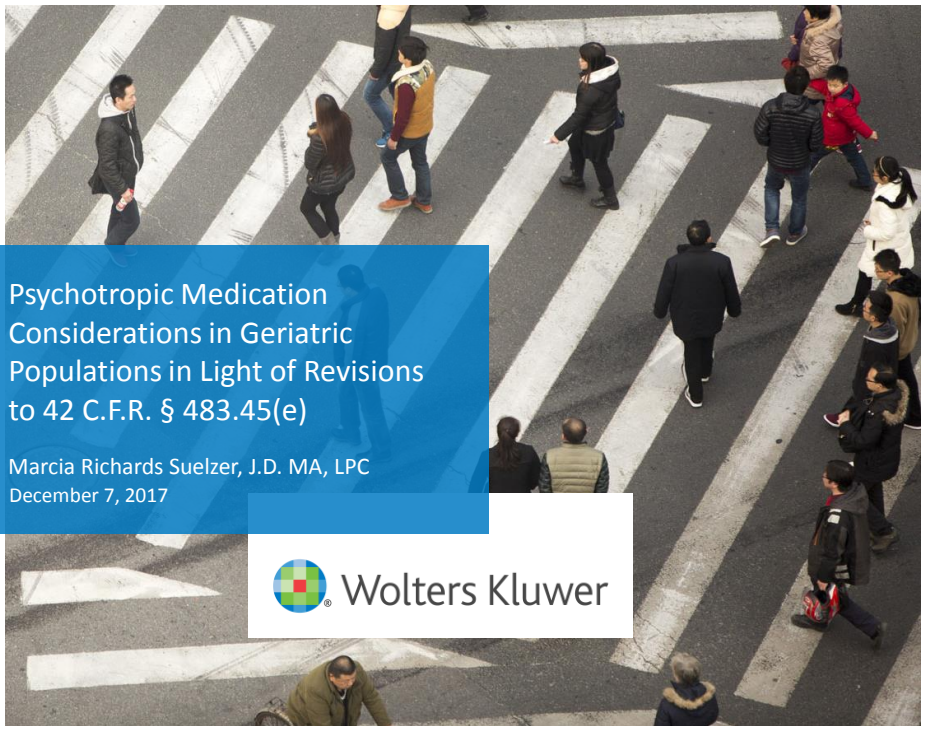

Psychotropic Medication Considerations in Geriatric Populations in Light of Revisions to 42 C.F.R. § 483.45(e)

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Specific learning objectives for this session

As a result of this presentation, participants will:

- Become aware of revisions made to Behavioral Health Services (§483.40) and Pharmacy Services (§483.45)
- Become familiar with rules contained in §483.45(e), *Psychotropic medications*, including:
  - Classes of medication targeted
  - Mandates for gradual dose reduction
  - Restrictions on PRN orders for these medications
- Become aware of increased need for documentation regarding appropriate use of psychotropic medications

The "Mega Rule" – Catching up with a quarter-century of change…

- In 1989, CMS issued first long-term care facility rules; last major revision was in 1991
- July 16, 2015 – Sweeping changes for participation by LTC facilities in Medicaid/Medicare proposed to reflect:
  - Innovations in medical care / quality assurance
  - New understanding of individual choice / resident safety
  - Changes in LTC populations
- September 26, 2016 – Revisions finalized
  - Over 360 existing provisions were re-designated and/or revised
  - Of existing provisions, only 6 provisions escaped unscathed

Mega Rule phased over three years

- New regulations provide 3-year phase-in due to the "comprehensive nature of the regulatory provisions"
  - Phase 1 took effect last year on 11/28/16
  - Phase 2 took effect **last month on 11/28/17**
  - Phase 3 will take effect next year on 11/28/18
- **IMPORTANT: Phase 2 is now effective, but there is an 18-month penalties / enforcement waiver for specific provisions**
  - Behavioral Health Services, §483.40
  - Sufficient/Competent Direct Care/Access Staff-Behavioral Health, §483.40(a)(1)- (a)(2)
  - Psychotropic Medications related to PRN Limitations, §483.45(e)(3)-(e)(5)
    - "Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to Nursing Home Compare," S&C 18-04-NH (2017-11-24)

