

THE QUARTERLY CONNECTION

Quarterly Report from Pharma-Care, Inc. / Creative Care Consulting

Third Quarter 2022

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Paxlovid

The Food and Drug Administration (FDA) recently gave Emergency Use Authorization (EUA) for the drug, Paxlovid, for treatment of mild-to-moderate COVID-19. Paxlovid contains 300 mg nirmatrelvir (two tablets of 150 mg) and 100 mg ritonavir tablet; all three tablets should be taken together twice daily for five days. Paxlovid may be taken without regards to meals, but should be taken at the same time each day. However, if you miss a dose and remember within 8 hours you may take the missed dose. After 8 hours skip the dose and resume with the next schedule dose. Paxlovid cannot be crushed.



The Center for Disease Control (CDC) recommends starting Paxlovid within 5 days of the first symptom(s) for those patients who fall into the following categories:

- Test positive for COVID-19
- Have mild to moderate illness
- Have one or more risk factors (such as Diabetes, Heart problems, Smoking, Obesity and more)
- Do not require hospitalization because of COVID-19
- Do not have evidence of severe kidney or liver impairment

Paxlovid does have many contraindications associated with it. Paxlovid, a CYP3A inhibitor, interacts with many medications that rely on this enzyme for clearance from the body. This interaction can cause life-threatening reactions for patients; examples of some medications are simvastatin, lovastatin, colchicine, sildenafil, ranolazine, clozapine, lurasidone and more. Paxlovid, also cannot be started immediately after stopping certain medications (examples: carbamazepine, phenytoin, phenobarbital and more) due to the loss of virologic response. It is highly recommended to check for such interactions before starting the patient on this therapy. Paxlovid is not recommended in patients with severe hepatic impairment. Dose adjustment is needed for patients whose eGFR is ≥ 30 to < 60 mL/min (one 150mg tablet of nirmatrelvir with one tablet of ritonavir 100mg) and it is contraindicated in patients with an eGFR < 30 mL/min. Paxlovid is also contraindicated in anyone that has been diagnosed with Steven-Johnson Syndrome in the past.

There have been cases of rebound illness for patients with normal immune response that have been treated with Paxlovid, which may develop 2-8 days after completing therapy. The CDC states that the rebound illness does not indicate resistance to Paxlovid or possible reinfection. On average the illness resolves in 3 days without any additional anti-viral treatment. These patients should re-isolate for a full 5 days. They can then end isolation upon completion of the 5 days, are fever free for 24 hours without fever-reducing medications, and symptoms are improving. The CDC is still recommending treatment with Paxlovid for COVID-19 despite patients developing this rebound illness. It is important to consider all factors when prescribing Paxlovid for patients.

FAQ Survey



You may have noticed that your consultant pharmacist will remind you to include a duration of 14 days for the initial order of certain PRN medications, based on CMS regulations. There is sometimes confusion regarding which medications and circumstances are included in this regulation. This may help to answer some of those questions. From "Frequently Asked Questions Related to Long-Term Care Regulations, Surveys Process and Training".

Regulation F758

Regulation F758 Unnecessary Drugs talks about requirements for psychotropic medications that are PRN and GDRs for these medications. Will Compazine (which is an antipsychotic according to some medication resources) which residents take for nausea and vomiting on a PRN basis expire every 14 days and have to be renewed every 14 days?

Compazine or prochlorperazine is considered an anti-psychotic, though it can be used to treat nausea and vomiting. Therefore, according to Federal requirements, a PRN order for Compazine would be limited to 14 days. A new PRN order cannot be renewed unless the attending physician or prescribing practitioner first evaluates the resident to determine if entering a new order for the PRN medication is appropriate.

PRN Anti-psychotic medications (specifically Haloperidol) have become a routine order by Hospice physicians. I see no exception to this type of order in the requirements of participation or supporting materials in Appendix PP. The Hospice PRN order may go unused for a period of 14 days, necessitating an in-person reevaluation by the physician, despite the desire of the physician to have the medication available to assist with potential symptoms of dying, particularly delirium associated with hyperactivity at the end of life or for its potent antiemetic properties. Good hospice care, honoring resident's choices and person-centered care, and Hospice clinical best practices all seem to be in conflict with the 14 day limit of PRN orders for anti-psychotic medications for persons receiving Hospice services.

