Pharmacy Related Regulatory Changes in LTC

By: Anastasia Sidor, PharmD, BCGP

Consultant Pharmacist Director

Brockie Pharmatech

Regulation vs. guidance

- All citations must be based on regulatory or statutory requirements
  - May not be cited on guidance
- Guidance to surveyors
  - “Must” and “shall” indicative of requirements
  - “May” and “should” suggest best practices
- Often the regulations are a few sentences, and guidance paragraphs/pages long

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter08-10.pdf

brockie pharmatech

F757 – Unnecessary drug

brockie pharmatech

Unnecessary drug

Defined as one or more of the following - *§483.45*

- Excessive dose
- Excessive duration
- Without appropriate monitoring
- Without appropriate indication for use
- Use in presence of adverse effects where dose should be reduced or discontinued

brockie pharmatech

F756 – Drug regimen review

brockie pharmatech

Irregularity definition

- Definition of **irregularity** updated to include unnecessary drug §483.45(c)
  - Inconsistent with the standard of practice
  - Not supported by evidence
  - Inhibits intended outcomes from being achieved
  - Untreated conditions that may require initiating medication
  - Unnecessary drug

brockie pharmatech

Changes to the MRR process

- Medical director provided with report of irregularities §483.45(c)(4)
- Attending physician must document response in medical record
  - Action taken to address irregularity or
  - Rationale provided if no changes made §483.45(c)(4)
- Pharmacist must report each irregularity and include resident name, drug, and specify irregularity §483.45(c)(4)

brockie pharmatech

Changes to the MRR process

- Policy and procedure (P&P) must be in place for the MRR - §483.45(c)(5)
  - Regulation:
    - **Must** include timeframes for steps in the process
    - **Must** have P&P specific to what a pharmacist does when immediate attention is needed
  - Guidance:
    - **Should** address procedure for residents staying for 30 days or less
    - **Should** address change in condition MRR

brockie pharmatech

Changes to the MRR process

- Related regulation F580 483.10(g)(14) – Immediate notification when treatment needs to be changed significantly
  - Physician
  - Resident
  - Resident's representative (if applicable)
- Guidance: includes wording such as *"potential adverse consequence of a medication."*

brockie pharmatech

F758 - Psychotropics

brockie pharmatech

Psychotropic definition

Definition psychotropic drug updated 483.45(c)(3)

"…any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to,

(i) Anti-psychotic;

(ii) Anti-depressant;

(iii) Anti-anxiety; and

(iv) Hypnotic."

brockie pharmatech

Psychotropic drugs

Guidance says "*Other medications which may affect brain activity such as central nervous system agents, mood stabilizers, anticonvulsants, muscle relaxants, anti-cholinergic medications, antihistamines, NMDA receptor modulators, and over the counter natural or herbal products must also only be given with a documented clinical indication consistent with accepted clinical standards of practice. Residents who take these medications must be monitored for any adverse consequences, specifically increased confusion or over-sedation.*"

brockie pharmatech

Psychotropic drugs

"§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that--

- *§483.45(e)(1) 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;*
- *§483.45(e)(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs…"*

brockie pharmatech

Gradual dose reduction (GDR) frequency

Guidance:

- Twice within the first year (of admission or of starting medication)
  - In 2 separate quarters
  - Separated by at least 1 month
- Annually after first year
- Noteworthy words
  - “Psychotropic medications” – classes of medication not specified
  - “Must”

brockie pharmatech

GDRs

- Guidance: *"However, some residents with specific, enduring, progressive, or terminal conditions such as chronic depression, Parkinson's disease psychosis, or recurrent seizures may need specific types of psychotropic medications or other medications which affect brain activity indefinitely."*

brockie pharmatech

GDRs

Guidance*: "NOTE: A medication may have been required to treat a medical symptom, and as a result, the medical symptom is no longer present. In some cases, the clinical goal of the continued use of the medication is to stabilize the symptoms of the disorder so that the resident can function at the highest level possible…Although the symptom may no longer be present, the disease process is still present. For example, diseases may include:*

- *Chronic psychiatric illness such as schizophrenia or schizoaffective disorder, bipolar disorder, depression, or post-traumatic stress disorder;*
- *Neurological illness such as Huntington's disease or Tourette's syndrome; and*
- *Psychosis and psychotic episodes."*

brockie pharmatech

Who's central nervous system is spinning?!?

