# Drug Regimen Review Item Pilot Test for Inpatient Rehabilitation Facilities, Skilled Nursing Facilities, and Long-Term Care Hospitals

# A Summary of Findings

Prepared for

#### The Division of Chronic & Post-Acute Care

Center for Clinical Standards & Quality Centers for Medicare & Medicaid Services Office of Research, Development, and Information Mail Stop C3-19-26 7500 Security Boulevard Baltimore, MD 21244-1850

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RTI Project Number HHSM-500-2013-13015I



# DRUG REGIMEN REVIEW ITEM PILOT TEST FOR INPATIENT REHABILIATION FACILITIES, SKILLED NURSING FACILITIES, AND LONG-TERM CARE HOSPITALS

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CMS Contract No. HHSM-500-2013-13015I

October 2016

This project was funded by the Centers for Medicare & Medicaid Services under contract no. 500-00-1234. The statements contained in this report are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare & Medicaid Services. RTI assumes responsibility for the accuracy and completeness of the information contained in this report.

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# **CONTENTS**

Executive Summary	1
Section 1 Pilot Overview	3
1.1 Purpose and Legislative Authority	
1.2 Pilot Objective	3
1.3 DRR Measure Overview	3
1.4 Summary of Pilot Activities	4
1.4.1 Analyses	6
1.5 Pilot Data Collection Form (Pilot Assessment)	6
1.5.1 Administrative Items	7
1.5.2 DRR Items	7
1.5.3 Time Estimate Items	8
1.5.4 Form Completion Items	8
1.5.5 Pilot Data Collection Notes	8
Section 2 Current processes in place	9
2.1 Current Processes at Admission.	
2.2 Current Processes During Stay and at Discharge	
2.3 Current MR/DRR Processes: Setting-Specific Themes	
Section 3 Findings	13
3.1 Definitions	
3.1.1 Coding Responses for DRR -01 and DRR -02	13
3.1.2 Coding Responses for DRR -03	
3.2 Data Sources	
3.3 Data Collection Challenges	
3.4 Coding Agreement	
Section 4 Lessons Learned by CMS/RTI	21
4.1 Existing Performance Gap	
4.2 Provider Input	
4.3 Additional Information Requested by Providers	
Section 5 Summary	23
5.1 Conclusion	
5.2 Post-DRR Item Pilot Test Actions by CMS	23
5.3 Future CMS Actions	24
References	25

# List of Tables

1	Characteristics of the 12 Pilot Sites	4
2	Clinician Composition of Data Collectors per Pilot Site	5

#### **EXECUTIVE SUMMARY**

CMS has adopted a patient assessment-based, cross-setting, process quality measure that assesses whether PAC providers were responsive to potential or actual clinically significant medication issue(s) when such issues were identified (Institute of Medicine, 2006). This quality measure titled, Drug Regimen Review Conducted with Follow-Up for Identified Issues (DRR), was developed for the Inpatient Rehabilitation Facility, Skilled Nursing Facility, and Long-Term Care Hospital Quality Reporting Programs. Specifically, the quality measure reports the percentage of patient/resident stays in which a drug regimen review was conducted at the time of admission and timely follow-up with a physician occurred each time potential clinically significant medication issues were identified throughout that stay. The DRR measure was developed to meet the Medication Reconciliation domain as mandated by the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act).

For this quality measure, drug regimen review is defined as the review of all medications or drugs the patient/resident is taking to identify any potential clinically significant medication issues. For this quality measure, potential clinically significant medication issues are defined as those issues that, in the clinician's professional judgment, warrant interventions, such as alerting the physician and/or others, and the timely completion of any recommended actions (by midnight of the next calendar day) so as to avoid and mitigate any untoward or adverse outcomes. The quality measure utilizes both the processes of medication reconciliation (MR) and a drug regimen review, in the event an actual or potential medication issue occurred. The measure informs whether the PAC facility identified and addressed each clinically significant medication issue and if the facility responded or addressed the medication issue in a timely manner. This measure is applied uniformly across the PAC settings.

Prior to the adoption of this measure, CMS with our measure contractor, RTI International, conducted a pilot test on the items that are used to calculate these adopted measures. The DRR Item Pilot Test was conducted in four SNFs, IRFs, and LTCH settings. Home Health Agencies were not included in this pilot testing. This pilot utilized mixed methods to collect data. Data on the DRR items was collected during the following dates: quantitative data collection began December 8, 2015 and ended December 21, 2015; and qualitative data collection began December 01, 2015 and ended December 30, 2015.

The post-acute care (PAC) facility settings who participated in the DRR Item Pilot Test were selected to represent variation across several key facility-level characteristics: geographic location, size, and profit status. Each facility selected two clinicians (known as data collectors) to complete Pilot Data Collection Forms, including DRR items and other relevant information, for the same sample of 10–20 patients/residents within their facility. The pilot sites participated in a pilot training conference call prior to pilot testing. Pilot participants from each facility also participated in one conference call prior to data collection and one conference call at the conclusion of data collection. These calls were used to obtain qualitative information related to the data collection for the three drug regimen review items.

RTI analyses revealed the following performance gaps in participating pilot facilities:

- 1. Analyses of the coding of the DRR items collected during the pilot suggested a performance gap related to physician follow-up and resolution for identified potential clinically significant medication issues (PCSMIs). These findings suggest that use of the DRR items can facilitate the identification of PCSMIs that were not resolved by midnight of the next calendar day, supporting the need for PAC facilities to collect the DRR items to drive enhanced quality assurance and patient/resident safety, especially surrounding transitions of care.
- 2. Analyses suggested insufficient documentation of MR/DRR activities at certain facilities, contributing to skewed distribution of identified PCSMIs at the facility-level. For example, while one pilot facility indicated that no PCSMIs were identified at admission for 90% of its pilot patient sample, and similarly, a high percentage (53%) of pilot facilities reported no PCSMIs during stay/at discharge, such findings might reflect incomplete/inconsistent documentation of MR/DRR activities at certain facilities rather than an absence of PCSMIs.
- 3. Analyses of DRR quantitative and qualitative data indicate the need for further clarification of DRR item definitions and response options, as evidenced by common coding errors. These analyses demonstrate the need for additional training/guidance related to certain data items used in the measure.

