

# the Remedi Pulse

REVISED  
PHARMACY  
REGULATIONS



A CLINICAL AND REGULATORY UPDATE FROM REMEDI SENIORCARE

SPRING 2017

## Survey Solutions

with William Vaughan, BSN, RN  
VP of Education & Clinical Affairs

### Revised Long-Term Care Regulations: Where We've Been, Where We're Going

Spring of 2017 marks the mid-point between the implementation of phase 1 and phase 2 regulations contained in the Centers for Medicare and Medicaid's "Mega Rule" (i.e., Reform of Requirements for Long-Term Care Facilities). This year will also usher in two other sentinel events which will significantly impact the regulatory landscape in which nursing facilities operate. CMS has promised to release updated guidance to surveyors, which will, hopefully, clarify regulatory expectations regarding the revised regulations, and a new survey process is scheduled to be rolled out before the phase 2 regulations are implemented. Below, we examine areas of increased survey risk related to medication management in the context of phase 1 regulations.

#### PHASE 1 (IMPLEMENTED NOVEMBER 28, 2016)

##### » Drug Irregularities

- The consultant pharmacist is required to identify and report all drug irregularities. The current

**definition of a drug irregularity, found in the guidance to surveyors under F428, reads as follows:**

"... any event that is inconsistent with usual, proper, accepted, or right approaches to providing pharmaceutical services (see definition in F425), or that impedes or interferes with achieving the intended outcomes of those services."

Phase 1 regulations have expanded this already broad definition to include the use of any drug meeting the criteria at F329 (Unnecessary Drugs). Given these parameters, it doesn't take much deviation in medication management (e.g., the failure to obtain a single routine lab)

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*"CMS has promised to release updated guidance to surveyors, which will, hopefully, clarify regulatory expectations regarding the revised regulations, and a new survey process is scheduled to be rolled out before the phase 2 regulations are implemented."*

continued on page 4

# PRN Psychoactive Drugs: The Good, the Bad, and the Ugly....

Prepared by: Jennifer Hardesty, Pharm.D., FASCP, Chief Clinical Officer

Clinicians should have the discretion to prescribe any medication that will improve the functioning and well-being of the residents under their care, assuming the benefits outweigh the risk of the drug. However, the current – and in the very near future, INCREASING level of scrutiny around psychoactive drugs in long-term care may have unintended repercussions as the industry struggles to safely and practically implement some of the new federal regulations around PRN psychoactive medications.

## **THE GOOD**

- Using a psychotropic medication on a PRN basis limits the exposure of the resident to that medication, as compared to a routine order given every day
- Having a PRN order available for acute situations minimizes the time a resident has to experience discomfort or agitation

## **THE BAD**

- PRN orders may remain active even though the initial condition they were prescribed for has passed, increasing the risk for unnecessary medication therapy
- Staff may use PRN orders for other conditions (e.g., lorazepam PRN initially for sleep, but is given for an episode of anxiety months later)

## **THE UGLY**

- Lack of clarity as to which drug to administer when multiple PRN orders are available for behavioral symptoms
- PRN psychoactives that are also controlled substances (e.g., lorazepam, zolpidem), require additional time and coordination, due to DEA prescription requirements
- A recurrent condition may not get the re-assessment it deserves, if the symptom is repeatedly suppressed with PRN medication

Under Phase 2 of the CMS Reform Requirements for long-term care, there are 2 rules that will become effective on November 28, 2017:

- PRN orders for PSYCHOTROPIC drugs (antianxiety, antidepressants, sedative/hypnotics) are limited to 14 days, unless the prescriber clearly identifies a different duration for the order, AND clearly documents the rationale for this duration in the resident's medical record.
- PRN orders for ANTIPSYCHOTIC drugs are limited to 14 days only - NO EXCEPTIONS. The prescriber must re-evaluate and re-write the order if therapy is to extend past 14 days.

Clinicians should be thoughtful of when and how to use PRN psychoactive medications, and processes should be implemented to monitor and ensure appropriate use. However, prohibiting the use of PRN psychoactive medications altogether may limit an entirely appropriate therapy for some residents. **BOTTOM LINE:** If a PRN psychoactive medication is prescribed, careful documentation of indication and rationale should be included in the patient assessment and medication orders. Care plans, reassessments, and nursing notes should also reflect these basic principles.