What is clear about psychotropic regs

- Indication/appropriate diagnosis documented in clinical record
- Behavioral interventions necessary
  - Prior to initiating psychotropics
  - To facilitate discontinuation of psychotropics
  - Document in clinical record

brockie pharmatech

What is clear about psychotropic regs

- GDRs required
  - There are no exemptions for end of life
  - There are no exemptions for diagnoses
  - GDRs must be attempted twice in the 1st year of admission or initiation, in 2 separate quarters, then yearly
  - Hypnotics are not specified as having to be done quarterly, but is still the accepted standard
  - Classes required: antidepressants, anxiolytics, antipsychotics, hypnotics

brockie pharmatech

What is unclear about GDRs

Do the drugs in the expanded definition of psychotropic (anticonvulsants, muscle relaxers, etc) need to have GDRs?

- According to regulation itself, GDRs could be expected for all “psychotropic drugs” which could include medications such as anticonvulsants, muscle relaxers, etc

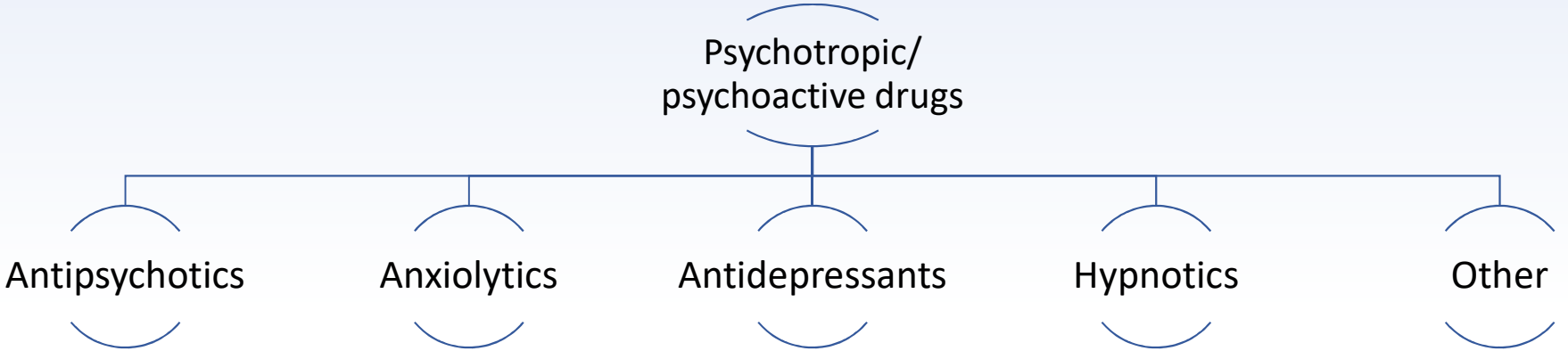
OR

- Guidance could imply for these other classes (anticonvulsants, muscle relaxants, etc) that requirements may only include
  - Clinical indication documented
  - Monitor for adverse effects

