Impairments in abilities such as memory, language, reasoning and judgement affect an estimated five million individuals in the United States. Further, an estimated 15 million people provide care for these patients, outside the formal health care process. In 2015, 1 in 9 individuals over the age of 45 reported some form of subjective cognitive decline. Of those, less than 50% spoke to a health care provider, 40% had to give up some day to day activities, 37% required help with household chores and 33% noted interference in social, work or volunteer settings.

Behavioral symptoms have consequences for the resident, family and nursing staff. They interfere with activities of daily living and caregiving, lead to falls and injuries, are disturbing to the resident and others and overall lead to a decreased quality of life. There are underlying conditions that may contribute to these behaviors including a variety of diseases both acute and chronic, drug therapy, mood disorders, delirium, interpersonal and environmental stressors and lastly psychiatric disorders.

Historically, behaviors associated with Dementia, Alzheimer’s Disease and cognitive decline have been treated with various antipsychotic, anxiolytic and mood stabilization medications in efforts to calm the resident and hopefully promote a return to baseline status. Unfortunately, currently available medications do little to correct the underlying pathology meaning return to baseline function is unlikely.

Recent CMS initiatives have further limited the use of antipsychotic medications in Skilled Nursing facilities, purposefully decreasing the availability of pharmacologic options. This leads to a not so new approach of non-pharmacologic treatment options. Objections raised to this approach include staffing limitations, time impact on caregivers and skepticism by caregivers of the validity of these modalities. However, mandates by CMS to decrease the use of psychoactive medication have prompted nursing facilities to re-review these alternative therapeutic options.

Focus on patient centered care

In 2015, CMS established a focused survey process for dementia care. One of the data points collected during this focused survey process reflects the facilities’ use of nationally recognized dementia care guidelines. These programs include CMS’ Hand in Hand Series, VA Program (STAR), OASIS program, Johns Hopkins...
Non-Pharmacologic Behavioral Interventions, cont.

DICE program and the AHCA toolkit. All of these programs promote person-centered care and the use of non-pharmacologic interventions. These programs are available at little or no cost to the facility and, if applied appropriately will reduce the need to use medications and decrease behaviors. Staff involvement is necessary but the benefits to both the staff and the residents are well documented.

Describe behaviors in categories

The how, why, when and what of these behaviors may offer insight into determination of the appropriate treatment regimen. Often, our resident may only need a little TLC, a change in surrounding or just a bit of quiet. Determining behavior triggers and the appropriate response to exhibited behaviors may be more beneficial than initiating a medication. Knowing the social history or “story” of the resident is a good place to start.

It is helpful to visualize behaviors categorically. This will aide in determining a course of action to modify or decrease the behavior. Residents generally exhibit behaviors of the following types:

Physically Aggressive
- hitting
- kicking
- biting
- pushing
- scratching

Physically Non-Aggressive
- pacing
- repetitious mannerisms
- wandering
- inappropriate disrobing

Verbally Aggressive
- screaming
- cursing
- outbursts of temper

Verbally Non-Aggressive
- constant requests for attention
- whining
- repetitive statements or questions
- complaining
- negativity

By observation and documentation, a list of target behaviors is developed for each resident. This list should include possible causes and triggers of the behaviors. It is important to identify potential medical causes for behaviors and correct those issues first. A second step is to implement a person-centered care strategy, taking into consideration the residents likes and dislikes, cultural background and life experiences, in short, know their “story”. Here are a few examples you may use as nonpharmacological treatment.

Medical and Nursing Care Interventions: Correct the vision or hearing, keep the resident comfortable and attend to their medical needs will decrease behaviors overall.

Music: Interventions ranged from social gatherings for sing alongs, music therapy and more recently, the use of personal devices with selections tailored for individuals.

Structured activities: Examples include flower arranging, coloring, reading, work-like activities, and manipulative activities such as jigsaw puzzles. Evidence suggests that these programs are beneficial in controlling behaviors. Work and manipulative activities had significant impact only with physical agitation.

Social Contact/Human Contact: Usually this is accomplished with an individual specifically trained in interventions and can be very effective for behavioral disorders. Humor therapy is included as a means of social contact and is shown to reduce behaviors.

Other: Interventions like aroma therapy, massage, and animal assistance may be beneficial to improve residents’ behavior. Focus on patient centered care.

