# Public Comment Summary Report Including Verbatim Comments

**Project Title:**
IMPACT Act of 2014 Cross-Setting Quality Measure: Drug Regimen Review

**Dates:**

- Dates of public comment period: September 18, 2015 through October6, 2015 (the original due date of October 2, 2015 was extended to October 6, 2015)

- The public comment summary was made on November 6, 2015.

**Project Overview:**

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 was signed into law on October 6, 2014.[1] This Act requires Post-Acute Care (PAC) providers to report standardized patient assessment data and quality measure data to the Secretary of the Department of Health and Human Services.

The Centers for Medicare & Medicaid Services (CMS) is working to ensure that data elements within PAC assessment instruments are standardized and interoperable. Current federal assessment instruments are setting-specific and contain assessment items with varying concepts, definitions, and measurement scales. The move towards standardized assessment data elements facilitates cross-setting data collection, quality measurement, outcome comparison, and interoperable data exchange.

The Centers for Medicare & Medicaid Services (CMS) has contracted with Abt Associates and RTI International to develop a cross-setting PAC measure for the quality measure domain—medication reconciliation. The contract names are Development and Maintenance of Symptom Management Measures (contract number HHSM-500-2013-13015I) and Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance Project (contract number HHSM-500-2013-13001I, Task Order HHSM-500T0002). As part of its measure development process, CMS asks contractors to convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure contractor during measure development and maintenance.

In this measure, medication reconciliation and drug regimen review are defined as:

Medication Reconciliation – the process of comparing the medications a patient is taking (and should be taking) with newly ordered medications in order to identify and resolve discrepancies. (Reference: The Joint Commission, National Patient Safety Goals).

Drug Regimen Review – a review of all medications the patient 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. (Reference: Home Health Conditions of Participation §484.55c).

**Project Objectives:**

- Introduce drug regimen data elements for capturing data for a drug regimen measure in the medication reconciliation domain for PAC settings.
- Refine measure specifications.

[1] https://www.govtrack.us/congress/bills/113/hr4994

- Identify setting-specific needs/concerns/barriers for capturing drug regimen review/medication reconciliation information using the data elements.
- Gather feedback on importance, feasibility, usability and potential impact of adding drug regimen review data elements for quality measurement as new items to existing PAC assessment instruments in Home Health (HH), Inpatient Rehabilitation Facilities (IRF), Long Term Care Hospital (LTCH) and Skilled Nursing Facilities (SNF) settings.
- Identify additional guidance required for the implementation in each setting of care.

**Information About the Comments Received:**

- *Web site used*: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/CallforPublicComment.html

- Public comments were solicited by the following methods:
  - Posting on CMS Public Comment website
  - Email notification to relevant stakeholders and stakeholder organizations
  - Email notification to Technical Expert Panel members

- *Volume of responses received*: CMS received 24 comment letters in total (the vast majority of letters contained more than one point). These comment letters represent a mix of perspectives, including providers, clinicians, and pharmacists in the post-acute care (PAC) industry with a clinical background, those in academic/research organizations with technical expertise in quality measurement and advocacy groups representing different PAC areas.

**Stakeholder Comments—General and Measure Specific**

**Clinical Importance**

Seven commenters expressed support for a cross-setting measure in the medication reconciliation domain and noted the clinical importance of this quality measure concept. Commenters cited the importance of reducing inappropriate medication redundancies and adverse drug events, and of improving safe transitions for patients/residents treated in the post-acute care settings. One home health professional further noted that the "transition from inpatient to the home with medication revisions presents multiple opportunities for new problems for many patients" adding that "over the counter medications are frequently not addressed in facilities and not reviewed for interactions, as they are not administered during their stay and if a home health provider is involved ." Another commenter noted that it was important to document not just the reconciliation process but also any warranted intervention.

**Response: CMS appreciates the commenters' support for the clinical importance of the quality measure concept and the goals of measurement in this domain. We concur that Drug Regimen Review includes considering all prescribed and over-the-counter drugs that the patient/resident is taking. As a process measure, medication reconciliation and Drug Regimen Review for potential clinically significant medication issues could lead to reduced re-hospitalizations, reduced adverse events related to medications/drugs and improved health outcomes.**

**Measure Specifications**

1. Measure Time Frame

Several commenters provided feedback on the "one calendar day" time frame for physician/physician-designee contact and implementation of recommended follow-up. Many commenters noted that the one calendar day timeframe is "unworkable" in some PAC settings, especially when a physician (or provider whose scope of practice includes medication management) is not regularly on staff or onsite. They noted that HHA and SNF settings which receive admissions, for example, during nights, weekends, and late nights would have great difficulty completing the requirement to identify potential clinically significant medication issues during the course

of care and followed-up with a physician or physician designee within the one-day timeframe because physicians or pharmacists would not be working nights, weekends, and late nights hours. Two commenters elaborated that the expectation of contact with a physician is not unreasonable but the expectation for completion of recommended action within the same 24 hour window is unreasonable. One HH provider commenter elaborated that it is beyond the PAC setting's control as to whether or not the provider responds and provides actionable guidance within that timeframe. A few commenters suggested a time frame to identify potential clinically significant medication issues to be within three business days of admissions or a 72-hour window for non-emergency situations.

Some commenters expressed concern with the use of the term "timely follow up" for non-urgent medication issues. These commenters stated that non-urgent medication issues should not be held to one calendar day, depending on physicians/physician-designees' availability. They also suggested that use of a tiered time frame, based on level of urgency of the potential medication issue could be useful to address medication reconciliation and not burden clinicians. Another commenter suggested that some urgent medication issues should be addressed in less than one day.

**Response: The focus of this measure is on potential clinically significant medication issues that in the care provider's clinical judgment require necessary action by midnight of the next calendar day (i.e., does (do) the issue(s) pose an actual or potential threat to patient health and safety?). CMS understands the concern about the commenter's reference to a "24 hour" timeframe. Based on feedback received during the Technical Expert Panel webinar the timeframe has been clarified as "by midnight of the next calendar day". This timeframe allows all PAC providers a minimum of 24 hours for necessary actions to address the identified potential clinically significant medication issues. Clinician action by midnight of the next calendar day would be advisable as part of a best practice standard for quality care in scenarios where a clinician deems the potential clinically significant issue merits timely response. CMS appreciates the commenters' concern with not adding to clinician burden in addressing non-significant medication issues within the proposed timeframe. Additionally, CMS recognizes there are some clinically significant medication issues that require urgent attention and this measure does not preclude a clinician from taking immediate action for more urgent clinically significant medication issues. This measure is designed to ensure prescribed/recommended actions for a potential clinically significant medication issues are completed by midnight of the next calendar day.**

2. Data collection points

A commenter suggested: "Based up the Drug Regimen Review Measure Justification Form, the highest percentage of medication discrepancies occurs between the hospital discharge and the post-acute care admission. It would be more feasible to implement this Drug Regimen Review measure on admission only". They further stated that assessing medications used outside of the admission assessment would be "broad and unworkable". One commenter highlighted that repeatedly contacting a physician to address medication issues may be burdensome for staff with both the agency and the provider. The commenter suggested that since the highest percentage of medication discrepancies occurs between the hospital discharge and the post-acute care admission it would be more feasible to implement this Drug Regimen Review measure on admission only. This would prompt a thorough review of all medications upon admission, thereby, enabling a Drug Regimen Review at the very onset of the stay.

**Response: CMS appreciates the commenter's concern that ongoing assessment of potential clinically significant medication issues in all PAC settings be feasible. CMS believes that ongoing review of potential clinically significant medication issues during the patient's/resident's stay, at every assessment time period, is essential for providing the best quality care for patients/residents.**

**Please refer to regulation protocol for IRF, LTCH, SNF and HH settings.**

3. Item Wording

*All Items*

One commenter suggested repeating "potentially clinically significant issue" instead of just "issue" throughout the three items used in the measure, to provide consistency in understanding that the measure refers to urgent medication issues. They further noted that if there was an intentional choice to use "potentially clinically significant" versus "clinically significant medication issue" at the end of episode description, a definition of the distinction will be needed.

**Response: CMS appreciates the feedback and has addressed this request for clarification by consistently using the term "potential clinically significant medication issue" across the items used for the measure.**

A commenter was concerned that the language used in the proposed measure specification was confusing relative to current language on the SNF MDS data assessment, adding that the language appears to be focused on wording utilized in home health.

**Response: Due to the need for standardized items that will appear in all settings' assessment sets, language that would be inclusive for all settings was included in the posted documents. For example, "admission/SOC/ROC" was utilized to be inclusive of terms used in all four PAC settings under consideration. The intention is to have setting-specific language on each PAC setting's assessment tool. For example, SNFs would only see terms used to refer to the SNF setting within each of the three DRR quality measure items:**

**Item 2 Medication Follow-up would read:**

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

**Item 3 Medication Intervention would read:**

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

*Item 1*

A commenter noted the lack of a response option under item one to address issues that may not be "potentially clinically significant" and suggested adding a category for issues that were present but not clinically significant. Another commenter sought clarification regarding the response option "Patient/resident is not taking any medications"; specifically if the statement addressed a patient/resident not taking a medication for which they have been prescribed or a patient/resident not being prescribed any medications. Finally, one commenter suggested that a thorough and effective medication regimen review should be done "within 3 business days".

**Response: The intent of the measure is to capture timely follow up for "potential clinically significant medication issues" only. If none are identified, clinicians would choose "O – No issues found during review." CMS appreciates the commenter's concern with clarifying language regarding patient/resident not taking medications. The intent of this response option is to identify**

*The strikethrough or text in the color red is used to illustrate how several words appearing in measure items will be customized per setting.

**patients/residents who have no prescribed medications, and are not using any over the counter medications. "Patient/resident is not taking any medications" is not an appropriate response for patient who are not taking required medications, as this scenario could represent a potential clinical significant medication issue. These issues, and the timeframe for completing an effective medication regimen review, would be addressed in the clinician assessment guidance manuals for each PAC setting. These included the OASIS Guidance Manual, the IRF - PAI Training Manual, LTCH Quality Reporting Program Manual, and Long Term Care Facility Resident Assessment Instrument User's Manual.**

*Item 2*

Two commenters expressed concern that Item 2 may create confusion as to whether the clinician only has to contact the physician or that the physician has to implement a treatment plan for the given issue. Another commenter recommended that item 2 should be separated into two separate questions; one regarding physician contact and the second regarding physician response. A fourth commenter noted that item 2 implies that there is no time requirement to complete the recommendation of the physician while item 3 suggests one calendar day.

**Response: CMS appreciates the commenter's suggestion to change the item's current design by separating the action of contacting the physician from the follow up action recommended by the physician; however, both actions are required to be completed by midnight of the next calendar day in order to fulfill the requirements of this item, if the clinician deems the issue to be potential clinically significant enough to merit such a timely response. These clarifications would be included in the clinician assessment guidance manuals for each PAC setting.**

A separate commenter noted that the "admission" language in item 2 would suggest that more than a calendar day is needed to address a mandated requirement for medication history and reconciliation in the SNF and LTCH settings.

**Response: We thank the commenter for requesting clarification about the use of the term "admission" and further clarify the intent of the use of the word "admission" refers to the actual day of entry of the patient/resident to any of the four PAC settings.**

*Item 3*

A commenter noted that item 3 omits the word "potential" and then asks if the measure is designed to assess significant medication issues yet to occur or ones that have already occurred.

**Response: CMS appreciates the commenter's concern with timely response to medication issues identified. CMS intends for this measure to address potential clinically significant medication issues, as well as medication issues that have already occurred. CMS will consider revisions to the language in item 3 to clarify this point, as well as providing appropriate guidance in the clinician assessment manuals.**

4. Measure Exclusions

A commenter suggested excluding patients from the measure who were unexpectedly discharged before the medication reconciliation process is completed. Another commenter recommended addressing unplanned discharges and patients who left against medical advice in the exclusions.

**Response: While CMS appreciates the potential challenges of collecting data after a patient/resident is unexpectedly discharged, such a discharge could be associated with a significant medication issue. Therefore, this measure will include all patients/residents (regardless of type of discharge) to evaluate whether medication issues were a factor in their discharge.**

5. Patient Population

One commenter recommended that all PAC settings assess the same populations with the IMPACT measures and the denominator be limited to Medicare fee-for-service enrollees only, as this is the population that is subject to changes in payment policy.

**Response: CMS will explore alternatives to assessing PAC populations for and by the quality measures developed under the mandate of the IMPACT Act. CMS believes that improvements in quality are an appropriate goal for all patients, regardless of payer source.**

**Measure Testing**

One commenter expressed concern that the final measure may not have been adequately tested in the home health setting and that requirements in the measures may reflect a facility-based perspective; for example, that timely follow up with physicians is more feasible for facilities.

**Response: The three items used to calculate the Drug Regimen Review measure are derived from existing OASIS items that have been used by home health agency clinicians since 2010. Therefore, the items for the final measure are derived for the OASIS, tested for appropriateness in a home health setting. CMS is planning additional comprehensive field testing of the OASIS to include all new and modified items, to further assess the reliability, feasibility, and validity of several items, including the items used in this measure. This field test will further inform guidance to home health clinicians on completing the Drug Regimen Review items. Additional testing of the items is also planned for the IRF, LTCH and SNF settings.**

**Data Validity**

One commenter questioned the validity of the "look back" information collected with each assessment tool. The commenter suggested it would be appropriate to review data from OASIS on the look back period to determine if the data is reliable. Another noted that it was important to have a mechanism to validate the data associated with this measure to ensure it is entered and completed. This commenter added that it is important that verification to indicate that this item was completed accurately (e.g. documentation) and offered to support CMS in developing such a mechanism.

**Response: CMS appreciates the commenters concerns about the validity of the self-reported data. As noted above, a comprehensive field test of all OASIS items is planned for 2016 that will include validation testing. Currently, a small sample of OASIS data is verified by surveyors during their agency visits. In addition, another sample of OASIS assessments is verified by medical review staff at the home health claims processing contractors (Medicare Administrative Contractors, or MACs). Additionally, data accuracy is very important for all quality reporting programs in post-acute care. CMS intends to align a process and program surrounding data validation and accuracy analysis for all quality reporting programs.**

**Potential Clinically Significant Medication Issues**

Numerous commenters noted that a definition of "clinically significant" was missing from the current version of the measure documentation and is needed to ensure consistent and accurate measurement of an organization's performance and of data exchange among post-acute care providers. Two commenters suggested using the definition from CMS' State Operations Manual (SOM) Appendix PP - Guidance to Surveyors for Long Term Care Facilities for medication regimen review (§483.60(c)). The SOM defines "clinically significant" as "*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, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status."* Another suggested using guidelines developed by the Centers for Disease Control or Federal Drug Administration. One commenter provided a list of potential adverse outcomes, including death, disability and hospitalizations, that could be used to define "potential clinically significant medication issues" as well as outcomes that would not meet this definition, such as expected medication reactions or physical disturbance consistent with the pathological state. Finally one commenter noted that their state defined the list of high risk medications and adverse reactions that clinicians must review.

**Response: CMS acknowledges the commenters' request for a definition of "clinically significant" for this measure. Potential clinically significant medication issues are those that, in the clinician's professional judgment, warrant outreach to a physician and timely completion of any recommended actions (by midnight of the next calendar day) to avoid adverse outcomes. CMS does not think it appropriate to define a specific list of high risk medications for review, as high risk is specific to each individual's conditions; determining high risk should rely on clinicians' professional judgment, although CMS recognizes that some states may have such requirements. More specific guidance will be included in the clinician assessment guidance manual for each post-acute care setting. CMS additionally appreciates the recommendation for specific guidelines to help formulate this guidance and will consider them when updating the respective post-acute care clinician assessment guidance manuals. These manuals include the OASIS Guidance Manual, the IRF – PAI Training Manual, LTCH Quality Reporting Program Manual, and Long Term Care Facility Resident Assessment Instrument User's Manual.**

One HH commenter suggested that it may not be feasible to identify "ineffective drug" therapies if the Drug Regimen Review occurs at the Start of Care (SOC) visit and the medication is new for the patient (i.e., was prescribed at time of discharge from the previous provider). To assess effectiveness of such medications, the commenter noted that subsequent Drug Regimen Reviews would be required and they wanted to know if/when these reviews would be required.

**Response: While CMS acknowledges that some newly prescribed medication may not have had sufficient time to take effect (e.g., antidepressants), for most conditions the patient should be stabilized before discharge from the previous provider and the condition(s) for which they are being treated also stabilized. Assessing the effectiveness of a medication is patient specific and CMS will provide detailed guidance in the clinician assessment guidance manual for each post-acute care setting to support this quality measure.**

**Drug Regimen Review is an ongoing activity, as clinically indicated, to identify and address any potential clinically significant medication issues. At the end of the episode or stay, the provider should review medical records to document that all potential clinically significant medication issues were identified throughout the episode or stay to ensure all issues were addressed in a timely manner.**

Several commenters noted that the proposed measure specification uses both "potentially significant" and "clinically significant" but does not define either term. It was further noted by one commenter that identifying "potentially significant" issues is highly subjective and would vary by clinicians and across post-acute care settings, thus putting at risk the reliability and validity of the proposed measure.