# SECTION 1 PILOT OVERVIEW

# 1.1 Purpose and Legislative Authority

The Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) was signed into law on October 6, 2014 (Civic Impulse, 2016). This Act requires the Secretary of State to specify a quality measure to address the Medication Reconciliation domain for Inpatient Rehabilitation Facilities (IRFs), Skilled Nursing Facilities (SNFs), and Long-Term Care Hospitals (LTCHs) by October 1, 2018 and for Home Health Agencies (HHAs) by January 1, 2017. The quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care (DRR), is a patient/resident assessment-based, cross-setting quality measure developed to meet the mandate of the IMPACT Act requirement, with data collection beginning 2018 for fiscal year (FY) 2020 payment determinations and subsequent years. RTI International has piloted this measure in SNF, LTCH, and IRF settings. This summary report details results from this pilot testing.

# 1.2 Pilot Objective

The objective of the DRR Item Pilot Test was to collect patient/resident quantitative data and provider qualitative data using the assessment items used to calculate the adopted quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues, for IRF, LTCH, and SNF settings. Findings from this pilot informed CMS of the feasibility of collecting this measure and the items used to calculate this measure in SNF, LTCH, and IRF settings. Additionally, provider feedback demonstrated current provider practices related to DRR/Medication Reconciliation (MR) documentation and how those processes could be adjusted in the future to better facilitate data collection of the items in the measure. Lastly, RTI gathered data on provider comprehension of item concepts, definitions, and coding responses.

#### 1.3 DRR Measure Overview

**Brief description of the drug regimen review quality measure:** The percentage of SNF, IRF, and LTCH stays in which a drug regimen review was conducted at the Admission and timely follow-up with a physician occurred each time potential clinically significant medication issues (PCSMIs) were identified throughout the stay.

**Rationale:** Medication review in PAC is generally considered to include MR and DRR for all medications and the identification of PCSMIs for the patient/resident. As a process measure, MR and DRR for PCSMIs are expected to reduce re-hospitalizations, reduce adverse events related to medications, and improve health outcomes. For this quality measure, MR and DRR are defined as:

**Medication Reconciliation**: The process of comparing the medications a patient/resident is taking (or should be taking) with newly ordered medications in order to identify and resolve discrepancies (The Joint Commission, 2016). Medication reconciliation, a component of drug regimen review, is a recognized process for reducing the occurrence of medication discrepancies that may lead to Adverse Drug Events (ADEs) (Institute of Medicine, 2006).

**Drug Regimen Review**: A review of all medications the patient/resident is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy (Centers for Medicare & Medicaid Services, 2005).

The DRR measure was finalized for adoption into the SNF, IRF, and LTCH QRPs in the FY 2017. The finalized DRR measure can be found on pages 52034-52039 of the SNF PPS final rule, available at <a href="https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18113.pdf">https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18113.pdf</a>; on pages 52111-52116 of the 2017 IRF PPS final rule, available at <a href="https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18196.pdf">https://www.gpo.gov/fdsys/pkg/FR-2016-08-05/pdf/2016-18196.pdf</a>; and on pages 57219-57223 of the FY 2017 LTCH PPS final rule, available at <a href="https://www.gpo.gov/fdsys/pkg/FR-2016-08-22/pdf/2016-18476.pdf">https://www.gpo.gov/fdsys/pkg/FR-2016-08-22/pdf/2016-18476.pdf</a>.

## 1.4 Summary of Pilot Activities

**Pilot site recruitment and selection**: Twenty-five facilities volunteered for the pilot, from which 12 pilot sites (4 SNFs, 4 IRFs, and 4 LTCHs) were selected for the final sample. The selected facilities represented variation across several key characteristics: Location (variation by state and by metropolitan area status), Average Daily Census (ADC), Average Length of Stay (ALOS), Profit Status, and Clinical Record System (e.g., EMR, Paper-based). Several of these characteristics of the pilot sites are provided in *Table 1*, below.

Table 1
Characteristics of the 12 Pilot Sites

Setting	ADC	ALOS	Profit Status	# of Data Collection Forms
SNF	14.0	53.3	For profit	24
SNF	15.0	23.0	Nonprofit	20
SNF	40.0	20.0	Nonprofit	20
SNF	30.0	27.8	Nonprofit	22
IRF	43.0	13.3	Nonprofit	24
IRF	74.2	16.4	Nonprofit	20
IRF	60.0	12.0	For profit	20
IRF	95.0	14.0	Nonprofit	30
LTCH	30.0	31.0	Nonprofit	20
LTCH	135.0	31.0	Nonprofit	40
LTCH	103.0	40.0	For profit	38
LTCH	23.9	28.0	Nonprofit	20
Total			<del></del>	298

<sup>\*</sup>Note: The DRR Item Pilot Test encouraged testing of providers with a variety of clinical record systems (i.e. paper, EMR, combination)

**Training:** Each of the 12 pilot sites participated in the DRR Item Pilot Test training led by RTI on December 1, 2015. During the 1.5- hour conference call, RTI instructed participants on the standardized processes to be employed for pilot data collection.

