

the Remedi Pulse

THE MEGA RULE:
LESSONS LEARNED



A CLINICAL AND REGULATORY UPDATE FROM REMEDI SENIORCARE

FALL 2018

Survey Solutions

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

A Look at Post Mega Rule Pharmacy Deficiencies

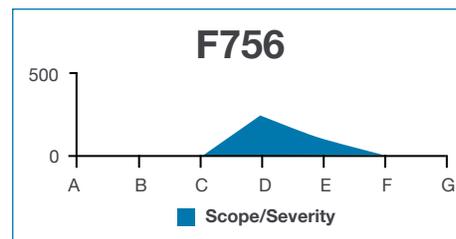
Ever since the Reform of Requirements for Long-Term Care Facilities (aka the Mega Rule) was published in October of 2016, it has dominated the educational agendas of long-term care conferences, conventions, and webinars. Experts and consultants reviewed the final rule and public comments, analyzed the wording of the regulations, dissected the guidance to surveyors, and then offered their opinions to facilities on how to achieve compliance. And while such advice has been helpful, ultimately, it's how survey agencies interpret and apply these new regulations that really counts.

We are now at the point that trends and patterns are emerging regarding deficiencies cited under the pharmacy regulations of the Mega Rule. Provided below is national data and a review of high-level, medication-related deficiencies cited since the implementation of the phase II regulations (November 28, 2017 to July 31, 2018):¹

F756 (DRUG REGIMEN REVIEW)

Mega Rule updates to the drug regimen review include reporting of drug irregularities

to the medical director, development of relevant policies/procedures, and a clear mandate that the monthly review must include a review of the medical chart. A total of 540 deficiencies have been cited under F756, the scope/severity distribution of those deficiencies is noted below:



In the only actual harm deficiency cited under F756, the surveyor noted a failure to report pharmacy recommendations to the attending physician in a timely fashion. When interviewed, the director of nurses stated that the numerous pharmacy recommendations "were not reviewed by facility staff and were not sent to the physician to be followed up on because they were

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Please do not hesitate to contact your Remedi Consultant Pharmacist or Account Manager if you have any questions or concerns.



"We are now at the point that trends and patterns are emerging regarding deficiencies cited under the pharmacy regulations of the Mega Rule."

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Hooked on that Feeling: An Update on America's Opiate Crisis

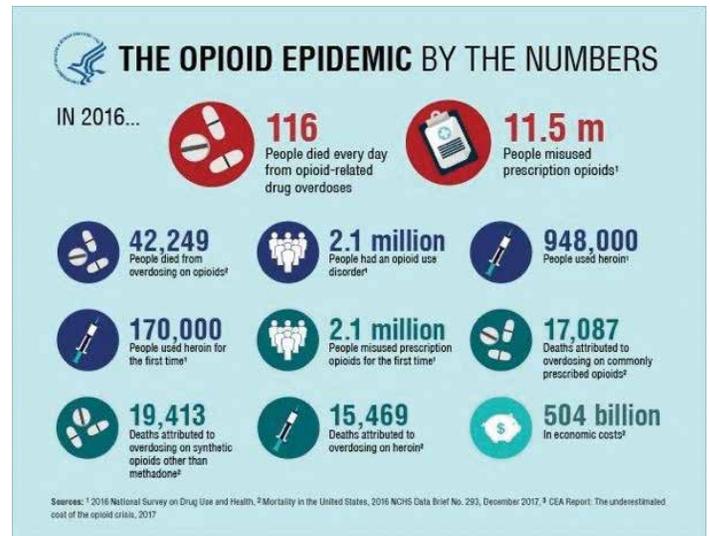
Prepared by: Erin M. Foti, Pharm.D., BCGP, Director of Consulting Services

Prescription opiates are powerful pain relieving medications that include oxycodone, hydrocodone, morphine, and fentanyl among others. In addition to pain relief, these substances also activate the reward sections of the brain causing euphoria or a "high." Opiates are used in a variety of indications from dental procedures, surgery, injury-related pain, cough, and even severe diarrhea. When taken as prescribed, these medications can be used safely and effectively; however, they still carry the risk of developing a substance use disorder. Short-term medical use rarely leads to abuse potential, but long-term, chronic use of opiates may lead to physical dependence, tolerance, and even addiction. Opiates, CNS depressants, and stimulant products are the classes of medications most commonly misused.