**PROPOSED RESPONSE**

**Response: CMS appreciates the comment regarding interpretation of these terms in the draft items and will consider revisions to the data collection items for consistency. Clinically significant medication issues (e.g., adverse effects and drug reactions) are referenced as "potential" to include those cases where a medication issue has not occurred; but, due to the patient's/resident's medical history of diagnoses (or comorbidities), places the patient/resident at risk for the occurrence of an adverse effect (e.g. drug reaction). Another example is the patient/resident with a prescription history of administered multiple medications, who have higher than average risk factors associated with one or more of these prescribed medications. Another example of a potential clinically significant medication issue would be an unexpected event occurring due to a patient taking a medication and once the issue was identified, the physician (or physician designee) took action to address the issue. Finally, the Drug Regimen Review also includes potential clinically significant medication issues that were avoided because the medication was discontinued and never administered.**

**Drug Regimen Review/Medication Reconciliation Definition and Scope**

Several commenters asserted that the proposed measure addresses Drug Regimen Review as defined for certified home health agencies, not "medication reconciliation" as listed in the IMPACT Act and therefore does not meet the Act's intent or requirement since Drug Regimen Review and medication reconciliation, although related, are distinct processes. Some commenters recommended development of a medication reconciliation measure only. One commenter went on to note that the intent of the IMPACT Act is to include both processes and, as such, the proposed measure should include aspects of both medication reconciliation and Drug Regimen Review. Another commenter suggested that the measure require medication reconciliation at all transitions of care, while another recommended that medication reconciliation should include medications the patient is not taking prescribed medications.

**Response: CMS acknowledges the reviewer's comments and notes that the foundation and intent of the quality measure is harmonized across PAC provider settings. CMS believes that the definition of Drug Regimen Review included in this measure encompasses the process of medication reconciliation; therefore, this quality measure meets the domain of Medication Reconciliation mandated by the IMPACT Act. This view was supported by the technical expert panel convened by the measure development contactors in July 2015.**

Several commenters noted that the current measure uses the definition of Drug Regimen Review from the Conditions of Participation for Home Health (§484.55c) and that this definition is not consistent with the definition of Medication Regimen Review (§483.60(c)) in the State Operations Manual (SOM) Appendix PP Guidance to Surveyors for Long-Term Care Facilities. Commenters went on to note that these definitions differ in two significant ways. First, the proposed definition does not promote involvement of all members on the interdisciplinary clinical care team in the review process. Second, the proposed definition simply states "review" in describing the process, while the SOM definition provides more explicit direction, including "preventing, identifying, reporting and resolving medication related problems, medication errors, or other irregularities." These commenters recommend using the SOM definition.

One commenter recommended aligning the definition of a Drug Regimen Review with operational definitions of existing regulatory and accreditation requirements (e.g., the Joint Commission and Meaningful Use Stage 2 Criteria).

One commenter noted that it is "infeasible" for admitting providers to assess "noncompliance with drug therapy, significant side effects, and ineffective drug therapy." In addition, one commenter recommended incorporating the "high alert" medications list developed by the Institute for Safe Medication Practices as part of a Drug Regimen Review process.

**Response: CMS appreciates the commenters' feedback and plans to develop standardized, cross-setting guidance in the clinician assessment guidance manuals for each post-acute care setting for the items used in the measure. This guidance will draw upon existing guidance for each post-acute care setting, and additional guidance will be considered according to accepted clinical practice and comply with facility policy, and State and Federal regulations. As noted above, CMS does not believe it is appropriate to define or require a specific but limited medication list for review. CMS believes that the addition of detailed guidance for each of the respective assessments, the proposed measure will provide a comprehensive assessment of the Drug Regimen Review process that is meaningful for patient care by providing a positive impact on patient outcomes and allows for cross-setting comparisons.**

One commenter suggested that "drug" should be replaced with "medication" since in the context of the proposed measure it is more appropriate. Another commenter noted that clinicians have no control over patients' use of non-prescribed over-the-counter medications and other substances.

**Response: The word "drug" was deliberately chosen in order to include both prescribed and over-the-counter medications, as well as other substances the patient may be taking, such as nutritional supplements. CMS believes that a review of all prescribed and non-prescribed drugs for potential clinically significant issues represents clinical best practice and poses best opportunities to reduce re-hospitalizations, reduce adverse events related to medications and improve health outcomes.**

**Physician Response Times and Accountability**

Several commenters addressed the issue of timely physician response to communicate potential clinically significant medication issues and physicians accountability in this process measure. Many commenters, the majority from the home health setting, noted the challenge of obtaining physician response within the 24-hour or one calendar day time frame (e.g. physician was contacted within 24 hours but was on vacation, didn't return a call, or didn't address the issue). One additional comment described the challenge in home health care of having to contact multiple physicians in some situations to confirm which will provide orders for the medication of concern, noting that completing the activity within 24 hours in this situation would be difficult. Three additional comments described the scenario where the usual physician is unavailable (after hours, weekend, vacation, other duties), and covering physician is unwilling to make changes to medications for a patient with whom they are unfamiliar. The majority of these commenters recommended that physicians, and not PAC providers, be held accountable for their timely response to clinician communications of a medication issue. One commenter noted that measuring physician notification after a clinically significant medication event happens is a separate and distinct quality measure, and one that should almost never take a full calendar day to occur.

One commenter noted that in a hospital setting, medication reconciliation is completed by physicians, who then write the orders for any necessary changes. This commenter recommended rewording the measure to reflect this care practice. Another commenter stressed the importance of holding hospitals accountable for providing post-acute settings with accurate medication lists upon patient transfer. Finally, two commenters recommended that CMS offer physician training on responding to outreach from home health clinicians on medication issues, to avoid penalizing agencies for clinician non-response.

**Response:**

**CMS appreciates the challenges in coordinating patient care in some post-acute care settings (e.g., HHAs, SNFs) that primarily work with external physicians or physician representatives, as well as the importance of accurate medication information from prior care settings. The measure focuses on those potential clinically significant medication issues that the clinician deems serious enough to warrant contact and follow up action within a maximum time frame of midnight of the next calendar day. CMS recognizes that some medication issues, including issues that have occurred, may require a more immediate response. CMS appreciates the suggestion regarding physician training and will take this under consideration.**

One commenter suggested adding a data field to explain the reason why the identified issue(s) that the physician (or physician-designee) prescribed/recommended actions were not completed within one calendar day.

**Response: CMS acknowledges that there may be situations where the prescribed/recommended actions cannot be completed by midnight of the next calendar day. However, since the definition of "potential clinically significant medication issues" is limited to issues that in the clinician's judgment should be resolved in this timeframe, CMS believes that the adherence to the one-day (by midnight of the next calendar day) time line is critical for ensuring the best care and safety for the patient/resident and currently is not collecting data as to why the time frame was not met.**

**Feasibility/Burden**

A few commenters noted the challenge of documenting action "each time clinically significant medication issues were identified". Specifically, the commenters noted that PAC settings may not have the ability to track the timeframe for review and action within their electronic health records (EHRs) without system modification, and that modifying paper charts would be subject to paper error and delays. Further, they stated paper charts would create a manifold workload on those who collect the data elements to be entered patient-by-patient into the assessment tools, such as the LTCH CARE registered nurse documentation. They added that limited interoperability of EMR/EHRs between many SNFs and the pharmacy systems can preclude any remote reviews that might increase access to providers in shortage areas (e.g. remote reviews). In addition, it was noted that higher risk medications would require multiple DRR reviews - each time clinically significant issues are identified it would be challenging to record all the reviews using the systems currently in place.

**Response: The intent of the measure is to capture timely follow up for all "potential clinically significant issues". CMS believes the timely review and follow up of potential clinically significant medication issues at every assessment time period and across the patient's/resident's PAC stay/episode of care is essential for providing the best quality care for patients/residents. Documenting that this review has occurred is an important component of safe and high-quality care.**

One commenter noted that there is less documentation for addressing over the counter medications, vitamins, and herbal supplements that the patient may be taking that may present a clinically significant risk, adding that providers will need guidance on assessing and addressing these as well.

**Response: CMS appreciates the comment and will address this issue in the documentation and training, to clarify the full scope of Drug Regimen Review.**

One commenter noted that limitations in their state's Scope of Practice law make it challenging for physical and speech therapists to complete the Drug Regimen Review.

**Response: CMS appreciates that some states' Scope of Practice legislation is more restrictive than the Conditions of Participation for certified home health agencies. The proposed Drug Regimen Review measure does not change existing policy on who may complete this review. Clinical assessments performed on patients in PAC settings should be completed according to accepted clinical licensure and practice as well as comply with facility policy, and State and Federal regulations.**

**Differences by Care Setting**

Two commenters expressed concern that a measure across PAC settings must take into account the differences in patient acuity and medical supervision between settings. One commenter noted that IRFs are providing more regular medical care to higher acuity patients with multiple medication adjustments necessary. Physicians in IRF settings oversee medication management issues far more frequently than SNF or HH settings. One commenter stated that due to the increased number of medication adjustments at an IRF, there is a potential increased risk of a clinically significant medication issue arising during the course of the patient's stay. The commenter stated that the draft measure does not permit an admission to be counted in the numerator if a clinically significant medication issue was not appropriately addressed even one time during the stay. The commenter stated that this is a disadvantage in PAC provider settings that regularly adjust patient medications to improve patient care. Another commenter noted that medication issues can be addressed more quickly in inpatient settings, relative to home health.

**Response: CMS appreciates the commenter's concern with the potential need to more frequently adjust medication issues, in higher acuity settings. CMS believes the review of potential clinically significant medication issues, as defined by the clinician, at every assessment time period and throughout the patient's/resident's stay/episode of care is essential for ensuring patient safety and providing the best quality care for patients/residents, particularly for higher acuity patients/residents. CMS will continue to monitor and analyze the effects of the measure across PAC settings.**

One commenter expressed concern that there is a high level of risk for patients to experience clinically important medication discrepancies at transition points (e.g. from a hospital discharge to admission to a PAC setting). The commenter advocates for a thorough medication reconciliation, stating the measure does not specifically address medication reconciliation at transitions of care.

**Response: CMS appreciates the commenter's concern with medication discrepancies that can occur at a patient's/resident's transition upon discharge from one setting to another. The Drug Regimen Review quality measure requires medication reconciliation as part of the measure to address both points of the care transition (admission to and discharge from the PAC) as well as during the patient's/resident's stay/episode of care. The intent of the measure is to capture timely follow up for "potential clinically significant issues" that may occur at both transition points and across the patient's/resident's PAC stay/episode of care.**

**Unintended Consequences**

Three commenters identified potential unintended consequences of the implementation of the draft Drug Regimen Review measure. One commenter was concerned that the measure would result in flagging issues that have already been considered by the physician and thus increase administrative burden. This commenter noted that use of the measure may result in unnecessary hospital readmissions or emergency department use if the

issue could not be resolved in the home health setting. One commenter said that the increased frequency of reviews and extremely short timeframe increases the workload and demand for consultant pharmacists, which is likely to cause them to reduce the number of beds they can oversee and the number of SNFs they could cover in a close geographic area, all worsening the shortage of pharmacist services. Another commenter suggested the lack of robust clinical evidence in support of this measure could lead to harm in the patient-centered care process that occurs in PAC settings. One final commenter raised the concern that the measure could discourage clinicians from reporting significant medication issues.

**Response: CMS appreciates the commenters' concerns about unintended consequences and challenges if providers address non-significant medication issues within the proposed timeframe. The measure focuses on identifying and addressing any potential clinically significant medication issues that the clinician believes require actions by physician or physician-designee by midnight of the next calendar day. Issues that have already resulted in previous physician contact and resolution would be included in the measure's numerator. We additionally appreciate the commenter's concern with avoiding unnecessary emergency department visits or re-hospitalizations. After careful consideration and clinical review, however, a clinician may determine it is in the best interest of the patient to access a care setting that can appropriately address the patient's current level of acuity. Finally, the measure was informed by current evidence surrounding medication reconciliation and drug regimen review, as well as a review of best practice and professional standards of care. Since it is best practice and a professional standard of practice for all providers to address potential clinically significant medication issues before they lead to avoidable harm to the patient, CMS does not feel that the measure will discourage a clinician from reporting a significant medication issue.**

**Guidance on Who May Complete Drug Regimen Review**

Two commenters requested guidance on which professionals should complete the Drug Regimen Review. One additionally noted that CMS may wish to consider requiring that the same type of qualified health care professionals perform the Drug Regimen Review across all PAC settings.

**Response: Current Conditions of Participation for each setting specify which clinician types should complete the comprehensive assessment, including medication review. Completion of the comprehensive assessment should be according to accepted clinical practice, clinical licensure and comply with facility policy, and State and Federal regulations.**

**Setting-specific Comments**

One commenter asked about how the IMPACT measures, including Drug Regimen Review, align with Home Health Compare measures, and how they will be phased into the rating system. This commenter noted that agencies need time to prepare for new requirements and train staff, and recommend that CMS develop an implementation timeframe "allowing at least a year following publication of final specifications before measures are reported."

**Response: CMS appreciates the commenters request for clarification regarding the timing of measure implementation and relationship to existing home health measures, as well as the request for sufficient time to prepare for new measures. The implementation and reporting of measures to support the requirements of the IMPACT Act are defined within the Act. For home health agencies, data collection to support the cross-setting Drug Regimen Review measure must begin on January 1, 2017 and public reporting will commence one year later (January 1, 2018).**

**CMS intends to provide guidance on revised OASIS items for use in 2017, including the items used in the Drug Regimen Review, available in 2016. Additionally, CMS will use rule-making to propose any changes to the existing Home Health Quality Reporting Program and to specify the timeline for any measure set changes, including IMPACT Act measures.**

One commenter noted that adding data collection items for this measure into the Minimum Data Set (MDS) (the assessment tool used in Medicare certified skilled nursing facilities) will have a significant impact on skilled nursing facilities including costs, resource intensity and training time. In addition, vendors also require adequate time to prepare electronic systems to support the changes. The commenter suggested that the changes to MDS with regard to this measure be incorporated into the MDS annual update.

Two commenters noted that changes to the data collection instrumentation (MDS, IRF-PAI) would have additional burden and costs associated with changing the instrumentation, changing the documentation and software to support instrumentation changes, additional training of staff, and changes to electronic health records. The commenters suggested that changes be timed to coincide with annual updates. The commenters also requested enough time between the change and implementation date ~~are~~ be provided so that the field can adequately make modifications to all the systems that will need to be changed.

**Response: CMS appreciates the commenter's note about the impact of the changes to MDS on skilled nursing facilities and vendors. The implementation and reporting of measures to support the requirements of the IMPACT Act are defined within the Act. For skilled nursing facilities, data collection to support the cross-setting Drug Regimen Review measure must begin on or before October 1, 2018. CMS intends to make the changes to MDS regarding the items used in the Drug Regimen Review part of the annual MDS update and make the guidance on this items available before the update to allow providers and vendors preparation time. Additionally, CMS will use rule-making to propose any changes to the existing Skilled Nursing Facility Quality Reporting Program, and MDS, and to specify the timeline for any measure set changes, including IMPACT Act measures.**

**Measure Justification Form**

CMS received four comments on the language in the "Importance" portion of the Measure Justification Form. Two commenters noted the absence of an "Outcome 1". In addition, three commenters expressed concern about specific targets within the goal of reducing polypharmacy, about guidelines for calculating creatinine clearance levels and about the Cockcroft Gault Score. Finally, the commenters noted that it is clinically unrealistic to have an expected outcome of "No adverse drug reactions, no drugs ordered to treat side effects or adverse reaction." Another commenter expressed support for the guidelines included in this section, and offered suggestions for modifying them to address pharmacogentic testing, the use of clinical decision support tools and the role of pharmacy services.

**Response: The Measure Justification Form has been completed in accordance with National Quality Forum (NQF) requirements. The response to this item is derived directly from the published clinical practice guidelines so the numbering of the outcomes cited in the Measure Justification Form is determined by that source. Outcome 1 (1a) included in the guideline is specific to functional status; since the concept of functional status was deemed as tangential to this process measure a search for relevant functional guidelines was not conducted and this outcome left blank. The guidelines were not generated or endorsed by the CMS team or contractors; they are the result from the required search of published Clinical Practice Guidelines. Per NQF requirements, this form includes the specifics from the search as quoted in the guideline, unedited. CMS appreciates the comments and their relevance to this measure; however, CMS is not permitted to make changes to the evidence guidelines yielded in the search.**

**Preliminary Recommendations**

We do not plan on making further changes to the measures' methodology in the immediate future, with the exception of changes to item wording. However, we will take under consideration suggestions for further testing. To the extent possible, we will also incorporate suggestions received during public comment on the implementation of these measures. Specifically, we will plan to:

- Continue measure testing and development
- Submit measures to the MAP for inclusion in the rulemaking cycle;
- Submit measures to NQF for review and endorsement; and
- Conducting pilot testing to assess feasibility, reliability, and validity of assessment data.