Conclusion

Determine and develop an appropriate behavioral intervention plan through multi-disciplinary observation and documentation. Identify patterns of the particular behavior and what, if anything, supplies relief. It is important to note the frequency, timing and length of the behavioral episodes. Use both verbal and non-verbal observations (look and listen) to attempt to determine factors, which may precipitate the behavior as some behaviors may arise from feelings of isolation, insecurity, loss of autonomy and overall restlessness. Keep communication simple, supportive and positive. Be aware of the resident’s verbal and nonverbal cues and observe your own. Most importantly, create a care plan for interventions, and train your staff to attempt the intervention and document results.
The cannabis plant is one of the most pharmacologically active plants. It contains close to 500 active chemicals called cannabinoids, flavonoids and terpenoids. Cannabis has at least 100 different cannabinoids, the two most well-known being THC (tetrahydrocannabinol) and CBD (cannabidiol). The basic difference is THC is psychoactive and CBD is not. Both the flowers, known as buds, and the leaves of the plant are cured into what is known as marijuana. Cannabis has been cultivated to have larger buds and higher concentrations of psychoactive compounds. Hemp contains CBD and only trace amounts of THC. Used industrially, hemp fiber is used in making products such as clothing, paper and rope, and has not been bred to have higher concentrations of psychoactive compounds such as THC.

Cannabinoids work with our endocannabinoid system, which is an internal harm reduction system. This system is essential for vital functions including sleep, immunity, appetite, and pain sensation. THC works directly with receptors in the endocannabinoid system. CBD works indirectly with these receptors and also inhibits enzymes which break down naturally occurring endocannabinoids. Two of these cannabinoid receptors are CB1 and CB2. CB1 receptors are found in the areas of the brain dealing with mood, memory, sleep, pain sensation and appetite while CB2 receptors are mostly found in the immune system and are responsible for anti-inflammatory effects.

THC stimulates cells to release dopamine and activate cannabinoid receptors. Within 10 to 30 minutes, the patient will be in a relaxed state and their eyes may dilate. Then, they may experience a mix of emotions such as happiness, elation, anxiety, and pain relief. However, THC may also change their thought processes, memory, and time perception and even cause hallucinations or delusions. CBD does not directly stimulate the CB1 and CB2 receptors, but activates a wide range of other receptors including vanilloid, adenosine and serotonin receptors which is evidenced through CBDs anti-anxiety and anti-inflammatory effects. CBD also inhibits the FAAH enzyme, which prevents activation of the CB1 receptor, and is what minimizes the psychoactive effects of THC. Therefore THC used in conjunction with CBD helps dampen the psychoactivity and reduce side effects that are medically undesirable. Effects of THC include euphoria, relaxation, appetite stimulation, drowsiness and analgesia. CBD has potential neuroprotective, anti-convulsant, anti-psychotic, anti-oxidant, anti-emetic, anti-inflammatory and anti-tumoral benefits. THC can act as a sleep aid while CBD may have the opposite effect.

The cannabis plant may be beneficial in treating many different ailments because of its potential effectiveness in treating inflammation and pain. Some diseases that may be treated with cannabis include psychiatric disorders, epilepsy, Huntington’s disease, insomnia, Parkinson’s disease, lupus, arthritis, IBS, Crohn’s disease, nausea, PTSD and multiple sclerosis.

Although some states have made THC legal, both THC and CBD are still classified as a Schedule 1 drug therefore, they are both illegal under federal law.

There are no FDA-approved indications for cannabis; therefore it cannot be dispensed by your pharmacy. Possession of cannabis on the premises of your facility may pose a legal risk.
Preparation of SHINGRIX should be conducted by a trained professional.

1. Draw up entire contents of the adjuvant suspension vial in a sterile syringe.
2. Slowly transfer entire contents of syringe into the vile containing the lyophilized component.
3. Shake vial gently to ensure proper mixing of the contents until completely dissolved.
4. Withdraw 0.5 mL from the vial containing reconstituted vaccine and administer intramuscularly.

Prior to reconstitution SHINGRIX should be stored in a refrigerator between 2°C - 8°C (35°F - 45°F), protected from light, and not frozen. After reconstitution, if not used immediately, the vial can be stored back in a refrigerator for up to 6 hours. If unused within 6 hours, vials must be discarded.

Patients receiving their first dose of SHINGRIX should be counseled on the importance of completing the 2-dose immunization series to complete the dosing schedule. Patients should be counseled on potential adverse effects. Common adverse effects (> 20%) seen are pain, redness, and swelling near the injection site which is consistent with intramuscular injections; myalgia, fatigue and headaches can be common as well. Of note, patients taking concomitant immunosuppressive therapies may have reduced effectiveness of SHINGRIX, and should consult a provider prior to vaccination. Concomitant administration of other vaccines has not been studied and is recommended that live vaccines should be avoided and dosed at an interval of at least two weeks.