brockie pharmatech

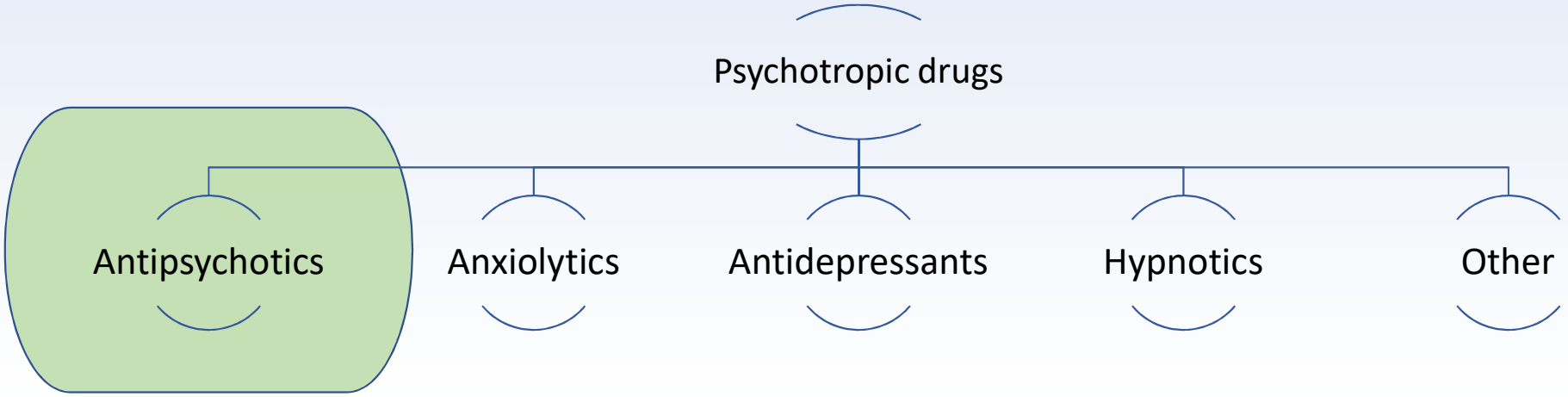
Point of clarification

- Psychotropic is not an interchangeable term with antipsychotic
- Psychotropic/psychoactive is a broad term that encompasses the following medication classes



brockie pharmatech

PRN antipsychotics



brockie pharmatech

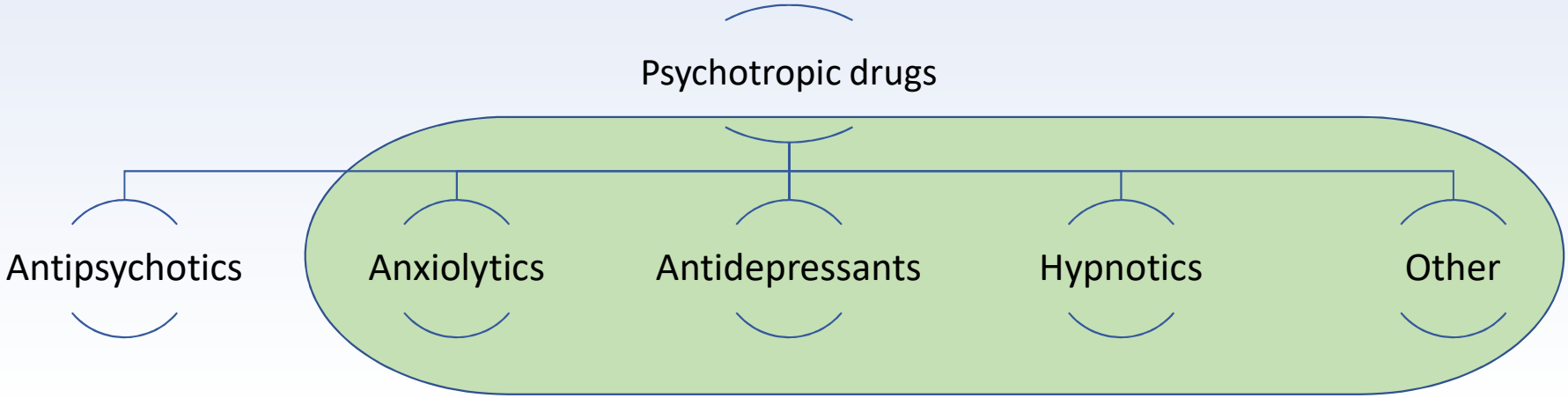
PRN antipsychotics

PRN antipsychotic order 483.45(e)(5)

- Diagnosis specified & documented in clinical record
- Strict 14 day order limit
- May only be ordered again for another 14 day period if the PCP evaluates the resident in person (per guidance) to assess appropriateness of the medication and provides rationale
  - Is the antipsychotic medication still needed on a PRN basis?
  - What is the benefit of the medication to the resident?
  - Have the resident's expressions/indications of distress improved as a result?
- Regulations do not mention exceptions for diagnoses or end of life situations
  - Example: prochlorperazine PRN n/v is a first generation antipsychotic and would be subject to this 14 day rule
  - Example: haloperidol PRN terminal restlessness also subject to 14 day rule

brockie pharmatech

PRN psychotropics



brockie pharmatech

Other PRN psychotropics

Other PRN psychotropics (anxiolytics, hypnotics, antidepressants) §483.45(e)(4)

- Diagnosis specified & documented
- Initial order only limited to 14 days
- To continue with PRN order, the prescriber must evaluate the resident, document rationale, and provide duration for PRN order
  - Duration should be a finite period of time – “indefinitely” not appropriate

brockie pharmatech

Recent survey results

- Increases in frequency of PRN orders are considered new orders and must have a 14 day stop date
- For example: lorazepam 0.5mg BID prn increased to lorazepam 0.5mg q8 hrs prn
  - Considered a new order
  - Should have had a 14 day stop date with rationale, duration, and indicated documented in clinical record

brockie pharmatech

F881 – Antibiotic stewardship

brockie pharmatech

Antibiotic stewardship (ABS)