*Overall Analysis of the Comments and Recommendations*

The comments and feedback received provided useful input for the development and implementation of the drug regimen review measure.

# Verbatim Comments

* The comments included here are verbatim and the content was not changed or edited

| ID | Date Posted | Text of Comments | Name, Credentials, and Organization of Commentor | E-Mail Address | Type of Organization | Recommendations /Actions Taken |
|---|---|---|---|---|---|---|
| 1 | 9/30/2015 | I would like to submit a comment for the Drug Regimen Review Measure.<br>I totally agree the need and purpose of the measure without reservation. The concern I have is not having an option to indicate that the organization identified and contacted the physician or designee timely but had not received final reconciliation prior to the midnight of the next day. This is an issue for Home Health Agencies (HHA) since there are not physicians on staff to address those call or that a patient is in an in-patient setting where physician calls are a higher priority. Ideally the physician would call back. HHAs have to repeatedly contact the physician's office which is annoying and some physicians elect to not refer to home health for patients who are in need of services.<br><br>Another way this timeframe effects HHA is when the patient is admitted late Friday (after physician hours) or on the weekend. The "on-call" physician has to be called who does not know or want to address most issues unless critical – instructed to contact physician on Monday. So the agency is out of the timeframe (except if admission is on Sunday – but the response must be obtained the same day in those cases). | Misty Kevech, RN, BS Ed, MS, COS-C<br>HHQI Project Coordinator<br>Quality Insights Quality Innovation Network Campaign | mkevech@wvmi.org | HH Association | |
| 2 | 9/30/2015 | I think medication safety in cross community setting is of utmost importance and could easily translate into a cross setting measure.<br>The key is to go beyond just the reconciliation process and document the intervention processes. The CDC and FDA addresses some medication safety issues: http://www.cdc.gov/MedicationSafety/program_focus_activities.html http://www.fda.gov/Drugs/DrugSafety/SafeUseInitiative/default.htm<br>Thank you,<br>Debbie Terkay<br>http://www.guideline.gov/content.aspx?id=39268<br>Did you use this guideline in your findings?<br>http://innovation.cms.gov/initiatives/enhancedmtm/<br>And have you looked at this model? | Debora A. Terkay, RN; Health Insurance Specialist<br>Division of Training<br>Creative Services Group, CMS | Debora.Terkay@cms.hhs.gov | CMS | |
| 3 | 9/30/2015 | Before medicare makes any major changes they need to train MD's and their offices to respond back when agencies communicate this information to them. Agencies don't need another way to penalize them because MD's do not respond when they are supposed to. There are many problems with Home health Agencies and Face to faces now because Medicare has failed to do it's job in training the MD's and their offices. | Tim Carpenter, RN, Orleans Essex VNA and Hospice | Tcarpenter@oevna.org | HH | |

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| 4 | 9/30/2015 | May biggest concerns for home care are as follows:<br>1. We have no control over the client as far as OTC, vitamin, herbals etc the client chooses to use whether they are helpful and appropriate for the client or not<br>2. Physician don't do a good job of addressing the OTC, vitamin, herbals etc even when we inform them the client is using these medications<br>3. Our ability to contact the physician within 24 hours is very difficult –we can call their office however it's very difficult to get a hold of the physician and get an answer to our reconciliation issues in 24 hours.<br>4. here in the rural area the physicians don't have a middle provider working with them that can assist us when the physician is unavailable due to other responsibilities, scheduled duties or on vacation and other physicians in the same clinic practice do not want to make medication decision on client's they have never seen.<br>5. The clinic setting and acute care setting needs to be an actively engaged partner in this process-we have worked very hard on trying to keep them actively engaged with some success. It's very difficult when the hospitals and clinics don't seem to be held to the same medication reconciliation standards as home care is held to. An example would be we rarely see all the OTC medications such as Acetaminophen, cough syrup, cold medication, pain medications, vitamin, herbals, creams, ointments etc. listed on medication reconciliation information we receive from these referral sources.<br>6. I wish we could add comments to the outcome results-example would be to be able to explain that we contacted the physician within 24 hours but the physician was on vacation, didn't return our call, physician didn't address the issue etc. that way we could explain a low outcome result instead of it looking like we didn't do our job. | Julie Pahlen, RN, PHN Director<br>LifeCare Medical Center | jpahlen@lifecaremc.com | HH, SNF, IRF, CAH | |
| 5 | 9/30/2015 | Just to clarify my understanding of this proposed rule; nothing is changing with the OASIS question itself, they are just recommending that this data be collected in other post-acute settings?<br>I might be missing something, and your guidance might be helpful. | Amanda Gartner RN, MSN, COS-C;<br>Interim QA/PI & OASIS Manager, Corridor Group | agartner@thecorridorgroup.com | HH Consulting | |

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| 6 | 9/30/2015 | My comments regarding the drug regimen questions on OASIS for home health providers are related to our current situation of needing to contact the MD w/in one calendar day when we find potentially clinically issues in our drug regimen/reconciliation review. The proposed questions appear to be the same as we currently have to use. My issue is this…I do not think it realistic to have the expectation that an MD will get back to a home health agency within one calendar day of the home health agency contact of potential concern. I believe the measure should be that the agency reached out to the MD w/in the one calendar day but NOT that the MD returned that communication. That is not realistic unfortunately—particularly if the MD does not see the med interaction as significant. They do not see the urgency to getting back to the home health agency. I do not feel it is right to hold the home health agency to a standard that is out of their control and dependent on a physician's action. Our job is to alert the MD and follow through when they give us something to follow through on. | Gretchen Anderson, MSPT, GCS, COS-C; Administrator, Sunshine Home Health | gretchena@shhc-llc.com | HH | |
| | 9/30/2015 | As Home health providers, we currently collect Oasis data at start of care and resumption of care on the Drug Regimen Review for M2000 regarding whether the review indicates potential clinically significant medication issues. It is problematic in home health when the Physical Therapist or Speech Therapist are completing the Drug Regimen Review. Due to the limitations within their Scope of Practice in California. We have a process for the nurse supervisor to review the medications recorded during the visit to collaborate and review the profile.<br>I think that the transition from inpatient to the home with medication revisions presents multiple opportunities for new problems for many patients. The problems are complicated by the lack of continuity with Physicians between settings whether inpatient or LTC to the community, with or without home health. Over the counter medications are frequently not addressed in facilities and not reviewed for interactions, as they are not administered during their stay and if a home health provider is involved.<br>M2002- Was Physician contacted within one calendar to resolve the clinically significant medications issues, does not take in consideration weekend Physician availability for reconciliation and the lack of Physician hand off from providers. Covering Physicians often are unaware of patients history and reluctant to address any medication revisions, therefore resolution is completed by the time the assessment is completed and does not need to be reported as an existing problem. The is a data collection waste of time and resources. | Nina Kaiser RN, COS-C MBA<br>QCE Lakeside Home Heath Sutter Care at Home | kaisern@sutterhealth.org | HH | |

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| | | The measure needs to be revised for all collection opportunities prior to being expanded to more collection, the without true effectiveness determined with Physicians involved in the care of patients both in long term care and in the community. | | | | |
| 8 | 10/1/2015 | As requested, I am providing stakeholder feedback on the proposed measure. Detailed definitions need to be included surrounding what is considered " clinically significant medication issues" and associated with the need to have a response from a physician within one calendar day. Additionally I have concerns around the "contact of the physician/designee within one calendar day".<br>Home health agencies could be penalized for the challenges in reaching physicians/prescribers within this one calendar day period, as historically reaching physicians an ongoing challenge due to patient load/availability etc. Also, in the event the SOC takes place on the weekend; reaching the prescriber/covering prescriber is further hampered, and may result in the patient being sent to the ER for med issues that may be able to wait until a weekday for follow up. There are various levels of side effects, adverse drug effects and drug to drug/drug to food interactions. Anything severe or life threatening would be addressed via 911. Also, perhaps there is a medication that is identified as causing a clinically significant medication issue, but the patient does not take/receive this medication on a daily basis; how would that then factor into the measure? There may be a need to have a "tiered" approach to the type and timeframes for contact of the prescriber. | Susan Bujalski RN, BSN, CRNI; Manager Performance Development Villagecare HomeCare | SusanB@villagecare.org | HH | |
| 9 | 10/2/2015 | I believe that the definition of reconciliation should be comparing what the patient is taking with what the patient should be taking (as evidenced by the med list obtained from referral source). Often the patient is NOT taking what he or she should be taking and those are the discrepancies that must be resolved. | Joy Chilton RN Central Vt Home Health & Hospice, Inc. Compliance Officer | JChilton@CVHHH.ORG | HH | |
| 10 | 10/2/2015 | We recently convened a call of senior operational and quality staff of our member home health agencies. The following issues were identified relating to the DRR measure and overall implementation of IMPACT Act Measures. I would be delighted to follow up with you if you have questions or need additional information about any of the comments below.<br>Definitions Needed<br>• The measure needs more definition as to the scope of the medication review. The requirements of the review should be consistent with the professional licensure and practice of clinicians conducting the review. | E. Liza Greenberg, RN, MPH Interim Vice President, Quality and Performance Improvement Visiting Nurse Associations of America | LGreenberg@vnaa.org | HH | |

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| | | • We are concerned that a pharmacist's expertise is needed to determine if there are "significant drug interactions," and to evaluate other aspects of the DRR having to do with potential effects. We recommend that pharmacy services be a covered service to carry out the DRR.<br>• Need to define "significant drug interactions," and "significant side effects," "any potential adverse effects," so that they can be standardized in clinical protocols and are consistent with scope of practice with home care clinicians<br>• Please describe how ineffective drug therapy is defined in the context of a home health visit and whether follow up care is required? How would effectiveness or ineffectiveness be assessed at a SOC visit if the patient was just discharged with a new medication such as an antidepressant? A clinician might not know if a new medication is effective or ineffective at the SOC visit. Is the implication that home health would be required to do another DRR to evaluate efficacy? Note that it is generally a physician scope of practice to determine treatment response (which may require additional examination or testing).<br>Administrative Burden<br>• Implementation of the measure could be potentially very burdensome for both home health and prescribing physicians, if home health is required to contact the physician for every potential concern identified in the DRR. We are also concerned that the measure does not allow for clinical judgment; the rigid requirements for follow up with the physician may harm the relationship of home health clinicians with PCPs.<br>• We recommend that there be variations in requirements for "timely" follow up based on the urgency of the medication concerned. "One calendar day" is too short a timeframe for medication questions that are not urgent. It adds tremendous burden on both physician and non-physician providers to require that all medication questions be addressed with the same urgency.<br>We are concerned that home health is held to the requirement of timely follow up with a physician but physicians have no requirement for timely response. Under the current description, home health may be penalized if a physician fails to respond, a covering physician defers a response until the attending physician is available, or if HH makes the clinical decision that the problem is not urgent enough to warrant a night or weekend call | | | | |

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| | | • We are concerned that the HHA may be penalized if the regimen review reveals drug interactions but the physician elects not to make a change or does not respond to the HHA in a timely manner.<br>Testing and Phase in<br>• We are concerned at the lack of information about how the IMPACT measures align with Home Health Compare measures, and how they will be phased into the rating system. Agencies need to update their assessment processes and information technology systems, as well as train staff on new requirements. We strongly recommend that CMS develops an implementation timeframe allowing at least a year following publication of final specifications before measures are report.<br>• We are concerned that the final measure may not have been adequately tested in the home health setting and that requirements in the measures may reflect a facility-based perspective (for example, timely follow up with physicians is more feasible for facilities.)<br>• We are concerned that the measure appears to require PAC providers to be accountable for physician prescribing and follow up actions. We strongly urge CMS to educate physicians on requirements of PAC providers and provide incentives or penalties for their cooperation.<br>• We are concerned that the measure may have unintended consequences by flagging many concerns that have already been considered by the physician (thus increasing administrative burden on prescribers) or result in unnecessary ED / readmissions if a concerned cannot be resolved at the HHA level and patients follow up in an acute setting | | | | |
| 11 | 10/2/2015 | Item 2 numerator wording implies that there is no required time for completion of recommendation by physician whereas item #3 wording implies a one calendar day deadline completion after contact of recommendations.<br>Since the term “Drug Regimen Review” is distinguished from “Medication Reconciliation” , it is not clear if the intention is to require a Drug Regimen Review or medication reconciliation or both throughout the required specifications.<br>It is not clear if there is one or three metrics being measured.<br>Clarification is needed on what healthcare professional should be required to conduct the initial Drug Regimen Review. | James Poullard, PharmD, MBA. Kindred Hospital Division Vice President of Pharmacy | James.Poullard@kindred.com | Kindred Healthcare is the largest diversified provider of post-acute care services in the United States | |

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| | | Thank you for your e-mail requesting comment on the proposed Drug Regiment Review and Follow up Measure. It my privilege to submit these comments on behalf Interim HealthCare Inc. and I hope that they are helpful.<br><br>Measure Description: If measure results are reported as written, how would CMS or the impacted agency/facility know if the issue was at start of care or subsequently? We would offer that agencies/facilities are able to make more rapid improvement when the measures discriminate as to the source of the process or quality problem.<br><br>Note: A clear definition of "… potentially clinically significant" is key to interpretation of the measure as well action to improve as the chart review and subsequent evaluation of results can be easily lost in a war of interpretation of the phrase.<br><br>Items Used:<br>• Recommend repeating "potentially clinically significant issue" in each choice. As it reads now it is just an 'issue'. Many staff don't read the stem or introductory phrase after initial training, therefore interrater reliability may be an issue. Don't you want to reinforce potentially clinically significant, not just any issue?<br>• Item 2 appears to incorporate 2 measures: 1) did the provider contact the physician within one calendar day; and 2) did the provider complete recommended action. When the data is collected and returned how will the agency/facility know which was the problem short of chart review?<br>End of Episode Question.<br>This is a "look back" question done by the person completing the episode end data set. They are expected to review each patient contact to answer this question? I would question the reliability of this process and ask if anyone has looked at validity of the "look back" question on OASIS now. | Barbara A McCann<br>Chief Industry Officer,<br>Interim HealthCare Inc. | BarbaraMcCann@InterimHealthCare.com | HH nationwide | |

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| 12 | 10/2/2015 | • When you read the question in this item, it appears to involve 3 measures-1) the decision that a potentially clinically significant issue was identified; 2) that the physician was contacted; and 3) the action recommended was completed. Any one of these items negatively answered would be a "NO". How do we know which process failed?<br>• In the wording of the end of episode statement the key phrase is not "potentially clinically significant", but "clinically significant medication issue" – do both phrases have the same meaning? If so, why not use same language? If no, definition of this phrase is also needed.<br>Endorsement Statement of the Numerator:<br>• A descriptive phrase is used that is not the same as in the Measure Description or the wording in the Items Used. Here it is "clinically significant medication issues". Strongly recommend using same phrase throughout and define it.<br>Summary Comments:<br>• The topic of the measure is very valuable, however as stated, when the measure is published you don't know what part of the process failed-the med rec process at start of care or subsequently that identified an issue; or the physician contact in one calendar day; or implementing the action. As this is a new topic for LTACH, SNF and IRF, wouldn't it be better to make this 1 measure with 3 subparts to note which process is failing? That would also be helpful for HHAs, as we still struggle with this.<br>We recommend that the target population needs to be clarified as the data collection sets in each setting collect data on very different populations, in fact HHAs use the OASIS in the assessment of long term Medicaid patients or Medicaid MCO patients who may receive 1 skilled visit every two weeks-namely medication set-ups or 1 visit a month to change catheters-very different populations. We strongly recommend that all PAC settings assess the same populations with the IMPACT measures. Can we limit the measure to Medicare FFS only enrollees? We are all clear that the measures will not identify potential issues in quality, but will also impact payment and the only payment that the Congress can IMPACT is the Medicare FFS population, MA is PMPM. | Barbara A McCann<br>Chief Industry Officer,<br>Interim HealthCare Inc. | BarbaraMcCann@InterimHealthCare.com | HH nationwide | |