Is there an opportunity, if the medical record indicates the PRN order for Haloperidol is being used to manage end-of-life symptoms for a patient on Hospice care, for an exception to this requirement? These issues were all raised during the comment period, with little to no response.

We understand your concerns and appreciate the importance of promptly addressing the needs of all residents, especially those residents who receive end of life or hospice care. There is no exception to the PRN antipsychotic requirement in the regulations. The intent of this requirement is to address the concern that use of an antipsychotic medication, on a PRN basis beyond 14 days without physician evaluation of the resident, could be detrimental to the resident. We are aware that the current Medicare Hospice requirements under 42 CFR 418.54 require updating of the comprehensive assessment every 15 days or more frequently as needed.

Is melatonin considered a hypnotic to be reduced every ninety days?

Melatonin does not fall under the requirements for psychotropic medications. Melatonin is a natural hormone that is classified as a dietary supplement by the Food and Drug Administration and, therefore, is not subject to the requirements of hypnotics under the new psychotropic medication category at 483.45(c)(3). However, residents should still be monitored with regard to benefits, risks, and potential adverse consequences.

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FAQ Related to Long Term Care Regulations, Survey Process, and Training

Continued from page 1

The regulations state that PRN orders for psychotropic drugs are limited to 14 days except 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. Say a resident takes Restoril (PRN for sleep), would it be acceptable for the physician to document a rationale that indicates the duration for the PRN order to be indefinite? Or is there a max on the duration of time for the PRN order?

There is no maximum duration for PRN orders for psychotropic medications. However, if an attending physician or prescribing practitioner believes it is appropriate to extend a PRN order for a psychotropic medication beyond 14 days, he or she may extend the duration and document the rationale for extending the duration. This requirement was written to address concerns about residents remaining on PRN psychotropic for prolonged periods which may not be appropriate. "Indefinitely" means for an unlimited or unspecified period of time so extending a PRN order indefinitely would not meet the intent of this regulation. It is also unlikely that a rationale could be provided to support an indefinite extension of a PRN order for a psychotropic medication.

Does a resident with a diagnosis of schizophrenia with an order for Seroquel (an on label use) require a 14 day PRN order and continuous 14 day reassessment and PRN order indefinitely?

There are no exceptions to the PRN antipsychotic medication requirements. Use of these medications, on a PRN basis, is limited to 14 days. If the attending physician or prescribing practitioner wishes to write a new order for the PRN antipsychotic, they must first evaluate the resident to determine if the new order is appropriate. If deemed appropriate, the new order would, again, be limited to 14 days. If the resident is assessed as needing an antipsychotic on a non-PRN basis, the PRN requirements would not apply.

If a medication such as Morphine Sulfate is ordered for an indication of Anxiety-would this need to have a 14 day stop date for PRN orders even though it is a pain medication?

Morphine sulfate is classified as an opioid pain medication. Opioids do not fall under this definition of psychotropic medications and are not be subject to the associated PRN requirements, however, the facility should monitor and document the benefits and/or any adverse effects of the morphine to ensure the medication is not an unnecessary drug.

§483.45(e)(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.

Would you clarify what constitutes an evaluation by the attending or prescribing physician? For instance does this suggest that the physician needs to have face to face contact with the resident, or would a review of the medical record and a written summary of the resident's condition sent to the physician be considered evaluation of the appropriateness of the medication? What are surveyors expected to look for in regard to this regulation?

The newly revised advance Interpretive Guidance for surveyors released via a CMS Survey & Certification memo on June 30, 2017 clarifies the required evaluation at F758:

The required evaluation of a resident before writing a new PRN order for an antipsychotic entails the attending physician or prescribing practitioner directly examining the resident and assessing the resident's current condition and progress to determine if the PRN antipsychotic medication is still needed. As part of the evaluation, the attending physician or prescribing practitioner should, at a minimum, determine and document the following in the resident's medical record:

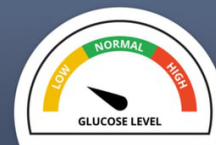
- Is the antipsychotic medication still needed on a PRN basis?
- What is the benefit of the medication to the resident?

