

SECTION N: MEDICATIONS

Intent: The intent of the items in this section is to record the number of days, during the last 7 days (or since admission/entry or reentry if less than 7 days) that any type of injection, insulin, and/or select medications were received by the resident.

In addition, *two medication sections have been added. The first is* an Antipsychotic Medication Review. Including this information will assist facilities to evaluate the use and management of these medications. Each aspect of antipsychotic medication use and management has important associations with the quality of life and quality of care of residents receiving these medications. *The second is a series of data elements addressing Drug Regimen Review. These data elements document whether a drug regimen review was conducted upon the start of a SNF PPS stay through the end of the SNF PPS stay and whether any clinically significant medication issues identified were addressed in a timely manner.*

N0300: Injections

N0300. Injections

Enter Days

Record the number of days that injections of any type were received during the last 7 days or since admission/entry or reentry if less than 7 days. If 0 → Skip to N0415, High-Risk Drug Classes: Use and Indication

Item Rationale

Health-related Quality of Life

- Frequency of administration of medication via injection can be an indication of stability of a resident's health status and/or complexity of care needs.

Planning for Care

- Monitor for adverse effects of injected medications.
- Although antigens and vaccines are not considered to be medications per se, it is important to track when they are given to monitor for localized or systemic reactions.

Steps for Assessment

1. Review the resident's medication administration records for the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
2. Review documentation from other health care locations where the resident may have received injections while a resident of the nursing home (e.g., flu vaccine in a physician's office, in the emergency room – as long as the resident was not admitted).
3. Determine if any medications were received by the resident via injection. If received, determine the number of days during the look-back period they were received.

N0300: Injections (cont.)

Coding Instructions

Record the number of days during the 7-day look-back period (or since admission/entry or reentry if less than 7 days) that the resident received any type of medication, antigen, vaccine, etc., by injection.

*Insulin injections **are** counted in this item as well as in Item N0350.*

- Count the number of days that **the resident received any type of injection while a resident of the nursing home.**
- Record the number of days that any type of injection (e.g., subcutaneous, intramuscular, or intradermal) was received in Item N0300.

Coding Tips and Special Populations

- For subcutaneous pumps, code only the number of days that the resident actually required a subcutaneous injection to restart the pump.
- If an antigen or vaccination is provided on one day, and another vaccine is provided on the next day, the number of days the resident received injections would be **coded as 2 days.**
- If two injections were administered on the same day, the number of days the resident received injections would be **coded as 1 day.**

Examples

1. During the 7-day look-back period, *Resident* T received an influenza shot on Monday, a PPD test (for tuberculosis) on Tuesday, and a Vitamin B₁₂ injection on Wednesday.

Coding: N0300 would be **coded 3.**

Rationale: The resident received injections on 3 separate days during the 7-day look-back period.

2. During the 7-day look-back period, *Resident* C received both an influenza shot and *their* vitamin B₁₂ injection on Thursday.

Coding: N0300 would be **coded 1.**

Rationale: The resident received injections on one day during the 7-day look-back period.

N0350: Insulin

N0350. Insulin

Enter Days

A. Insulin injections - Record the number of days that insulin injections were received during the last 7 days or since admission/entry or reentry if less than 7 days

Enter Days

B. Orders for insulin - Record the number of days the physician (or authorized assistant or practitioner) changed the resident's insulin orders during the last 7 days or since admission/entry or reentry if less than 7 days

Item Rationale

Health-related Quality of Life

- Insulin is a medication used to treat diabetes mellitus (DM).
- Individualized meal plans should be created with the resident's input to ensure appropriate meal intake. Residents are more likely to be compliant with their DM diet if they have input related to food choices.

Planning for Care

- Orders for insulin may have to change depending on the resident's condition (e.g., fever or other illness) and/or laboratory results.
- Ensure that dosage and time of injections take into account meals, activity, etc., based on individualized resident assessment.
- Monitor for adverse effects of insulin injections (e.g., hypoglycemia).
- Monitor HbA1c and blood glucose levels to ensure appropriate amounts of insulin are being administered.

Steps for Assessment

1. Review the resident's medication administration records for the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
2. Determine if the resident received insulin injections during the look-back period.
3. Determine if the physician (or nurse practitioner, physician assistant, or clinical nurse specialist if allowable under state licensure laws) changed the resident's insulin orders during the look-back period.
4. Count the number of days insulin injections were received and/or insulin orders changed.

Coding Instructions for N0350A

- Enter in Item N0350A, the number of days during the 7-day look-back period (or since admission/entry or reentry if less than 7 days) that insulin injections were received.

Coding Instructions for N0350B

- Enter in Item N0350B, the number of days during the 7-day look-back period (or since admission/entry or reentry if less than 7 days) that the physician (nurse practitioner, physician assistant, or clinical nurse specialist **if allowable under state licensure laws**) changed the resident's insulin orders.

N0350: Insulin (cont.)

Coding Tips and Special Populations

- For sliding scale orders:
 - A sliding scale dosage schedule that is written to cover different dosages depending on lab values **does not** count as an order change simply because a different dose is administered based on the sliding scale guidelines.
 - If the sliding scale order is new, discontinued, or is the first sliding scale order for the resident, these days **can** be counted and coded.
- For subcutaneous insulin pumps, code only the number of days that the resident actually required a subcutaneous injection to restart the pump.

