

the Remedi Pulse

CMS MEGA RULE
AND PHARMACY
PARTNERSHIP



A CLINICAL AND REGULATORY UPDATE FROM REMEDI SENIORCARE

WINTER 2019

Survey Solutions

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

The Mega Rule: Approaching the Finish Line

During November 2019, the phase 3 regulations of the Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities, will be fully implemented. While phase 1 and 2 regulations were generally focused on care delivery, those included in phase 3 will require facilities to take a comprehensive look at their systems, processes, and even their culture. Below we examine the phase 3 quality assurance and performance improvement regulation in the context of pharmacy services and medication management.

QUALITY ASSURANCE/PERFORMANCE IMPROVEMENT (QAPI)

Self-identification and correction of quality issues is not a new concept in nursing homes. However, the sophistication of systems used and the resources allotted to conduct quality activities varies greatly among providers. The QAPI regulations outline a "roadmap" which facilities must follow, the cornerstone of which is data gathering and analysis. The good news is that providers have discretion over their QAPI agendas. For example, the regulatory language at F867 reads in part:

"The facility must set priorities for its performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, resident safety, resident autonomy, resident choice, and quality of care."

And while there are numerous aspects of care and services that could benefit from performance improvement activities, medication management clearly meets the criteria of a high-risk, high-volume and problem-prone area in nursing homes. (See CMS memo S&C: 15-47-NH: Medication-Related Adverse Events in Nursing Homes. <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-47.pdf>) But how can individual facilities determine if they should spend their finite performance improvement resources on medication management versus something else? The answer is

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"...those included in phase 3 will require facilities to take a comprehensive look at their systems, processes, and even their culture."

CMS Mega Rule Phase 3-The Final Chapter & PTSD

Presented by: Erin M. Foti, Pharm.D., BCGP
 Director of Consulting Services

The last chapter of the CMS Mega Rule, which goes into effect in November 2019, will have the primary focus of implementing “trauma-informed care” and making sure our residents who have experienced trauma in life have the proper care and services that they need. Roughly 70 percent of Americans have experienced some type of traumatic event in their lives, 20 percent of these individuals will go on to develop Post Traumatic Stress Disorder (PTSD). PTSD is a mental health condition that is triggered by a terrifying event, either by experience or witness. Symptoms may include anxiety, nightmares, flashbacks, and depression. Assessment challenges in the geriatric population will include those who may have cognitive impairment that may further need more comprehensive diagnostic evaluation. Older adults also tend not to report emotions, but rather physical problems, such as insomnia, pain, or more generalized ailments. With the previous phases of the Mega Rule focusing primarily on psychotropic medication use, let us revisit both non-pharmacological and approved medications used to treat this condition.

PSYCHOTHERAPY

There are three psychotherapies used in the treatment of PTSD that have the most evidence for effectiveness. Prolonged Exposure Therapy teaches an individual to face the negative feelings. It includes discussions relating to the event and focuses on ways to help cope with negative or frightening feelings. Stress management skills and techniques can be developed with the individual in order to assist in handling further stressful situations or “trigger” events. Cognitive Processing Therapy is often paired with exposure therapy and includes talk therapy to help re-organize negative thoughts related to the trauma. Finally, Eye Movement Desensitization and Reprocessing (EMDR), combines exposure therapy and a series of eye movements that will help process and change how one reacts to the events.

PHARMACOTHERAPY

Medications, such as antidepressants, are effective in treating the core symptoms of PTSD, as well as the associated depression.

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Medications for Treatment of PTSD