The current crisis is rapidly becoming one of the top leading causes of death in certain states, surpassing vehicular accidents and reducing overall life expectancy. States are developing programs and increasing the availability of the opiate reversal product, naloxone, in addition to the medical legalization of marijuana to treat chronic pain syndromes. The estimated economic cost nationally is \$504 billion due to health care costs, loss of productivity, rehabilitation, and criminal justice involvement. The opiate epidemic is also directly related to the increased use of heroin. Eighty percent of heroin users first misused opiates. Synthetic opiate abuse, such as fentanyl and carfentanil, has also increased -- these medications are 50-100 times more potent than morphine and are also sometimes mixed with heroin.

Many steps have been taken to alleviate the current crisis. In 2016, the CDC released a guideline for prescribing opiates to treat chronic pain. Prescribers are reminded to discuss goals with patients, consider non-opiate treatment as first line therapy, and present non-pharmacological interventions for pain control. Prescription Drug Monitoring Programs (PDMPs) are individually state-run specific electronic tracking databases which collect and monitor prescribing and dispensing of controlled substances to patients. Information pulled from these sources is used to monitor prescribing trends and "doctor shoppers." Other actionable measures include increased awareness, availability of treatment and prevention programs, and more strict prescribing laws.

Healthcare workers are at an increased risk for opiate abuse due to direct access to these medications, stress levels, caregiver burnout, and the thought process of medical professionals that they have the ability to ward off substance abuse. In nursing communities, having a visible program in place and early



intervention is vital to deter diversion or abuse practices. Nursing communities should have an identifiable process that all staff is aware of and is routinely audited in the following areas:

- Chain of custody for controlled substances upon entry and exit from facility
- Access and storage of controlled substances
- Record keeping, documentation on administration record, shift counts
- Removal of controlled substances from medication carts when discontinued, expired, or resident discharged/expired
- Emergency kit controlled substance shift counts

If potential or actual diversion is suspected or found within your community, please contact your Remedi SeniorCare consultant pharmacist or follow state-specific procedure(s). For a diversion investigation checklist, please review the Resource section in MyRemedi.

References:

- <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>
- <https://www.fda.gov>
- <https://www.hhs.gov/opioids/>
- https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf

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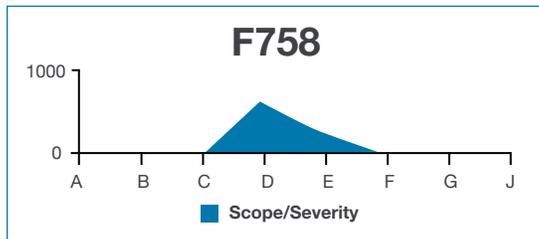
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too busy.” She further acknowledged that the facility did not have a policy addressing medication regimen review. A resident fall and resulting hip fracture was attributed, in part, to medications referenced in several unanswered pharmacy recommendations, leading to the determination of actual harm.

Of note, a disproportionate number of high scope/severity deficiencies under F758, 58% of all F and G level citations cited nationally, were written by surveyors in just one state, Texas. This could be due to any number of variables ranging from timely data entry into Nursing Home Compare to the prioritization of the drug regimen review by the survey agency.

F758 (PSYCHOTROPIC DRUGS)

This regulation defines psychotropic drugs, identifies processes (i.e., documentation, behavioral interventions, and gradual dose reduction) that must be in place when they are administered and places limits on their PRN use. A total of 1,123 deficiencies have been cited under F758 with the scope/severity distribution noted below:



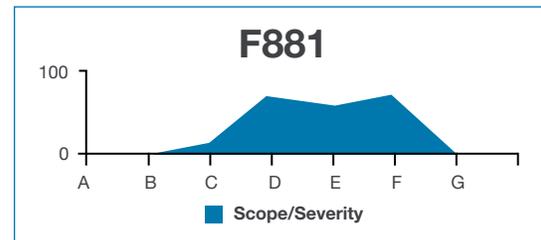
Two immediate jeopardy deficiencies have been cited under F758, both centered on a lack of an adequate indication for the use of antipsychotics. In the first case, a psychiatrist prescribed Trilafon to a resident, in error, based on misinformation from the nursing staff. The resident was administered the drug for approximately 45 days during which time he experienced “lethargy, decreased oral intake, excessive sleeping, decreased physical abilities and decreased participation in activities.” The drug was not discontinued until the surveyor intervened.

The second deficiency involved a resident admitted to the facility from her home on hospice care. Within two weeks of admission, and without any indication documented in the record, she was ordered Haldol 0.25 milligrams twice a day for 14 days. Using the facility’s electronic health record, a nurse erroneously entered the dose as 20 milligrams twice a day. After receiving 4 doses of Haldol 20 milligrams, the resident condition suddenly declined. She was admitted to the hospital and treated for an adverse drug reaction / drug overdose. Based on this deficiency, CMS imposed a civil money penalty of \$98,455.00.

