

## **Why do Nursing Homes have requirements for psychopharmacology review and Gradual Dose Reductions (GDR's)? And what are the exact rules?**

As context for what may appear at first glance to be illogical and bureaucratic, I want to provide a brief history of this requirement.

Atypical antipsychotics were introduced in the 1990s, beginning with Risperidone and then Quetiapine and Olanzapine, raising the rate of antipsychotic use in NH's. This was accomplished by *illegal marketing for off-label use of all of these medications, culminating in fines for each drug manufacturer; the highest paid from mega-company Johnson and Johnson (makers of Risperdal™)* at \$2.2 BILLION. By 2011, use of antipsychotics in nursing homes had reached 24 percent. Now, it's back down to a historic low of 16 percent. This decline was spurred by an Office of Inspector General report of 2011, "Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents." In response to this disturbing report, the Centers for Medicare and Medicaid Services (CMS) launched its "National Partnership to Improve Dementia Care in Nursing Homes," which combined public reporting, educational resources, and renewed regulatory enforcement.

It is important to underscore that when Pharma was pushing these drugs to nursing homes, antipsychotic medications were not FDA approved for the treatment of the symptoms of dementia (thus the fines for breaking the law by marketing drugs for non-FDA approved indications). Not only have studies failed to demonstrate that antipsychotics, old or new, work in dementia, but the FDA also issued a black box warning indicating that they have been associated with stroke and sudden death (again, both traditional and newer atypical ones). In summary, evidence shows that they do not work and cause harm. Behavioral psychology (predictably irrational) prevailed because most providers did not believe drug detailing influenced them. But it did, and still does.

Depakote™ was also swept up in a disinformation campaign. Omnicare, the leading distributor of prescription drugs to nursing homes, instructed its pharmacists to provide false information to nursing home doctors—in return for a kickback from Abbott, the company that manufactured the drug Depakote (again, off-label) for treating the behavioral symptoms of dementia. Abbott paid in excess of \$1.5 BILLION to settle the claims of illegal marketing in 2012, and Omnicare paid another 28 million in 2016 when they got caught for taking kickbacks. This largely explains the overuse of Depakote for BPSD in nursing homes despite its considerable harms and lack of efficacy.

The multi-pronged approach to antipsychotic reduction in nursing homes has fortified a drug review committee obligation that had largely become perfunctory. These meetings now have a process and strategy for gradual dose reductions (the infamous GDR's) and moreover, provide a venue to review all potentially dangerous CNS medications. The heart of the regulation is to prevent the use of unnecessary or

potentially harmful medications. Happily, reducing and stopping unnecessary medications is a win-win for patients, facilities and payers. And when targeted medications make a *measurable difference* in behaviors and quality of life, a risk/benefit justification can be documented and the medication continued. The devil, of course, is in the details – in this case, the details of documentation.

CMS requires that new admissions to NH's have an attempt at GDR in two separate quarters the first year, and annually thereafter. If a resident is receiving antipsychotics for a disorder *other than* BPSD, clinicians must document specifically why a GDR is contraindicated.

Psychopharmacology review is required to review ALL psychotropics, and now also opioids and other pain medications. Further guidance on these classes of medications is available. Of most importance is to note that the co-prescription of benzodiazepines and opioids now carries a *black box warning* with risk for respiratory depression and death, and must be avoided. Opioids must also have a specific indication, site of pain, and must adhere to CDC and CMS guidelines for maximum morphine milligram equivalents. PRN medications are discouraged (if necessary, try scheduled dosing with built in tapers) and will soon be automatically discontinued after two weeks, *requiring face-to-face visits for renewal*.