N0415: High-Risk Drug Classes: Use and Indication

N0415. High-Risk Drug Classes: Use and Indication

1. **Is taking**

Check if the resident is taking any medications by pharmacological classification, not how it is used, during the last 7 days or since admission/entry or reentry if less than 7 days

2. **Indication noted**

If Column 1 is checked, check if there is an indication noted for all medications in the drug class

	1. Is taking	2. Indication noted
	↓ Check all that apply ↓	
A. Antipsychotic	<input type="checkbox"/>	<input type="checkbox"/>
B. Antianxiety	<input type="checkbox"/>	<input type="checkbox"/>
C. Antidepressant	<input type="checkbox"/>	<input type="checkbox"/>
D. Hypnotic	<input type="checkbox"/>	<input type="checkbox"/>
E. Anticoagulant (e.g., warfarin, heparin, or low-molecular weight heparin)	<input type="checkbox"/>	<input type="checkbox"/>
F. Antibiotic	<input type="checkbox"/>	<input type="checkbox"/>
G. Diuretic	<input type="checkbox"/>	<input type="checkbox"/>
H. Opioid	<input type="checkbox"/>	<input type="checkbox"/>
I. Antiplatelet	<input type="checkbox"/>	<input type="checkbox"/>
J. Hypoglycemic (including insulin)	<input type="checkbox"/>	<input type="checkbox"/>
Z. None of the above	<input type="checkbox"/>	

N0415: High-Risk Drug Classes: Use and Indication (cont.)**Item Rationale****Health-related Quality of Life**

- Medications are an integral part of the care provided to residents of nursing homes. They are administered to try to achieve various outcomes, such as curing an illness, diagnosing a disease or condition, arresting or slowing a disease's progress, reducing or eliminating symptoms, or preventing a disease or symptom.
- Residents taking medications in these medication categories and pharmacologic classes are at risk of side effects that can adversely affect health, safety, and quality of life.
- While assuring that only those medications required to treat the resident's assessed condition are being used, it is important to assess the need to reduce these medications wherever possible and ensure that the medication is the most effective for the resident's assessed condition.
- As part of all medication management, it is important for the interdisciplinary team to consider non-pharmacological approaches. Educating the nursing home staff and providers about non-pharmacological approaches in addition to and/or in conjunction with the use of medication may minimize the need for medications or reduce the dose and duration of those medications.

DEFINITIONS**ADVERSE
CONSEQUENCE**

An unpleasant symptom or event that is caused by or associated with a medication, impairment or decline in an individual's physical condition, mental, functional or psychosocial status. It may include various types of adverse drug reactions (ADR) and interactions (e.g., medication-medication, medication-food, and medication-disease).

**NON-
PHARMACOLOGICAL
INTERVENTION**

Approaches that do not involve the use of medication to address a medical condition.

N0415: High-Risk Drug Classes: Use and Indication (cont.)

Planning for Care

- The indications for initiating, withdrawing, or withholding medication(s), as well as the use of non-pharmacological interventions, are determined by assessing the resident's underlying condition, current signs and symptoms, and preferences and goals for treatment. This includes, where possible, the identification of the underlying cause(s), since a diagnosis alone may not warrant treatment with medication.
- Target symptoms and goals for use of these medications should be established for each resident. Progress toward meeting the goals should be evaluated routinely.
- Possible adverse effects of these medications should be well understood by nursing staff. Educate nursing home staff to be observant for these adverse effects.
- Implement systematic monitoring of each resident taking any of these medications to identify adverse consequences early.

Steps for Assessment

1. Review the resident's medical record for documentation that any of these medications were received by the resident *and for the indication of their use* during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
2. Review documentation from other health care settings where the resident may have received any of these medications while a resident of the nursing home (e.g., valium given in the emergency room).

Coding Instructions

- Code *all high-risk drug class* medications according to their pharmacological classification, not how they are being used.
 - **Column 1:** *Check if the resident is taking any medications by pharmacological classification during the 7-day observation period (or since admission/entry or reentry if less than 7 days).*
 - **Column 2:** *If Column 1 is checked, check if there is an indication noted for all medications in the drug class.*

DEFINITIONS

INDICATION

The identified, documented clinical rationale for administering a medication that is based upon a physician's (or prescriber's) assessment of the resident's condition and therapeutic goals.

DOSE

The total amount/strength/concentration of a medication given at one time or over a period of time. The individual dose is the amount/strength/concentration received at each administration. The amount received over a 24-hour period may be referred to as the "daily dose."

MONITORING

The ongoing collection and analysis of information (such as observations and diagnostic test results) and comparison to baseline and current data in order to ascertain the individual's response to treatment and care, including progress or lack of progress toward a goal. Monitoring can detect any improvements, complications, or adverse consequences of the condition or the treatments and support decisions about adding, modifying, continuing, or discontinuing any interventions.

N0415: High-Risk Drug Classes: Use and Indication (cont.)

- **N0415A 1. Antipsychotic:** *Check if* an antipsychotic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415A2. Antipsychotic:** *Check if there is an indication noted for all antipsychotic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415B 1. Antianxiety:** *Check if* an anxiolytic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415B2. Antianxiety:** *Check if there is an indication noted for all anxiolytic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415C 1. Antidepressant:** *Check if* an antidepressant medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415C2. Antidepressant:** *Check if there is an indication noted for all antidepressant medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415D 1. Hypnotic:** *Check if* a hypnotic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415D2. Hypnotic:** *Check if there is an indication noted for all hypnotic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415E 1. Anticoagulant (e.g., warfarin, heparin, or low-molecular weight heparin):** *Check if* an anticoagulant medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415E2. Anticoagulant:** *Check if there is an indication noted for all anticoagulant medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415F 1. Antibiotic:** *Check if* an antibiotic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415F2. Antibiotic:** *Check if there is an indication noted for all antibiotic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).*
- **N0415G 1. Diuretic:** *Check if* a diuretic medication was **taken** by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).

N0415: High-Risk Drug Classes: Use and Indication (cont.)

- **N0415G2. Diuretic:** Check if there is an indication noted for all diuretic medications received by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).
- **N0415H1. Opioid:** Check if an opioid medication was *taken* by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- **N0415H2. Opioid:** Check if there is an indication noted for all opioid medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).
- **N0415I1. Antiplatelet:** Check if an antiplatelet medication (e.g., aspirin/extended release, dipyridamole, clopidogrel) was taken by the resident at any time during the 7-day observation period (or since admission/entry or reentry if less than 7 days).
- **N0415I2. Antiplatelet:** Check if there is an indication noted for all antiplatelet medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).
- **N0415J1. Hypoglycemic (including insulin):** Check if a hypoglycemic medication was taken by the resident at any time during the 7-day observation period (or since admission/entry or reentry if less than 7 days).
- **N0415J2. Hypoglycemic (including insulin):** Check if there is an indication noted for all hypoglycemic medications taken by the resident any time during the observation period (or since admission/entry or reentry if less than 7 days).
- **N0415Z1. None of the above:** Check if none of the medications above were taken by the resident at any time during the observation period (or since admission/entry or reentry if less than 7 days).