For more information on SHINGRIX, contact your PharMerica Consultant Pharmacist.
In October 2016, CMS published major changes to the regulations for Long-Term Care Facilities. This represented the first major revision to the regulations since the 1990s. These revisions to the Code of Federal Regulation for Long Term Care are of such magnitude that CMS has approached the changes gradually; using a phased in approach.

We will focus on Pharmacy related changes to F-Tag numbering. Keep in mind there are multiple changes in Phase II include sections on Resident Rights, Admission Discharge and Transfer, Comprehensive Person Centered Care, Nursing Services, Behavioral Health Services, Pharmacy, Dental, Food and Nutrition, Administration, Infection Control and Physical Environment.

The table below is a guide to the implementation requirements and highlights the changes to the F-Tag numbering system for pharmacy related areas. It is not a complete listing of all requirements for compliance with regulations. For complete information, please refer to the current CMS publications. PharMerica has already modified our current policy and procedures to reflect medication related regulatory changes.

Our consultants will 1) review each medication regimen and medical chart of each resident at least monthly and 2) during our monthly review will be focusing on all Psychotropic PRN orders to ensure the rationale and duration are indicated on the orders. A Daily Psychotropic report is available on ViewMasteRx that is designed to identify new starts that have the 14 day requirement.

### Pharmacy Specific F-Tags

<table>
<thead>
<tr>
<th>New F-Tag</th>
<th>Replaces</th>
<th>Changes</th>
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<tbody>
<tr>
<td>F 755</td>
<td>Combines F425, F431</td>
<td>• Focus on Controlled substance accountability; to immediately identify a loss or diversion&lt;br&gt;• Delivery <strong>and Receipt</strong> of Medication&lt;br&gt;• Addresses “borrowing” of medications;</td>
</tr>
<tr>
<td>Pharmacy Services / Procedures / Pharmacist / Records</td>
<td>Establishes a system of records of receipt and disposition of all controlled drugs in sufficient detail to enable an accurate reconciliation; and&lt;br&gt;§483.45(b)(3) Determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled.</td>
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*continued on page 6*
Pharmacy Specific F-Tags

<table>
<thead>
<tr>
<th>New F-Tag</th>
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<th>Changes</th>
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</thead>
<tbody>
<tr>
<td>F756</td>
<td>Replaces F428</td>
<td>Establishes that:</td>
</tr>
<tr>
<td>§483.45(c) Drug Regimen Review.</td>
<td></td>
<td>• A complete medical record review done at least monthly</td>
</tr>
<tr>
<td>§483.45(c)(1) The drug regimen of each resident must be reviewed at least once a month by a licensed pharmacist.</td>
<td></td>
<td>• <strong>Any</strong> irregularities must be identified and communicated to the attending physician, who 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.</td>
</tr>
<tr>
<td>§483.45(c)(2) This review must include a review of the resident’s medical chart.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§483.45(c)(4) The pharmacist must report any irregularities to the attending physician, the facility’s medical director and director of nursing, and these reports must be acted upon.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>§483.45(c)(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.</td>
<td></td>
<td>• Policies and Procedures must be established for the medication 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.</td>
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</tbody>
</table>

F757

§483.45(d) Unnecessary Drugs—General.

Each resident’s drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used—

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

§483.45(d)(2) For excessive duration; or

§483.45(d)(3) Without adequate monitoring; or

§483.45(d)(4) Without adequate indications for its use; or §483.45(d)(5) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or §483.45(d)(6) Any combinations of the reasons stated in paragraphs (d)(1) through (5) of this section.

Unnecessary Drugs, this is essentially unchanged from F329

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Pharmacy Specific F-Tags

<table>
<thead>
<tr>
<th>New F-Tag</th>
<th>Replaces</th>
<th>Changes</th>
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<tbody>
<tr>
<td>F758</td>
<td></td>
<td>Unnecessary drugs, specific to Psychoactive Medications</td>
</tr>
</tbody>
</table>

F758

§483.45(c)(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

§483.45(e) Psychotropic Drugs. Based on a comprehensive assessment of a resident, the facility must ensure that:

§483.45(e)(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;

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

§483.45(e)(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

§483.45(e)(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.

§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.