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| 13 | 10/2/2015 | We are enthusiastic that, via the IMPACT Act, CMS is moving toward standardized patient assessment data and quality measurement data. Such harmonization is long overdue. We continue to be disappointed that CMS is still utilizing the existing non-standard post-acute care assessment instruments and methods to collect these data, namely the MDS, OASIS, IRF-PAI and LTCH CARE, which is inconsistent with its drive toward electronic health records and interoperability.Specific to the proposed Drug Regimen Review:<br><br>Numerator, Item 1: "The agency/facility conducted a Drug Regimen Review at the [Admission/SOC/ROC]."<br>☐ This element is a standard of care and practice in post-acute care, although it is not necessarily documented. A field can be created in the electronic health record (EHR) or in the paper records more commonly used in skilled nursing facilities, to capture this item.<br>☐ Home Health may be better positioned to meet this, as the OASIS contains several questions, M2000 Drug Regimen Review, M2002 Medication Follow-up, M2004 Medication Intervention, M2010 Patient/Caregiver High Risk Drug Education, M2015 Patient/Caregiver Drug Education Interventions and M2020 Management of Oral meds. The Home Health Conditions of Participation require review of medication regimen at SOC, ROC and Recertification. Some Home Health providers have a way to document this in their electronic health records.<br><br>Numerator, Item 2: "If clinically significant medication issues were identified at the [Admission/SOC/ROC] (Item 1 = [1]), then the agency/facility contacted a physician (or physician-designee) within one calendar day and completed prescribed/recommended actions in response to the identified issues."<br>☐ The lack of definition of "clinically significant medication issues" is concerning. This must be very clearly defined so that it can be consistently applied to the heterogeneous patient populations in the IRF, LTCH, SNF and HH settings. We would recommend very specific, objective items. Those listed in the definition of Drug Regimen Review are still too vague and subjective. | Karen S. Nelson, RN<br>Vice President, Quality, Compliance & Regulatory Affairs<br>Partners Continuing Care Care (PCC) | KNELSON@PARTNERS.ORG | PCC serves multiple PAC settings | |

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| | | ☐ The timeframe to make contact "within one calendar day" may be reasonable for some inpatient facilities, although it will require PAC entities to develop tracking mechanisms to log the time frame, as has been done with logging the times for reporting critical values. For paper-based systems more common in SNFs, this will be an additional effort that is subject to paperwork error and delays. This timeframe is more challenging in Home Health however, which have a high percentage of patient admissions on weekends. Home Health agencies do not as a rule employ or credential physicians or other providers who could intervene on a patient with whom they are not familiar.<br>☐ "Completed prescribed/recommended actions in response to the identified issues" is difficult to define. If the recommend action is to perform patient assessment such as vital signs at a certain frequency, or to draw a laboratory test the next day or the next week, how could this be tracked? Again, this is subject to interpretation, difficult to establish the time frame for "completion," and seems impossible to document and record in a reliable manner.<br><br>Numerator item 3: " ... each time clinically significant medication issues were identified since the [Admission/SOC/ROC]"<br>☐ This is problematic for two reasons. One, the definition, as noted previously, is lacking, and two, it confounds the requirement for "each time." If it's each "each time" a current high risk medication such as insulin or heparin is dose-adjusted, that would be a logistical impossibility to record this in an additional place, besides the usual documentation practices. Further, this would create a manifold workload on those who collect the data elements to be entered patient-by-patient into the assessment tools, such as the LTCH CARE registered nurse.<br>☐ Instead, it makes more sense to limit the requirement for a full DRR to those circumstances where a new medication is added (not a dose adjustment to a current medication), and the new medication is on a published list of the known highest risk medications. As proposed, the scope of "each time clinically medication issues were identified" is so broad as to be unworkable into practice and documentation. Post-acute care provider organizations already pay wages to highly paid clinical staff to manually track the elements of the CMS Quality Reporting Programs which are unfortunately designed to have no interface to clinical systems or data bases, the LASER being the worst. | | | | |

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| | | ☐ Based up the Drug Regimen Review Measure Justification Form, the highest percentage of medication discrepancies occurs between the hospital discharge and the post acute care admission. It would be more feasible to implement this Drug Regimen Review measure on admission only. This would prompt a thorough review of all medications upon admission, thereby, enabling a Drug Regimen Review at the very onset of the stay. Furthermore, as this measure will be captured at all the post acute care settings upon admission via their respective instruments, MDS, LASER , OASIS and IRF-PAI, medication reconciliation would occur at each point of care whether discharged from an acute setting or from one post acute care setting to another. Limiting this DRR to admission only would enable the capture of this measure throughout the spectrum of post acute care, without requiring additional clinical staff to perform administrative data collection.<br>Thank you for the opportunity to provide public comment on the IMPACT Act of 2014 Cross-Setting Quality Measure: Drug Regimen Review. | | | | |
| 14 | 10/4/2015 | Public comment on proposed IMPACT Act of 2014 Cross-Setting Quality Measure: Drug Regimen Review<br>Areas Support:<br>1. Recognize and support importance of Drug Regimen Review and medication reconciliation in reducing unnecessary rehospitalizations, preventable adverse events, and improving health care outcomes.<br>2. Support standardized process for evaluation of medication use across multiple care settings to improve safe transitions and care experience for the individual patient/resident.<br>3. Support the desired outcome of reducing inappropriate polypharmacy and adverse drug events.<br><br>Areas Oppose:<br>1. The measure information form states “Centers for Medicare & Medicaid Services (CMS) has contracted with Abt Associates and RTI International to develop a cross-setting post-acute care measure for the quality measure domain—medication reconciliation”. The proposed measure addresses Drug Regimen Review, not medication reconciliation. Thus, this measure does not meet the intent or requirement of IMPACT.<br>This proposed measure also lacks the acknowledgement of Pharmacists critical role in medication reconciliation, medication regimen review. This should be revisited to support and facilitate effective care processes that are so important to achieving positive outcomes.<br>Medication reconciliation and Drug Regimen Review are two different activities. Medication reconciliation refers to matching lists of medications | Holly Harmon, RN, MBA, LNHA;<br>American Health Care Association | hharmon@ahca.org | Other | |

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| | | across settings or time. It is something that can be done while reviewing a medication regimen, but it does not include in-depth analysis of a medication regimen. Failure to recognize the difference undermines the important and essential role of medication reconciliation in supporting patient safety.<br><br>2. The measure uses a definition of Drug Regimen Review which is defined from Conditions of Participation for Home Health. This definition is not consistent with current CMS definition for SNF in State Operations Manual at §483.60(c) Drug Regimen Review, defined as Medication Regimen Review. Proposed definition of "Drug Regimen Review – a review of all medications the patient 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. (Reference: Home Health Conditions of Participation Home Health §484.55c)."<br><br>CMS definition of "Medication Regimen Review (MRR) is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-related problems, medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team."<br><br>The proposed definition is inadequate in capturing the scope of a drug/medication regimen review. It is important to acknowledge the differences between the proposed definition of Drug Regimen Review and the current CMS definition of medication regimen review for SNFs. First, the proposed definition does not address involvement of interdisciplinary team members which is acknowledged in the SNF definition. Interdisciplinary approach is critical to providing effective care that supports positive outcomes.<br>Second, the proposed definition does not include preventing, identifying, reporting and resolving issues, as the SNF definition addresses more comprehensively. Review alone without follow up and preventative action is inadequate and is less likely to support positive outcomes.<br><br>3. The proposed measure description includes measurement of "timely follow-up with a physician occurred each time potentially significant medication issues were identified throughout the stay". There is no | | | | |

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| | | definition for what constitutes “potentially significant medication issues”. The proposed measure specification uses both “potentially significant” and “clinically significant” but does not define either. Lack of definition will result in unnecessary confusion and inconsistent measurement.<br>In the CMS State Operations Manual for SNFs at §483.60(c) Drug Regimen Review, “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, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status.”<br>This existing definition serves the intent of this proposed measure and is consistent with CMS requirement.<br><br>4. The proposed specification for this measure expects: If clinically significant medication issues were identified at the [Admission/SOC/ROC] (Item 1 = [1]), then the agency/facility contacted a physician (or physician-designee) within one calendar day and completed prescribed/recommended actions in response to the identified issues (Item 2 = [1]).<br><br>One "calendar day" is an unreasonable expectation for SNFs. Many SNFs admit around the clock, including holidays. Many new admissions occur Friday evenings through Sundays. Pharmacists are not available to visit nursing homes on a daily basis, nor as often or as quickly as would be necessary to meet a “within one calendar day” requirement. For example, a consultant pharmacist review on the following Monday of a medication regimen for someone who is admitted to a SNF at 4pm on Friday would fail this measure.Requiring a pharmacist to perform medication regimen review within one calendar day is of questionable value and would require many more hours from the pharmacist than the current rules require. Most likely, the review would have to be done remotely, which would be an unrealistic option because of limited interoperability of EMR/EHRs between many SNFs and the pharmacy systems. This increased frequency and extremely short timeframe is likely to cause consultant pharmacists to have to reduce the number of beds they can oversee and the number of SNFs they could cover in a close geographic area, all worsening the shortage of pharmacist services. Alternatively, expecting “within 3 business days” is reasonable and provides opportunity for a thorough and effective medication regimen review with timely action and response.<br><br>5. The language used in the proposed measure specification is confusing and | | | | |

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| | | inconsistent with SNF language, particularly as it relates to the MDS. It appears to be derived from Home Health requirements that differ significantly from SNFs. For example, “Agency”, “Resumption of Care (ROC)” and “Start of Care (SOC)” are not consistent with SNF language. In addition, it is unclear how “episode” would translate to a SNF.<br><br>6. There are several areas of content on the Drug Regimen Review Measure Justification Form that need to be addressed.<br>☐ Outcome 1 is missing.<br>☐ 1a.4.2. Specific Guideline:<br>o Outcome 2: Decrease Polypharmacy<br>☐ Poor evidence level C throughout.<br>☐ Proposed “Assessment: The creatinine clearance level will be calculated on admission, with changes in condition, and at least annually. (Evidence Grade = C-1).”<br>☐ Proposed “Assessment Action: The Cockcroft Gault Score (see Appendix B in the original guideline document) and laboratory results will be used to determine dosing. Major Drug Guides and prescribing references provide medication dosing guidelines for initial as well as individualized suggestions based on disease severity and therapeutic responses. (Evidence Grade = C-1).”<br>☐ It is standard of practice to calculate creatinine clearance when there is a medication that should be dosed based onrenal function; for example, antibiotics such as Vancomycin or Gentamycin. However, calculating creatinine clearance is not necessarily applicable or relevant upon every change of condition. For instance, a change in condition caused by a fall with injury does not generally impact renal function. This proposed expectation could result in unnecessary labs and costs with no additional clinical benefit. It is important to note that calculating creatinine clearance requires serum creatinine level through blood draw. It is often not possible to obtain blood draw and lab results within one calendar day of admission to SNF.<br>☐ There are many medications where renal function should be considered when an individual is first started on medication therapy, however it is a consideration and the dose can be increased depending on the patient's response. It would not be in the patient's best interest to assume that the dose upon transfer to a SNF should be the lowest starting dose, as the individual may have been started on a lower dose that was increased over time. A good example is 'statins' or cholesterol lowering medications. It is generally suggested to start at lower dose with decreased renal function but increase the dose based on cholesterol levels. A patient could be on a | | | | |

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| | | relatively high dose, which started as a lower dose, but the dose had been appropriately increased based on cholesterol levels.<br>☐ It is inappropriate for CMS to specify a formulary. There is not one "gold standard" or single standard of practice, especially for the elderly. It is important to evaluate each individual and use professional judgement in selecting and adjusting medications to support positive outcomes and prevent adverse events.<br>☐ Proposed "Expected Outcome: "Goal: 9 or fewer scheduled medications with number of administrations no more than 3 different times daily." This is an arbitrary goal for which no supporting evidence was provided. Note example of an individual with COPD, Hypertension, Diabetes and Dementia per national treatment guidelines recommend a total of 12 routine medications, of which all would be appropriate, however would be seen as not meeting this expected outcome.<br>☐ The concept of assuming polypharmacy based on a number of medications is outdated, as evidenced by CMS having discontinued use of a prior Quality Indicator of 9 or more medications. In the past, it was assumed that an indicator for polypharmacy was 9 or more medications, however treatment guidelines have indicated more aggressivemedication usage for specific conditions such as diabetes and heart failure.<br>☐The true issue here is not the number of medications, but whether all medications for a given individual are indicated to treat their conditions and/or prevent complications, whether they are effective and not causing adverse consequences.<br><br>o Outcome 3: Avoid Adverse Drug Reactions (ADRs)<br>☐ Proposed "Expected Outcome: No adverse drug reactions, no drugs ordered to treat side effects or adverse reactions, and no hospitalizations or ED visits resulting from adverse drug reactions. (Evidence Grade = C-1)."<br>☐tIis reasonable to seek "minimal" ADRs but not to expect 'No adverse drug reaction, no drugs ordered to treat side effects or adverse reaction ….' Medications can be used with the desired outcome based on adverse effects or the benefit of a medication therapy may outweigh the adverse drug reaction.<br>7. The measure is proposed to be calculated from new item sets in the MDS for SNFs. Changes to MDS and RAI manual have a significant impact on SNFs including costs, resource intensity and training time. In addition, vendors are impacted and require adequate time to prepare electronic systems to support the changes. Therefore, MDS/RAI changes should only occur annually. This has typically been in October. Any change in MDS items per | | | | |

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| | | this measure should be coordinated with the annual update.<br>8. It is not clearly stated if this measure will only apply to short stay or also to long stay residents/patients in SNFs. Since this measure is developed as a result of IMPACT, we assume this measure would apply to short stay individuals only. In particular, it is not specified as to which types of MDS assessments would have the proposed item set added in order to capture data for this measure. Clarification is needed.<br>Recommendations:<br><br>Primary Recommendation:<br>1. Do not proceed with this proposed measure as it does not address medication reconciliation as required by IMPACT. Return to develop medication reconciliation measure. CMS should start with a measure on medication reconciliation and then consider creating a medication regimen review measure.<br><br>Secondary Recommendations: If CMS proceeds with this measure versus development of medication reconciliation measure, then:<br>2. Use CMS definition for Medication Regimen Review from State Operations Manual for SNFs. This definition is superior to the proposed definition as it reflects interdisciplinary collaboration and action to prevent and address identified issues.<br>3. Use CMS definition of “clinically significant” from State Operations Manual for SNFs. Use consistent language of “clinically significant” versus “potentially significant”.<br>4. Change measure specification from “within one calendar day” to “within 3 business days” to allow thorough and effective medication regimen review and response.<br>5. Address inconsistencies of language used in this proposed measure to clarify for SNFs.<br>6. Address areas noted in Measure Justification Form:<br>a. Provide Outcome 1<br>b. Remove expected creatinine clearance calculation and expected Cockcroft Gault Score and replace with “renal function is evaluated”. A specific list of medications that would be contraindicated based on renal function in the elderly can be referred to which is already addressed in the CMS State Operations Manual. Here is an example from SOM's F-329 Table 1: Nitrofurantoin<br>i. “Indications - It is not the anti-infective/antibiotic of choice for treatment of acute urinary tract infection or prophylaxis in individuals with impaired | | | | |

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| | | renal function (CrCl <60 ml/min) because of ineffectiveness and the high risk of serious adverse consequences."<br>c. If CMS does not follow 6.b. recommendation then:<br>i. Change expected creatinine clearance calculation to "when indicated" versus specifying set timeframes that may not be clinically indicated.<br>ii. Change Cockcroft Gault Score to "may" be used and acknowledge a modified formula may be used for elderly.<br>d. Remove goal of 9 or fewer medications or provide evidence supporting its use.<br>e. Change expected outcome of "no adverse drug reaction" to allow for real-life situations where benefits outweigh the risks or where they are unavoidable.<br>7. Coordinate changes to MDS items to capture information for this measure with annual RAI/MDS updates (usually occurring in October each year).<br>8. Clarify which residents/patients this measure will capture - short stay, long stay. Specify which types of MDS assessments would be affected by the proposed items addition in order to capture data for this measure.<br>References:<br>CMS State Operations Manual https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf | | | | |
| 15 | 10/5/2015 | Public Comment of TRHC<br>TRHC strongly supports the initiatives put forward by CMS pertaining to Drug Regimen Review. While supporting the quality measures initiative, TRHC respectfully offers the following comments and observations for consideration.<br><br>Outcome 2: Decrease Polypharmacy<br>We read with great care CMS's position on the role of various professionals pertaining to the outcome of "Decrease Polypharmacy". We noticed that pharmacists and pharmacy services were not included in the list of participants who would be asked to intervene at this very important step of therapy management. It is our experience that extensive knowledge of pharmacology is required during any medication reconciliation and/or review as numerous agents from similar drug classes are typically combined, although not appropriately in every case. Also, compounding the issue, is the practice of generic and automatic substitutions which occur regularly as a result of institution-specific drug formularies when patients transfer from one facility to another. This situation is well recognized by CMS in section 1 a.8 .2 while referring to the high rate of medication errors and discrepancies that result from care transitions. Medication reconciliation and regimen | Carlos F. Perez<br>MSN, RN-BC VP, Client Outcomes<br>TabulaRasa Healthcare | CPerez@tabularasahealthcare.com | Other | |