Key Behavioral Health and Pharmacy Services changes were deferred to Phase 2

- **NEW:** Behavioral Health Services – §483.40

  "This section will be implemented in Phase 2 with the following exceptions: • *(a)(1) As related to residents with a history of trauma and/or post-traumatic stress disorder*—Implemented in Phase 3. • *(b)(1), (b)(2), and (d) Comprehensive assessment and medically related social services*—Implemented in Phase 1."

- **REDESIGNATED/REVISED:** Pharmacy Services – §483.45

  "This section will be implemented in Phase 1 with the following exceptions: • *(c)(2) Medical chart review*—Implemented in Phase 2. • *(e) Psychotropic drugs*—Implemented in Phase 2."

New § 483.40 Behavioral Health Services

Behavioral Health Services now has its own subsection: §483.40

- Stated goal of new §483.40 is
  - To "ensure that assessment and treatment of behavioral health issues are viewed with the same importance as the physical and receive the resources necessary to provide appropriate treatment to residents in need of behavioral health service."
- This is a move toward parity between behavioral health and physical health.
- There does not need to be a mental health diagnosis for an resident to receive behavioral health services

New focus reflects advances in behavioral health

- In the 25+ years since the first LTC regulations, there have been sweeping changes in the diagnosis and treatment of behavioral health disorders—both pharmacological and non-pharmacological advances
- An aging population coupled with advances in medical treatment has resulted in a higher prevalence of dementia-related impairments & increased risk for adverse outcomes from polypharmacy
  - In 2012, "more than 48 percent of LTC facility residents were estimated to have some form of dementia, including Alzheimer's disease, and/or depression." (80 FR 42202)

What must each LTC facility do?

- **§483.40** ***(Behavioral health services.)*** states:

  "Each resident must receive and the facility must provide the necessary behavioral health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders."
- NOTE: § 483.65(a)(2) allows for facilities to have services provided by outside sources, rather than facility staff
- LTC facilities do not have admit an individual if they cannot provide appropriate care for that individual's behavioral health needs

Behavioral Health Services & Pharmacy Services provisions intersect

- Behavioral Services provisions and the revised Pharmacy Services rules must be considered together – especially those designed to reduce "inappropriate use of psychotropic medication"
- Key Pharmacy Services provisions are
  - Medical chart review (implemented in phase 1)
  - Unnecessary drug criteria (implemented in phase 1)
  - Psychotropic medications (implemented in phase 2)

Medical Chart Review & Unnecessary Drugs

Expanded monthly chart review reflects increased concern about "unnecessary drugs"

- Monthly Drug Regimen Review (old §483.60(c)) was re-designated and expanded as new §483.45(c)
- New §483.45(c)(2) added **medical chart review** as part of the monthly drug regimen review, effective in Phase 1
  - Addressed concern over potential drug interactions, given the large number of drugs that many residents are prescribed
  - Monthly review of medical chart in conjunction with drug regimen review should help spot side effects and identify irregularities in prescribing earlier
  - Chart review must cover the entire chart—not just doctors' orders

"Unnecessary drug" scrutiny aims to reduce polypharmacy and adverse reactions

- Polypharmacy: "more medications than clinically indicated"
  - Prevalence of polypharmacy was 40% nursing home patients
  - Average of 6.7 medications ordered per resident, with 27 percent of residents taking nine or more medications.
- Elderly have compromised ability to metabolize & excrete drugs and (generally) have more long-term / severe health conditions than younger individuals
  - Prevalence of chronic kidney disease may be as high as 39%
  - Hepatic blood flow drops as one ages (often at 40% in very elderly)
  - Clearance of drugs from the body is significantly compromised
- Drugs are not tested on the very old or those with multiple pre-existing conditions—which means adverse outcomes may increase