**Pre-Data Collection Calls:** Individual pre-data collection conference calls were held with each pilot site, following the DRR Item Pilot Test training call, prior to the onset of the data collection period. The purpose of these calls was to: (1) answer any questions that pilot sites had following the DRR Item Pilot Test training call, (2) allow RTI to obtain contextual information about each pilot site's existing practices and protocols related to DRR activities, and (3) review each pilot site's decision in finalizing their selection of the most appropriate clinical staff members to act as pilot data collectors. For the purposes of this pilot testing, pilot sites were asked to verify their understanding the measure requirements and to confirm the facility's choice of a clinician to collect pilot data. *CMS does not dictate who can collect data, and providers follow facility, State, Federal and professional licensure guidelines for assessment completion.* 

**Data Collection:** DRR Pilot Data Collection Forms were completed for 10–20 patients/residents at each pilot site over the course of a 2-week data collection period.

• **Data Collectors:** Two Data Collectors from each pilot site completed the DRR Pilot Data Collection Forms for the same set of 10-20 identified patients/residents. See *Table 2* below for a breakdown of the clinical staff completing these forms. RTI requested that providers select clinical staff as data collectors for the pilot. These clinicians normally collect medication data and were expected to provide informed feedback on the DRR collection experience.

Table 2 Clinician Composition of Data Collectors per Pilot Site

# of Pilot Sites	# of Pilot Sites Clinician Composition of Data Collectors per Pilot Site	
1 SNF, 1 IRF, 1 LTCH	Pharmacist, Pharmacist	
3 SNF, 1 LTCH	Nurse, Nurse	
3 IRF, 2 LTCH	Pharmacist, Nurse	

#### • Patient/Resident Eligibility for DRR Pilot Inclusion:

- Patients/residents who were eligible to be assessed per the providers' current admission and discharge assessment instruments (i.e. Minimum Data Set [MDS] for SNFs, Independent Rehabilitation Facilities Patient Assessment Instrument [IRF- PAI] for IRFs, and Long-Term Care Hospital Continuity Assessment Record and Evaluation Data Set [LTCH CARE Data Set] for LTCHs).
  - Patients/residents with accessible and completed admission and discharge medical records before the onset of the data collection period. This pilot collected data for all three items after the patient/resident was discharged

which differs from how the data will be collected (first two items at admission assessment period, third item at discharge).

- In addition, pilot sites were instructed to choose a patient/resident sample that included the following:
  - A distribution of admission and discharge times and days of week.
  - Short and long length of stay (LOS). For example, a resident whose length of stay was 90 days at the SNF.
  - Complex or multiple medical primary/secondary diagnoses

**Data Submission**: Pilot sites uploaded their data collection forms to RTI via a secure website over the 2-week data collection period. After each pilot site submitted their first set of data (one form from each data collector), RTI performed a data quality check by reviewing the forms to ensure data collector understanding of the pilot data collection process. RTI provided prompt feedback to each provider to promote standardization of data quality. Feedback given to providers included: correct use of skip patterns, correct use of coding, increasing content of qualitative pilot notes to include whether issues were identified at admission or during stay/discharge and daytime vs. nighttime issue was identified and addressed by physician.

**Structured Debriefing Calls:** At the end of the 2-week data collection period, pilot sites participated in one of five group structured debriefing conference calls with RTI. The primary purpose of the structured debriefing calls was to discuss pilot site experiences with data collection, pilot site understanding of item definitions and instructions for completion, and how pilot sites might implement this measure, given the diversity of current processes and medical record data collection systems for identifying DRR information.

#### 1.4.1 Analyses

- Qualitative: Detailed notes were taken during the pre-data collection calls and structured debriefing calls and were analyzed to identify themes. Pilot data collection notes and quantitative analyses were used to compare data for accuracy and to support, explain, and expand upon the identified themes.
- Quantitative: Data collection forms containing DRR item coding was compared to corresponding pilot data collection notes in order to analyze and validate DRR item coding.

#### 1.5 Pilot Data Collection Form (Pilot Assessment)

The pilot data collection form included five main sections: (1) Administrative Items; (2) DRR Items; (3) Time Estimate Items; (4) Form Completion Items; and (5) Pilot Data Collection Notes.

#### 1.5.1 Administrative Items

- A-01. Admission Date (month, day, year) and Time (daytime vs. night-time)
- A-02. Discharge Date (month, day, year) and Time (daytime vs. night-time)

#### 1.5.2 DRR Items

The three items used to calculate the DRR quality measure

- DRR -01\*. Drug Regimen Review (admission)
- DRR -02\*. Medication Follow-up (admission)
- DRR -03\*. Medication Intervention (coded at discharge)-for the pilot, DRR items were collected post-patient/resident discharge; thus, the specific skip pattern.
- \* Note: "DRR -01", "DRR -02", & "DRR -03" numbering was used only during the DRR Item Pilot Test.

ADMISSION (beginning of stay)			
DRR -01*.	DRR -01*. Drug Regimen Review		
Enter Code	Did a complete drug regimen review identify potential clinically significant medication issues?		
Ш	<ul> <li>No- No issues found during review → Skip to DRUG REGIMEN REVIEW -03**</li> <li>Yes- Issues found during review</li> </ul>		
	<ol> <li>9. NA- Patient/resident is not taking any medications → Skip to DRUG REGIMEN REVIEW -03**</li> </ol>		
DRR -02*.	DRR -02*. Medication Follow-up		
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		
	DISCHARGE (end of stay)		
DRR -03*. N	DRR -03*. Medication Intervention		
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 patient/resident is not taking any medications.		