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| | | reviews reside well within pharmacists' domain of expertise and are part of mandatory steps in the establishment of appropriate pharmaceutical care, TRHC would like to highlight the importance of inclusion of clinical pharmacy services in the reconciliation and review process which can provide additional inputs and should be considered as an endorsement entity in the provision of an adequately appropriate medication reconciliation and regimen review.<br><br>Also, under Outcome 2, calculation of creatinine clearance is suggested as a mandatory assessment upon admission and whenever patients' condition changes, but not less than annually. TRHC supports this position and currently includes creatinine clearance consideration in its own mainstream of drug regimen evaluation, making the recommendations personalized. With the information garnered from the clearance testing dose adjustments required, relative to changes in creatinine clearance, are routinely considered in the recommendations made by our clinical teams. TRHC acknowledges and supports the validity mid use of the well-recognized Cockcroft Gault Score. However, we would suggest that a lab-generated, accurate measurement of patient's creatinine clearance be performed at least upon admission, but no less than annually, as it can easily be obtained (one blood sample and/or one urine collection). Such measurement provides more precise information on patient's condition and required dose adjustments or drug selection than the proposed formula-based estimation. Finally, also under Outcome 2, the goal of "9 or fewer scheduled medications with number of administration no more than 3 different times daily" is referenced for adoption. TRHC recognizes that such a directive could be associated with a decrease in medication errors pertaining to drug distribution and could also be associated with a decrease in nursing work load for patients who are residing in facilities. But, TRHC would respectfully challenge the practicality and efficacy of implementing such a directive. TRHC has adopted and maintains a drug administration schedule with (4) different times daily as it gives more flexibility in patients who require polypharmacy due to the number of comorbidities which are often found in the geriatric and frail populations. In our experience, working with these populations, supporting a 4-dosing-time schedule avoids the incidence of unwanted cumulative effects at certain times of the day (e.g., cumulative anticholinergic and sedation effects) and allows for the circumventing of drug interactions such as those related to competitive inhibition on CYP450s or drug transporters which may lead to unintentional overdosing. TRHC therefore respectfully suggests and supports a baseline of 4 different time | | | | |

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| | | daily schedule for drug administration for greater flexibility in order to avoid cumulative adverse drug effects at certain times of day and to circumvent drug-drug interactions.<br><br>Outcome 3: Avoid Adverse Drug Reactions (ADRs)<br>As the Workgroup/Expert Panel is undoubtedly aware, adverse drug events ADEs have a significant impact on downstream costs and can negatively impact patients and caregivers lives. Many ADEs are related to drug-drug interactions (DDIs) and/or multi-drug interactions yet, surprisingly, the current proposed initiative remains silent relative to the proactive monitoring and detection of potential ADEs as they relate to this outcome. It is well known that the prevalence of ADEs increases as the number of drugs being prescribed augment. For instance, in an elderly population, the probability of at least 1 significant DDT was 50% in patients taking 5-9 drugs, 81% with 10-14 drugs, 89% with 15-19 drugs, and 100% with 20 or more drugs. [1] Addition of each medication to a 5-drug regimen conferred a 12% increased risk of potential ADEs. [1] Many DDIs and adverse drug events are avoidable but command proper recognition of interacting drug pairs and multi-drug interactions, as well as appropriate action. One has to recognize that the number of possible combinations and load of manageable information become rapidly unbearable when patient's drug regimen comprise 10, 15, 20 or more drugs. With no surprise, studies show that prescribers' and pharmacists' ability to recognize well-documented drug interactions is limited if not altogether lacking.[2-4]<br>Several groups and organizations have therefore deployed significant resources and efforts to develop databases and multi-drug interaction screening software (DISS). These strategies have proven their efficacy in sensitively detecting potential drug interactions, improving compliance and pharmacological management in high risk patients and over all, improving clinical management and outcome of patients.[5-6] However, despite these advantages, the major downside associated with several DISS or databases is the over-alerting of a large number of DDIs of low clinical relevance and the subsequent "alert fatigue." In a review of 30 million prescriptions dispensed in a community pharmacy, 70.8% of initially detected DDIs were removed when applying additional filters to increase specificity and an additional 80.6% of DDIs were removed when reviewed by pharmacists. At the end, only 5.7% of initially detected DDIs were considered as clinically relevant. [7] These observations support the basic principles of the approach adopted at TRHC in the last few years leading to the development of a Medication Risk Mitigation Matrix as a meaningful clinical decision support system (CDSS).[8- | | | | |

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| | | 9] In our experience, CDSSs must permit rapid access to the most complete and accurate interaction information between all drugs in a patient regimen, not just single drug-drug interactions, and should strengthen the clinicians ability to elaborate on meaningful recommendations considering patient's age, background, previous experience, disease condition, time of dosing, dose prescribed, personal situation, genetics, metabolism pathways, etc. TRHC, therefore, recommends monitoring of DDIs and ADEs be enforced proactively with the use of a validated CDSS and be rendered mandatory during medication reviews to avoid ADEs and DDIs.<br><br>Outcome 4: Decrease Inappropriate Prescribing<br>TRHC supports the initiative proposed requiring the comparison of the Medication Administration Record to Beers list and the CMS guidelines to ascertain appropriateness of current medication regimen. We would further comment that in addition to Beers list, considerable evidence in the literature supports the use of genetic testing for a better medication selection and to avoid inappropriate prescribing in some patients. For instance, the NIH has supported an important pharmaco genetic initiative (PharmGKB) where the Clinical Phartnaco genetics Implementation Consortium has developed several guidelines for drug use. Similar guidelines have also been developed by the Royal Dutch Association for the Advancement of Pharmacy — Phanuacogenetics Working Group, by the Canadian Pharmacogenomics Network for Drug Safety (CPNDS) Clinical Recommendations Group, and by other groups around the world. The number of guidelines recommending genetic testing for appropriate drug use currently includes more than 65 drugs, depending on the country. In United States, the FDA has currently retained 34 of these guidelines and included in drug labelling recommendations or requirements for pharmacogenetic testing for appropriate use of these drugs. Several of these drugs such as anti-depressants, anti-psychotics, codeine, allopurinol or warfarin are likely to be used in elderly patients. Pharmacogenetic testing is also very helpful in determining the time-of-day that a multi-drug regimen should be adopted, in order to avoid competitive inhibition sequencing, which otherwise yields unintentional overdosing. Therefore, TRHC recommends that CMS consider supporting and promoting the use of pharmacogenetic testing when appropriate in order to decrease incidents of inappropriate prescribing and to optimize the time-of-day dosing schedule. | | | | |

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| 16 | 10/6/2015 | My agency has been doing medication reconciliation and Drug Regimen Review for about two years because we are accredited with Joint Commission and State. However my concern is that where we were able to chose other high risk meds as an agency and we had two the State may now chose them for us and they may very well be more than two. Also where we were able to decide as an agency what any adverse reaction was once again the State may now decide for us. If this is truly the case I believe the time frame , the means of communication, and the person the findings can be communicated to would need to be reviewed, I understand the State is looking for best practice and more physician involvement . But when the patient has three physicians it is near impossible to speak to all within one day if one prescribed a high risk med. and two prescribed meds that had adverse reactions. The agency is set up to fail. | Carol Lloyd MSN RN; Augusta Division, University Home Health and Extended Care Services | Lloydcs901@gmail.com | HH | |
| 17 | 10/6/2015 | See appendix. | Susan M. Levy, MD President (elect), Society for Post-Acute and Long Term Care Medicine, Medical Director/VP Medical Affairs Levindale Hebrew Geriatric Center and Hospital | smstrohm1@gmail.com | Specified that this did not represent her organization. | |
| 18 | 10/6/2015 | REVIEW AND COMMENTS ON PROPOSED MEASURE<br>The proposed measure “Percentage of care episodes or stays in which a Drug Regimen Review was conducted at the Admission /SOC /ROC, and timely follow-up with a physician occurred each time potentially significant medication issues were identified throughout the care episode or stay” is intended to be collected by 3 items:<br>☐ Item 1 asks providers if a complete Drug Regimen Review conducted at admission identified any “potentially clinically significant issues” for a patient.<br>☐ Item 2 asks providers if they contacted a physician within one calendar day and completed the recommended course of action for the “identified clinically significant medication issues” found at admission, if any.<br>☐ Item 3 asks providers if they contacted a physician and completed the recommended actions within one calendar day each time clinically significant medication issues were identified following admission. | Mary Ellen DeBardeleben, MBA, MPH National Quality Manager HealthSouth Corporation | mary.debardeleben@healthsouth.com | Large HC system | |

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| | | While the IMPACT Act designated "medication reconciliation" as one of several domains for which cross-setting quality measures are required, the proposed measure instead utilizes "Drug Regimen Review" to calculate the measure numerator. Although there is an overlap between "medication reconciliation" and "Drug Regimen Review," Drug Regimen Review is a fundamentally distinct process from medication reconciliation. According to the definition of "Drug Regimen Review" as stated by the Home Health (HH) Conditions of Participation (CoPs) at §484.55c, the intent is to "review medications a patient is currently using in order to identify potential adverse effects or drug reactions." This most notably includes noncompliance with drug therapy, significant side effects, and ineffective drug therapy – all of which are typically infeasible for an admitting facility to assess during a medication reconciliation process at admission. Such Drug Regimen Review is distinct from the medication reconciliation act of "comparing the medications a patient is taking (and should be taking) with newly ordered medications in order to identify and resolve discrepancies, including omissions, duplications, contraindications, unclear information, and changes."1 Furthermore, the proposed Drug Regimen Review tracks medication issues at any point during the care episode or stay (dividing the episode of care into "admission" and "after admission") even though medication reconciliation occurs only during transitions of care, i.e. admission, transfer, and discharge. According to The Joint Commission, medication reconciliation occurs at transition points of care where new medications are ordered or existing orders are rewritten.2 The Institute for Healthcare Improvement also considers the medication reconciliation process to occur at transition points only: "Each time a patient moves from one setting to another where orders change or must be renewed, clinicians should review previous medication orders alongside new orders and plans for care, and reconcile any differences. If this process does not occur in a standardized manner that is designed to ensure complete reconciliation, medication errors may lead to adverse events and harm."3<br>A measure that tracks variables associated with Drug Regimen Review throughout the patient's stay (as proposed by the measure) is fundamentally different from a measure that tracks variables associated with the medication reconciliation processes that occur only when the patient moves from one setting to another. Additionally, by lumping discharge into the overly-general "after admission" timeframe, the proposed measure also fails to adequately capture the discharge process, even though CMS'<br>proposed Drug Regimen Review Measure Justification Form lists the importance of discharge as a critical part of medication reconciliation:<br>"Hospital discharge is one high risk time point with evidence that there are | | | | |

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| | | high levels of discrepancy. In fact, there is evidence that 50% of patients experience a clinically important medication error after hospital discharge."<br>A thorough and complete medication reconciliation as part of the discharge planning process is critical for a patient's successful transition to her/his discharge destination, whether to home or community or to another inpatient care setting. It is troubling that the proposed medication reconciliation measure fails to distinguish this important aspect of a patient's episode of care in a post-acute setting.<br>1 The Joint Commission NPSG 03.06.01, EP 3<br>2 Joint Commission – Sentinel Event Alert "Using Medication Reconciliation to Prevent Errors."<br>www.jointcommission.org/assets/1/18/SEA_35.pdf<br>3 Institute for Healthcare Improvement – "Reconcile Medications at All Transition Points."<br>http://www.ihi.org/resources/Pages/Changes/ReconcileMedicationsatAllTransitionPoints.aspx<br><br>We encourage CMS to propose a "medication reconciliation" measure that focuses on medication review at transition points of care and remove elements related to Drug Regimen Review, as they fundamentally differ in scope and definition.<br><br>Our comments related to the existing measure as proposed follow:<br>COMMENTS RELATED TO ITEMS 1 AND 2<br>Drug Regimen Review activities that occur prior to the medication order<br>The term "medication reconciliation" as defined by The Joint Commission NPSG 03.06.01, and used in the proposed measure, involves comparing "the medication information the patient brought to the hospital [either from the discharging facility or from home] with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies." Based on this definition, medication reconciliation only includes medications that have been ordered for the patient, but not medications that were prevented from being ordered by a drug regimen process. For example, hospitals that use an electronic medical record ("EMR") typically utilize computer physician order entry ("CPOE") that has safeguards in place to prevent a physician from ordering medications which may have potential adverse effects and drug reactions for the particular patient. Since these medications were never ordered, they would not be part of the medication reconciliation and drug regimen review as defined by the proposed quality measure. We ask that CMS clarify whether the measure is intended to include or exclude instances where | | | | |

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| | | a drug was reviewed for potential adverse<br>effects and drug reactions prior to the medication actually being ordered (thus eliminating potential adverse effects and drug reactions).<br>For example, patients admitted to inpatient rehabilitation hospitals are typically on anticoagulation therapy. If a physician attempts to submit an order for the anticoagulant Coumadin in the EMR, a CPOE may trigger an alert to the physician that this medication duplicates the existing order for Lovenox, another anticoagulant. The physician could then cancel the prescription and the medication would never be ordered, thus avoiding a potential "duplicate drug therapy" result. Because Coumadin was never actually "ordered," the process engineered by the CPOE's alert system would not be captured as an act of medication reconciliation in the proposed quality measure. It is unclear whether such processes were intended to be captured as part of the Drug Regimen Review since, in this<br>illustrative example, the potentially clinically significant medication issues were avoided by virtue of a drug order never being executed in the first place. Further, the physician can accept or override this type of alert in a CPOE system depending on patient-specific circumstances and his/her own clinical judgment. If they choose to override the alert, the medication would be ordered and therefore become subject to a medication reconciliation process and Drug Regimen Review. While an EMR allows these changes and alerts to be identified and tracked before a medication is actually ordered, this would be far more difficult to capture in a non-electronic system, if these decisions occurred prior to the ordering process. Referring to the previous anticoagulation example, if a physician considered writing a prescription for Coumadin but caught this potential "duplicate drug therapy" issue prior to writing the actual order, no one would ever know.<br><br>Definition of "Clinically significant medication issue"<br>We encourage CMS to specifically define what constitutes a "potential clinically significant medication issue." Without an explicit and detailed definition of this term, it will likely vary widely across providers and care settings, which will in turn cause serious integrity issues for the resulting quality measure data. It is also important to specify what would not constitute a "potential clinically significant medication issue." For HealthSouth's recommendations of "potential clinically significant medication issue," please see Appendix A.<br>Subjectivity of "Potential" The proposed measure asks clinicians to predict if a medication issue (potential adverse effect or drug reaction) found during a Drug Regimen Review would be "potentially clinically significant." | | | | |

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| | | While some medication issues might undoubtedly cause clinically significant issues (however such issues are defined), others would be left to subjective judgment about whether the issue would or would not potentially cause clinically significant patient effects. This type of subjectivity is concerning when developing a measure that will be utilized by a wide variety of clinicians across post-acute care settings, and one that is intended to achieve standardized data points for subsequent comparison between such settings. As such, this high level of subjectivity would be a significant concern to reliability and validity of the proposed quality measure.<br>Item 1 – Answers "0/1/9"<br>It is unclear how a hospital would answer Item 1 if they found medication issues that were considered "issues," but not deemed to be "potentially clinically significant." It is implied that 0 "No, no issues found" and 1 "Yes, issues found" apply only to "potentially clinically significant medication issues" (particularly given the logic that an answer of "1" requires Item 2 to be completed), not any "issue" at all. Therefore, if a hospital finds a medication issue they deem not clinically significant (by the defined term), there is no available answer option. Accordingly, we recommend that, for answers 0 and 1, the language be clarified from "issues" to "potential clinically significant medication issues" and an additional selection be added for "Yes, medication issues were identified but were not deemed potentially clinically significant." This additional answer choice would also presumably skip Item 2, like current selections "0" and "9".<br><br>Item 2 - Medication Follow-Up<br>Under Item 2, it is unclear whether the facility/agency has one calendar day to "complete prescribed/recommended actions in response to the identified clinically significant medication issue" or whether that applies only to contacting the physician (or physician designee). If the proposed measure is intended to capture whether the physician was contacted and the recommendation action all occurred in one calendar day, this could be reworded to clarify. Notably, in Item 3, providers are given one calendar day for both actions.<br><br>Admission Clarification<br>The assessment timing for Item 1 and Item 2 are identified as "admission" for SNF, IRF, LTCH, and SOC/ROC for HH. However, "admission" remains undefined. Admission orders at a receiving IRF (and likely SNF and LTCH) typically follow the discharging orders from the prior level of care until a full reconciliation of the medical record and medication history can occur. | | | | |