Unnecessary drug criteria unchanged, but focus expanded for psychotropic drugs

- An unnecessary drug is any drug that meets one or more of the following criteria:
  - The dose is excessive (this includes duplicate drug therapy)
  - The duration is excessive
  - There is not adequate monitoring
  - There are not adequate indications for its use
  - There are adverse consequences that indicate the dose should be reduced or discontinued
- These criteria were not changed in the new rule, but special focus now placed on "psychotropic drugs"

Irregularities must be reported and resolved

- Irregularities include (but are not limited to) any drug that meets the criteria for an unnecessary drug
- The pharmacist must document irregularities discovered and report the finding to:
  - Attending physician
  - Director of Nursing
  - **Medical director of the facility** (NEW)
- Attending physician must review and document action taken in response. If medication will be continued as prescribed, the rationale must be documented.
- **§483.45(c)(5)** requires that facilities create policies/procedures that provide
  - Timeframes for each step in the DRR process
  - Steps a pharmacist should take when immediate action is needed due to potential harm to the resident.

§ 483.45(e) Psychotropic drugs

What a difference a word makes: "psychotropic" replaces "antipsychotic"

- One of most significant changes to medication protocols is the substitute of just 1 word: "psychotropic" rather than "antipsychotic"
- Revised 42 C.F.R. § 483.45 added subsection (e) which broadens the scope from "antipsychotic" to "psychotropic" medications, imposes a directive to taper/discontinue these medications, and places stringent restrictions on PRN use.
  - This provision took effect in Phase 2 on 11/28/17
- Use of psychotropic drugs are subject to specific documentation requirements

Significant constraints placed on prescriptions for "psychotropic" medications

- Concerns addressed:
  - Inappropriate use of antipsychotics as chemical restraints
    - "Residents have the right to be free from chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms."
  - Dangers of antipsychotic use in the geriatric population
    - Polypharmacy, increased risk of side effects, adverse events
- New rules are intended to reduce/eliminate the need for psychotropic drugs, **if not clinically contraindicated.**

What is a psychotropic drug?

- A "psychotropic drug" is any drug that affects brain activities associated with mental processes and behavior (§483.45(e))
- Nearly every drug with the ability to pass through the blood-brain barrier may be considered a psychotropic drug.
  - Example: Acute delirium induced by metoprolol, a very commonly prescribed beta-blocker
    - Excellent article: "Watch for nonpsychotropics causing psychiatric side effects." Sidhu, K. (2008). *Current Psychiatry, 7*(4), 61-74. http://www.mdedge.com/currentpsychiatry/article/63080/watch-nonpsychotropics-causiwng-psychiatric-side-effects
  - Be alert for any mental status change whenever ANY medication is added or the resident's physical condition changes
- However, rules (in effect) limit definition to 4 classes of drugs

Four classes of drugs are defined as psychotropic, subject to special rules

- §483.45(e) defines these classes of drugs as psychotropic:
  - Antipsychotic (singled out in PRN rules)
  - Antidepressant
  - Antianxiety
  - Hypnotic
- Opioid medications and a "catch-all" statement were included in proposals, but eliminated in the Final Rule
- Mood-stabilizers used to manage bipolar disorders not included in proposal or final rule
- Subregulatory guidance may address opioids and add other classes of drugs to the four enumerated in the regulations

Specific, documented diagnosis required when psychotropic medications are prescribed

- Residents cannot be prescribed psychotropic drugs unless "the medication is necessary to treat a specific condition **as diagnosed and documented in the clinical record**."
  - Requirement seeks to eliminate using these meds to control agitation, wandering, etc.
- Note: If a patient is admitted on a psychotropic medication, the LTC facility should ensure that it was prescribed as a result of a documented diagnosis
  - Be alert. If patient has been under care of a PCP, this requirement might not be met. 61% of time antidepressants are prescribed with NO diagnosis!