Coding Tips and Special Populations

- Code medications in Item N0415 according to the medication's therapeutic category and/or pharmacological classification, not how it is used. For example, although oxazepam may be prescribed for use as a hypnotic, it is categorized as an antianxiety medication. Therefore, in this section, it would be coded as an antianxiety medication and not as a hypnotic.
- Medications that have more than one therapeutic category and/or pharmacological classification should be coded in **all** categories/classifications assigned to the medication, regardless of how it is being used. For example, prochlorperazine is dually classified as an antipsychotic and an antiemetic. Therefore, in this section, it would be coded as an antipsychotic, regardless of how it is used.
- Include any of these medications given to the resident by any route in any setting (e.g., at the nursing home, in a hospital emergency room) while a resident of the nursing home.
- *Do not code antiplatelet medications such as aspirin/extended release, dipyridamole, or clopidogrel as N0415E, Anticoagulant.*

N0415: High-Risk Drug Classes: Use and Indication (cont.)

- *Anticoagulants such as Target Specific Oral Anticoagulants (TSOACs), which may or may not require laboratory monitoring, should be coded in N0415E, Anticoagulant.*
- *Do not code flushes to keep an IV access port patent.*
- Code a medication even if it was given only once during the look-back period.
- Count long-acting medications, such as fluphenazine decanoate or haloperidol decanoate, that are given every few weeks or monthly **only** if they are given during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
- *Transdermal patches are generally worn for and release medication over a period of several days. To code N0415, only capture the medication if the transdermal patch was applied to the resident's skin during the observation period.* For example, if, during the 7-day look-back period, a fentanyl patch was applied on days 1, 4, and 7, N0415H Opioid would be *checked*, because the application occurred during the look-back period.
- Combination medications should be coded in all categories/pharmacologic classes that constitute the combination. For example, if the resident receives a single tablet that combines an antipsychotic and an antidepressant, then **both** antipsychotic and antidepressant categories should be coded.
- Over-the-counter sleeping medications are not coded as hypnotics, as they are not categorized as hypnotic medications.
- In circumstances where reference materials vary in identifying a medication's therapeutic category and/or pharmacological classification, consult the resources/links cited in this section or consult the medication package insert, which is available through the facility's pharmacy or the manufacturer's website. *If necessary, request input from the consulting pharmacist.*
- *Herbal and alternative medicine products are considered to be dietary supplements by the Food and Drug Administration (FDA). These products are not regulated by the FDA (e.g., they are not reviewed for safety and effectiveness like medications) and their composition is not standardized (e.g., the composition varies among manufacturers). Therefore, they should not be counted as medications (e.g., melatonin, chamomile, valerian root). Keep in mind that, for clinical purposes, it is important to document a resident's intake of such herbal and alternative medicine products elsewhere in the medical record and to monitor their potential effects as they can interact with medications the resident is currently taking. For more information consult the FDA website <http://www.fda.gov/food/dietarysupplements/usingdietarysupplements/>.*
- *Opioid medications can be an effective intervention in a resident's pain management plan, but also carry risks such as overuse and constipation. A thorough assessment and root-cause analysis of the resident's pain should be conducted prior to initiation of an opioid medication and re-evaluation of the resident's pain, side effects, and medication use and plan should be ongoing.*
- *Residents who are on antidepressants should be closely monitored for worsening of depression and/or suicidal ideation/behavior, especially during initiation or change of dosage in therapy. Stopping antidepressants abruptly puts one at higher risk of suicidal ideation and behavior.*

N0415: High-Risk Drug Classes: Use and Indication (cont.)

- When residents are having difficulty sleeping, nursing home staff should explore non-pharmacological interventions (e.g., sleep hygiene approaches that individualize the sleep and wake times to accommodate the person's wishes and prior customary routine) to try to improve sleep prior to initiating pharmacologic interventions. If residents are currently on sleep-enhancing medications, nursing home staff can try non-pharmacologic interventions to help reduce the need for these medications or eliminate them.
- Many psychoactive medications increase confusion, sedation, and falls. For those residents who are already at risk for these conditions, nursing home staff should develop plans of care that address these risks.
- Doses of psychoactive medications differ in acute and long-term treatment. Doses should always be the lowest possible to achieve the desired therapeutic effects and be deemed necessary to maintain or improve the resident's function, well-being, safety, and quality of life. Duration of treatment should also be in accordance with pertinent literature, including clinical practice guidelines.
- Since medication issues continue to evolve and new medications are being approved regularly, it is important to refer to a current authoritative source for detailed medication information, such as indications and precautions, dosage, monitoring, or adverse consequences.
- Anticoagulants must be monitored with dosage frequency determined by clinical circumstances and duration of use. Certain anticoagulants require monitoring via laboratory results (e.g., Prothrombin Time [PT]/International Normalization Ratio [INR]).
 - Multiple medication interactions exist with use of anticoagulants (information on common medication-medication interactions can be found in the **State Operations Manual, Appendix PP, Guidance to Surveyors for Long Term Care Facilities** [the **State Operations Manual** can be found at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html>]), which may
 - significantly increase PT/INR results to levels associated with life-threatening bleeding, or
 - decrease PT/INR results to ineffective levels, or increase or decrease the serum concentration of the interacting medication.

DEFINITION**SLEEP HYGIENE**

Practices, habits and environmental factors that promote and/or improve sleep patterns.

DEFINITION**MEDICATION INTERACTION**

The impact of medication or other substance (such as nutritional supplements including herbal products, food, or substances used in diagnostic studies) upon another medication. The interactions may alter absorption, distribution, metabolism, or elimination. These interactions may decrease the effectiveness of the medication or increase the potential for adverse consequences.

