Chapter	Section	Page(s) in version 1.18.11	Change
3			Updated language throughout to be gender neutral.
3			Updated screen captures of all items.
3		N-1	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 has been included. 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.
3	N0300	N-1	Replaced screenshot. OLD 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 N0410, Medications Received NEW N0300. Injections Enw 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
3	N0415	N-4	N0410: Medications Received 5: High-Risk Drug Classes: Use and Indication

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3	N0415	N-4	Replaced screenshot. OLD
			NO410. Medications Received Indicate the number of DAYS the resident received the following 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. Enter "0" if medication was not received by the resident during the last 7 days. Enter Days Enter Days C. Antidepressant D. Hypnotic Enter Days Enter Days Enter Days F. Antibiotic Enter Days F. Antibiotic Enter Days G. Diuretic Enter Days H. Opioid
			NEW No415. 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. 2. Is taking Indication noted ↓ Check all that apply↓ A. Antipsychotic B. Antianxiety C. Antidepressant D. Hypnotic E. Anticoagulant (e.g., warfarin, heparin, or low-molecular weight heparin) F. Antibiotic
			G. Diuretic
3	N0415- N2005	N-6- N-27	Page length changed due to revised content.
3	N0415	N-6	 Steps for Assessment 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). 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).

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-6	Coding Instructions
			NO410A H: 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.
3	N0415	N-6	
			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.
3	N0415	N-7	• N04105A1, Antipsychotic: Record the number of daysCheck if an antipsychotic medication was receivedtaken 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).

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-7	• N04105B1, Antianxiety: Record the number of daysCheck if an anxiolytic medication was receivedtaken 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).
3	N0415	N-7	• N04105C1, Antidepressant: Record the number of days Check if an antidepressant medication was received 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).
3	N0415	N-7	• N04105D1, Hypnotic: Record the number of daysCheck if a hypnotic medication was receivedtaken 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).

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-7	• N04105E1, Anticoagulant (e.g., warfarin, heparin, or low-molecular weight heparin): Record the number of daysCheck if an anticoagulant medication was receivedtaken by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days). Do not code antiplatelet medications such as aspirin/extended release, dipyridamole, or clopidogrel here.
			• 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).
3	N0415	N-7	• N04105F1, Antibiotic: Record the number of days Check if an antibiotic medication was received 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).
3	N0415	N-7- N-8	• N04105G1, Diuretic: Record the number of daysCheck if diuretic medication was receivedtaken by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
			• 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).

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-8	• N04105H1, Opioid: Record the number of daysCheck if an opioid medication was receivedtaken by the resident at any time during the 7-day look-back period (or since admission/entry or reentry if less than 7 days).
			• NO415H2. 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).
3	N0415	N-8	• 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).
			• NO41512. 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).
3	N0415	N-8	• 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).

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-8	Coding Tips and Special Populations
			Code medications in Item N04105 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-(e.g., PO, IM, or IV) 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.

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-9	 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).
			• A transdermal patch is designed to release medication over a period of time (typically 3–5 days); therefore, transdermal patches would be considered long acting medications for the purpose of coding the MDS, and only the days the staff attaches the patch to the skin are counted for the MDS. 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, N04105H Opioid would be coded 3checked, because the application occurred on 3 days during the look-back period.

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-9	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.

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-10	 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. 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.

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-10	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.
			 During the first year in which a resident on a psychoactive medication is admitted, or after the nursing home has initiated such medication, nursing home staff should attempt to taper the medication or perform gradual dose reduction (GDR) as long as it is not medically 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 (the State Operations Manual can be found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html). Prior to discontinuing a psychoactive medication, residents may need a GDR or tapering to avoid withdrawal syndrome (e.g., for medications such as selective scrotonin reuptake inhibitors [SSRIs], tricyclic antidepressants [TCAs], etc.). 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.

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-10	
			DEFINITIONS
			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.
			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.
3	N0415	N-10	 Anticoagulants such as Target Specific Oral Anticoagulants (TSOACs), which may or may not require laboratory monitoring, should be coded in N0410E, Anticoagulant. 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/usingdiet arysupplements/.

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0415	N-10	 Anticoagulants such as Target Specific Oral Anticoagulants (TSOACs), which may or may not require laboratory monitoring, should be coded in N0410E, Anticoagulant.
3	N0415	N-11	Example 1. The Medication Administration Record for Mrs. Resident Preflects 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 I 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 N04195, would be coded as follows: A.N0415A1 and N0415A2. Antipsychotic = 3,checked; risperidone is an antipsychotic medication, B. and indication of use for bipolar disorder noted. N0415B1 and N0415B2. Antianxiety = 7,checked; lorazepam is an antianxiety medication, and D. and indication of use for bipolar disorder noted. N0415D1. Hypnotic = 2,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 eategories 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.

Chapter	Section	Page(s) in version 1.18.11	Change
3	N0450	N-14	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 in Appendix PP of the State Operations Manual). The State Operations Manual can be found at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.
3	N0450	N-15	 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.).
3	N0450	N-15	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.

Chapter	Section	Page(s) in version 1.18.11	Change
3	N2001	N-17	N2001: Drug Regimen Review Intent: The intent of the drug regimen review items is to document whether a drug regimen review was conducted upon the resident's admission (start of Skilled Nursing Facility [SNF] Prospective Payment System [PPS] stay) and throughout the resident's stay (through Part A PPS discharge) and whether any clinically significant medication issues identified were addressed in a timely manner. Complete only if A0310B = 01.
3	N2001	N-18	Steps for Assessment
			Complete if A0310B = 01.
3	N2001	N-18	 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. 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.

Chapter	Section	Page(s) in version 1.18.11	Change
3	N2001	N-18	 34. 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 eoprescribed).
3	N2001	N-19	 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.
3	N2005	N-24	N2005: Medication Intervention
			Complete only if $A0310H = 1$.