Gradual dose reductions (GDR) and behavioral interventions are expected alternatives to meds

- 483.45(e)(2) provides: "Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs"
- GDR: "Stepwise tapering of a dose to determine if symptoms, conditions, or risks can be managed by a lower dose or if the dose or medication can be discontinued." SOM Appendix PP
- Commentators expressed great concern that this requirement would cause harm to a person whose condition was stabilized on their current regime & whose diagnosis warranted life-long medication
  - Medication is first-line & essential treatment for: schizophrenia, bipolar disorder, recurrent endogenous major depressive disorder

SOM, Appendix PP recognizes that GDR is not always appropriate

- Possibility of life-long need for medications is acknowledged:

  "Sometimes, the decision about whether to continue a medication is clear; for example, someone with a history of multiple episodes of depression or recurrent seizures may need an antidepressant or anticonvulsant medication indefinitely."
- But in other cases, GDR is expected:

  "Often, however, the only way to know whether a medication is needed indefinitely and whether the dose remains appropriate is to try reducing the dose and to monitor the resident closely for improvement, stabilization, or decline."

  SOM, Appendix PP, page 355

Exceptions to GDR and/or behavioral interventions must be documented

- Dangers of GDR can be avoided by
  - Sound diagnosis of a condition where medication is the established first-line treatment
  - Documentation that the current drug regimen is necessary and GDR (or behavioral interventions) are clinically contraindicated
- **CLINICALLY CONTRAINDICATED** is a vital component that must be documented!! And, documented prominently.
  - If GDRs and behavioral interventions for a particular psychotropic drugs are clinically contraindicated, the physician should document that in the resident's medical record. https://www.federalregister.gov/d/2016-23503/p-1103

Expectations Regarding Gradual Dose Reduction		
Psychotropic Medication Class	When GDR Must Be Attempted (unless clinically contraindicated)	Establishing Clinical Contraindication
Antipsychotics—prescribed for behavioral symptoms of dementia	In 1st Year after admission or initiation: In 2 separate quarters (with at least 1 month between attempts) After 1st Year: Annually	The resident's target symptoms returned / worsened after most recent attempt at a GDR within the facility AND Physician documents clinical rationale why any attempted GDR would be likely to impair resident's function or increase distressed behavior.
Antipsychotics (prescribed for psychiatric disorders, not dementia behaviors) **Antidepressants** **Psychotropic drug not otherwise listed**	In 1st Year after admission or initiation: In 2 separate quarters (with at least 1 month between attempts) After 1st Year: Annually	Continued use is in accordance with relevant current standards of practice ***OR*** The resident's target symptoms returned / worsened after most recent attempt at a GDR within the facility AND Physician documents clinical rationale why any attempted GDR would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder
Anti-anxiety / Hypnotics	Quarterly	Continued use is in accordance with relevant current standards of practice ***OR*** The resident's target symptoms returned / worsened after most recent attempt at a GDR within the facility AND Physician documents clinical rationale why any attempted GDR would be likely to impair the resident's function or cause psychiatric instability by exacerbating an underlying medical or psychiatric disorder

PRN orders for all psychotropic drugs are tightly regulated

- In general, the presumption is that residents will not receive PRN psychotropic medications
- In most cases, a PRN order for antidepressant, anti-anxiety, or hypnotic medications is limited to **14 days**
- However, a PRN order for these 3 medication classes can be written for a longer period if:
  - The attending physician / prescribing practitioner believes that a longer time frame is appropriate AND
  - The rationale for this longer time period is documented in the resident's medical record AND
  - The duration for the PRN order is indicated.