<sup>\*</sup>Note: "DRR -01", "DRR -02", & "DRR -03" numbering was used only during the DRR Item Pilot Test \*Note: This specific skip pattern was only used during the DRR Item Pilot Test

#### 1.5.3 Time Estimate Items

- TE-01A. Items DRR -01 and DRR -02
- TE-01B. Item DRR -03

## **1.5.4** Form Completion Items

- Z-01A. Signature of person completing the Pilot Data Collection Form
- Z-01B. Date of completion of Pilot Data Collection Form

#### 1.5.5 Pilot Data Collection Notes

Data Collectors were asked to record a brief description of each of the PCSMIs that were identified (1) upon the patient/resident's admission, and (2) any time during the patient/resident's stay, and upon discharge. These descriptions included:

- Medication issue(s)
- Identified date and time met or not, according to measure requirement
- Issue location within type of medical record
- Where communication of physician (or physician designee) follow-up information was found
- The length of time the follow-up actions took place
- Action used to resolve issue

# SECTION 2 CURRENT PROCESSES IN PLACE

The primary purpose of the pre-data collection calls was to obtain background and contextual information about each pilot site's existing practices and protocols related to DRR activities.

All pilot sites indicated current completion of DRR activities at admission, during stay, and at discharge; however, most providers indicated an absence of processes in place to document DRR activities in a systematic manner that would facilitate easy access to and accurate collection of DRR data. During pre-data collection calls, many providers predicted that retrospective data collection would be challenging and require pulling data from multiple medical record sources.

#### 2.1 Current Processes at Admission

A DRR occurs at multiple time points immediately upon (and in a few cases, before) admission, and typically is a collaborative effort among multiple clinical staff members (e.g. registered nurse [RN], physician, pharmacist, pharmacy assistant, nurse practitioner, physician assistant). Frequently described processes included the following examples (though not necessarily in this order), some of which illustrate how an initial step of medication reconciliation process may be combined with a review of the patient/resident's drug regimen:

- PAC facility receives referral medication list/paperwork from discharging acute care
  hospital. For this initial process of medication reconciliation, most pilot sites
  indicated no access to the admitting hospital's EMR or other systems of
  documentation. Two pilot facilities, however, reported full access to patient/resident's
  prior acute records, due to shared EMR systems.
- Typically, an RN, but sometimes a physician, pharmacist, or non-clinician administrative staff member, enters the patient/resident's medications into the PAC facility's EHR or non-EHR system. This DRR process combines medication reconciliation with drug regimen review when comparing former medication list/documentation with new medication orders and entered in EHR or non-EHR systems regarding medications, dosage, dosage timing, contraindications, drug interactions, etc. by the PAC provider.
- Some facilities with EMR systems in place noted that they have alerts ("flags") that indicate any potentially problematic medication orders entered into the EHR system. These electronic prompts add an additional layer of safety to their DRR process.
- Finally, the physician may crosscheck data entered within the medical record with the
  referral paperwork, checking for contraindications, dosage timing, drug interactions,
  etc., in order to finalize medication orders. Again, this DRR process combines
  medication reconciliation with drug regimen review when changes are made in
  medications, dosage, dosage timing, contraindications, drug interactions, etc., by the
  PAC provider.

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- The pharmacist typically reviews the medications, either before or after the MD, checking for contraindications, dosage timing, drug interactions, etc. The pharmacist will follow up with the physician with any questions or concerns before finalizing medication orders.
- Some facilities interview patients/residents or their caregivers/family members about home medications to be entered into the medical record but this practice was not always done systematically, if at all.

Though pre-data collection calls revealed high variation in DRR processes across facilities, most pilot sites indicated that DRR and follow-up for any identified issue are almost always completed in less than 24 hours.

At admission, DRR activities for PAC providers are critical to patient/resident safety during their transition from an acute care provider or another PAC provider. The importance of accurate and consistent communication and documentation of MR/DRR activities at admission was emphasized by many providers who described MR/DRR processes that are unique to the admission assessment period. Some providers currently include multiple types of clinicians for the admission DRR processes. Miscommunication and missing data from discharging facilities were common barriers at admission that prompted PAC providers to emphasize the need for thorough DRR processes. Many pilot sites noted that medication interventions at admission are more likely to be consistently and systematically documented than activities that occur during the stay and at discharge.

# 2.2 Current Processes During Stay and at Discharge

All pilot sites stated that DRR is an ongoing process throughout a patient/resident's stay. Many pilot sites noted that much of the DRR communication among nurses, physicians, and pharmacists post admission, as well as resulting medications adjustments, are not systematically documented. The location where DRR-associated activities, such as when issues are flagged, are documented in the medical records varies depending on many contextual factors (e.g., who identified the issue, type of issue, required follow-up action). Commonly, medication interventions initiated by the nurse (e.g., dosage adjustment of physician pre-prescribed sliding scale insulin, noting drug reactions and contacting MD) are documented in the nurse's notes. Medication issues identified by the physician or the pharmacist and the related follow-up actions (e.g., change of medication brand or dosage) may be less consistently documented depending on the provider. Facility-level variation was seen in whether or not the identification of PCSMIs and their subsequent resolution were time stamped.

The results when comparing the data collection forms containing DRR item coding when compared to the same coder's corresponding pilot data collection notes were analyzed to validate DRR item coding. There was variability between providers in the percentage of providers who reported the noted time and date the PCSMI was identified and or addressed.

Many providers noted that their processes for admission vs. discharge DRR differ significantly. For example, some sites reported that their DRR processes at discharge are less structured than DRR processes at admission, noting that medication issues are consistently being

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addressed throughout the patient/resident's stay and therefore, expected to be up-to-date at discharge and reflect all medication interventions made throughout their stay.

Several providers identified a gap in discharge DRR that they perceived to be outside of their facilities' control. They stated that medication lists sent home with patients/residents upon discharge from a PAC facility are intended to be reviewed by a patient/resident's primary care physician. This post-discharge step in the DRR process is not easily regulated by the PAC facility.

## 2.3 Current MR/DRR Processes: Setting-Specific Themes

**Skilled Nursing Facility (SNF):** All of the SNF pilot sites indicated that MR/DRR at admission started with the nurse entering orders, followed by a physician review of the orders entered. Lastly, the orders are sent to the pharmacy (typically offsite), where the pharmacist completes the final DRR step. Pre-data collection calls with SNF providers revealed the following themes:

- RNs have significant involvement in DRR activities. For example, RNs review patient medications and maintain close communication with physicians and other clinical staff regarding patient medication-related issues.
- Communications between clinical staff members may be more indirect (e.g. informal, undocumented conversations).
- Pharmacy input was available via offsite computer access or off-site communication.