- *"§483.80(a) The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements:*
- *§483.80(a)(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use."*

brockie pharmatech

Antibiotic stewardship

Guidance*: "…protocols must:"*

- Play a role in overall infection prevention/control program
- Be reviewed at least yearly or as needed
- Establish a system to monitor and report antibiotic use and resistance patterns
- Establish frequency of monitoring/review of orders and how this feedback will be disseminated
- Utilize standardized tools and criteria
- Include mode of education on ABS to prescribers and staff

brockie pharmatech

Antibiotic stewardship & the MRR

Guidance:

- Licensed pharmacist must review antibiotic order during MRR
- Review may occur retrospectively
- Pharmacist must report any irregularities

brockie pharmatech

Phase 2 CMS memo – issued 11/24/17

- Moratorium on certain Phase 2 requirements
  - F758 Psychotropic medications – related to PRN psych limitations
  - F881 Antibiotic stewardship
  - Other non-pharmacy related requirements included
- 18 month moratorium on financial penalties
- F-tags incurred from specified requirements will not be used to calculate Star Rating for 12 months
- Facilities required to follow Phase 2 requirements and may be cited on all F-tags

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-18-04.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending

brockie pharmatech

F759 & F760 – Medication errors

brockie pharmatech

Medication errors

Guidance:

- *“Crushing Oral Medications – To address concerns with physical and chemical incompatibility and complete dosing, best practice would be to separately crush each medication and separately administer each medication with food.*
- *However, separating crushed medications may not be appropriate for all residents and is generally not counted as a medication error unless there are instructions not to crush the medication(s). Facilities should use a person-centered, individualized approach to administering all medications. If a surveyor identifies concerns related to crushing and combining oral medications, the surveyor should evaluate whether facility staff have worked with the resident/representative and appropriate clinicians (e.g., the consultant pharmacist, attending physician, medical director) to determine the most appropriate method for administering crushed medications which considers each resident’s safety, needs, medication schedule, preferences, and functional ability.”*

brockie pharmatech

Person-centered care

F760 guidance:

- Resident has right to choose health care schedules
- Medication administration times must be considered
  - Some medications have flexible administration times
  - Some medications remain time-critical to achieve therapeutic effect

brockie pharmatech

Odds & ends

- F661 483.21(c)(2) - pre/post discharge medication reconciliation
- F880 483.80(d) – guidance that recommends that PPSV23 & PVC13 be administered in appropriate time frames to all adults older than 65 per ACIP

brockie pharmatech

F755 – Pharmacy services

brockie pharmatech

Liquid controlled medications

Guidance: *"Liquid controlled medications are often dispensed in multi-dose containers which indicate approximate volume. The containers may also be opaque to protect the medication from light. It should be noted that absolute accuracy in tracking volume and use of liquid controlled medications may not be possible. The actual volume in these containers may be slightly over or under the manufacturer's stated volume depending on the shape and material of the container and the formulation of the medication such as thick liquid suspensions. The opaque container, measurement markings, manufacturer fill volume variation, and method for recording usage all make detection of diversion for liquid controlled medications more difficult. The general standard of practice for documenting usage of liquid controlled medications is to record the starting volume from the label, record each dose administered, subtract the dose administered from the previously recorded volume, and record the remaining amount. Any observed discrepancy between the recorded amount and what appears to be remaining in the container should be reported according to facility policy. Manufacturer's instructions may list the estimated volume variance (e.g., 30 mL plus or minus 2.5 mL). For liquid controlled medications, signs of diversion may include: an observable discrepancy between the written balances of remaining medication compared to the remaining amount in the bottle upon visual inspection; changes in the viscosity or color of the medication; reports of spills; and, as with other controlled medications, statements from a resident that the medication is not working."*

brockie pharmatech

References

1) Centers for Medicare and Medicaid Services. (2008). *Use of Interpretive Guidance by Surveyors for Long Term Care Facilities.* Retrieved from: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter08-10.pdf

2) Centers for Medicare and Medicaid Services. (2017). *State Operations Manual.* Retrieved from: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf

3) Centers for Medicare and Medicaid Services. (2017). *Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to Nursing Home Compare.* Retrieved from: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/Survey-and-Cert-Letter-18-04.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending

brockie pharmatech

Questions?

Email: asidor@brockie.biz

Phone: 1-888-276-2543