

CMS MEGA RULE UPDATE: FOCUS ON CHANGES TO PHARMACY SERVICES

- ◆ On October 4, 2016, CMS released updated requirements for Long Term Care Facilities. These requirements must be met in order for LTC facilities to participate in Medicare and Medicaid programs. The table below summarizes those changes made to Pharmacy Services and other portions that pharmacy could be involved with. For a complete list of changes, please refer to the document at the following link:
<https://www.gpo.gov/fdsys/pkg/FR-2016-10-04/pdf/2016-23503.pdf>
- ◆ The changes will occur in 3 Phases. Those regulations included in Phase 1, must be implemented by November 28, 2016. Those included in Phase 2, must be implemented by November 28, 2017. And those included in Phase 3, must be implemented by November 28, 2019.

Phase 1 (November 28, 2016)

- Adds the requirement that each facility should establish policies and procedures that address the entire DRR process, especially the time frames for various actions in the process and a procedure for a pharmacist to follow when he or she believes the irregularity must be addressed immediately due to the potential for harm to the resident.
- Adds requirement that any irregularities identified by the consultant pharmacist must be communicated in writing to the [medical director](#) (as well as the attending physician and DON which were previously required) and must contain [at least resident's name, relevant drug, and nature of the irregularity](#).
- Requires the attending physician to document in the medical record that the irregularity has been reviewed and what, if any action has been taken to address it. If there is no change in the medication, the attending physician should document his rationale [in the medical record](#).
- Requires the nursing home to establish an infection prevention and control program (IPCP). This program must include the following: 1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual agreement; (2) Written standards, policies, and procedures for the program.

Phase 2 (November 28, 2017)

- Requires the pharmacist to review the medical chart once a month with the DRR.
- Revises the definition from psychopharmacological drug to psychotropic drug. This is defined as any drug that affects brain activities associated with mental processes and behavior. These drugs include, but are not limited to, drugs in the following categories: Antipsychotic, Antidepressant, Anxiolytic, Hypnotic.
- Residents who use psychotropic drugs receive gradual dose reductions, and [behavioral interventions](#), unless clinically contraindicated, in an effort to discontinue these drugs
- Limits [PRN orders for psychotropic drugs to 14 days](#). If the attending physician or prescribing practitioner believes that it is appropriate for the PRN order to be extended beyond 14 days, he or she should document their rationale in the resident's medical record and [indicate the duration for the PRN order](#).
- Facilities must develop and implement a baseline care plan for each resident, within 48 hours of their admission.
- [Antibiotic Stewardship](#): nursing homes must have an antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

Phase 3 (November 28, 2019)

- [Infection Preventionist \(IP\)](#): The nursing home must designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's infection prevention and control program (IPCP). The IP must have primary professional training in nursing, medical technology, microbiology, epidemiology, or other related field, have completed specialized training in infection control and prevention and work at least part-time in the nursing home.
- The IP must participate on and regularly report to the QAA committee regarding the IPCP.