**Long-Term Care Hospital (LTCH):** In general, LTCHs described extremely thorough DRR processes, though not necessarily thorough documentation of these processes. Pre-data collection calls with LTCH providers revealed the following themes:

- MDs and pharmacists have significant involvement in DRR activities. Providers reported the following activities: review of patient medical records; medication lists; prescription eliminations, adjustments, and additions; and communication between clinicians.
- Frequent communication between physicians and pharmacists is not always systematically documented. Providers reported that some medication adjustments are communicated verbally and therefore may not be manually recorded.
- Prompt physician follow-up and resolution for identified issues.

**IRF processes at admission:** Among the four IRF pilot sites, there was significant variation in type of facility staff primarily involved in DRR at admission and at discharge. Predata collection calls with IRF providers revealed the following themes:

• Variation in clinician roles and responsibilities related to DRR activities. Some providers reported varied combinations of clinician involvement at admission and

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during the stay versus at discharge. For example, the pharmacist may not be involved at discharge unless directly consulted, as pharmacist input had already been utilized at admission and throughout the patient's stay.

• Informal, often undocumented, communication between clinical staff members. Facilities reported that casual, undocumented consult that may occur between clinical team members may not be recorded in the patient's medical record.

# SECTION 3 FINDINGS

#### 3.1 Definitions

"Potential Clinically Significant Medication Issues (PCSMI)": Pilot sites suggested further clarification of this definition to improve data accuracy. During the structured debriefing calls, almost all of the pilot sites mentioned the subjective nature of a PCSMI, noting that whether or not something is identified as a PCSMI depends on the clinician's interpretation, and the unique characteristics of the patient/resident. Providers felt that offering clinical examples in the item guidance manual would be extremely helpful in clarifying what should and should not be included in item coding. Providers requested a list of specific types of medication issues to exemplify what would be considered as PCSMI and examples of what issues would not be considered as PCSMIs.

**Time frame:** Though most pilot sites stated that they fully understood the time frame requirement of "by midnight the next calendar day," a few sites reported confusion surrounding this time frame. They noted difficulty in determining whether to attribute "midnight" to the day leading into versus the day following the midnight time point. They offered several suggestions for clarifying this issue including (1) using military time, (2) providing clarification through a specific example in the manual, and (3) changing the time frame to read "by 11:59 p.m. of the next calendar day".

# 3.1.1 Coding Responses for DRR -01 and DRR -02

DRR -01*. I	DRR -01*. Drug Regimen Review	
Enter Code	Did a complete drug regimen review identify potential clinically significant medication issues?	
	0. No- No issues found during review → <b>Skip to DRUG REGIMEN REVIEW -03**</b> 1. Yes- Issues found during review	
	<ol> <li>NA- Patient/resident is not taking any medications → Skip to DRUG REGIMEN REVIEW -03**</li> </ol>	
DRR -02*. Medication Follow-up		
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	

<sup>\*</sup>Note: "DRR -01", "DRR -02", & "DRR -03" numbering was used only during the DRR Item Pilot Test \*Note: This specific skip pattern was only used during the DRR Item Pilot Test

#### Skip Pattern Issues

• For several providers, skip patterns were not completed correctly. Skip pattern for DRR -01 (responses 0-No or 9- NA). If DRR -01 was coded 0 or 9 DRR -02 would then be skipped resulting in no coding completed for DRR -02.

• During the structured debriefing calls, most pilot sites stated that they understood the skip pattern for DRR -01. In general, analyses of item coding also demonstrated very little provider confusion related to the skip pattern; however, it is an important clarification to emphasize during training. Further, for providers with EMR software, the training can note EMR software capabilities for managing skip patterns.

## 3.1.2 Coding Responses for DRR -03

DRR -03*. N	DRR -03*. Medication Intervention	
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?	
	<ul> <li>0. No</li> <li>1. Yes</li> <li>9. NA- There were no potential clinically significant medication issues identified since Admission or patient/resident is not taking any medications.</li> </ul>	

\*Note: "DRR -01", "DRR -02", & "DRR -03" numbering was used only during the DRR Item Pilot Test

- **Difference between coding 0 and 9 for** DRR **-03:** According to provider input during the structured debriefing calls, as well as coding errors on the pilot data collection forms, there was significant provider confusion related to the response options for Item DRR -03, more specifically, distinguishing between response option 0 (No) and response option 9 (NA). This misunderstanding was partially a result of the fact that the meaning of response option 0 (No) differs between Item DRR -01 and DRR -03.
  - For DRR -01, coding 0 (No) indicates that no PCSMIs were found during a drug regimen review.
  - For DRR -03, coding 0 (No) indicates that yes there were PCSMIs identified, but the facility did not contact and/or complete physician (or physician-designee) prescribed/recommended actions by midnight of the next calendar day each time those issues were identified.

#### Types of DRR -03 Coding Errors

- The meaning of the response option 9 (N/A) also differs between Item DRR -01 and DRR -03.
  - For DRR -01, coding 9 (N/A) indicates that the patient/resident is not taking any medications.
  - For DRR -03, coding 9 (N/A) indicates that no PCSMIs were identified at any point during the patient/resident's stay or at discharge.

Some providers stated that these discrepancies in code definitions might result in coder misunderstanding and thus, inaccurate data. This issue was apparent upon reviewing the content of the pilot data collection notes: (1) Notes did not describe PCSMI during stay or at discharge; the omission of written data results in inability to verify that coding was correct (2) Notes describe PCSMI during stay or at discharge resulting in coder error in use of code-9 when DRR -03 should have been coded 1 or 0.