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# THE MEGA RULE AND ANTIDEPRESSANTS THE CONUNDRUM OF A DOSAGE REDUCTION

Prepared by: Rob Shulman, BS, R.Ph., CGP, FASCP, Director of Consultant Pharmacy Services

Beginning on November 28, 2017, psychotropic medications – including antidepressants – will be heavily scrutinized under phase 2 of the new CMS Mega Rule; gradual dosage reductions (GDRs) (or documentation of a contraindication to dose reduction) will be expected for all psychotropics. This presents a dilemma for practitioners treating depression in LTC residents, as attempts to reach a minimum effective dose to reduce risk of adverse events needs to be achieved, but residents with long-standing depression may require lifelong, full dose therapy. Consider the viewpoints below – the “Pros” and “Cons” of gradual dose reductions in antidepressant therapy:

**“PRO” GDR:** Although the newer classes of antidepressants are much safer than their older counterparts, they are not without side effects and drug interactions, particularly in the elderly. Class side effects of the newer (SSRIs/SNRI) antidepressants include:

- Headache, Nausea, Dizziness
- Hyponatremia: If left unchecked, hyponatremia can become severe and cause an SIADH-like syndrome, which can become life threatening.
- Nervousness/Insomnia: In many cases, elderly residents with depression present with anxiety as a symptom. The side effect of nervousness can exacerbate the anxiety, producing an additive effect that becomes problematic.
- Suicidal Ideation: Risk is increased amongst those depressed residents with concomitant anxiety.
- Serotonin Syndrome: The new classes of antidepressants carry a risk of causing serotonergic syndrome, a potentially fatal elevation of serotonin levels characterized by hyperthermia, muscle rigidity and twitching, and changes in mental status. The risk of serotonergic syndrome is amplified through drug interactions when used with other drugs that effect serotonin or further raise antidepressant blood levels (e.g., other antidepressants, anti-psychotics, dextromethorphan, opioids, metoclopramide, and others).
- Prolongation of the QT interval by citalopram (Celexa™) is an issue in the elderly, especially those using more than 20 mg per day or taking concomitant medications that prolong QT intervals or raise the antidepressant level such as haloperidol, fluoroquinolone antibiotics (ciprofloxacin, levofloxacin), amiodarone, methadone, and others.

Performing a GDR to achieve the lowest effective dose may help minimize adverse effects, risk of serotonergic syndrome, and drug interactions.

**“CON” GDR:** The goal of antidepressant therapy should be a complete resolution of symptoms and full long-term recovery.

- In a 2002 study published in JAMA, only 19% of older adults had a significant reduction of symptoms after one year of treatment for depression by their primary care physician, indicating that the disease is not as easy to treat as practitioners commonly think.
- There is evidence that the elderly need the same doses of antidepressants as their younger counterparts, and lower doses of

antidepressants have been proven to be no better than a placebo in several trials. This is why doses of antidepressants such as Prozac™, Lexapro™, and Celexa™ rarely deviate from the standard 20 mg dose.

- The enhanced safety profiles of the SSRIs/SNRI antidepressants allow for longer, safer use.
- Evidence also suggests late-onset depression, and multi-episode depression may require a lifetime of therapy since relapse rates are extremely high. If attempted without careful evaluation, GDRs may do more harm than good for all of the reasons stated above.

In summary, GDRs with antidepressants should certainly be considered with residents on a dose higher than the standard (e.g., Celexa 30 mg, Prozac 40 mg). However, if the goal of therapy is a complete resolution of symptoms, then GDRs for residents on a standard antidepressant dose should be considered only after judicious evaluation of symptoms, tolerance of therapy, and potential for relapse.