- Have the resident's expressions or indications of distress improved as a result of the PRN medication?

NOTE: Report of the resident's condition from facility staff to the attending physician or prescribing practitioner does not constitute an evaluation. Therefore, a review of the medical record and a written summary of the resident's condition sent to the physician would not meet the intent of this requirement. When assessing concerns related to PRN antipsychotic medications, surveyors should review the medical record for evidence of the required evaluation and interview staff as appropriate to assess compliance.

It is important to note that if any of these orders are to be continued after the initial 14 days, documentation from the prescriber is required. A clear note regarding continued benefit would be adequate for those medications that are not antipsychotic agents. A full exam and review with documentation is required along with a new order for antipsychotic agents regardless of indication for use. For further review and clarification of the 14 day PRN ruling, your Pharma-Care consultant would be happy to provide a staff inservice .

Glucose Monitoring Systems



With the growing use of continuous glucose monitoring systems to improve over-all glycemic control there is an increased chance that you may see new admission with these devices in place. This year the ADA has address the use of these devices in its update standards of practice. The ADA recommendations focus on user and care-giver education and accessibility. It is important, if you have a resident with one of these devices, that your staff is educated on the use and monitoring of the devices and that there is a facility policy in place addressing all procedures documentation, and responsibilities surrounding the use of these devices.

Some important points regarding each of the systems:

Dexcom G6:

- Approved for use in healthcare facilities
- The sensor must be replaced every 10 days
- The transmitter applied on top of the sensor must be replaced every 90 days
- Apply to rotating sides on the abdomen
- Medical tape may be used to ensure adhesion

Freestyle Libre:

- Not recommended for use in LTC. Review with the prescriber and have risk vs. benefit documented
- The sensor must be replaced every 14 days
- The sensor must be scanned with the reader to obtain data
- Clean and disinfect the reader once a week-Clorox Healthcare Bleach Germicidal wipes are recommended by the manufacturer.

For more in depth information on these products and recommended documentation, please set up an in-service with your Pharma-Care consultant.

STATE SURVEY TRENDS

Unnecessary drugs:

PRN orders for behaviors that are not antipsychotics, may be renewed after 14 days if there is supporting documentation indicating continued benefit. *This documentation must include a note from the prescribing physician.*

Ativan continued without an MD note addressing benefit.

Infection control:

Trace testing not initiated after a staff member, who was working all day, tested positive for Covid-19.

Proper use of PPE, N95 mask not worn securely.

Appropriate frequency of Covid screening, based on vaccination status and facility situation.

Documentation:

Follow up on the pharmacy consultant's report in a timely manner.

Missing shift to shift signatures

Missing signatures for Back-up CDS count (at least daily, or per facility policy).

Physician orders not signed monthly

Incorrectly filled out DEA 222 forms-both upon ordering and after receipt or medications. Pre-signing of DEA 222 forms.

Med Pass Observations:

Not rinsing mouth after steroid inhaler use.

Semaglutide administered with 8am meds. Should be 30 minutes prior to meals. We recommend adding these cautions to your EMAR even if the time is correct & the provider puts label on the bingo card.

Calcium acetate and Levothyroxine not spaced appropriately

Crushing Klonopin (clonazepam)-Klonopin should be swallowed whole per literature addressing abuse potential. If the resident requires Klonopin to be crushed, just obtain an MD order that states "may be crushed for this resident."

Order for Klonopin via g-tube. Two dosage forms sent, tablets and wafers, on the med cart

Metoprolol not given with a meal for an order written "every 8 hours." This did not become a deficiency as literature was presented to the survey team indicating that the MD could override this recommendation, but we recommend that if the MD requires "Q8H" or "Q12H" dosing, the order includes "May be administered without regard to meals for this resident per MD"

Liquid Supplement (ex. TwoCal)-nurse did not use a measuring cup (one ounce med cup) to measure out 4oz of a liquid supplement.