N0415: High-Risk Drug Classes: Use and Indication (cont.)

Example

1. The Medication Administration Record for *Resident P* reflects the following *during the 7-day observation period*:

- Risperidone 0.5 mg PO BID PRN: Received once a day on Monday, Wednesday, and Thursday *for bipolar disorder*.
- Lorazepam 1 mg PO QAM: Received every day *for bipolar disorder*.
- Temazepam 15 mg PO QHS PRN: Received at bedtime on Tuesday and Wednesday only.

Coding: Medications in N0415, would be coded as follows: **N0415A1 and N0415A2. Antipsychotic = checked;** risperidone is an antipsychotic medication *and indication of use for bipolar disorder noted*. **N0415B1 and N0415B2. Antianxiety = checked;** lorazepam is an antianxiety medication *and indication of use for bipolar disorder noted*. **N0415D1. Hypnotic = checked;** temazepam is a hypnotic medication. **N0415D2. Hypnotic = not checked;** *indication for use of temazepam was not noted*.

Please note: if a resident is receiving medications in all three *of these high-risk drug classes* simultaneously there must be a clear clinical indication for the use of these medications. Administration of these types of medications, particularly in this combination, could be interpreted as chemically restraining the resident. Adequate documentation is essential in justifying their use.

Additional information on psychoactive medications can be found in the **Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)** (or subsequent editions) (<https://www.psychiatry.org/psychiatrists/practice/dsm>), and the **State Operations Manual, Appendix PP, Guidance to Surveyors for Long Term Care Facilities** [the **State Operations Manual** can be found at (<https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html>)].

The following resources and tools provide information on medications including classifications, warnings, appropriate dosing, drug interactions, and medication safety information.

- GlobalRPh Drug Reference, <http://globalrph.com/drug-A.htm>
- USP Pharmacological Classification of Drugs, <http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines/medicare-model-guidelines-v50-v40#Guidelines6>. *Directions:* Scroll to the bottom of this webpage and click on the pdf download for “USP Medicare Model Guidelines (With Example Part D Drugs)”
- Medline Plus, <https://www.nlm.nih.gov/medlineplus/druginformation.html>

N0415: High-Risk Drug Classes: Use and Indication (cont.)

The above resource list is not all-inclusive, and use of these resources is not required for MDS completion. The resources are being provided as a convenience, for informational purposes only, and CMS is not responsible for their accessibility, content, or accuracy. Providers are responsible for coding each medication's pharmacological/therapeutic classification accurately. Caution should be exercised when using lists of medication categories, and providers should always refer to the details concerning each medication when determining its medication classification.

NOTE: References to non-CMS sources do not constitute or imply endorsement of these organizations or their programs by CMS or the U.S. Department of Health and Human Services and were current as of the date of this publication.

N0450: Antipsychotic Medication Review

N0450. Antipsychotic Medication Review

Enter Code

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A. Did the resident receive antipsychotic medications since admission/entry or reentry or the prior OBRA assessment, whichever is more recent?

0. **No** - Antipsychotics were not received → Skip N0450B, N0450C, N0450D, and N0450E
1. **Yes** - Antipsychotics were received on a routine basis only → Continue to N0450B, Has a GDR been attempted?
2. **Yes** - Antipsychotics were received on a PRN basis only → Continue to N0450B, Has a GDR been attempted?
3. **Yes** - Antipsychotics were received on a routine and PRN basis → Continue to N0450B, Has a GDR been attempted?

Enter Code

☐

B. Has a gradual dose reduction (GDR) been attempted?

0. **No** → Skip to N0450D, Physician documented GDR as clinically contraindicated
1. **Yes** → Continue to N0450C, Date of last attempted GDR

C. Date of last attempted GDR:

<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month			Day			Year			

Enter Code

☐

D. Physician documented GDR as clinically contraindicated

0. **No** - GDR has not been documented by a physician as clinically contraindicated → Skip N0450E, Date physician documented GDR as clinically contraindicated
1. **Yes** - GDR has been documented by a physician as clinically contraindicated → Continue to N0450E, Date physician documented GDR as clinically contraindicated

E. Date physician documented GDR as clinically contraindicated:

<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	-	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month			Day			Year			

N0450: Antipsychotic Medication Review (cont.)

Item Rationale

Health-related Quality of Life

- The use of unnecessary medications in long term care settings can have a profound effect on the resident's quality of life.
- Antipsychotic medications are associated with increased risks for adverse outcomes that can affect health, safety, and quality of life.
- In addition to assuring that antipsychotic medications are being utilized to treat the resident's condition, it is also important to assess the need to reduce these medications whenever possible.

Planning for Care

- Identify residents receiving antipsychotic medications to ensure that each resident is receiving the lowest possible dose to achieve the desired therapeutic effects.
- Monitor for appropriate clinical indications for continued use.
- Implement a system to ensure gradual dose reductions (GDR) are attempted at recommended intervals unless clinically contraindicated.

Steps for Assessment

1. Review the resident's medication administration records to determine if the resident received an antipsychotic medication since admission/entry or reentry or the prior OBRA assessment, whichever is more recent.
2. If the resident received an antipsychotic medication, review the medical record to determine if a gradual dose reduction has been attempted.
3. If a gradual dose reduction was not attempted, review the medical record to determine if there is physician documentation that the GDR is clinically contraindicated.

Coding Instructions for N0450A

- **Code 0, no:** if antipsychotics were not received: Skip N0450B, N0450C, N0450D and N0450E.
- **Code 1, yes:** if antipsychotics were received on a routine basis only: Continue to N0450B, Has a GDR been attempted?
- **Code 2, yes:** if antipsychotics were received on a PRN basis only: Continue to N0450B, Has a GDR been attempted?
- **Code 3, yes:** if antipsychotics were received on a routine and PRN basis: Continue to N0450B, Has a GDR been attempted?

N0450: Antipsychotic Medication Review (cont.)

Coding Tips and Special Populations

- Any medication that has a pharmacological classification or therapeutic category of antipsychotic medication must be recorded in this section, regardless of why the medication is being used.

