Guardian Consulting Services, Inc.

Consultant Pharmacists for Healthcare Organizations, Industry and the Community.

To: All Operators, Administrators, Directors of Nursing, Medical Directors, and Prescribers
From: Dr. William C. Hallett, Pharm.D., MBA, CGP, C-MTM
November 28, 2016

FINAL RULE Update: Pharmacy Services Section

As most everyone is aware, on October 4th, 2016, CMS issued the Final Rule, effectively revising and updating the requirements that must be met for LTC facilities to participate in the Medicare and Medicaid programs. This wide-ranging revision of the rules goes into effect in three annual phases, beginning November 28th, 2016. You can access the rule here: https://www.federalregister.gov/documents/2016/10/04/2016-23503/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities.

In addition to adding new requirements for Pharmacy Services, the revisions effectively consolidated and moved the requirements currently found in under 4 separate areas of the law into one relocated section, § 483.45, titled "Pharmacy Services" (formerly located at § 483.60). For cross-reference purposes, you can find the existing requirements of these relocated sections in the current State Operation Manual at F332/333 (Medication Errors), F329 (Unnecessary Medications); F425 (Pharmacy Services); and F428 (Drug Regimen Review).

To simplify things, I have created and attached a **consolidated unofficial version of the new § 483.45 Pharmacy Services regulation,** along with **our recommended update to the existing policy and procedure on Drug Regimen Review,** designed to address the new requirements.

Below is a summary of the new requirements along with our actions and recommendations. Key elements include:

- **A requirement that the Administrator, Director of Nursing, and Medical Director be made aware of all Drug Regimen Review findings in a *separate report*.**
    - We will now be supplying each facility a monthly "Executive Summary" of all Drug Regimen Review findings via email for review by the Administrator, DNS, and Medical Director.

- **The Policy and Procedure for Drug Regimen Review must include time frames for the process.**
    - We have revised the P&P on Drug Regimen Review to require a response by the clinician within 7-14 days or less. Obviously, the sooner responses are obtained, the better.
- **The Policy and Procedure for Drug Regimen Review must include provisions for handling urgent action.**
    - Our procedure on this remains unchanged. We will continue to verbally notify the DNS/Designee and/or the Nursing Supervisor in charge immediately when urgent issues are identified.
- **The physician must document drug regimen review responses in the medical record, including a rationale when there is to be no change in the medication.**
    - To accommodate this, we are updating our software to more efficiently ***print each resident's DRR finding on individual pages.*** Once answered by the practitioner, these become a permanent part of the Medical Record. To be clear, ***we strongly recommend that no drug regimen review findings be added to the medical record until they have been answered.*** Further, we continue to recommend that the recommendations and responses be maintained by the facility in a separate binder for easy QA of adherence to the policy on response time and fast retrieval and presentation to the surveyors, then filed with each resident's permanent medical record once the survey year is complete.
- **Beginning November 28, 2017, orders for PRN psychoactives will be limited to no more than 14 days.**
    - We will continue to maintain and recommend a position that PRN psychoactives not be used at all, as the burden of behavioral documentation prior to each dose administered is high, and the possibility of inappropriate use, even inside of 14 days, remains great.

It is important to note that ***CMS has yet to update the State Operations Manual (SOM) and guidance to surveyors on these new regulations***. Once the revised SOM guidance on the new regulations are published, we expect that further revisions to policies and procedures will likely be necessary. As always, we will address these immediately and keep you informed.

In the meantime, please do not hesitate to call or email if you have questions or we can be of assistance in any way.

Respectfully,

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§483.45 Pharmacy Services *(formerly §483.60)*

(Effective November 28, 2016, except (c)(2) and (e), effective November 28, 2017)
Legend: Regular Font Text = Existing regulations; *Italics = Existing regulations relocated to this section*; **Bold Text = New regulations**

The facility must provide routine and emergency drugs and biologicals to its residents, or obtain them under an agreement described in § 483.70(g) of this part. The facility may permit unlicensed personnel to administer drugs if State law permits, but only under the general supervision of a licensed nurse.

(a) Procedures. A facility must provide pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident.

(b) Service consultation. The facility must employ or obtain the services of a licensed pharmacist who—

(1) Provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and

(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.

(c) Drug regimen review.

(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.

(2) This review must include a review of the resident's medical chart.

(3) A psychotropic drug is 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:

(i) Anti-psychotic;

(ii) Anti-depressant;

(iii) Anti-anxiety; and

(iv) Hypnotic.