PRN orders for antipsychotics limited to 14 days

- In recognition of the overuse of antipsychotics to manage behavior (rather than treat psychosis) and the risk of death posed by these medications in an elderly, medically compromised population, tighter limits were put on PRN orders for anti-psychotics (§ 483.45(e)(5).)
- PRN orders for anti-psychotic drugs are limited to 14 days
- PRN orders **cannot be renewed** without an evaluation of the resident by the attending physician/prescribing practitioner to determine the appropriateness of that medication.
  - A NEW prescription is required every 14 days

42 C.F.R. § 483.45(e) ushers in sweeping changes to psychotropic medication management

- Newly effective Phase 2 of revised 42 C.F.R. § 483.45 broadens safeguards from “antipsychotic” to “psychotropic” medications, imposes a directive to taper/discontinue these medications, and places stringent restrictions on PRN use.
- These changes necessitate education regarding uses, side effects, and interactions of a broad range of medications
- This presentation will delve into the new requirements, address the appropriate uses of psychotropic medications, and the need for documentation to support use of these medications

Questions??

Thank you for attending.

Appendix 1

Selected Text of Response to Comments

Response to comments re: anti-drug bias (1)

"Commenters believed there was an emphasis on non-pharmacological interventions over the judicious and appropriate use of medications. The commenters did not believe that the approach in the proposed rule was based upon sound clinical judgment. Some commenters were supportive of the efforts to reduce unnecessary anti-psychotic drug use in LTC facilities, but they also believed in the judicious use of medications for appropriate indications with adequate monitoring of efficacy and side effects. They were particularly concerned about what they perceived as an anti-medication orientation that was obsessive and counterproductive and could inhibit the appropriate use of necessary medications that can effectively and safely relieve symptoms such as distressing delusion, hallucinations, and self-harming behaviors."

Response: We appreciate the commenters concerns; however, these requirements neither mandate specific techniques or care nor do they require facilities to forego the use of any medically acceptable drugs or techniques. The requirements finalized in this rule regarding behavioral and non-pharmacological interventions, as well as those concerning psychotropic and anti-psychotic drugs in § 483.45, are all intended to encourage appropriate care for the residents. We disagree that these finalized requirements have an anti-medication orientation. The requirements regarding medications are intended to promote the safe and effective use of medications and discourage the inappropriate use of these medications. Non-pharmacological or behavioral interventions are required in an attempt to reduce or eliminate psychotropic medications, but only if these non-pharmacological methods are not clinically contraindicated for the resident."

https://www.federalregister.gov/d/2016-23503/p-1003

Response to comments re: anti-drug bias (2)

"As we said in the proposed rule, "[w]e want to emphasize that the proposed requirements concerning psychotropic medications are not intended to have a chilling effect or in any manner discourage the prescription or use of any medication intended for the benefit of a resident who has been diagnosed [with] a specific condition that requires these medications. Our proposed requirements are intended to protect LTC facility residents from drugs that are not being prescribed for their benefit" (80 FR 42204). In addition, as described below, we have not finalized all of the requirements as proposed. As discussed below in responses to comments, we have made modifications in this proposed rule in response to such comments. We do not believe that the requirements finalized in this rule are so burdensome that any practitioner should be discouraged from using any psychotropic medication when it is appropriate for the resident and is being prescribed for the resident's benefit.

https://www.federalregister.gov/d/2016-23503/p-1057

Response to comment re: "off label" use

"We do not believe that the additional language recommended by the commenter is necessary. In addition, restricting the ability of health care practitioners to prescribe medication for uses other than those that have received FDA approval could violate the prohibition against interference with the practice of medicine at §tion 1801 of the Act."
https://www.federalregister.gov/d/2016-23503/p-1109