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| | | This includes an evaluation by the pharmacist, a discussion with the patient and/or family, and a review by a physician. While medication review and reconciliation are initiated immediately upon admission it can take up to 48 hours for a full "admission medication reconciliation" to be completed. Therefore, we suggest the "admission" timeframe be 2 calendar days – the day of admission and the following calendar day.<br><br>COMMENTS RELATED TO ITEM 3<br>The proposed quality measure information begins with a definition of medication reconciliation and Drug Regimen Review:<br>Medication reconciliation – the process of comparing the medications a patient is taking (and should be taking) with newly ordered medications in order to identify and resolve discrepancies. (Reference: The Joint Commission, National Patient Safety Goals).<br>Drug Regimen Review – a review of all medications the patient 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. (Reference: Home Health Conditions of Participation<br>Home Health §484.55c). Medication reconciliation and Drug Regimen Review are intended to identify and avoid potential medication issues, but the wording of Item 3 omits the word "potential."4 We ask CMS to clarify whether Item 3 is intended to measure potential clinically significant medication issues or clinically significant medication issues that have already occurred. This is a critically important distinction. Reconciling medication instructions before the administration of medication is a structured, deliberate clinical activity. But handling a clinically significant issue, such as an adverse drug reaction, is highly variable and may call for anything from the application of a reversal agent to readmission to a general acute hospital. Treating these two types of medication-related events under one measure conflates two processes that are fundamentally<br>different from one another. While we agree that measuring the timeliness of notifying the physician after a clinically significant medication issue is extremely important to patient safety, we believe it is outside the scope of "medication reconciliation" – which is intended to identify potential issues before medication is administered. Measuring physician notification after a clinically significant medication event4 "The agency/facility contacted a physician (or physician-designee) and completed prescribed/recommended actions within one calendar day each time clinically significant medication issues were identified since the [Admission/SOC/ROC]" happens is a separate | | | | |

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| | | and distinct quality measure, and one that should almost never take a full calendar day to occur.<br><br>ADDITIONAL COMMENTS<br>Unintended Consequences<br>The purpose of medication reconciliation is to find and correct errors. No measure, either now or in the future, should be designed so as to discourage clinicians from reporting and correcting errors in patient medication.<br><br>Numerator/Denominator Exclusions<br>Patients who were admitted and unexpectedly discharged prior to a medication reconciliation processbeing completed should be excluded from this measure. It is assumed this would be indicated on the respective assessment instruments with a dash ("-") as currently documented for other quality measures.<br><br>Care Setting Differences<br>The Drug Regimen Review that may occur in a home health setting would be significantly different from an inpatient setting where the patient is receiving 24-hour care. If clinically significant medication issues occur in the inpatient setting, they are handled more immediately than in home health settings.<br>Larger Emphasis on Medication Reconciliation at Discharge<br>We encourage CMS to consider an aspect of "medication reconciliation" specifically at the discharge timeframe. A thorough and complete medication reconciliation and Drug Regimen Review at this point in the patient's care is part of the discharge planning process, as it is critical for a patient's successful transition to her/his discharge destination, whether to home or community or to another inpatient care setting.<br>Thank you for your time and attention to these comments. | | | | |
| 19 | 10/6/2015 | The National Association for Home Care & Hospice (NAHC) is the nation's largest trade association representing home health and hospice agencies including Visiting Nurse Associations, government-based agencies, multi-state corporate organizations, health system affiliated providers, and freestanding proprietary agencies. NAHC members serve over 3 million<br>Medicare home health and hospice beneficiaries each year. In general, NAHC supports the Drug Regimen Review measure as proposed. However, to ensure accurate measure comparison and data exchange among the post-acute care providers, we urge the developers to establish clear definitions for the terms "clinically significant" medication issues and "one calendar day".<br>Thank you for the opportunity to comment. | Mary K. Carr; Vice President, Regulatory Affairs, National Association for Home Care & Hospice | mkc@nahc.org | HH | |

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| 20 | 10/6/2015 | We understand the Center for Medicare and Medicaid Services (CMS) has requested public comment on the development of a cross-setting Post Acute Care (PAC) measure for the quality measure domain medication reconciliation. 1 CMS has identified medication reconciliation2 and Drug Regimen Review3 as areas for requested input. Specifically, CMS has requested comments on the Drug Regimen Review Measure Information Form and the Drug Regimen Review Measure Justification Form.4 The Information Form includes a proposed drug regimen draft measure (the "Draft Measure"). CMS requests that comments be directed to Abt Associates at the e-mail address above. The agency notes that as a "process measure, medication reconciliation and medication review for high risk medications are expected to reduce re-hospitalizations, reduce adverse events related to medications, and improve health outcomes."5<br>Any medication measure that will measure patient outcomes across PAC settings must take into account the differences in patient acuity and medical supervision between settings. RIC understands the importance of standardized cross-setting measures in most PAC settings. However, IRFs are functionally similar to acute care settings and differ only in that they provide specialized services to lower acuity patients. Although IRF patients are in general more stable than patients in acute care settings, they are more acute than patients in other PAC settings like Skilled Nursing Facilities (SNFs) or home health settings. Additionally, physicians in IRF settings oversee medication management issues far more frequently than they do in SNFs or home health settings. The Draft Measure appears to be directed towards and is more relevant for settings with generally less regular medical monitoring and less frequent medication review.In addition to the general comments above, RIC provides the following comments specific to the Draft Measure:<br><br>The Draft Measure relates to Drug Regimen Review, not to medication reconciliation.<br><br>The Draft Measure does not include measurements of medication reconciliation. It is titled "Drug Regimen Review Conducted with Follow-Up for Identified Issues" and relates to Drug Regimen Review and follow-up from that review. As currently described, the Draft Measure contains no specific measurement of medication reconciliation but rather just presumes that "medication review in post-acute care is generally considered to include medication reconciliation."6 Specifically, the Draft Measure does not require medication reconciliation to be performed, either at admission or at any time during the patient's stay. | Sangeeta Patel, MD MPH; Rehabilitation Institute of Chicago/ Peggy Kirk Senior Vice President, Chief Clinical Operating Officer | spatel@ric.org | IRF | |

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| | | To the extent CMS plans to promulgate any measure specific to medication reconciliation, CMS should have a single measure for medication reconciliation and Drug Regimen Review, rather than two separate measures.<br>CMS may wish to consider a measure focused on medication reconciliation that is consistent with other regulatory and accreditation requirements, such as those provided by the Joint Commission which are listed in the table on the following page. The Justification Form specifically notes the importance and evidence in support of medication reconciliation at times of transition of care and review of 'high-risk medications' in the PAC setting. It notes limited evidence in support of general Drug Regimen Review and follow up, yet medication reconciliation is not actually captured in the Draft Measure.<br>RIC supports reviewing the "high alert" medications on the list developed by the Institute for Safe Medication Practices as part of a Drug Regimen Review or a medication reconciliation review.<br><br>The Draft Measure should incorporate existing PAC medication standards that are applicable across PAC sites, where such standards help to improve patient care.<br><br>The Justification Form acknowledges that the Draft Measure is supported by limited evidence. CMS may wish to consider existing PAC medication standards that could be applied across sites of PAC care, where such standards help to improve patient care. For example, the Joint Commission standards for IRFs include certain requirements for inpatients. The table on the next page summarizes some of the Joint Commission's key requirements and compares them to the elements of the Draft Measure | | | | |

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| *Joint Commission*[7] | *Present in Draft Measure?* |
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| Obtain information on the medications the patient is currently taking when he or she is admitted to the hospital. | *Yes*; PAC site to conduct a drug review at Admission/SOC/ROC (Item 1 |
| Document the information in a format useful to those who manage medications; | *No* |
| Compare the medication information the patient brought to the hospital with the medications ordered for the patient by the hospital in order to identify and resolve discrepancies | *No*; the Draft Measure instead require regimen review at Admission/SOC/RO 1), before the site will have medications that may conflict with mec prescribed prior to patient admission. |
| Provide the patient (or family as needed) with written information on the medications the patient should be taking when he or she is discharged from the hospital | *No* |

While RIC supports the process of medication reconciliation as defined in the Information Form, we strongly advocate for a measure and an operational definition that is consistent with existing regulatory and accreditation requirements, such as Joint Commission and Meaningful Use Stage 2 Criteria. Uniform definitions and measures are essential to avoid complex or conflicting tracking systems and reporting of data and information in different formats that address the same medication issues.

3. The use of "clinically significant medication issue" invites the opportunity for abuse.

The Draft Measure requires that the agency/facility take certain steps upon identification of a clinically significant medication issue. However, the Draft Measure does not require an agency/facility to take steps to identify clinically significant medication issues, except at Admission/SOC/ROC. This deficiency could be abused by PAC sites that take steps to limit identification of clinically significant medication issues in order to artificially increase their score.

7 Joint Commission Standards and Elements of Performance NPSG 03.06.01: Maintain and communicate accurate patient medication information

Additionally, the term "clinically significant medication issue" is not defined. For example, CMS should clarify if a clinically significant medication issue is defined by a contraindication, the duration of the complication the patient would experience (such as a short-term, intermediate, or long-term

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| | | complication), or some other factor or combination of factors. A common definition should be included with the measurement, so that PAC sites do not use their own judgment in determining what medication issues are clinically significant (defeating the purpose of having a measurement that can be applied to multiple sites).<br>4. The Draft Measure disadvantages PAC sites that regularly adjust patient medications to improve patient care. Given the likely increased medication management efforts of some PAC settings, such as IRFs, CMS should revise the Draft Measure so that the medication management requirements of patients in different PAC sites of care do not lead to certain types of care settings being artificially rated higher than other care settings. Patient medications are likely adjusted more frequently at some PAC care settings, like IRFs, than other care settings, like SNFs or home-based care. As in the acute care setting, IRFs regularly monitor, review and adjust patient medications to improve patient care and outcomes. Elsewhere, CMS has explained that a "primary distinction between the IRF environment and other rehabilitation settings is the high level of physician supervision that accompanies the provision of intensive rehabilitation therapy services. For this reason, the information in the patient's IRF medical record must document a reasonable expectation that at the time of admission to the IRF the patient's medical management and rehabilitation needs require an inpatient stay and close physician involvement."8<br><br>For example, an inpatient who receives care at RIC for a brain injury will generally have his or her medications adjusted multiple times throughout the inpatient stay, including changes to neurostimulants, sleep medications, and medications aimed at treating depression and agitation. An IRF may adjust medications for a brain injury patient every few days depending on the patient's symptoms. Due to the increased number of medication adjustments, which are appropriate for a patient, there is a potential increased risk of a clinically significant medication issue arising during the course of the patient's stay. The Draft Measure does not permit an admission to be counted in the numerator if a clinically significant medication issue was not appropriately addressed even one time during the stay.<br>For example, an IRF may complete a Drug Regimen Review at admission for a brain injury patient. Soon after admission, the physician adjusts the patient's neurostimulant medication.<br>8 MLN Matters, January 14, 2010, available at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6699.pdf (last accessed October 5, | | | | |

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| | | 2015) (emphasis added).<br><br>The adjustment causes an issue in increased blood pressure and tachycardia, so the physician promptly decreases the neurostimulant dosage. A day later, the physician adjusts the patient's sleep medication. That causes an issue with daytime sedation so the physician promptly changes the sleep medication to another agent. The frequency of medication adjustments given in the above example is not unusual in IRFs, and is likely more frequent than adjustments made in other PAC settings, such as in SNFs or home health.<br>5. The Draft Measure does not specify which provider is required to complete the drug review. The Draft Measure requires a Drug Regimen Review but does not specify whether nurses, pharmacists, physicians, or other health care professional, as appropriately qualified, are required to complete it. To ensure that different PAC settings are treated the same, CMS may wish to consider requiring across all PAC settings that the same type of health care professionals, who are appropriately qualified, perform the Drug Regimen Review.<br>6. The one calendar day time period in the Draft Measure may not be the appropriate time period for responding to urgent medication issues. The Draft Measure requires that the facility complete the physician/designee recommended action within one calendar day of the issue being identified. Some medication issues may need to be resolved more quickly than one calendar day to avoid delays in clinical resolution or other complications. Under the Draft Measure, an urgent issue that is not timely addressed in a timely fashion may still be reported as a success as long as it was addressed within one calendar day, but in reality, for the patient's well-being should have been done sooner.<br>7. The element "Patient/resident is not taking any medications" should be clarified. The Draft Measure allows a PAC site to select "patient/resident is not taking any medications". This language is unclear. Does it mean the patient/resident has not been prescribed any medications (which would be very rare in a PAC setting, as almost every patient/resident will be prescribed some medication, for example Tylenol as needed)? Does it mean the patient/resident has been prescribed a medication but is not taking it (in which case the PAC site should contact a physician or physician-designee and complete the prescribed/recommended actions)? Or does it have some other meaning?<br>8. Existing electronic medical record systems (EMRs) likely do not include data collection and reporting capabilities required by the Draft Measure. Without EMR systems in place to collect and report the information | | | | |

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| | | required by the Draft Measure, compliance would require manual data collection. This data will be self-reported, cost prohibitive to collect, and runs a high risk of inaccuracy. Structured data fields that would be required include:<br>• Drug review conducted<br>• Specific areas queried<br>• Issues identified<br>• MD notified<br>• Person conducting the review<br>• Recommended action completed within one day/or specific time frame.<br>Conclusion<br>We appreciate the opportunity to comment on this important effort and again re¬emphasize that the Justification Form includes little evidence-based support for the Draft Measure. RIC supports the development of a true medication reconciliation measure, such as one that includes the Joint Commission elements outlined above, with specific, clear, and measurable admission and discharge requirements that are consistent with other applicable existing regulatory and accreditation requirements. We agree with CMS that "because of the high prevalence of and potential medication errors among PAC patients and because there are best practices and regulatory standards that are associated with high quality care, reporting is beneficial for quality standards as the morbidity associated with incorrect medication regiment may be substantial."9 However, as currently drafted, the Draft Measure does not ascribe to this rationale and does not comport with best practices or take advantage of existing regulatory standards and requirements pertaining to medication reconciliation. As such, we respectfully urge CMS to revise the Draft Measure so it is meaningful for patient care and will have a greater positive impact on patient outcomes.<br>Thank you for the opportunity to provide these comments. | | | | |
| 21 | 10/6/2015 | ASCP is pleased to have the opportunity to provide comments on the IMPACT Act of 2014 Cross-¬Setting Quality Measure: Drug Regimen Review. We support the goals of improving clinical outcomes and agree that a careful medication regimen review and medication reconciliation performed by an appropriately trained clinical specialist such as a pharmacist results in improved clinical outcomes and ultimately reduces unnecessary hospitalizations and adverse events. Having a standardized process to evaluate medication use across different care settings can help to improve safe transitions and care for hospital patient and long-term care residents. We also agree with and support the desired outcome of reducing inappropriate medication redundancies and adverse drug events. | Arnold E. Clayman, PD, FASCP<br>VP of Pharmacy Practice & Government Affairs<br>American Society of Consultant Pharmacists | aclayman@ascp.com | Other | |

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| | | However, there is great concern with how the quality measures are derived and summarized in the document. We list our concerns and suggested verbiage changes below.<br><br>1. The measure information form states “Centers for Medicare & Medicaid Services (CMS) has contracted with Abt Associates and RTI International to develop a cross-¬setting post-¬acute care measure for the quality measure domain—medication reconciliation.” The proposed measure addresses Drug Regimen Review as defined for Home Health, not medication reconciliation. Thus, this measure does not meet the intent or requirement of the IMPACT Act. As defined by CMS, these are two separate, critically important, but by no means synonymous, clinical services. The intent of the IMPACT Act is for both processes to occur through standardized patient assessment data that is shared across all providers. As such, the measure should be changed to reflect both care processes.<br><br>As the pharmacotherapy experts on the clinical care team, any meaningful discussion of medication management, including reconciliation and medication regimen review, must include the consultant and dispensing pharmacist.<br><br>ASCP RECOMMENDATIONS: CMS needs to determine which components of medication management are to be the subject matter of this document, and then ensure that they are adequately addressed. In addition, these measures need to ensure that all medication discussions include the pharmacist as the medication management expert on the clinical care team. As defined by CMS, medication reconciliation and medication regimen review are two processes and the differences between these processes must be discussed in detail. The reconciliation process must be much broader to include medication reconciliation as well as aspects of MRR in order to meet the intent of the IMPACT Act. This would allow the pharmacist and other clinicians on the care team, especially during transitions of care, to provide person-¬centered, holistic care, of which medications are just a part.<br><br>2. The measure uses a definition of Drug Regimen Review that is defined from Conditions of Participation for Home Health. This definition is not consistent with current CMS definition for skilled nursing facilities (SNFs) in State Operations Manual at §483.60(c) Drug Regimen Review, defined as Medication Regimen Review. | | | | |