(4) The pharmacist must report any irregularities to the attending physician and the facility's medical director and director of nursing, and these reports must be acted upon.

(i) Irregularities include, but are not limited to, any drug that meets the criteria set forth in paragraph (d) of this section for an unnecessary drug.

(ii) Any irregularities noted by the pharmacist during this review must be documented on a separate, written report that is sent to the attending physician and the facility's medical director and director of nursing and lists, at a minimum, the resident's name, the relevant drug, and the irregularity the pharmacist identified.

(iii) The attending physician must document in the resident's medical record that the identified irregularity has been reviewed and what, if any, action has been taken to address it. If there is to be no change in the medication, the attending physician should document his or her rationale in the resident's medical record.

(5) The facility must develop and maintain policies and procedures for the monthly drug regimen review that include, but are not limited to, time frames for the different steps in the process and steps the pharmacist must take when he or she identifies an irregularity that requires urgent action to protect the resident.

(d) Unnecessary drugs—General. Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

(1) In excessive dose (including duplicate drug therapy); or

(2) For excessive duration; or

(3) Without adequate monitoring; or

(4) Without adequate indications for its use; or

(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or

(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

(e) Psychotropic drugs. Based on a comprehensive assessment of a resident, the facility must ensure that—

(1) Residents who have not used psychotropic drugs are not given these drugs unless the medication is necessary to treat a specific condition as diagnosed and documented in the clinical record;

(2) Residents who use psychotropic drugs receive gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these drugs;

(3) Residents do not receive psychotropic drugs pursuant to a PRN order unless that medication is necessary to treat a diagnosed specific condition that is documented in the clinical record; and

(4) PRN orders for psychotropic drugs are limited to 14 days. Except as provided in § 483.45(e)(5), 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.

(5) PRN orders for anti-psychotic drugs are limited to 14 days and cannot be renewed unless the attending physician or prescribing practitioner evaluates the resident for the appropriateness of that medication.

(f) Medication errors. The facility must ensure that its—

(1) Medication error rates are not 5 percent or greater; and

(2) Residents are free of any significant medication errors.

(g) Labeling of drugs and biologicals. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.

(h) Storage of drugs and biologicals.

(1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.

(2) The facility must provide separately locked, permanently affixed compartments for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected.

Title: Drug Regimen Review-Monthly Policy #PHNY02

Policy: In accordance with Code of Federal Regulations 42 CFR 483.45, the Consultant Pharmacist shall review the medical record of each resident and perform a Drug Regimen Review at least once each calendar month. The Consultant Pharmacist shall identify, document and report possible medication irregularities for review and action by the attending Physician, where appropriate. The attending Physician or licensed designee shall respond to the Drug Regimen Review within 7-14 days or more promptly, whenever possible. Any identified irregularities of an urgent nature shall be communicated to the Director of Nursing and/or Nursing Supervisor for immediate notification and action of the attending physician or licensed designee. The facility Administrator, Director of Nursing, and Medical Director shall be notified of all findings.

Procedure:

Consultant Pharmacist:

1. Shall perform Medication Regimen Reviews for each resident at least monthly. This review shall be performed by evaluating the medical record of each resident, which contains the current Medication Regimen as documented on the most recent Physician's Order Sheets or electronic record of current orders.

2. Shall provide written documentation of all recommendations and submit to the facility for attending Prescriber or designee's review and response. (See attached sample format for reporting findings.) The written documentation and prescriber response shall be considered a permanent part of each resident's medical record.

3. Shall document that monthly Drug Regimen Review has been completed and whether there were any recommendations on the electronic medical record of each resident. If no electronic medical record is in use, shall document on a signature page maintained on the paper chart for each resident.

4. Shall provide a monthly summary report of all Drug Regimen Review findings to the facility for review by the Medical Director, Attending Physician, and Facility Administrator.

Prescriber/Licensed Designee:

1. Shall act upon the Drug Regimen Review findings/recommendations in a timely manner of 7-14 days or less.

2. Shall document on the drug regimen review form whether he/she agrees or disagrees with the recommendation, and provide a brief clinical rationale if no change is to be made.

Facility:

1. Shall maintain all Drug Regimen Review recommendations along with prescriber responses in an easily retrievable location for presentation to surveyors, upon request.

2. Shall file all Drug Regimen Review recommendations with the permanent medical record for each resident after one year.

PHNY02- End of Policy.