Medication	Drug Class	Dosing Schedule	Special Considerations	Geriatric Considerations
PAROXETINE	Antidepressant; SSRI	Initial dose: 20 mg daily, increase gradual to 60 mg/day max	SIADH; weight loss	Beers list due to anticholinergic properties, orthostasis; Renal dosing/severe hepatic: CrCl < 30 start 10 mg daily, max 40 mg/day
FLUOXETINE	Antidepressant; SSRI	Initial dose: 20 mg daily, increase gradual to 80 mg/day max	SIADH, weight loss, caution for QT prolongation	No renal adjustment
SERTRALINE	Antidepressant; SSRI	Initial dose: 50 mg daily, increase gradual to 200 mg/day max	SIADH, weight loss, caution for QT prolongation	No renal adjustment
VENLAFAXINE	Antidepressant; SNRI	Initial dose: 37.5 mg daily, increase gradual to 225 mg/day max	SIADH, weight loss, HTN	Renal dosing: CrCl 10-70 decrease dose 25-50% CrCl < 10 decrease dose 50% Hepatic: mild-moderate decrease dose 50%
TOPIRAMATE	Seizure; Headache/ Migraine; PTSD	Initial dose 25 mg at bedtime for 7 days, increase by 25 mg weekly to recommended dose 75 mg at bedtime	Weight loss, caution if risk for metabolic acidosis, osteoporosis	Renal dosing: CrCl 10-70 decrease dose by 50% CrCl < 10 decrease dose 75% HD give supplement Extended release: CrCl <70 decrease dose 50%
PRAZOSIN	Alpha-Blocker	Dose range: 3-15 mg at bedtime Initial dose 1 mg at bedtime, increase by 1-2 mg/day every 3-4 days; max 15 mg/day	Hypotension, orthostatic hypotension, syncope, dizziness	No renal adjustment; Beers List for high risk of hypotension

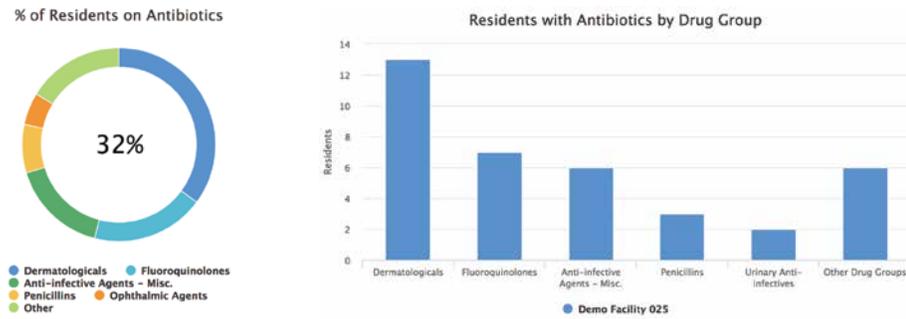
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simple, look at the data. Data that is real time, easy to use, and actionable, provides an evidence based foundation to drive QAPI activities. Looking at both process and outcome data helps facilities isolate areas of greater risk. For example, several metrics from the MyRemedi® web portal are highlighted below with corresponding regulatory references:

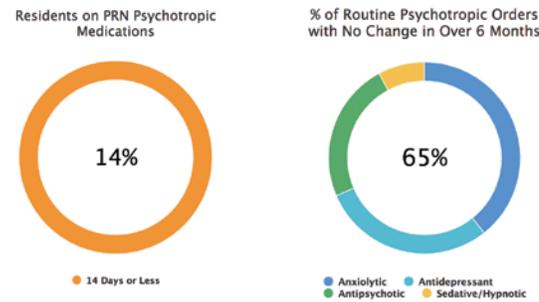
F881: ANTIBIOTIC STEWARDSHIP

(a system to monitor antibiotic use)



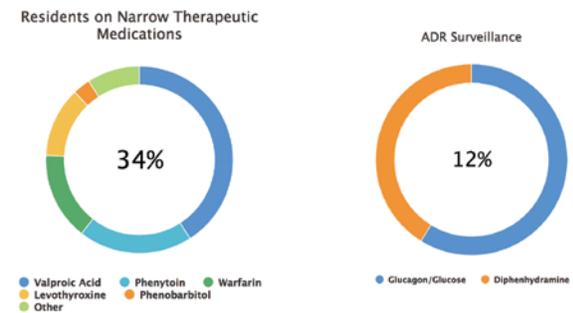
F758: PSYCHOTROPIC DRUG

(GDR, limits on PRN duration)



F757: UNNECESSARY DRUGS

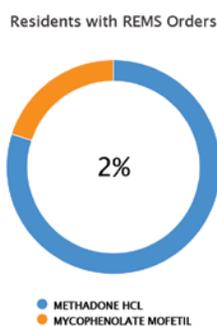
(without adequate monitoring, in the presence of adverse consequences)



F755: PHARMACY SERVICES

(medication availability to meet the needs of residents)