Coding Instructions for N0450B

- Code 0, no:** if a GDR has not been attempted. Skip to N0450D, Physician documented GDR as clinically contraindicated.
- Code 1, yes:** if a GDR has been attempted. Continue to N0450C, Date of last attempted GDR.

Coding Instructions for N0450C

- Enter the date of the last attempted Gradual Dose Reduction.

Coding Tips and Special Populations (N0450B and N0450C)

- Within the first year in which a resident is admitted on an antipsychotic medication or after the facility has initiated an antipsychotic medication, the facility must attempt a GDR in two separate quarters (with at least one month between the attempts), unless physician documentation is present in the medical record indicating that a GDR is clinically contraindicated. After the first year, a GDR must be attempted at least annually, unless clinically contraindicated. *Information on GDR and tapering of medications can be found in the State Operations Manual, Appendix PP, Guidance to Surveyors for Long Term Care Facilities* (see F758). *The State Operations Manual can be found at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984>.*
- In N0450B and N0450C, include GDR attempts conducted since the resident was admitted to the facility, if the resident was receiving an antipsychotic medication at the time of admission, **OR** since the resident was started on the antipsychotic medication, if the medication was started after the resident was admitted.
- Do not include gradual dose reductions that occurred prior to admission to the facility (e.g., GDRs attempted during the resident's acute care stay prior to admission to the facility).
- If the resident was admitted to the facility with a documented GDR attempt in progress and the resident received the last dose(s) of the antipsychotic medication of the GDR in the facility, then the GDR would be coded in N0450B and N0450C.
- If the resident received a dose or doses of an antipsychotic medication that was not part of a documented GDR attempt, such as if the resident received a dose or doses of the medication PRN or one or two doses were ordered for the resident for a specific day or procedure, these are not coded as a GDR attempt in N0450B and N0450C.

N0450: Antipsychotic Medication Review (cont.)

- Prior to discontinuing a psychoactive medication, residents may need a GDR or tapering to avoid withdrawal syndrome (e.g., for medications such as selective serotonin reuptake inhibitors [SSRIs], tricyclic antidepressants [TCAs], etc.).*
- Discontinuation of an antipsychotic medication, even without a GDR process, should be coded in N0450B and N0450C as a GDR, as the medication was discontinued. When an antipsychotic medication is discontinued without a gradual dose reduction, the date of the GDR in N0450C is the first day the resident did not receive the discontinued antipsychotic medication.
- Do not count as a GDR an antipsychotic medication reduction performed for the purpose of switching the resident from one antipsychotic medication to another.
- The start date of the last attempted GDR should be entered in N0450C, Date of last attempted GDR. The GDR start date is the first day the resident received the reduced dose of the antipsychotic medication.
- In cases in which a resident is or was receiving multiple antipsychotic medications on a routine basis and one medication was reduced or discontinued, record the date of the reduction attempt or discontinuation in N0450C.
- If multiple dose reductions have been attempted since admission OR since initiation of the antipsychotic medication, record the date of the most recent reduction attempt in N0450C.
- Federal requirements regarding GDRs are found at 42 CFR 483.45(d) Unnecessary drugs and 483.45(e) Psychotropic drugs.

DEFINITION**GRADUAL DOSE
REDUCTION (GDR)**

Step-wise tapering of a dose to determine whether or not symptoms, conditions, or risks can be managed by a lower dose or whether or not the dose or medication can be discontinued.

N0450: Antipsychotic Medication Review (cont.)

Coding Instructions for N0450D

- **Code 0, no:** if a GDR has not been documented by a physician as clinically contraindicated. Skip N0450E Date physician documented GDR as clinically contraindicated.
- **Code 1, yes:** if a GDR has been documented by a physician as clinically contraindicated. Continue to N0450E, Date physician documented GDR as clinically contraindicated.

Coding Instructions for N0450E

- Enter date the physician documented GDR attempts as clinically contraindicated.

Coding Tips and Special Populations (N0450D and N0450E)

- In this section, the term physician also includes physician assistant, nurse practitioner, or clinical nurse specialist.
- In N0450D and N0450E, include physician documentation that a GDR attempt is clinically contraindicated since the resident was admitted to the facility, if the resident was receiving an antipsychotic medication at the time of admission, **OR** since the resident was started on the antipsychotic medication, if the medication was started after the resident was admitted to the facility.
- Physician documentation indicating dose reduction attempts are clinically contraindicated must include the clinical rationale for why an attempted dose reduction is inadvisable. This decision should be based on the fact that tapering of the medication would not achieve the desired therapeutic effects and the current dose is necessary to maintain or improve the resident's function, well-being, safety, and quality of life.

N2001: Drug Regimen Review

Complete only if A0310B = 01.

N2001. Drug Regimen Review - Complete only if A0310B = 01

Enter Code

☐

Did a complete drug regimen review identify potential clinically significant medication issues?

- 0. **No** - No issues found during review
- 1. **Yes** - Issues found during review
- 9. **NA** - Resident is not taking any medications

Item Rationale

Health-related Quality of Life

- Potential and actual resident medication adverse consequences and errors are prevalent in health care settings and often occur during transitions in care.
- Adverse consequences related to medications may result in serious harm or death, emergency department visits, and rehospitalizations and affect the resident's health, safety, and quality of life.
- Drug regimen review is intended to improve resident safety by identifying and addressing potential and actual clinically significant medication issues at the time of a resident's admission (start of SNF PPS stay) and throughout the resident's stay (through Part A PPS discharge).

Planning for Care

- Drug regimen review is an important component of the overall management and monitoring of a resident's medication regimen.
- Prevention and timely identification of potential and actual medication-related adverse consequences reduces the resident's risk for harm and improves quality of life.
- Educate staff in proper medication administration techniques and adverse effects of medications, as well as to be observant for these adverse effects.
- Implement a system to ensure that each resident's medication usage is evaluated upon admission and on an ongoing basis and that risks and problems are identified and acted upon.