Response to comment re: patients admitted on psychotropic medications

"§tion 483.45(e) requires that residents who have not used psychotropic drugs not be given those drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record, but that all resident who received psychotropic drugs receive GDRs and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs. This requirement does not assume that psychotropic drugs that were prescribed prior to admission are appropriate. It is intended to ensure that residents are not put on psychotropic drugs without there being a diagnosed and documented condition for which they are appropriate. Then, all residents who are on psychotropic drugs must then receive the GDRs or behavioral interventions, unless they are clinically contraindicated, as discussed above."
https://www.federalregister.gov/d/2016-23503/p-1105

Response to comments re: GDR

"Some commenters were concerned about the requirement for gradual dose reductions (GDRs) and behavioral interventions for all psychotropic drugs. Commenters argued that GDRs are not appropriate for many residents on psychotropic drugs. The commenters argued that GDRs are not appropriate for, among others, residents with mental disorders who are stable on their current drug regimen, such as residents diagnosed with depression, schizophrenia or bi-polar disorder or residents with seizure disorders." https://www.federalregister.gov/d/2016-23503/p-1102

"For those residents taking psychotropic drugs, we expect that each resident would be evaluated by their attending physician to determine whether GDRs and behavioral interventions for a psychotropic drug are clinically contraindicated. If GDRs and behavioral interventions for a particular psychotropic drugs are clinically contraindicated, the physician should document that in the resident's medical record." https://www.federalregister.gov/d/2016-23503/p-1103

Response to comment re: PRN orders (1)

"Based upon our own experience with LTC facilities, as well as other comments, there are situations in which PRN prescriptions for psychotropic drugs are appropriate for residents. Some residents may require a therapeutic trial to determine if a particular medication addresses the diagnosed disorder and what the correct dosage should be. In addition, some residents may only require a psychotropic drug for intermittent symptoms. We are also concerned that prohibiting PRN prescriptions for psychotropic drugs could result in either overmedication from physicians prescribing these drugs on a specific schedule when a PRN order would be appropriate or under medication from physicians not prescribing drugs they believe are needed for the resident's health. In addition, we believe that it is appropriate, and within their scope of practice, for nurses to make decisions on when drugs prescribed via PRN orders should be administered, including psychotropic medications." https://www.federalregister.gov/d/2016-23503/p-1113

Response to comment re: PRN orders (2)

"Thus, we are establishing a 14-day limitation on psychotropic drugs. By establishing this 14-day limitation, each resident who is taking a psychotropic drug will have his or her prescription reviewed by the physician or prescribing practitioner every 14 days and also by a pharmacist every month. Since there was no previous limitation on PRN prescriptions for psychotropic or anti-psychotic drugs, this will provide residents receiving this type of medication on a PRN basis additional protections against unnecessary drugs, drugs with another type of irregularity, and drugs that might be prescribed for reasons other than the resident's own benefit.

EXCEPTION: We are also aware that some residents might require psychotropic drugs on a PRN basis for prolonged periods of time. Thus, we have established an exception to this 14-day limitation. For psychotropic drugs that the attending physician believes a PRN prescription Start Printed Page 68774for longer than 14 days is appropriate, the attending physician can extend the prescription beyond 14 days for the resident by documenting their rationale in the resident's medical record. However, we believe this exception would be inappropriate for anti-psychotic drugs. If the attending physician believes that the resident requires an anti-psychotic drug on a PRN basis for longer than 14 days, he or she will be required to write a new PRN prescription every 14 days after the resident has been evaluated. Detailed requirements for this evaluation will be developed in sub-regulatory guidance."

https://www.federalregister.gov/d/2016-23503/p-1117

Appendix 2

Resources

Key Primary Source Resources

- Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, 81 FR 68688
  https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities
- *State Operations Manual,* Appendix PP, "Guidance to Surveyors of Long-term Care Facilities" (Transmittal 168, March, 8, 2017), accessed Dec. 2, 2017) [Cited as SOM Appendix PP] https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R168SOMA.pdf
- "Temporary Enforcement Delays for Certain Phase 2 F-Tags and Changes to Nursing Home Compare,"
  S&C 18-04-NH (2017-11-24)