#### Coding Errors Related to Time Period for Review in DRR -03

The following information applied to the DRR items collected during the pilot period only, see footnote below\*.

If admission item DRR -01, is coded 1-Yes (PCSMIs were found at admission) and DRR -02 is coded 0-No, the facility *did not meet the measurement requirements* that a physician (or physician-designee) was contacted by midnight of the next calendar day and/or the provider *did not* complete prescribed/recommended actions in response to the identified PCSMI. Thus, DRR -03 would be coded 0-No (the measure criteria were not met). The provider codes DRR -03 by reviewing the patient/resident's medical records beginning from the discharge assessment period looking back through the entire stay. Note that given revisions to the item interpretation since the pilot testing, the item *now* includes the patient/resident's admission. Therefore, if the provider did not meet the measure criteria at admission this *now* results in DRR -03 being coded as 0-No.

This information indicates the importance of providing sufficient guidance on the lookback period for item DRR -03, as this was a source of confusion for providers during the Pilot. According to discussions during the structured debriefing calls, there was some provider confusion related to the time period of review for item DRR -03. Some data collectors did not understand that they were not to include PCSMIs identified at admission as documented on the admission assessment (in other words, PCSMIs considered in the coding of Items DRR -01 and DRR -02) in provider coding of DRR -03. During the pilot this would have indicated the provider completed the item incorrectly.

The presence of this confusion was further corroborated by item coding errors. The coding errors might suggest accidental consideration of PCSMIs captured at admission when coding item DRR -03. Coding of the pilot data collection forms suggests that some providers mistakenly coded DRR -03 as 0 (No) in instances where no issues were identified. This error was seen on 36/298 pilot data collection forms, where DRR -03 = 0 but there were no pilot data collection notes corresponding to PCSMIs identified during the stay or at discharge.

\*Note: Since this pilot was conducted, CMS has updated the DRR discharge item to <u>include</u> the admission period when coding the DRR -03 item. During the pilot, item DRR -03 <u>did not</u> include the admission coding results and only included the duration

of a patient/resident's stay: starting after the admission assessment period up to and including discharge.

#### 3.2 Data Sources

Providers looked to a number of different sources to find the data they needed to complete DRR items including the following:

- Official Medication List from discharging acute care hospital.
- Extraneous notes from discharging acute care hospital.
- Pharmacist's medication intervention lists.
- Pharmacist's software programs.
- Medication Administration Record (electronic -eMAR or paperMAR.
- MD (or physician designee) orders (written notes, phone notes, and verbal orders).
- Nurse's progress notes (electronic or paper).
- Pharmacist notes (electronic or paper).
- Lab reports.

Incident reports were discussed with providers during the structured debriefing calls. Some providers expressed concern that these confidential reports, which currently protect the identity of the employee who reports an incident, may be at risk of being exposed if these data are required for review by DRR coders. CMS determined that incident reports would not be a required data source, as the medical records should contain information about the medication issue/intervention that *prompted* the incident report.

#### 3.3 Data Collection Challenges

**Challenges related to documentation:** During the structured debriefing calls, providers noted a number of challenges in DRR data collection related to documentation.

Pocumentation from discharging acute facility: One of the most commonly reported challenges in completing Items DRR -01 and DRR -02 was related to the documentation provided to facilities by the discharging acute facility upon patient/resident admission. This observation is reinforced in the literature as one of the most likely times for medication errors to take place (Smith et al., 2004; Coleman et al., 2005). Pilot sites noted that this documentation is often incomplete, insufficient, or contradictory and, as a result, abstracting data for the DRR -01 and DRR -02 required deciphering this information.

- **Distinguishing who identified the issue:** Several pilot sites reported that distinguishing whether a physician or nurse identified the PCSMI is challenging, particularly when the physician is onsite and often entering information directly into the patient/resident's chart.
- Informal communication between clinical staff members: Many pilot sites noted the prevalence of informal (undocumented) DRR-related communication. For example, some sites stated that calls to physicians are not systematically documented, particularly when contact between nurse and physician or between pharmacy and physician is frequent.
- Offsite pharmacists: Several sites mentioned that documentation of pharmacist interventions occurring outside of the facility is not accessible to facility staff. This challenge is specific to the SNF pilot participants.
- Different locations and styles of documentation: Many pilot sites noted that multiple health professionals enter information in different parts of the patient/resident chart, using different communication styles. This contributes to multiple sources of information for DRR data collection and challenges in interpreting differing styles of documentation. For example, a pharmacist might have trouble interpreting information entered by a nurse and vice versa. Several pilot sites stated that the quality of documentation of DRR activities often depended on which clinical staff member identified the PCSMI. Several sites noted that medication interventions made by pharmacy staff were not difficult to identify, but interventions initiated by the nursing staff were not as easy to identify within the medical record. Although pharmacists often log medication interventions in spreadsheets or medication intervention lists, communication between a nurse and physician regarding a PCSMI might not be as formally documented or easy to identify. Additionally, one site noted that physicians do not always document sufficiently, which rendered locating information about PCSMI resolution more difficult.
- Time frame for follow-up/resolving the issue unclear: Several pilot sites reported that identifying the exact time frame in which physician follow-up and resolution occurred was challenging. However, most sites that said they couldn't identify an exact time frame indicated that they could typically infer that the item time frame was met, on the basis of the documentation that was available or based on facility practice/protocol in which immediate follow-up and resolution is required for identified medication issues. In many cases, pilot sites reported making assumptions about time frame, determining that the specified time frame was met on the basis of documentation of a medication change, even though information about the specific time at which the PCSMI was identified was unavailable.
- Paper-based record keeping systems: In general, pilot sites with paper-based record keeping systems, or record keeping systems that are only partially electronic, tended to have more difficulty completing these items. Some providers noted an absence of a

centralized location to identify DRR data that could be used by all clinical staff members.