DEFINITION

DRUG REGIMEN REVIEW

A drug regimen review includes medication reconciliation, a review of all medications a resident is currently using, and a review of the drug regimen to identify, and if possible, prevent potential clinically significant medication adverse consequences. The drug regimen review includes all medications, prescribed and over the counter (OTC), nutritional supplements, vitamins, and homeopathic and herbal products, administered by any route. It also includes total parenteral nutrition (TPN) and oxygen.

N2001: Drug Regimen Review (cont.)

Steps for Assessment

1. Complete a drug regimen review upon admission (start of SNF PPS stay) or as close to the actual time of admission as possible to identify any potential or actual clinically significant medication issues.
2. Review medical record documentation to determine whether a drug regimen review was conducted upon admission (start of SNF PPS stay), or as close to the actual time of admission as possible, to identify any potential or actual clinically significant medication issues.

Medical record sources include medical records received from facilities where the resident received health care, the resident's most recent history and physical, transfer documents, discharge summaries, medication lists/records, clinical progress notes, and other resources as available.

3. Discussions (including with the acute care hospital, other staff and clinicians responsible for completing the drug regimen review, the resident, and the resident's family/significant other) may supplement and/or clarify the information gleaned from the resident's medical records.
4. Clinically significant medication issues may include, but are not limited to:
 - Medication prescribed despite documented medication allergy or prior adverse reaction.
 - Excessive or inadequate dose.
 - Adverse reactions to medication.
 - Ineffective drug therapy.
 - Drug interactions (serious drug-drug, drug-food, and drug-disease interactions).
 - Duplicate therapy (for example, generic-name and brand-name equivalent drugs are *both* prescribed).
 - Wrong resident, drug, dose, route, and time errors.
 - Medication dose, frequency, route, or duration not consistent with resident's condition, manufacturer's instructions, or applicable standards of practice.
 - Use of a medication without evidence of adequate indication for use.
 - Presence of a medical condition that may warrant medication therapy (e.g., a resident with primary hypertension does not have an antihypertensive medication prescribed).
 - Omissions (medications missing from a prescribed regimen).
 - Nonadherence (purposeful or accidental).

N2001: Drug Regimen Review (cont.)

Coding Instructions

- **Code 0, No:** if no clinically significant medication issues were identified during the drug regimen review.
- **Code 1, Yes:** if one or more clinically significant medication issues were identified during the drug regimen review.
- **Code 9, NA:** if the resident was not taking any medications at the time of the drug regimen review.

Coding Tips

- A dash (–) value is a valid response for this item; however, CMS expects dash use to be a rare occurrence.
- The drug regimen review includes all medications, prescribed and over the counter (OTC), including nutritional supplements, vitamins, and homeopathic and herbal products, administered by any route. The drug regimen review also includes total parenteral nutrition (TPN) and oxygen.
- *Adverse drug reaction (ADR) is a form of adverse consequence. It may be either a secondary effect of a medication that is usually undesirable and different from the therapeutic effect of the medication or any response to a medication that is noxious and unintended and occurs in doses for prophylaxis, diagnosis, or treatment. The term “side effect” is often used interchangeably with ADR; however, side effects are but one of five ADR categories, the others being hypersensitivity, idiosyncratic response, toxic reactions, and adverse medication interactions. A side effect is an expected, well-known reaction that occurs with a predictable frequency and may or may not constitute an adverse consequence.*

DEFINITIONS

POTENTIAL OR ACTUAL CLINICALLY SIGNIFICANT MEDICATION ISSUE

A clinically significant medication issue is a potential or actual issue that, in the clinician's professional judgment, warrants physician (or physician-designee) communication and completion of prescribed/recommended actions by midnight of the next calendar day at the latest.

“Clinically significant” means effects, results, or consequences that materially affect or are likely to affect an individual's mental, physical, or psychosocial well-being, either positively, by preventing a condition or reducing a risk, or negatively, by exacerbating, causing, or contributing to a symptom, illness, or decline in status.

Any circumstance that does not require this immediate attention is not considered a potential or actual clinically significant medication issue for the purpose of the drug regimen review items.

N2001: Drug Regimen Review (cont.)

Examples

1. The admitting nurse reviewed and compared the acute care hospital discharge medication orders and the physician's admission medication orders for *Resident D*. The nurse interviewed *Resident D*, who confirmed the medications *they were* taking for *their* current medical conditions. The nurse found no discrepancies between the acute care hospital discharge medications and the admitting physician's medication orders. After the nurse contacted the pharmacy to request the medication, the pharmacist reviewed and confirmed the medication orders as appropriate for *Resident D*. As a result of this collected and communicated information, the nurse determined that there were no potential or actual clinically significant medication issues.

Coding: N2001 would be coded **0, No**—No issues found during review.

Rationale: The admitting nurse reviewed and compared *Resident D*'s discharge medication records from the acute care hospital with the physician's admission medication orders, collaborated with the pharmacist, and interviewed the resident. The nurse determined there were no potential or actual clinically significant medication issues.

2. *Resident H* was admitted to the nursing facility after undergoing cardiac surgery for mitral valve replacement. The acute care hospital discharge information indicated that *Resident H* had a mechanical mitral heart valve and was to continue receiving anticoagulant medication. While completing a review and comparison of *Resident H*'s discharge records from the hospital with the physician's admission medication orders and admission note, the nurse noted that the admitting physician had ordered *Resident H*'s anticoagulation medication to be held if the international normalized ratio (INR) was below 1.0, however, the physician's admission note indicated that the desired therapeutic INR parameters for *Resident H* was 2.5–3.5. The nurse questioned the INR level listed on the admitting physician's order, based on the therapeutic parameters of 2.5–3.5 documented in the physician's admission note, which prompted the nurse to call the physician immediately to address the issue.

Coding: N2001 would be coded **1, Yes**—Issues found during review.

Rationale: The admitting nurse reviewed and compared *Resident H*'s discharge health care records from the acute care hospital with the nursing facility physician's admission medication orders and admission note. The nurse identified a discrepancy between the physician's documented therapeutic INR level (2.5–3.5) for *Resident H* in the admission note and the physician's order to hold anticoagulation medication for an INR level of 1.0. The nurse considered this discrepancy to be a potential clinically significant medication issue that could lead to potential clotting issues for *Resident H*.