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| | | Proposed definition of "Drug Regimen Review – a review of all medications the patient 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. (Reference: Home Health Conditions of Participation Home Health §484.55c)."<br><br>CMS definition of "Medication Regimen Review (MRR) is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication. The review includes preventing, identifying, reporting, and resolving medication-¬related problems, medication errors, or other irregularities, and collaborating with other members of the interdisciplinary team." The proposed definition only captures the home health sector of care. This is not acceptable nor is it adequate for an interdisciplinary measure designed for use across many different care settings. The proposed definition falls far short of capturing the complete significance of drug/medication regimen review. It is important to acknowledge the substantial differences in content between the proposed definition of Drug Regimen Review and the current CMS definition of medication regimen review for SNFs. Notably, the proposed definition does not address involvement of all members on the interdisciplinary clinical care team. The current definition of Medication Regimen Review (MRR) in the State Operations Manual (SOM) clearly acknowledges the collaborative work of the team, which is important in all care settings. While the proposed (home health) definition focuses on "review" in describing the process, the SOM definition clearly states, "MRR is a thorough evaluation of the medication regimen of a resident, with the goal of promoting positive outcomes and minimizing adverse consequences associated with medication." The proposed definition does not include "preventing, identifying, reporting and resolving medication---related problems, medication errors, or other irregularities" that the SOM definition addresses in a comprehensive and clear manner. The SOM definition is far more cross---setting compatible and provides for a much more robust analysis.<br><br>ASCP RECOMMENDATIONS: The current SOM definition of the medication regimen review for SNFs is far more inclusive and clinically detailed than the proposed Home Health reference. It should be noted that this document could be used in many post-¬acute care settings, including home health agencies, skilled nursing facilities, inpatient rehabilitation facilities, and long- | | | | |

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| | | ¬term care hospitals. ASCP suggests that the SOM definition of MRR be used in this document. We also suggest that a consistent moniker for the process be used throughout the document. The SOM uses the word "medication" rather than "drug," and ASCP agrees that "medication" is a more appropriate word than "drug" in this context. We suggest the phrase "medication regimen review" be used consistently to avoid potential confusion.<br><br>3. The proposed measure description includes measurement of "timely follow-¬up with a physician occurred each time potentially significant medication issues were identified throughout the stay." There is no definition for what constitutes "potentially significant medication issues."<br>The proposed measure specification uses both "potentially significant" and "clinically significant" but does not define either phrase. Lack of definition will result in unnecessary confusion and inconsistent quality measurement.<br>CMS State Operations Manual for SNFs at §483.60(c) Medication Regimen Review defines "clinically significant" as "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, stabilizing, or improving a condition or reducing a risk, or negatively by exacerbating, causing, or contributing to a symptom, illness, or decline in status."<br>The definition of "clinically significant" from the SOM provides needed clarity in defining this important phrase.<br><br>ASCP RECOMMENDATIONS: The word "significant" should not be used without a clear definition in this context. As such, we recommend that the existing SOM definition of "clinically significant" be used for clarification across all settings.<br><br>4. The proposed specification for this measure expects: If clinically significant medication issues<br>were identified at the [Admission/SOC/ROC] (Item 1 = [1]), then the agency/facility contacted a physician (or physician-¬designee) within one calendar day and completed prescribed/recommended actions in response to the identified issues (Item 2 = [1]). One "calendar day" is an unreasonable expectation for SNFs. Many SNFs admit 24 hours a day, 7 days a week including holidays. Many new admissions occur on Friday evenings through Sunday afternoons. Consultant pharmacists must review the complete medical record to perform medication regimen review, which must be done after admission, and upon changes in condition. Some members of the clinical team may not be onsite at the SNF on a daily basis, nor could they visit the | | | | |

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| | | facility on the short notice that would be necessary to meet a "within one calendar day" requirement. For example, if an individual is admitted to a SNF on Friday at 4pm and has their medication regimen reviewed by a consultant pharmacist on Monday, they would fail this measure.<br><br>Any sort of one-day requirement would mean that clinicians, including consultant pharmacists, would need to perform clinical reviews remotely, which would be an unrealistic option for many SNFs that lack an EMR/EHR system with interoperable capability. Until SNFs can provide access to electronic health records in a secure manner to clinicians who are offsite, an expectation of a one-day review is unrealistic.<br><br>ASCP RECOMMENDATIONS: As many clinicians cover several different SNFs and may not be onsite at time of a resident's admission, we recommend a 72-¬hour window be considered for non-¬emergency situations.<br>5. There are several areas of content on the Drug Regimen Review Measure Justification Form that need to be addressed.<br>· Outcome 1 is missing. The document begins with Outcome 2.<br>· 1a.4.2. Specific Guideline:<br>o Outcome 2: Decrease Polypharmacy – "Goal: 9 or fewer scheduled medications with number of administrations no more than 3 different times daily."<br>This section is based on a decrease in medication use that is not clinically supported by pharmacotherapeutic practices. It is not acceptable clinical practice to merely suggest that someone taking multiple medications reduce use arbitrarily. An example of "polypharmacy" that is clinically necessary would be a nursing home resident diagnosed with COPD, hypertension, diabetes, and dementia. If this resident is treated per nationally recognized guidelines, they would be expected to receive 12 routine medications. It is not good medical practice to set numerical limits on the number of medications a patient should take. This decision should be made using the expertise of the consultant pharmacist in conjunction with the prescriber and other clinical team leaders. While medication redundancies should be avoided in many cases, it is not safe clinical practice to set arbitrary medication limits to reduce use. It should be noted that this part of the document has poor clinical evidence levels (grade C), and therefore should not be included.<br><br>· ASCP RECOMMENDATIONS: It is not clinically appropriate to set pre-¬determined limits on the number of medications a patient is prescribed, nor is it appropriate to set pre-¬determined goals to meet a certain number of | | | | |

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| | | medications without strong clinical rationale for such prescribing rules. The number of medications a patient needs, including those taken pro re nata (PRN) is based on person-¬centered care with careful examination of the entire clinical picture. It requires the expertise of a diagnostician and a consultant pharmacist to make this determination. In light of unacceptable clinical evidence (Grade C) and a high propensity for poor clinical outcomes, ASCP recommends this section of the document be removed or completely restructured to reduce the near-¬certainty of medication misadventures that would occur were it included.<br>· Proposed "Assessment: The creatinine clearance level will be calculated on admission, with changes in condition, and at least annually. (Evidence Grade = C-¬1)."<br>· It is the standard of practice to only calculate creatinine clearance when there is a medication that should be dosed based on renal function. It is also important to note that calculating creatinine clearance requires serum creatinine level through blood draw. It is most often not possible to obtain blood draw and lab results within 24 hour of admit to a SNF. Creatinine clearance is not applicable or necessary to be calculated upon every change of condition. This proposed content could result in unnecessary labs and costs with no additional benefit.<br>☐ Proposed "Assessment Action: The Cockcroft Gault Score (see Appendix B in the original guideline document) and laboratory results will be used to determine dosing. Major Drug Guides and prescribing references provide medication dosing guidelines for initial as well as individualized suggestions based on disease severity and therapeutic responses. (Evidence Grade = C-¬1)."<br>· Relying on data obtained using the Cockcroft Gault scoring system is not always appropriate in the elderly. A modified formula is often used. Dosing and tests should be based on the recommendations of the consultant pharmacist and the prescriber, taking all clinical concerns, including renal impairment, into consideration. In general, dosing algorithms are meant to be a guide and should never take the place of clinical expertise in determining appropriate dosages. The consultant pharmacist's expertise should be used in determining whether dosage adjustments are warranted based on hepatic or renal insufficiency as well as concomitant co-morbidities and medications with scored guidelines used only as a starting point.<br>o Outcome 3: Avoid Adverse Drug Reactions (ADRs)<br>☐ Proposed "Expected Outcome: No adverse drug reactions, no drugs ordered | | | | |

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| | | to treat side effects or adverse reactions, and no hospitalizations or ED visits resulting from adverse drug reactions. (Evidence Grade = C-¬1)."<br>· It is clinically unrealistic to have an expected outcome of "No adverse drug reactions, no drugs ordered to treat side effects or adverse reaction." Medications are ordered by the prescriber and assessed by the consultant pharmacist with the goal of clinical improvement. Sometimes, even with appropriate clinical oversight and care, adverse reactions can happen. Indeed, medication choices are based on a risk/benefit analysis done by pharmacotherapy experts, prescribers, and in consultation with patient and caregivers. Many times, an unpleasant side effect is outweighed by clinical benefits the medication therapy provides. Despite a shared goal of the fewest possible adverse medication events, person-centered care requires careful analysis based on risk vs. benefit.<br>ASCP RECOMMENDATIONS: While ASCP agrees that consultant pharmacists and prescribers should work in tandem to ensure preventable adverse medication events do not occur, it is clinically unrealistic to assume that no adverse events will occur. We recommend the language of this section employ more robust research (an evidence level of C) and set realistic goals for adverse event reduction used instead. It would be prudent for CMS to review the work of the National Coordinating Council for Medication Error Reporting and Prevention (NCC--MERP, www.nccmerp.org) and the Agency for Healthcare Research and Quality (AHRQ, www.ahrq.gov) to develop appropriate expectations with respect to reduction of adverse medication events.<br><br>SUMMARY<br>ASCP agrees that guidelines for outcome measure should be developed to provide exceptional care across different care settings and supports the goals of the IMPACT Act. However, in order for these goals to be met, it is important to develop guidelines that have the most robust clinical evidence for use. The current draft relies far too heavily on weak clinical evidence and does not meet the intent of the IMPACT Act ASCP does not support this document in the current incarnation as there is genuine concern that the guidance could harm rather than ameliorate the person-centered care process. The IMPACT Act requires the development of post-acute care measures for medication reconciliation, and this document does not adequately address medication reconciliation. ASCP wishes to once again emphasize that medication reconciliation and medication regimen review are currently two separate processes as defined by CMS.i<br>We would suggest that CMS revisit this measure with the contractor. We | | | | |

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| | | would be pleased to have the opportunity to work with CMS on refining the measure to make it useful and clinically appropriate for use across all sectors. Once again, we wish to thank CMS for the opportunity to share our feedback on this important document. | | | | |
| 22 | 10/6/2015 | On behalf of the American Medical Rehabilitation Providers Association (AMRPA), please accept our comments in response to the Centers for Medicare and Medicaid Services' (CMS) request for feedback on the Drug Regimen Review Measure Information and Justification Forms.<br>AMRPA is the sole trade organization representing the interests of inpatient rehabilitation hospitals and units (IRH/Us), known under Medicare as inpatient rehabilitation facilities (IRFs) and their patients. These patients often present with significant, complex medical issues including strokes, traumatic brain injuries, spinal cord injuries, and/or multiple chronic comorbid conditions. Consequently, we believe it is critically important that the measure meets the needs of these patients without proving unduly burdensome on our member hospitals. The Information and Justification Forms were developed to meet the Improving Post-Acute Care Transformations (IMPACT) Act of 2014's (P.L. 113-185) mandate, which requires the establishment of such measures for all post-acute care (PAC) settings including IRFs, skilled nursing facilities (SNFs), long-term care hospitals (LTCHs), and home health agencies (HHAs).<br>AMRPA is concerned that the information form describes a process that is inconsistent with hospital practices. The form describes how a PAC setting should reconcile medications and then contact the physician within one day. In the hospital, it is the physician who takes the initiative to review and reconcile medications that the patient was taking prior to admission, and then writes orders for those which should be continued, deleted, or changed. We recommend appropriate changes to the documents to reflect standard hospital practice. The information form states that the data associated with this measure will be collected via the Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI). While the IRF-PAI is an excellent instrument for this type of data collection, significant changes were made to it in the Fiscal Year (FY) 2016 Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS) final rule expanding it in length from eight to eighteen pages. Therefore, any additions to the IRF-PAI should be considered carefully in terms of any additional administrative burden, even if such additions are limited to a few items or questions. Further, changes to the IRF-PAI can require staff training, the hiring of additional staff, and changes to electronic health records and billing and documentation software all of which take time and can be costly. These changes should be considered | Sarah Warren, MA<br>Government Relations and Policy Development Associate<br>American Medical Rehabilitation Providers Association | swarren@amrpa.org | Rehab | |

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| | | when determining the timeline for modifying the IRF-PAI to give the field adequate time to make the required changes. Finally, having a mechanism in place to validate the data associated with this measure to ensure it is entered and completed is critically important. As proposed, a provider could easily check a box "yes" to indicate the requirements of the measure were met. We believe the documentation or other form of verification that this measure was completed accurately is important and we are happy to work with you to develop such a mechanism in a manner that minimizes the administrative burden. Thank you for your consideration of our comments. | | | | |
| 23 | 10/7/2015 | I would like to weigh in on the new mandates for the IMPACT for drug review across PAC settings. I work in Home Health and this is something that is critical for us to manage and navigate.<br><br>My concern with making this a publically reported outcome based solely on the OASIS as it stands now is that while it is our expectation and practice is to have our SOC/ROC clinicians call the physician with any medication discrepancies and problems, the challenge we face is that the doctors often to not call us back within 24 hours. This is not specific to Steward Home Care but is inherent in the tribulations we face in home care in general. My fear therefore is that, much like the Face to Face requirement was originally intended to hold MDs accountable and now is a financial hardship on many agencies, this item that is speaking to the level of response from the physician will somehow end up negatively impacting our outcome scores in the long run.<br><br>Ideally, I would like to this as two separate questions within the OASIS. One, "did you contact the physician to resolve issues?" Two, "Did the physician resolve this issue within 24 hours?"<br><br>Thank you for your time and consideration in this matter. | Robin Thomas, OTR/L, MS, COS-C Clinical Educator Steward Home Care -- Westwood | Robin.Thomas@steward.org | HH | |
| 24 | 10/19/2015 | AMDA - The Society for Post-Acute and Long-Term Care Medicine (AMDA) appreciates the opportunity to provide comments on the IMPACT Act of 2014 Cross-Setting Quality Measure: Drug Regimen Review. AMDA is the professional society of nursing home medical directors, nursing home attending physicians, and other professionals practicing in the post-acute and long-term care (PA/LTC) continuum. We work to ensure excellence in patient care and to promote the delivery of quality PA/LTC medicine.<br>We support the intent of this measure and agree that a careful medication regimen review and medication reconciliation performed by an appropriately | Alex Bardakh, MPP, PLC Director, Public Policy AMDA – The Society for Post-Acute and Long-Term Care Medicine | abardakh@amda.com | Cross-setting | |

| ID | Date Posted | Text of Comments | Name, Credentials, and Organization of Commentor | E-Mail Address | Type of Organization | Recommendations /Actions Taken |
|---|---|---|---|---|---|---|
| | | trained clinician improves patient care and reduces drug-related adverse events. This is compatible with AMDA recommendations included in our Clinical Practice Guideline on Transitions of Care in the Post-Acute and Long-Term Care Continuum. Having a standardized process to evaluate medication use across different care settings can help to improve safe transitions and care for hospital patients and long-term care residents. We also agree with and support the desired outcome of reducing inappropriate medication redundancies and adverse drug events.<br><br>However, we are concerned that this particular measure falls short of achieving these desired outcomes. The DRR Measure Information Form should specify (i.e., define) what is meant by "clinically significant medication issues" as referenced within it. It is uncertain if this is meant to include only errors such as omissions or duplications noted in medication reconciliation and/or use of high risk medications, or is to be considered more broadly e.g. assessment of need for certain medications. If a "clinically significant medication issue" is identified, the expectation appears to be to contact with a physician within one calendar day and completion of any recommended actions resulting from that physician contact. Although contact with a physician is not unreasonable within one calendar day for a "clinically significant medication issue", it is uncertain if the expectation for completion of recommended action within the same 24-hour window is reasonable. Issues will likely arise after hours, on weekends, and holidays, and covering medical staff may understandably, in certain instances, be reluctant to make medication or other clinical adjustments in the absence of timely direct resident examination and assessment, especially in residents who have been on a stable regimen without adverse clinical consequences.<br><br>In the DRR with Follow Up measure, there is an expectation that polypharmacy will be decreased, but this approach may negates scenarios where the benefits of adjusting the medication regimen – i.e., adjusting doses or adding medications - may be most appropriate. Language within this measure should be revised or the measure should be eliminated as stated. On page 4 of the DRR with Follow Up measure, there is a statement that "medications found to be in conflict with the Beers criteria should be discontinued or adjusted unless...". The Beers List, as specified, indicates medications that are potentially inappropriate. The use of some of these may be appropriate under certain clinical circumstances, or have been well tolerated for long periods of time by patients who may therefore refuse to discontinue them. Although the DRR may appropriately identify potentially | | | | |

| ID | Date Posted | Text of Comments | Name, Credentials, and Organization of Commentor | E-Mail Address | Type of Organization | Recommendations /Actions Taken |
|---|---|---|---|---|---|---|
| | | inappropriate medications (PIMs), it is the responsibility of the physician to incorporate all clinical data and use best medical judgment, consistent with the resident's goals of care, in making informed decisions regarding medications. This component requires revision.<br>Given the demonstrated limited evidence supporting medication review (p. 7) and the absence of data on the value or impact of medication review on any clinical outcome, the evidence support for the DRR with Follow Up measure is poor and its use will understandably be questioned.<br><br>In addition, while the physician quality reporting system (PQRS) is beyond the scope of this request, we note that there are no similar measures being proposed or implemented in PQRS. Given that physicians play an important role in helping facilities achieve these facility-based measures, we urge CMS to better align its quality reporting programs. | | | | |

# Appendix

Susan M. Levy, MD, President (elect), Society for Post-Acute and Long Term Care Medicine, Medical Director/VP Medical Affairs

Levindale Hebrew Geriatric Center and Hospital

Email address: smstrohm1@gmail.com

Type of Organization: Specified that this did not represent her organization.