## ANTIDEPRESSANT “TO DO” LIST:

- DO perform routine Depression Monitoring Scales to monitor for drug efficacy (e.g., the PHQ-9, GDS-15, CES-D, ZSDS)
- DO periodically assess the choice of antidepressant used
- DO continually monitor for adverse reactions
- DO change antidepressants after two months of therapy if the symptoms have not improved
- DO consider adding non drug therapy treatment modalities (i.e., psychotherapy, participation in activities, and light therapy for residents with Seasonal Affective Disorder (SAD), etc.)
- DO refer residents to a specialist, if treatment is refractory to standard therapy
- DO document when a GDR is not warranted, indicating why in this particular resident, a GDR may be detrimental to his/her physical or psychological well-being
- DO have a systematic evidenced-based process in place for monitoring successes and failures of antidepressant therapy, individualized to the needs of the specific resident

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# Remedi Superstar Nurse

LORETTA JOHNSON, LPN

Blakehurst Retirement Community, Towson, MD



**CONGRATULATIONS** to Loretta Johnson, LPN, at Blakehurst Retirement Community, in Towson, MD, for being chosen as the Remedi Superstar Nurse. Loretta was nominated by her DON, Janine Norris, RN, MHA, CDONA. Per Janine “Loretta has been an LPN for 25 years. For the past 22 years, she has been employed at Blakehurst Retirement Community. Great nurses are born, not made. Loretta is the epitome of what one expects of a great nurse. She empathizes with the residents and the families and is able to convey a depth of understanding and knowledge of what loved ones are experiencing, and she has the desire to go above and beyond to help. Loretta has an innate gift of unconditional compassion. Equally as impressive as her compassion is her humor. She is often heard (and seen) singing or dancing for an audience to old tunes (and old dance moves) to the delight of the residents. Having been employed at one place for so long, Loretta has become very close to the residents and their families who, over the years, have cherished her tender care, compassion, and humor. Loretta served in the United States Army and her military experience has assisted her in the training of many nurses, who are known as ‘Loretta-Like!’”

Email your Superstar Nurse nomination(s) to [Rebecca.Ogden@RemediRx.com](mailto:Rebecca.Ogden@RemediRx.com)

## Survey Solutions

*continued from page 1*

to rise to the level of a drug irregularity. This ultimately translates into more demand on the consultant pharmacist’s time and resources, as well as additional work for facilities which are required to respond to every consultant pharmacist’s recommendation. A failure in either one of these processes can result in significant deficiencies.

- The consultant pharmacist is now required to report all drug irregularities to the medical director in addition to the attending physician and the director of nursing. While it’s the attending physician who, by regulation, is required to respond to these reports, it’s clear that CMS considers the medical director’s involvement important in the overall process. Pending the release of the updated guidance to surveyors on point, facilities should review the current regulations governing medical directors at F501 which reads in part:

“The medical director is responsible for (i) Implementation of resident care policies; and (ii) The coordination of medical care in the facility.”

Now is an opportune time for facilities to discuss these regulatory standards with their medical directors and set clear expectations for their involvement with the drug irregularity review process. For example, many facilities have policies and procedures identifying high-risk drugs and their management. If multiple reports from the consultant pharmacist note that such policies are not being followed, it seems clear that those are the type of trends the medical director should identify and address.

- Facilities are now required to develop and maintain policies and procedures regarding the drug regimen review which must address time frames in the process. As with all regulations, such time frames should be crafted to meet the needs of each individual resident. The same factors used to determine if a significant drug error exists under F333 (resident condition, drug category, and frequency of the irregularity), can also be used to determine if facilities have developed reasonable time frames to manage the drug irregularity reporting and response process. Ignoring any one of these factors may make it difficult to defend a deficiency centering on the timeliness. Lastly, provided that the identified drug irregularity does not require an urgent intervention, there is value in having the physician address it at his/her next regularly scheduled visit (when the complete medical record is available for review). However, for this approach to be successful, the facility must have a method to triage the drug irregularity reports, so that a timely response is always provided.

Medication management and the processes surrounding it continue to attract intense scrutiny from surveyors. A clear take away from the phase 1 revised pharmacy regulations is that facilities must have solid systems in place to address drug irregularities--or their survey and resident outcomes will both suffer.

*Note: Bill was a surveyor with the Maryland State Survey Agency from 1988 until 2001. He became Chief Nurse of the agency in 2001 and remained in that position until joining Remedi Senior-Care in 2013.*