N2003: Medication Follow-up

N2003. Medication Follow-up - Complete only if N2001 = 1

Enter Code

☐

Did the facility contact a physician (or physician-designee) by midnight of the next calendar day and complete prescribed/recommended actions in response to the identified potential clinically significant medication issues?

- 0. No
- 1. Yes

Item Rationale

Health-related Quality of Life

- Integral to the process of safe medication administration practice is timely communication with a physician when a potential or actual clinically significant medication issue has been identified.
- Physician-prescribed/recommended actions in response to identified potential or actual clinically significant medication issues must be completed by the clinician in a time frame that maximizes the reduction in risk for medication errors and resident harm.

Planning for Care

- When a potential or actual clinically significant medication issue is identified, prompt communication with the physician and implementation of prescribed actions is necessary to protect the health and safety of the resident.

DEFINITION

MEDICATION FOLLOW-UP

The process of contacting a physician to communicate an identified medication issue and completing all physician-prescribed/recommended actions by midnight of the next calendar day at the latest.

Steps for Assessment

This item is completed if one or more potential or actual clinically significant medication issues were identified during the admission drug regimen review (N2001 = 1).

- Review the resident's medical record to determine whether the following criteria were met for any potential or actual clinically significant medication issues that were identified upon admission:
 - Two-way communication between the clinician(s) and the physician was completed by midnight of the next calendar day, AND
 - All physician-prescribed/-recommended actions were completed by midnight of the next calendar day.

Medical record sources include medical records received from facilities where the resident received health care, the resident's most recent history and physical, transfer documents, discharge summaries, medication lists/records, clinical progress notes, and other resources as available.

Discussions (including with the acute care hospital, other staff and clinicians responsible for completing the drug regimen review, the resident, and the resident's family/significant other) may supplement and/or clarify the information gleaned from the resident's medical records.

N2003: Medication Follow-up (cont.)

Coding Instructions

- **Code 0, No:** if the facility did not contact the physician and complete prescribed/recommended actions in response to **each** identified potential or actual clinically significant medication issue by midnight of the next calendar day.
- **Code 1, Yes:** if the facility contacted the physician AND completed the prescribed/recommended actions by midnight of the next calendar day after each potential or actual clinically significant medication issue was identified.

Coding Tips

- If the physician prescribes/recommends an action that will take longer than midnight of the next calendar day to complete, then **code 1, Yes**, should still be entered, if by midnight of the next calendar day the facility has taken the appropriate steps to comply with the prescribed/recommended action.
 - Example of a **physician-recommended action that would take longer than midnight of the next calendar day to complete:**
 - The physician writes an order instructing the clinician to monitor the medication issue over the next three days and call if the problem persists.
 - Examples of **by midnight of the next calendar day:**
 - A clinically significant medication issue is identified at 10:00 AM on 9/12/2017. The physician-prescribed/-recommended action is completed on or before 11:59 PM on 9/13/2017.
 - A clinically significant medication issue is identified at 11:00 PM on 9/12/2017. The physician-prescribed/-recommended action is completed on or before 11:59 PM on 9/13/2017.
- A dash (–) value is a valid response for this item; however, CMS expects dash use to be a rare occurrence.

DEFINITION

CONTACT WITH PHYSICIAN

- Communication with the physician to convey an identified potential or actual clinically significant medication issue, and a response from the physician to convey prescribed/recommended actions in response to the medication issue.
- Communication can be in person, by telephone, voice mail, electronic means, facsimile, or any other means that appropriately conveys the resident's status.

N2003: Medication Follow-up (cont.)

Examples

1. *Resident* P was admitted to the nursing facility with active diagnoses of pneumonia and atrial fibrillation. The acute care facility medication record indicated that *Resident* P was on a seven-day course of antibiotics and had three remaining days of this treatment plan. The nurse reviewing the discharge records from the acute care facility and the nursing facility admission medication orders noted that *Resident* P had an order for an anticoagulant medication that required INR monitoring, as well as the antibiotic. On the date of admission, the nurse contacted the physician responsible for *Resident* P and communicated a concern about a potential increase in *Resident* P's INR with this combination of medications that could place *them* at greater risk for bleeding. The physician provided orders for laboratory testing so that *Resident* P's INR levels would be monitored over the next three days, starting that day. However, the nurse did not request the first INR laboratory test until after midnight of the next calendar day.

Coding: N2003 would be coded **0, No.**

Rationale: A potential clinically significant medication issue was identified during the drug regimen review; the staff did contact the physician before midnight of the next calendar day, but did not complete, to the extent possible, the physician-prescribed actions related to the INR laboratory test until after midnight of the next calendar day.

2. *Resident* S was admitted to the facility from an acute care hospital. During the admitting nurse's review of *Resident* S's hospital discharge records, it was noted that *Resident* S had been prescribed metformin. However, laboratory tests at admission indicated that *Resident* S had a serum creatinine of 2.4, consistent with renal insufficiency. The admitting nurse contacted the physician to ask whether this medication would be contraindicated with *Resident* S's current serum creatinine level. Three hours after *Resident* S's admission to the facility, the physician provided orders to discontinue the metformin and start *Resident* S on a short-acting sulfonylurea for ongoing diabetes management. These medication changes were implemented within the hour.

Coding: N2003 would be coded **1, Yes.**

Rationale: A potential clinically significant medication issue was identified during the drug regimen review; the physician communication occurred, and the nurse completed the physician-prescribed actions, by midnight of the next calendar day.

N2005: Medication Intervention

Complete only if A0310H = 1.

N2005. Medication Intervention - Complete only if A0310H = 1

Enter Code

☐

Did the facility contact and complete physician (or physician-designee) prescribed/recommended actions by midnight of the next calendar day each time potential clinically significant medication issues were identified since the admission?

