chemical restraints to control or sedate residents for the convenience of staff.
- In May 2011, the U.S. DHHS Inspector General said **nursing home residents and their families should be “outraged”** by his office’s report that well over a quarter of a million residents were receiving antipsychotic drugs for medically unaccepted, off-label uses.
- In a 2012 review of resident records, his office found that 91% did not contain evidence that the resident or the resident’s family or legal representative participated in the care planning process. **Every resident in this study was administered an antipsychotic drug.**
- Recent updates to federal regulations strengthen government expectations for **good dementia care** and **avoiding inappropriate drugging**.

+ A Word About Dementia

- Dementia, and dementia care, is a growing concern for individuals and families as our population ages and more people live longer with Alzheimer's and other forms of dementia.
- Most nursing home residents have some level of dementia.
- Some common "behavioral symptoms" of dementia:

Restlessness

Wandering

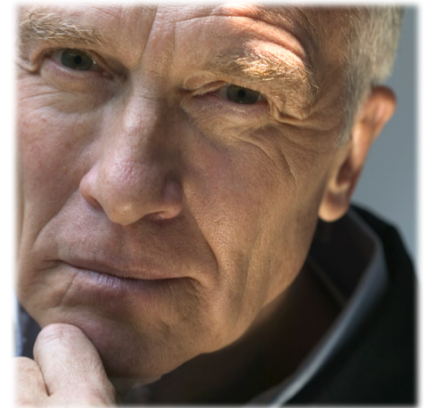
Agitation

Aggression

- Too often, residents with behavioral symptoms are given powerful, dangerous drugs instead of care that responds to the needs they are trying to express.
- Too often, these drugs are given without informed consent of the resident & family and without appropriate clinical oversight.
- **Though the focus is often on residents with dementia, inappropriate drugging can happen to anyone.**

+ What is the problem we are trying to address?

- One in five (20%) of our nursing home residents are being given powerful antipsychotics. Only about 2% of the population is **ever** diagnosed with a psychotic condition recognized by CMS.
- Over the years, it became a common practice to sedate residents with dementia who are distressed or exhibiting other “behavioral symptoms” of dementia.
- The Food & Drug Administration (FDA) “Black Box” warning states, “Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an **increased risk of death....**”
- Antipsychotics commonly have **serious side-effects**, including: movement disorders, falls, hip fractures and strokes.
- Antipsychotics stupefy residents and can seriously **exacerbate functional and cognitive limitations**.
- **Antipsychotic drugs are NOT EFFECTIVE for more than a short period of time in addressing “behavioral symptoms of dementia.”**



+ Important to keep in mind...

The focus of our discussion – and of the federal standards in general – is on nursing home care.

HOWEVER, this is a serious problem for people in assisted living, adult homes and home care too.

A recent study found that:

- 76% of assisted living residents have a documented diagnosis of dementia.
- 37% of those individuals were being given antipsychotic drugs.
- Residents in an assisted living that had a “memory care unit” were more likely to be treated with both dementia medications and antipsychotic drugs.

This problem affects people with dementia in ALL settings.

+ The Law: Residents' Rights

ALL of the rights we are talking about today have been in place since 1991, under the US Nursing Home Reform Law.

- **Informed Decision-Making:** Residents have the right to be informed about the risks and benefits of any medication.
- **Right to Refuse:** Residents have the right to refuse a medication.
- **Freedom from Chemical Restraints:** It is against the law to give medications that do not benefit the resident, such as for convenience of staff.

+ The Law: Informed Consent

The resident has the right to...

- Participate in planning care and treatment.
- Be fully informed in language that he or she can understand of his or her total health status.
- Be informed, in advance, of the care to be furnished and the type of caregiver or professional that will furnish care.
- Be fully informed of any proposed changes in care or treatment that may affect the resident's well-being.
- Be informed in advance, by the physician or other practitioner, of the risks and benefits of proposed care, of treatment alternatives and treatment options and to choose the alternative or option he or she prefers.
- Refuse treatment (regardless of whether doing so may be detrimental).

How does this apply to residents with dementia? If a resident is judged incompetent under the laws of the state, "the rights of the resident are exercised by the person appointed under State law to act on the resident's behalf."



"Informed consent is an ethical concept—that all patients should understand and agree to the potential consequences of their care."

+ Informed Consent Checklist

CHECKLIST FOR RESIDENTS, FAMILIES & OMBUDSMEN

The physician/prescriber (not a delegated representative) should disclose and discuss:

- ✓ The diagnosis, if known
- ✓ The nature and purpose of a proposed treatment or procedure
- ✓ The risks and benefits of proposed treatment or procedures
- ✓ Alternatives (regardless of costs or extent covered by insurance)
- ✓ The risks and benefits of alternatives
- ✓ The risks and benefits of not receiving treatments or undergoing procedures

This checklist is from
LTCCC's "Informed
Consent" factsheet.
All of our factsheets
are available for free
at

www.nursinghome411.org

+ The Law: Free from Unnecessary Drugs

Each resident's drug regimen must be free from unnecessary drugs.

*An unnecessary drug is **any drug** when used-*

- *In excessive dose (including duplicate drug therapy); or*
- *For excessive duration; or*
- *Without adequate monitoring; or*
- *Without adequate indications for its use; or*
- *In the presence of adverse consequences which indicate the dose should be reduced or discontinued.*

What's an unnecessary drug?