**Patient/resident-level characteristics:** Pilot sites identified several patient/resident characteristics that made data collection for DRR items more difficult:

- Complexity of patient/resident: Several pilot sites noted that data collection for the DRR items, particularly for DRR -03, was more difficult/time-consuming for more complex/ higher-acuity patients/residents. They noted that these patients/residents might experience frequent medication issues and interventions throughout their stay. Additionally, one pilot site noted that the more specialists involved in a patient/resident's care, the more documentation there is that must be reviewed to identify medication issues and interventions.
- LOS: As expected, pilot sites noted that completing Item DRR -03 was more time-consuming for patients/residents with a longer LOS, because there were more records to review and, often, more PCSMIs to account for. However, their coding of TE-01B did not corroborate this perceived relationship between LOS and time it took to complete Item DRR -03.

**PCSMI:** Resolved vs. Unresolved by Admission Time

• Day/time of admission/discharge: All pilot sites indicated that day and time of admission and discharge did not affect the ease or accuracy of data collection. Several pilot sites reported being surprised by this, as they would have expected either (1) decreased follow-up within the specified time frame for PCSMIs identified, or (2) incomplete documentation for patients/residents admitted or discharged on nights or weekends. Quantitative analyses also revealed that the time of admission/discharge was not significantly associated with the prevalence of unresolved PCSMIs.

#### 3.4 Coding Agreement

Analysis of the pilot data collection forms revealed significant coding disagreement between data collectors at the same facility, particularly for Item DRR -03. It is important to note that some of this coding disagreement was likely because of coding errors, and not because of discrepancies in interpretation of the information available in patient/resident charts. About one-third of the pilot records demonstrated inter-rater dyads disagreement; however, this was based upon 10-20 assessments per provider. There was not a significant difference for each composition of inter-rater dyads per facility. According to information gathered from the pilot data collection notes and during the structured debriefing calls, coding discrepancies between data collectors within a facility might have been the result of several factors:

• **Differing interpretations** of item definitions (e.g., PCSMIs, time frame, inclusion of data within admission when completing the discharge DRR items), as outlined in the "Definitions" section, above.

- Access to information: A number of pilot sites noted that pharmacists and nurses
  within their facility use separate systems of documentation; sometimes resulting in
  differing levels of access to data that might affect their ability to consistently code the
  DRR items. For example, medication interventions are often documented within the
  pharmacy system, which is sometimes inaccessible to the nurse.
- Clinical background: Many pilot sites stated that a pharmacist would be able to identify PCSMIs more accurately than nurses, because they are more attuned to medication issues. However, several pilot sites noted that nurses might be more familiar with the documentation system as well as assessment coding practices (e.g., standard coding responses) and thus would be able to more-easily locate data needed to complete the three DRR items. Pilot participants opined that if pharmacists were to code the proposed DRR quality measure items, additional training would be necessary.
- Errors in use of coding: Some coding discrepancies were the result of one coder not understanding the intended use of the response codes and the other coder correctly understanding and using the response codes. This was confirmed by comparing the quantitative codes and qualitative notes in the data collection forms for the same patients/residents.



# SECTION 4 LESSONS LEARNED BY CMS/RTI

# 4.1 Existing Performance Gap

Unresolved PCSMIs or Potentially Unresolved PCSMIs: Analyses suggest a performance gap related to physician follow-up and resolution for identified PCSMIs. The total number of unresolved or potentially unresolved PCSMIs out of 298 pilot assessments: (1) For admission items DRR -01 and -02, a total of 31 pilot assessments had unresolved or potentially unresolved PCSMIs as determined upon comparison to the pilot assessments and the companion pilot data collection notes; (2) For discharge item DRR -03, a total of 24 pilot assessments had unresolved or potentially unresolved PCSMIs as determined upon comparison to the pilot assessments and the companion pilot data collection notes. This included the number of pilot assessments for which the qualitative pilot data indicate an unclear time frame in the companion pilot data collection notes for when the issue was followed-up/resolved. In these instances, the item requirement may or may not have been met, but the companion pilot data collection notes (documentation) was insufficient to fully support that the item requirement was met.

**Observed incomplete or insufficient documentation of PCSMIs:** The pilot testing revealed that certain facilities had insufficient documentation of DRR measure related activities, as assessed by means of the DRR items.

#### • At admission:

DRR -01.* Drug Regimen Review	
Enter Code	Did a complete drug regimen review identify potential clinically significant medication issues?  0. No- No issues found during review → Skip to DRR -03** 1. Yes- Issues found during review 9. NA- Patient/resident is not taking any medications → Skip to DRR -03**

\*Note: "DRR -01", "DRR -02", & "DRR -03" numbering was used only during the DRR Item Pilot Test \*Note: This specific skip pattern was only used during the DRR Item Pilot Test

No PCSMIs were identified at admission for 54 percent of the 149 patients/residents included in the pilot testing. The percentage of patients/residents for which at least one PCSMI was identified at admission varied significantly at the facility level. For example, one pilot site indicated that *no* PCSMIs were identified at admission for 90 percent of their pilot sample. This skewed distribution of identified PCSMIs at the facility level suggests that low numbers of PCSMIs at admission might reflect the incomplete or inconsistent documentation of DRR activities at certain facilities, rather than an absence of PCSMIs.

## • At discharge:

DRR -03.* N	DRR -03.* Medication Intervention	
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?	
	<ul><li>0. No</li><li>1. Yes</li><li>9. NA- There were no potential clinically significant medication issues identified since Admission or patient/resident is not taking any medications.</li></ul>	

\*Note: "DRR -01", "DRR -02", & "DRR -03" numbering was used only during the DRR Item Pilot Test

No PCSMIs were identified during the stay/at discharge for 53 percent of the 149 patients/residents included in the pilot testing. The percentage of patients/residents for which at least one PCSMI was identified during stay/at discharge varied significantly at the facility-level. This high percentage might again reflect incomplete/inconsistent documentation of DRR activities at certain facilities, rather than an absence of PCSMIs.