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### Pharmacy Specific F-Tags

<table>
<thead>
<tr>
<th>New F-Tag</th>
<th>Replaces</th>
<th>Changes</th>
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<tbody>
<tr>
<td>F759</td>
<td>Replace F332 with F759 and Replace F333 with F760</td>
<td>Renumbered only, wording is unchanged</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F759</th>
<th>§483.45(f) Medication Errors. The facility must ensure that its— §483.45(f)(1) Medication error rates are not 5 percent or greater; and</th>
</tr>
</thead>
<tbody>
<tr>
<td>F760</td>
<td>The facility must ensure that its— §483.45(f)(2) Residents are free of any significant medication errors.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>F761</th>
<th>Replaces F431</th>
<th>The facility, in coordination with the licensed pharmacist, provides for:</th>
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</thead>
<tbody>
<tr>
<td>§483.45(g) Labeling of Drugs and Biologicals</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>§483.45(h) Storage of Drugs and Biologicals</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>§483.45(h)(2)</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>F761 (cont.)</td>
<td>The Facility is required to secure all medications in a locked storage area and to limit access to authorized personnel (for example, pharmacy technicians or assistants who have been delegated access to medications by the facility's pharmacist as a function of their jobs) consistent with state or federal requirements and professional standards of practice.</td>
<td></td>
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</table>

| F761 (cont.) | The Facility is required to secure all medications in a locked storage area and to limit access to authorized personnel (for example, pharmacy technicians or assistants who have been delegated access to medications by the facility's pharmacist as a function of their jobs) consistent with state or federal requirements and professional standards of practice. |

*continued on page 9*
Multi-Dose Vials:
- Facility staff should date the label of any multi-use vial when the vial is first accessed and access the vial in a dedicated medication preparation area:
- If a multi-dose vial has been opened or accessed (e.g., needle-punctured), the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.

Other Revisions of Note:
1. In addition to other changes CMS has addressed crushing oral medications – In the recent revision (Revision 11-22-2017) to the State Operations Manual it states:
   “To address concerns with physical and chemical incompatibility and complete dosaging, best practice would be to separately crush each medication and separately administer each medication with food. However, separating crushed medications may not be appropriate for all residents and is generally not counted as a medication error unless there are instructions not to crush the medication(s). Facilities should use a person-centered, individualized approach to administering all medications. If a surveyor identifies concerns related to crushing and combining oral medications, the surveyor should evaluate whether facility staff have worked with the resident/representative and appropriate clinicians (e.g., the consultant pharmacist, attending physician, medical director) to determine the most appropriate method for administering crushed medications which considers each resident’s safety, needs, medication schedule, preferences, and functional ability.”

2. Medication administration time may need modified for residents undergoing dialysis. The attending practitioner and nephrologist determine which medications are to be administered during dialysis, which are to be held prior to dialysis, whether any specific medications are to be given prior to dialysis and any medications (such as antibiotics or ESA’s) that are to be given by dialysis staff. All such medication administration must be coordinated, communicated and documented between dialysis staff, nursing home staff, and practitioners. (For issues related to medications and or pharmacy review, refer to F757 Unnecessary Medications, and/or F755 Pharmacy Services and/or F756 Drug Regimen Review.)


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The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements: §483.80(a)(3) An antibiotic stewardship program that includes antibiotic use protocols and a system to monitor antibiotic use.

The intent of this regulation is to ensure that the facility:

- Develops and implements protocols to optimize the treatment of infections by ensuring that residents who require an antibiotic, are prescribed the appropriate antibiotic;
- Reduces the risk of adverse events, including the development of antibiotic-resistant organisms, from unnecessary or inappropriate antibiotic use; and
- Develops, promotes, and implements a facility-wide system to monitor the use of antibiotics.

PharMerica has established a model facility Antibiotic Stewardship Program designed for easy adoption and implementation. Information on this program is available from the account manager or consultant pharmacist. We have the ability to complete reviews of antibiotic orders through the iMRR process, in addition to the prospective review process used by the consultant pharmacist.

There are additional resources available through Centers for Disease Control (CDC) to determine if the facility’s program compliance with the current regulations. This can be accessed through the CDC website, https://www.cdc.gov/getsmart/healthcare/implementation/checklist.html

Please refer to the full text document (appendix PP, State Operations Manual) for full interpretation of the changes to the regulations.

Antibiotic Stewardship Facility Program

PharMerica’s Model Antibiotic Stewardship Facility Program will help keep you compliant with new CMS requirements. Contact your Account Manager or Consultant Pharmacist for more details.