With meals medications administered late.

Dialysis:

Not posted that dialysis vitals taken.

Missing communication log entries.

Dating of medications:

Undated insulin Pens, Nebulizer treatments, inhalers, Heparin.

Please check manufacturer labeling.

Other Concerns:

Expired medication found in a storage area that the consultant was never told about. Please update your consultant on any storage areas that you would like audited during the unit inspection process.

Staffing ratios continue to be an issue.

Complaint by resident to the surveyor initiated a facility wide investigation.

EPIC Corner

ELECTRONIC PHARMACIST INFORMATION CONSULTANT
(MEDICATION REVIEWS WITHIN 48 BUSINESS HOURS)

EPIC Phone: 732-943-3573

EPIC Fax: 732-574-3469 or 3926

Email: epic@pharmacareinc.com

FACILITY RESPONSIBILITY RECEIPT OF EPIC

Upon receipt of the EPIC review, the facility is responsible for initiating nursing recommendations in a timely manner according to facility policy except for Clinically Significant recommendations that need to be addressed by midnight of the following day. The nurse should sign and date the EPIC review after the necessary changes and/or adjustments are made.

Upon receipt of the EPIC review, the facility is responsible for contacting the physician for review of EPIC concerns directed to the physician in a timely manner according to facility policy except for Clinically Significant recommendations that need to be addressed by midnight of the following day. The physician either accepts the recommendation and makes the necessary changes and/or adjustments or does not accept and needs to document clinical rationale for continuing on the EPIC review and/or in the resident's medical record. The EPIC needs to be signed and dated when all concerns are addressed.

Upon completion of both tasks, the facility is responsible for placing the EPIC review in a readily retrievable location. The completed EPIC review is ideally placed in the resident's chart or if the facility is chart-less scanned into their EMAR system.

If EPIC has EMAR access to your facility, please remind the nurses DO NOT FAX IN A REQUESTS FOR NEW ADMISSIONS AND/OR READMISSIONS, only for Change of Status and Antibiotic Stewardship (if your facility utilizes these types of EPICs.)

Please make sure your fax machine is sending over legible information. Many times, EPIC receives requests with blank lines going through the pages which makes it difficult to read. Not sure, send a fax from one device to another device at your facility and review.

EPIC has 4 fax numbers: (732) 574-3469
(732) 574-3926
(732) 943-3571
(732) 943-3572

If one of those numbers is busy, please go to the next. We have multiple facilities faxing in throughout the day.

Please reach out to the EPIC Department with any concerns or questions about services at (732) 943-3573.

Drink Water!

STAY HYDRATED THIS SUMMER

Proper hydration allows your body to cool down during the hot summer months.



Pharma-Care, Inc. Services

Pharma-Care started 46 years ago providing consultant pharmacist services to long-term care facilities. During the course of the company's history it has expanded the scope of services to the community in all areas of healthcare including the following:

- Long-Term Care/Skilled Nursing Facilities
- Assisted Living/Personal Care Facilities
- Ambulatory Surgery Centers
- Dialysis Centers
- Drug and Alcohol Rehabilitation
- Pediatric and Adult Medical Day Care
- Medication Therapy Management
- Disease State Management
- COVID-19 Vaccinations Clinics (Pfizer or Moderna)
- COVID-19 PCR Testing
- Mock Survey-Preparedness, Education and Audit

As the healthcare industry continues to be in a state of flux, Pharma-Care strives to stay flexible in the areas in which we can be of assistance. Along with traditional services such as Chart Review, Med Pass Observations and Unit Inspection oversight we have expanded into areas of non-acute care. We have successfully provided a disease state management program to multiple municipalities to help decrease their overall medical and prescription drug spend.

At the height of the COVID-19 pandemic in New Jersey, Pharma-Care supplied pharmacists required to operate three field hospitals 24 hours a day, 7 days a week.