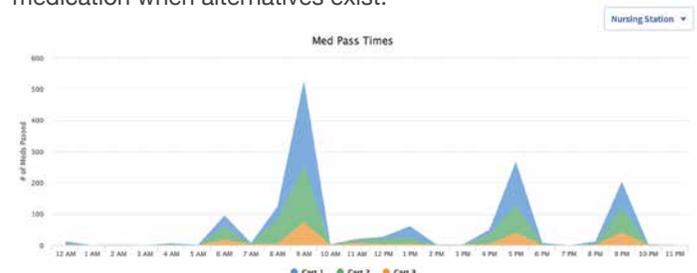
Residents on FDA Risk Evaluation and Medication Strategies (REMS) Drugs have specific requirements that must be met before they can be dispensed from the pharmacy.



F561: SELF-DETERMINATION

(residents' rights to choose their schedule)

Person-centered care and resident rights may be negatively impacted by disrupting a resident's sleep to administer a medication when alternatives exist.



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Remedi Superstar Nurse

BRIAN PETRAK, LPN, ADON

Takoda Trails ICF, Fairfield, Ohio



CONGRATULATIONS to Brian Petrak, LPN, ADON, at Takoda Trails ICF, in Fairfield, Ohio, on being chosen as the Remedi Superstar Nurse. Brian has worked at Takoda Trails for 18 years and has been an LPN for more than 20 years. He was nominated by his DON, Lynne Whitaker. Per Lynne, "I have worked with Brian for over 10 years. He demonstrates excellent leadership qualities, is very fair in his interactions with the nursing staff, and encourages everyone to perform their jobs with success. Brian excels at being organized and has helped me immensely in this area. He writes all of the nursing reviews for the residents, meets with their families on a yearly and as needed basis, and does not hesitate to reach out to a family member if an issue arises. Brian oversees the psychiatric clinic and helped to develop a form that

has been an important tool in tracking our residents' progress. He is knowledgeable in all aspects regarding our residents and their medications. Brian handles himself very well in emergency situations and ensures that the best care is always given, regardless of the situation. He is a team player and will perform additional responsibilities that are not part of his job. His sense of humor and calming manner are always appreciated and help in tense situations. Brian should be recognized as a Superstar nurse, as our facility is where it is largely because of him."

Email your Superstar Nurse nomination(s) to Rebecca.Ogden@RemediRx.com

CMS Mega Rule Phase 3-The Final Chapter & PTSD

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Psychotherapy is the treatment of choice with adjunctive medication management, but medications can be utilized alone if an individual expresses preference not to engage in therapy, or has failed therapy. It is important to note, these medications take four to six weeks for full effect. If there is a response to a drug, the length of therapy is recommended to be 12 months and the medications should not be abruptly discontinued. Benzodiazepines, commonly used to treat anxiety conditions, are not recommended for treatment of PTSD. Topiramate and Prazosin have reported results with positive outcomes associated with sleep disturbances and nightmares.

As health care professionals, it is important to be well-informed regarding the recognition of PTSD and the appropriate interventions available. Treatment strategies should be individualized based on a person-centered approach to care. For more information regarding PTSD and current treatment options, refer to the websites listed below.

Selected Resources:

https://www.ptsd.va.gov/professional/treat/specific/assess_tx_older_adults.asp

<http://www.ptsdunited.org/>

<https://www.guidelinecentral.com/summaries/american-geriatrics-society-2015-updated-beers-criteria-for-potentially-inappropriate-medication-use-in-older-adults/#section-date>

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The functionality of MyRemedi is also helpful in complying with an additional QAPI requirement, the use of data in addressing adverse events:

"A facility must establish and implement written policies and procedures for feedback, data collections systems, and monitoring, including adverse event monitoring. The policies and procedures must include ... the methods by which the facility will systematically identify, report, track, investigate, analyze, and use data and information relating to adverse events in the facility, including how the facility will use the data to develop activities to prevent adverse events."

Finally, while powerful, data is just one component of the QAPI process. Without thoughtful analysis by knowledgeable staff (in the context of medications, think medical director / consultant pharmacist) and evidence based interventions, data itself doesn't demonstrate compliance with regulations. More importantly, it doesn't prevent adverse events or improve the lives of those residing in nursing homes.

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 SeniorCare in 2013.