# 4.2 Provider Input

Staff Participation in Data Collection: During the structured debriefing calls, RTI asked providers which facility staff they anticipated would code the three DRR items if this measure was implemented at the national level. Many pilot sites noted that nursing staff would complete these items, as they currently complete all MDS, IRF-PAI, and LTCH-CARE Data Set assessments. From a feasibility perspective, these pilot sites felt that asking pharmacists to complete these items would be too burdensome. Several pilot sites, however, expressed concerns regarding the ability of nursing staff to accurately complete these items. They felt that pharmacists might be able to provide more accurate data for the DRR items and intended to use pharmacists if the measure was implemented. Several pilot sites noted that, though nursing staff would ultimately complete the DRR items, documentation processes would have to be implemented to allow the nursing staff to pull DRR information directly as it has been documented by the pharmacist. Thus, nursing staff would code the actual DRR items, but pharmacists would be responsible for all documentation related to PCSMIs. One pilot site anticipated that administrative staff would complete the coding for the measure.

# 4.3 Additional Information Requested by Providers

Findings from the DRR item pilot test demonstrated provider need for additional information/guidance related to the DRR items used to calculate the quality measure. Pilot sites felt that many of the item definitions needed further clarification (e.g., "potential clinically significant medication issue," "by midnight of the next calendar day", "admission"). Providers wanted further clarification regarding the time during stay that should be used during the review for coding Item DRR -03. Providers felt that the item response options, particularly for DRR -03, needed further clarification, ideally within the item language itself. Providers requested the option to use a "dash" when information was not available to complete certain items.

# **SECTION 5 SUMMARY**

#### 5.1 Conclusion

The exploratory pilot testing revealed several significant findings. The qualitative data from the DRR Item Pilot Test supported the need for and use of the DRR measure, as evidenced by the pilot testing findings. The pilot data indicated that 47 percent of pilot facilities reported PCSMIs during stay/at discharge; however, analyses suggested the measure items captured a wide variability in provider-reported rates of PCSMIs. This variability may indicate a variation in quality at the facility-level pertaining to the processes of patient medication reconciliation and drug regimen review. For example, without the use of a systematic approach to the processes of patient medication reconciliation and drug regimen review, lower PCSMI rates may reflect unidentified PCSMIs or incomplete/insufficient documentation of MR/DRR activities, indicating facility process issues rather than an absence of PCSMIs. Use of the DRR items can facilitate use of a systematic approach to the processes of patient medication reconciliation and drug regimen review, driving enhanced quality assurance and patient/resident safety in PAC facilities.

Further, the quantitative data supported the need for and use of the measure, indicated by the quantity and variation of PCSMIs reported during the patient/resident's stay and reported by participant providers. Analyses of the coding of the DRR items collected during the pilot suggested a performance gap related to physician follow-up and resolution for identified PCSMIs. These findings suggest that use of the DRR items can facilitate the identification of PCSMIs that were not resolved by midnight of the next calendar day, supporting the need for PAC facilities to collect the DRR items to drive enhanced quality assurance and patient/resident safety, especially surrounding transitions of care.

An overarching theme revealed by the DRR Item Pilot Test was the need for enhanced communication between clinicians regarding the medication reconciliation and drug regimen review processes. Several pilot testing participant providers noted that nursing staff would likely complete the measure items, but cautioned that requests for pharmacists to complete the items would be too burdensome. Most providers specifically stated that their facilities would include input and additional documentation by pharmacists.

Additionally, several DRR Item Pilot Test participant providers stated that the DRR measure will drive process improvement. Many providers stated that their facilities currently have processes in place that facilitate data collection for the DRR measure; and several providers indicated that their current medical record system for collecting and aggregating the data to code this measure would benefit from further development to facilitate ease of coding the DRR measure.

#### 5.2 Post-DRR Item Pilot Test Actions by CMS

A technical expert panel (TEP) convened by our measure development contractor provided input on the technical specifications of the quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC QRP, including components of reliability, validity and the feasibility of implementing the measure across PAC settings. The

TEP supported the measure's implementation across PAC settings and was supportive of our plans to standardize this measure for cross-setting development. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Video Web site at <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html</a>

Since the TEP input, the NQF-convened MAP met on December 14 and 15, 2015 and provided input on the use of the measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues-PAC QRP. The MAP encouraged continued development of the measure to meet the mandate added by the IMPACT Act. The MAP agreed with the measure gaps identified by CMS, including medication reconciliation, and stressed that medication reconciliation be present as an ongoing process. More information about the MAP's recommendations for the measure is available at <a href="http://www.qualityforum.org/Publications/2016/02/MAP\_2016\_Considerations\_for\_Implementing\_Measures\_in\_Federal\_Programs\_-\_PAC-LTC.aspx">http://www.qualityforum.org/Publications/2016/02/MAP\_2016\_Considerations\_for\_Implementing\_Measures\_in\_Federal\_Programs\_-\_PAC-LTC.aspx</a>

Since the MAP's review and recommendation of continued development, CMS has continued to refine the measure in compliance with the MAP's recommendations. The measure is consistent with the information submitted to the MAP and supports its scientific acceptability for use in quality reporting programs.

#### **5.3** Future CMS Actions

CMS plans to provide thorough training to providers pertaining to the coding and collection of the finalized quality measure, Drug Regimen Review Conducted with Follow-Up for Identified Issues (DRR), including measure item definitions. With training, CMS will issue guidance on the measure and the concepts pertaining to the measure. Further, with the measure development process, CMS will continue ongoing analysis of the finalized measure in order to identify whether additional clarification or modification of the measure is necessary.

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