Recently requested to partner with the NJ Department of Health to provide COVID-19 vaccinations to skilled nursing facilities and assisted living residents and their staff. Some of these facilities are not even clients of Pharma-Care. During the period started in March through the end of May, our team has vaccinated more than 1,000 individuals.

We partnered with siParadigm Laboratories to provide COVID-19 PCR testing to both our client facilities and the general community at large. Pharma-Care is available to provide testing in your facility with results coming back normally within 24 hours (as of distribution of this memo).

Our newest service, that we are proud to announce is a full-service Mock Survey program. With an interdisciplinary team consisting of consultant pharmacists, nurses, dietitians, social workers and a structural engineer that will not just identify issues, but help your staff solve those problems in the short and long term.

The New Jersey Department of Health has requested Pharma-Care, Inc. of Clark to work with and assist in their booster Covid-19 vaccination program to all healthcare facilities and their employees. Offering 1st, 2nd, Booster 1 and Booster 2. Additional information on how Pharma-Care can help your facility please contact:

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WEB | Connections

Additional Resources for Articles in this Issue

An official website of the United States government [Here's how you know](#) ↓

U.S. Dept. of Health & Human Services
Guidance Portal

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Frequently Asked Questions Related to Long Term Care Regulations, Survey Process, and Training

Guidance for Frequently Asked Questions Related to Long Term Care Regulations, Survey Process, and Training. It contains questions and answers about Long Term Care regulations, the survey process, technical questions, and other related LTC areas and makes a distinction using font color between newly added questions and answers (red color) versus older questions and answers (black color).

[Download the Guidance Document](#)

Final

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HHS is committed to making its websites and documents accessible to the widest possible audience, including individuals with disabilities. We are in the process of retroactively making some documents accessible. If you need assistance accessing an accessible version of this document, please reach out to the guidance@hhs.gov.

<https://www.hhs.gov/guidance/document/frequently-asked-questions-related-long-term-care-regulations-survey-process-and-training>

Topic(s)

Health Care

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**BE SURVEY
READY
EVERY DAY!**

Since 1976, Pharma-Care, Inc. has been setting the standard in the field of consultant pharmacy. Our pharmacy consultants provide services to a variety of health care facilities. Our consultants are continually kept abreast of the latest developments on drug interactions along with clinical outcomes, quality assurance, and state and Federal regulations.

Let our team of experts help you to provide the highest level of quality care and have that reflected in your outcomes, STAR rating and survey results.

The Reasons Your Nursing Facility Needs Our Mock Survey

During these trying times it is often difficult to always operate at the highest possible level; sometimes it takes a fresh set of eyes to evaluate and mend breakdowns in processes. Here are just a few reasons why engaging with Pharma-Care's consulting group for your facility's mock survey needs is the best way for you to prepare for survey. Pharma-Care has an interdisciplinary team of certified consultants working with nursing homes, assisted living facilities, rehabilitation centers, and other healthcare providers throughout the state. We utilize the same checklist as the actual survey team, giving you the ability to correct potential deficiencies before your survey, and have the foundation in place to provide the highest level of quality care.

Our team will work collaboratively with yours to determine the specific needs of your facility. We will work with you and your team to not only discover any areas of concern but also come up with and help implement solutions.

- Full or Focused Mock Survey
- Review past surveys (deficiencies & plans of corrections)
- Review quality measures & quality indicators
- Provide Pre and Post survey education to your staff
- Medication Reconciliation
- Documentation Review (wound, restraint, etc.)
- Assist with writing Plans of Corrections and developing audit tools
- Assist with culture change (doing the right thing the first time)

Review and/or Recommend:

- Changes to policies
- Infection Control practices
- Accident and Investigation reports
- Process changes in other departments (dietary, housekeeping, maintenance, etc.)

OTHER SERVICES MAY BE AVAILABLE UPON REQUEST

**CONTACT PHARMA-CARE TODAY AT (732) 574-9015, EXT 105
TO SCHEDULE A COLLABORATIVE ONSITE FACILITY ASSESSMENT**



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