F881 (INFECTION PREVENTION AND CONTROL/ ANTIBIOTIC STEWARDSHIP)

A new requirement, facilities must now have in place an antibiotic stewardship program that includes use of protocols, as well as a system to monitor antibiotics. A total of 259 deficiencies have

been cited under F881, but this number reflects deficiencies attributed to all aspects of the infection prevention and control program, not just antibiotic stewardship. Keeping that fact in mind, below is the scope/severity distribution:



No deficiencies at F881 were cited at an actual harm or immediate jeopardy level. The majority were written, not surprisingly, at an F level indicating a widespread potential for more than minimal harm. As reflected in the deficiency statements below, the primary cause of widespread level deficiencies related to antibiotic stewardship was simply the failure to develop and implement a program:

“In an interview on 04/19/18 at 11:40 a.m. the RDO said they did not currently have an antibiotic stewardship program up and running ... In an interview on 04/19/18 at 12:20 p.m., the Administrator said she was not aware that the facility had not started the antibiotic stewardship program” (Texas)

“On 05/09/18 at 10:45 A.M. interview with Registered Nurse (RN) #12 verified the facility had not implemented an antibiotic stewardship program to date.” (Ohio)

“On 5/23/18 at 3:00 PM, Administrative Nurse D stated he/she managed the infection control program and verified the logs were not complete. Administrative Nurse D stated there were multiple urinary tract infections, including several on one hallway, and he/she verified the facility had no antibiotic stewardship program in place.” (Kansas)

CONCLUSION

Perhaps the take away from this preliminary data is that most post Mega Rule, high-level pharmacy deficiencies could have been cited under previous regulations. Poor communication, misuse of high-risk drugs, medication errors, and the failure to implement specific regulatory requirements has historically contributed to poor survey outcomes. Meeting the requirements related to the medication aspects of the Mega Rule ultimately gets back to basic, safe practices.

¹Source: <https://data.medicare.gov>/accessed 7/31/18

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.

Remedi Superstar Nurse

MARCY DESANTIS, LPN

Chase City Health and Rehab Center, Chase City, VA



CONGRATULATIONS to Marcy DeSantis, LPN, at Chase City Health and Rehab Center in Chase City, VA, for being chosen as the Remedi Superstar Nurse. Marcy was nominated by her ADON, Jacquelyn Miles, RN. Per Jacquelyn, "Marcy has been an LPN for seven years and started her nursing career as an LPN at Chase City, where she is currently the Unit 2/Garden Manager. Marcy ensures that every single resident is taken care of and every need is met. She is willing to go above and beyond for our facility and residents. Marcy is extremely thorough and a gracious

team player. She is very confident in her nursing abilities and is knowledgeable with clinical situations. Marcy is also a wonderful leader because she leads by example, is willing to help, and would never ask someone else to do something that she can do herself!"

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

Order Clarification Dashboard

WHAT IS IT?

The clarification Dashboard provides a real-time view on any orders Remedi SeniorCare has attempted to clarify and was unable to obtain clarification. The Clarification Dashboard shows order details such as resident, document type, and details on what needs clarified.

1 From the main menu, click "Med Alerts" then select Clarifications.

2 Click the arrow to expand clarification details.

NOTE

Exception Date: This is the date the order was identified as needing a clarification

Order Date: This is the written date on the order

View Document: View the order image the pharmacy has identified as needing a clarification

Notes: This displays the type of clarification needed

Document Type: This displays the type of document the pharmacy has identified as needing a clarification

6 Order Clarifications Needed							Download Excel
Facility	Exception Date	Order Date	Resident	MS/Room	Note	Document Type	
› Demo Facility	8/18/2018		Doe, Resident		Valid Rx Needed	Order	
› Demo Facility	8/20/2018	8/18/2018	Doe, Resident	Outlook Pointe Cart 1, Rooms 300-312 / 303	Provide Stop Date	E-Order	
› Demo Facility	8/22/2018	8/22/2018	Doe, Resident	Outlook Pointe Cart 1, Rooms 300-312 / 303	Provide Stop Date	E-Order	
› Demo Facility	8/22/2018	8/22/2018	Doe, Resident	Riverview Lane Cart 1, Rooms 100-104 / 204	Valid Rx Needed	Order	
› Demo Facility	8/23/2018		Doe, Resident		Valid Rx Needed	E-Refills	
▼ Demo Facility	8/23/2018	8/22/2018	Doe, Resident	1 South Team 2, Rooms 107-112 /109	Rx Clarification	E-Order	
			Medication: LANTUS SOLOSTAR 100U/ML				
			 View Document				