+ The Law: Psychotropic Drugs

Based on a comprehensive assessment of a resident, the facility must ensure that-

- *Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;*
- *Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;*
- *Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and*
- *PRN orders for psychotropic drugs are limited to 14 days. [With ltd exceptions.]*

Additional requirements for psychotropic drugs



+ The Law: Drug Regimen Review

- *The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.*
- *This review must include a review of the resident's medical chart.*
- *The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.*



Federal
Requirements
for Nursing
Homes

+ The Law: Drug Irregularities

- Irregularities include, but are not limited to, **any drug that meets the criteria for an unnecessary drug.**
- Any irregularities noted by the pharmacist during this review **must be documented on a separate, written report.**
- The **written report must be sent** to the attending **physician** and the facility's **medical director** and **director of nursing.**
- The report must list, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.
- The **attending physician must document in the resident's medical record** that the identified irregularity has been reviewed and what, if any, action has been taken to address it.
- If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

LONG TERM CARE COMMUNITY COALITION

Advancing Quality, Dignity & Justice

LTCCC FACTSHEET DEMENTIA CARE & DRUGGING STANDARDS

There are many standards which nursing homes are required to follow in order to ensure that residents receive appropriate care, have a good quality of life and are treated with dignity. **YOU** can use these standards to support better care in your nursing home.

Below are standards important to dementia care and the use of psychotropic drugs with information that can be used to support resident-centered advocacy. [Notes: The brackets provide the relevant federal regulation (CFR) and F-tag (category of deficiency). Emphases added.]

THE LAW

I. Drug Regimen Review [42 CFR 483.45(c) F-756]

The drug regimen of each resident **must** be reviewed at least once a month by a licensed pharmacist.

This review must include a review of the resident's medical chart.

The pharmacist **must** report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.

- Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d)... [see "Free from Unnecessary Drugs" below] for an unnecessary drug.
- **Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified. The attending physician **must** document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.**

II. Free from Unnecessary Drugs [42 CFR 483.45(d) F-757]

Each resident's drug regimen **must** be free from unnecessary drugs. An unnecessary drug is any drug when used-

- In excessive dose (including duplicate drug therapy); or
- For excessive duration; or
- Without adequate monitoring; or
- Without adequate indications for its use; or
- In the presence of adverse consequences which indicate the dose should be reduced or discontinued....

III. Psychotropic Drugs [42 CFR 483.45(e) F-758]

Based on a comprehensive assessment of a resident, the facility **must** ensure that-

- Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;
- Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;
- Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and
- PRN orders for psychotropic drugs are limited to 14 days.¹

BASIC DEMENTIA CARE REQUIREMENTS & EXPECTATIONS

1. **Obtain details about the person's behaviors** (nature, frequency, severity, and duration) and risks of those behaviors, and discuss potential underlying causes with the care team and (to the extent possible) resident, family or representative;
2. **Exclude potentially remediable causes of behaviors** (such as medical, medication-related, psychiatric, physical, functional, psychosocial, emotional, environmental) and determined if symptoms were severe, distressing or risky enough to adversely affect the safety of residents;
3. **Implement non-pharmacological approaches to care** to understand and address behavior as a form of communication and modify the environment and daily routines to meet the person's needs;
4. **Implement the care plan consistently** and communicated across shifts and among caregivers and with the resident or family/representative (to the extent possible); and
5. **Assess the effects of the approaches**, identify benefits and complications in a timely fashion, involve the attending physician and medical director (as appropriate for the resident's well-being) and **adjust treatment accordingly**.

RESOURCES

- WWW.NURSINGHOME411.ORG. LTCCC's website includes materials on the relevant standards for nursing home care, including our Tool-Kit for a listing of antipsychotic drug names and other resources.
- WWW.THECONSUMERVEICE.ORG. The Consumer Voice has numerous materials and resources for residents, family members and LTC Ombudsmen.

¹ There is a limited exception "if the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and indicate the duration for the PRN order." PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

+ Our Goal: To Provide **You With Knowledge and Resources** to Support Your Resident-Centered Advocacy

■ Knowledge...

- **Free monthly training programs** for Resident & Family Councils, LTC Ombudsmen and those who work with them.
- Each program will focus on a nursing home standard that is relevant to resident care, dignity or quality of life.

■ Resources...

- **WWW.NURSINGHOME411.ORG** has a **Learning Center for Residents, Families, Ombudsmen** and those who work with them.
- For every standard we will post a **free handout** on our website that you can use now and in the future to know your rights about a specific issue or standard.
- **Presentation materials** are posted on the website after each program for future reference.
- **Technical support for your questions** or concerns on the quality standards via our NYS List-serve and email. Email info@ltccc.org.

You DON'T need to memorize every Resident Right!
Just remember www.nursinghome411.org for free info & resources.

+ Thank You For Joining Us Today!

Email info@ltccc.org or call 212-385-0355 if you would like to...

- Receive alerts for future programs or
- Sign up for our newsletter and alerts.

You can also...

- Join us on **Facebook** at www.facebook.com/ltccc
- Follow us on **Twitter** at www.twitter.com/LTCconsumer
- Visit us on the **Web** at www.nursinghome411.org.

For LTC Ombudsmen in NY State

If you would like us to let your supervisor know that you attended this training program, please take the quick survey at:

www.surveymonkey.com/r/ltccc-ltccop1.

For Family Members in NY State

connect with the Alliance of NY Family Councils at www.anyfc.org (or email info@anyfc.org).



Questions?

Comments?