- 0. No
- 1. Yes
- 9. NA - There were no potential clinically significant medication issues identified since admission or resident is not taking any medications

Item Rationale

Health-related Quality of Life

- Integral to the process of safe medication administration practice is timely communication with a physician when a potential or actual clinically significant medication issue has been identified.
- Physician-prescribed/-recommended actions in response to identified potential or actual clinically significant medication issues must be completed by the clinician in a time frame that maximizes the reduction in risk for medication errors and resident harm.
- Potential or actual clinically significant medication issues can occur throughout the resident's stay.

Planning for Care

- Every time a potential or actual clinically significant medication issue is identified throughout the resident's stay, it must be communicated to a physician, and the physician-prescribed/-recommended actions must be completed by the clinician in a time frame that maximizes the reduction in risk for medication errors and resident harm.

Steps for Assessment

The observation period for this item is from the date of admission (start of SNF PPS stay) through discharge (Part A PPS discharge).

1. Review the resident's medical record to determine whether the following criteria were met for any potential and actual clinically significant medication issues that were identified upon admission or at any time during the resident's stay:
 - Two-way communication between the clinician(s) and the physician was completed by midnight of the next calendar day, AND
 - All physician-prescribed/-recommended actions were completed by midnight of the next calendar day.
- Medical record sources include medical records received from facilities where the resident received health care, the resident's most recent history and physical, transfer documents, discharge summaries, medication lists/records, clinical progress notes, and other resources as available.
- Discussions (including with the acute care hospital, other staff and clinicians responsible for completing the drug regimen review, the resident, and the resident's family/significant other) may supplement and/or clarify the information gleaned from the resident's medical records.

N2005: Medication Intervention (cont.)

Coding Instructions

- **Code 0, No:** if the facility did not contact the physician **and** complete prescribed/recommended actions by midnight of the next calendar day each time a potential or actual clinically significant medication issue was identified since admission (start of SNF PPS stay).
- **Code 1, Yes:** if the facility contacted the physician **and** completed prescribed/recommended actions by midnight of the next calendar day each time a potential or actual clinically significant medication issue was identified since admission (start of SNF PPS stay).
- **Code 9, NA:** if there were no potential or actual clinically significant medication issues identified at admission or throughout the resident's stay or the resident was not taking any medications at admission or at any time throughout the stay.

Coding Tips

- If the physician prescribes an action that will take longer than midnight of the next calendar day to complete, then **code 1, Yes**, should still be entered, if by midnight of the next calendar day, the clinician has taken the appropriate steps to comply with the recommended action.
 - Example of a **physician-recommended action that would take longer than midnight of the next calendar day to complete:**
 - The physician writes an order instructing the clinician to monitor the medication issue over the next three days and call if the problem persists.
 - Examples of by **midnight of the next calendar day:**
 - A clinically significant medication issue is identified at 10:00 AM on 9/12/2017. The physician-prescribed/-recommended action is completed on or before 11:59 PM on 9/13/2017.
 - A clinically significant medication issue is identified at 11:00 PM on 9/12/2017. The physician-prescribed/-recommended action is completed on or before 11:59 PM on 9/13/2017.
- A dash (–) value is a valid response for this item; however, CMS expects dash use to be a rare occurrence.

N2005: Medication Intervention (cont.)

Examples

1. At the end of the resident's Part A PPS stay, the discharging nurse reviewed *Resident* T's medical records, from the time of admission (start of SNF PPS stay) through *their* entire Part A PPS stay (Part A PPS discharge) and noted that a clinically significant medication issue was documented during the admission assessment. *Resident* T's medical records indicated that a nurse had attempted to contact the assigned physician several times about the clinically significant medication issue. After midnight of the second calendar day, the physician communicated to the nurse, via telephone, orders for changes to *Resident* T's medications to address the clinically significant medication issue. The nurse implemented the physician's orders. Upon further review of *Resident* T's medical records, the discharging nurse determined that no additional issues had been recorded throughout the remainder of *Resident* T's stay.

Coding: N2005 would be coded **0, No**—the facility did not contact the physician **and** complete prescribed/recommended actions by midnight of the next calendar day **each** time a potential or actual clinically significant medication issue was identified since the resident's admission (start of SNF PPS stay).

Rationale: Coding of this item includes all potential or actual clinically significant medication issues identified at any time during the resident's stay. When reviewing *Resident* T's medical record at discharge, the nurse found that a clinically significant medication issue was identified during the admission (start of SNF PPS stay) drug regimen review, but the facility did not communicate with the physician **and** complete prescribed actions by midnight of the next calendar day. Although no other potential or actual clinically significant medication issues were identified during the remainder of the resident's stay, the facility did not communicate with the physician and complete prescribed/recommended actions by midnight of the next calendar day each time a potential or actual clinically significant medication issue was identified during the resident's SNF PPS stay.

N2005: Medication Intervention (cont.)

2. At discharge, the nurse completing a review of *Resident* K's medical records found that two clinically significant medication issues had been identified during the resident's stay. During the admission drug regimen review, the admitting nurse had identified a clinically significant medication issue, contacted the physician, and implemented new orders provided by the physician on the same day. Another potentially significant medication issue was identified on day 12 of *Resident* K's stay; the nurse communicated with the physician and carried out the orders within one hour of identifying the potential issue. Both medication issues identified during *Resident* K's stay were communicated to the physician and resolved by midnight of the next calendar day after identification. There were no other clinically significant medication issues identified during *Resident* K's stay.

Coding: N2005 would be coded as **1, Yes**—all potential or actual clinically significant medication issues identified at any time during the resident's stay (admission through discharge) were communicated to the physician and prescribed/recommended actions were completed by midnight of the next calendar day after each issue was identified.

Rationale: While a medication issue was identified as a clinically significant medication issue at admission, it was resolved by midnight of the next day. During *Resident* K's stay, an additional clinically significant medication issue was identified; it too was resolved by midnight of the following day. Each time a clinically significant medication issue was identified (at admission and during the stay), it was communicated to the physician and resolved through completion of prescribed/recommended actions by midnight of the next calendar day after identification.