Text of Comments:

Pg. 1 MIF – Med rec not the same as DRR. Impact Act asking for med rec measure. The two complement but are different

Is this the same definition as used in regs for nursing homes? May need to change COPs and ROPs so consistent definitions across the different levels of care.

Pg. 3 MIF – Need to account for unplanned discharges and AMA discharges

Pg. 4 MIF – Some concerns about resolving in one calendar day so maybe just address in one calendar day. MD/NP/PA may want to wait until they assess the patient in 48-72 hours.

Pg. 5 MIF – Again med rec needs to be done on admit to NH and issues resolved. DRR can take longer not just to complete but to resolve concerns

Will need to have definition of clinically significant. Many issues are significant but level of urgency varies.

I think the notification within 24 hours reasonable for nursing home but may take some time to resolve.

Pg. 8 MIF – I assume will need to add to MDS items to capture med rec and DRR

Pg. 1 MJF – Should this just be about med rec to start as one measure and then think through the DRR/MRR measure?

Will definitions need to be changed in the various COPs/ROPs for the different post-acute levels of care?

Pg. 2 MJF ( “Linkage” heading) – Let’s hope so!!!

Pg. 3 MJF- Need to clarify medication review vs. drug review

At the time of regulatory visits the MD/NP/PA usually review the POC which includes the meds. The number is not that important but documenting the medical necessity is important. We recognize polypharmacy concern but with complexity of patients … The GFR is usually obtained from lab test which now typically provide estimated GFR.

Although ideal this is not that realistic. Would agree we try to use drugs that require less frequent dosing because in NH take more nursing time.

This reflect collaboration of RN/prescriber/and pharmacist

Pg. 4 MJF – Are you limiting these drugs? What about other classes such as opiods? Other anticoagulants?

Although ideal ADEs are sometimes not predictable or avoidable

These are guidelines and there are exceptions. Sometimes medication is working and sometimes patient/family want the medication in spite of “relative” contraindications

Pg. 4 (expected outcome) No is not realistic and may not be appropriate

Pg. 7 MIF – The better evidence is around med rec and I would suggest start with just a med rec measure. Getting the list correct as we transition patients is important.

Pg. 8 MJF – Need to hold hospitals accountable for providing post –acute settings with authenticated accurate list of medications on transfer.

# Drug Regimen Review Measure Information Form

## *Project Title*

IMPACT Act of 2014 Cross-Setting Quality Measure: Drug Regimen Review

## *Project Overview*

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 was signed into law on October 6, 2014.[1] This Act requires Post-Acute Care (PAC) providers to report standardized patient assessment data and quality measure data to the Secretary of the Department of Health and Human Services.

The Centers for Medicare & Medicaid Services (CMS) is aligning quality measurement with PAC assessment instruments. Current federal assessment instruments are setting-specific and contain assessment items with varying concepts, definitions, and measurement scales. The move towards standardized assessment data elements facilitates cross-setting data collection, quality measurement, outcome comparison, and interoperable data exchange.

The Centers for Medicare & Medicaid Services (CMS) has contracted with Abt Associates and RTI International to develop a cross-setting post-acute care measure for the quality measure domain—medication reconciliation. The contract names are Development and Maintenance of Symptom Management Measures (contract number HHSM-500-2013-13015I) and Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance Project (contract number HHSM-500-2013-13001I, Task Order HHSM-500T0002). As part of its measure development process, CMS asks contractors to convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure contractor during measure development and maintenance.

In this measure, medication reconciliation and drug regimen review are defined as:

Medication reconciliation – the process of comparing the medications a patient is taking (and should be taking) with newly ordered medications in order to identify and resolve discrepancies. (Reference: The Joint Commission, National Patient Safety Goals).

Drug regimen review – a review of all medications the patient 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. (Reference: Home Health Conditions of Participation Home Health §484.55c).

[1] https://www.govtrack.us/congress/bills/113/hr4994

## *Date*

Information included is current on September 18th, 2015.

## *Measure Name*

Drug Regimen Review Conducted with Follow-Up for Identified Issues

## *Descriptive Information*

**Measure Name (Measure Title De.2.);**
**Drug Regimen Review Conducted with Follow-Up for Identified Issues**

**Measure Type De.1.;**
Process

**Brief Description of Measure De.3.;**
Percentage of stays Inpatient Rehabilitation Facility (IRF), Long Term Care Facility (LTCH), and Skilled Nursing Facility (SNF) or care episodes Home Health (HH) in which a drug regimen review was conducted at the Admission (IRF, LTCH or SNF)/ Start of Care (SOC)/ Resumption of Care (ROC) (HH) and timely follow-up with a physician occurred each time potentially significant medication issues were identified throughout the stay (IRF, LTCH, or SNF) or care episode (HH).

**If Paired or Grouped De.4.;**
N/A

**Subject/Topic Areas De.5.;**
Prevention: Prevention

**Crosscutting Areas De 6.;**
Care Coordination: Care Coordination
Safety: Medication Safety

## *Measure Specifications*

### Measure-specific Web Page S.1.;

| Measure Title: Drug Regimen Review Conducted with Follow-Up for Identified Issues | |
|---|---|
| Measure Description | Percentage of care episodes or stays in which a drug regimen review was conducted at the Admission /SOC /ROC, and timely follow-up with a physician occurred each time potentially significant medication issues were identified throughout the care episode or stay. |
| Numerator | Number of care episodes or stays in which ***all of the*** following are each true:<br><br>1. Item 1 = [0, 1, 9]<br>The agency/facility conducted a drug regimen review at the [Admission/SOC/ROC] (Item 1 = [0,1])<br><br>OR<br><br>Patient/resident is not taking any medications (Item 1 = [9])<br>AND<br><br>2. If Item 1 = [1], then Item 2 = [1]<br>If clinically significant medication issues were identified at the [Admission/SOC/ROC] (Item 1 = [1]), then the agency/facility contacted a physician (or physician-designee) within one calendar day and completed prescribed/recommended actions in response to the identified issues (Item 2 = [1]).<br><br>AND<br><br>3. Item 3 = [1, 9]<br>The agency/facility contacted a physician (or physician-designee) and completed prescribed/recommended actions within one calendar day each time clinically significant medication issues were identified since the [Admission/SOC/ROC] (Item 3 = [1])<br>OR<br>No clinically significant medications issues were identified since the [Admission/SOC/ROC] ( Item 3 = [9]) |
| Numerator Exclusion | **Home Health** – None<br>**SNF** – None<br>**IRF** – None<br>**LTCH** – None |
| Denominator | Care episodes or stays ending during the reporting period (end of care/discharge). |
| Denominator Exclusions | **Home Health** – None<br>**SNF** – None<br>**IRF** – None<br>**LTCH** – None |

| | |
|---|---|
| Items Used | **Beginning of care episode or stay**<br>**Item 1 Drug Regimen Review:** Did a complete drug regimen review identify potential clinically significant medication issues?<br>☐ 0 – No – No issues found during review [Skip to XXXX]<br>☐ 1– Yes – issues found during review<br>☐ 9 – N/A – patient/resident is not taking any medications [Skip to XXXX]<br>**Beginning of care episode or stay**<br>**Item 2 Medication Follow-up:** Did the agency/facility contact a physician (or physician-designee) within one calendar day and complete prescribed/recommended actions in response to the identified clinically significant medication issues?<br><br>☐ 0 – No<br>☐ 1 – Yes<br>**End of care episode or stay**<br>**Item 3 Medication Intervention:**<br>**LTCH/SNF/IRF**: Did the facility contact and complete physician (or physician-designee) prescribed/recommended actions within one calendar day each time clinically significant medication issues were identified since the **Admission**?<br>**HHA:** Did the agency contact and complete physician (or physician-designee) prescribed/recommended actions within one calendar day each time clinically significant medication issues were identified since the **SOC/ROC**?<br>☐ 0 – No<br>☐ 1 – Yes<br>☐ 9 – N/A –There were no clinically significant medication issues identified since [Admission/SOC/ROC] or patient/resident is not taking any medications. |
| Assessment Timing | **Beginning of care episode or stay:**<br>**Item 1**<br>• **HH** – SOC or ROC<br>• **SNF** – Admission<br>• **IRF** – Admission<br>• **LTCH** – Admission<br>**Item 2**<br>• **HH** – SOC or ROC<br>• **SNF** – Admission<br>• **IRF** – Admission<br>• **LTCH** – Admission<br><br>**End of care episode or stay:**<br>**Item 3**<br>• **HH** – Transfer or Discharge<br>• **SNF** – Discharges<br>• **IRF** – Discharge<br>• **LTCH** – Discharges |

### If this is an eMeasure S.2a.;

No HQMF specs

### Data Dictionary, Code Table, or Value Sets S.2b.;

No data dictionary/code table – all information provided in the submission form

**For Endorsement Maintenance S.3.;**
N/A

**Numerator Statement S.4.;**
Number of patients/resident's whose medical record contains documentation of a drug regimen review conducted at admission or start-of-care or resumption-of-care with all significant medication issues identified during the course of care and followed-up with a physician or physician designee.

**Time Period for Data S.5.**
TBD

**Numerator Details S.6.;**
Number of stays (IRF, LTCH, or SNF) or care episodes (HH) in which all of the following are each true:

1. Item1 = [0, 1, 9]

The agency/facility conducted a drug regimen review at the [Admission/SOC/ROC] (Item 1= [0, 1])

OR

Patient/resident is not taking any medications (Item 1 = [9])

AND

2. If Item 1 = [1], then Item 2= [1]

If clinically significant medication issues were identified at the [Admission/SOC/ROC] (Item 1 = [1]), then the agency/facility contacted a physician (or physician-designee) within one calendar day and completed prescribed/recommended actions in response to the identified issues

(Item 2= [1]).

AND

3. Item 3 = [1, 9]

The agency/facility contacted a physician (or physician-designee) and completed prescribed/recommended actions within one calendar day each time clinically significant medication issues were identified since the [Admission/SOC/ROC] ( Item 3 = [1])

OR

No clinically significant medications issues were identified since the [Admission/SOC/ROC] (Item 3 = [9])

**Denominator Statement S.7.;**
Stays (IRF, LTCH, and SNF) or care episodes (HH) ending during the reporting period (end of care/discharge).

**Target Population Category S.8.;**

**Denominator Details S.9.**
All patients/residents who had a start of care, resumption of care or admission assessment completed during the reporting period

**Denominator Exclusions (NQF Includes "Exceptions" in the "Exclusion" Field) S.10.;**
Home Health – None
SNF – None
IRF – None
LTCH – None

**Denominator Exclusion Details (NQF Includes "Exceptions" in the "Exclusion" Field) S.11.;**
None

**Stratification Details/Variables S.12.;**
N/A – measure not stratified

**Risk Adjustment Type S.13.;**
No risk adjustment or risk stratification

**Statistical Risk Model and Variables S.14.;**
N/A – process measure

**Detailed Risk Model Specifications S.15.;**

**Type of Score S.16.;**
**Count**
Ratio

**Interpretation of Score S.17.;**
Better quality = higher score

**Calculation Algorithm/Measure Logic S.18 (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.);**

**Calculation Algorithm/Measure Logic Diagram URL or Attachment S.19.**

**Sampling S.20.;**
N/A

**Survey/Patient-Reported Data S.21.;**
N/A

**Missing Data S.22.;**
N/A

**Data Source S.23.;**
Electronic Clinical Data: Electronic Clinical Data

**Data Source or Collection Instrument S.24.;**

**IMPACT Act**
The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 requires the submission of standardized and interoperable data by post-acute care providers including Long-Term Care Hospitals (LTCHs), Skilled Nursing Facilities (SNFs), Home Health Agencies (HHAs) and Inpatient Rehabilitation Facilities (IRFs). Furthermore, the IMPACT Act authorizes Health and Human Services (HHS) to modify post-acute care assessment instruments to provide for the submission of standardized data.

**Home Health Agency**
The measure could be calculated based on the data obtained from the Outcome and Assessment Information Set (OASIS), which is a core standard assessment data set that home health agencies integrate into their patient-specific, comprehensive assessment to identify each patient's need for home care. The OASIS is the assessment instrument used to collection and report data for the Home Health Quality Reporting Program (HH QRP). The OASIS is the foundation for valid and reliable information for patient assessment, care planning, and service delivery in the home health setting, as well as for the home health quality assessment and performance improvement program. Home health agencies are required to collect OASIS data on all non-maternity Medicare/Medicaid patients, 18 or over, receiving skilled services. Data are collected at specific time points (admission, resumption of care after inpatient stay, recertification every 60 days that the patient remains in care, transfer, and at discharge). Home health agencies are required to encode and transmit patient OASIS data to the national QIES ASAP System. Each HHA has on-line access to outcome and process measure reports based on their own OASIS data submissions, as well as comparative state and national aggregate reports, case mix reports, and potentially avoidable event reports. CMS makes measures based on submitted OASIS data (to include the Drug Regimen Review Conducted with Follow-Up for Identified Issues measure) available to consumers and to the general public through the Medicare Home Health Compare website.

### LTCH, SNF, IRF Settings

This measure could be calculated based on the quality reporting data collected from the Long Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set; Minimum Data Set Version 3.0 Instrument (MDS 3.0); and Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI). At present the LTCH CARE Data Set, MDS and the IRF-PAI instruments do not include drug regimen review or medication reconciliation quality measure items but could be modified to include items for the Drug Regimen Review Conducted with Follow-Up for Identified Issues quality measure.

### LTCH

The LTCH CARE Data Set Version 3.0 (to be implemented April 1, 2016; [note: LTCH CARE Data version 2.01 is currently in use through March 31, 2015]) is a standard assessment for all patients receiving inpatient services in a facility certified as a hospital and designated as an LTCH under the Medicare program. These hospitals are certified as acute-care hospitals that treat patients requiring extended hospital-level care, typically following initial treatment at a general acute-care hospital. If a hospital is classified as an LTCH for purposes of Medicare payments it is subject to the requirements of the LTCH Quality Reporting (LTCHQR) Program. It is not applicable to patients receiving services in LTCH units that are not designated as LTCHs under the Medicare program.

The LTCH CARE Data Set Version 3.0 is the assessment instrument used to collect and submit data to CMS as part of the LTCH Quality Reporting Program (QRP). The LTCH CARE Data Sets include Admission, Unplanned Discharge, Planned Discharge, and Expired Assessments. These data sets are completed for individual LTCH patients who are admitted to, discharged from, or die in the LTCH, and are considered part of the patient's medical record. Data collection using the LTCH CARE Data Set is applicable regardless of patient's age, diagnosis, length of stay, or payment/payer source. Each year, LTCHs are required to report data to meet the LTCH QRP requirements. The LTCH CARE Data Set is transmitted to CMS through the Assessment Submission and Processing (ASAP) system to the Quality Improvement Evaluation System (QIES).

### SNF

The MDS 3.0 is part of the federally mandated process for clinical assessment of all residents in Medicare or Medicaid certified nursing homes (including skilled nursing facilities [SNF] and nursing facilities [NF]) and non-critical access hospital swing beds (SB). This process provides a comprehensive assessment of each resident's functional capabilities and health characteristics and helps nursing home staff identify health problems. MDS assessment forms are completed for all residents in certified nursing homes, regardless of source of payment for the individual resident.

MDS assessments are required for residents on admission to the nursing home and then periodically, within specific guidelines and time frames. In most cases, participants in the assessment process are licensed health care professionals employed by the nursing home. MDS information is transmitted electronically by nursing homes to the MDS database in

their respective States. MDS information from the State databases is captured into the national MDS database at CMS.

**IRF**

The submission of Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI) is required by the Centers for Medicare & Medicaid Services (CMS) as part of the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS) and the IRF QRP.

The completion of the IRF-PAI is required for every Medicare Part A fee-for-service and Medicare Part C (Medicare Advantage) patient discharged from an IRF.

IRF-PAI data are submitted to CMS per IRF PPS requirements and the IRF QRP allows corrections based on quarterly deadlines. The IRF-PAI must be transmitted to CMS through the Assessment Submission and Processing (ASAP) system to the Quality Improvement Evaluation System (QIES). Each IRF provider has access to the Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system that provides validation reports for successful data submission based on the IRF-PAI record specifications.

**Data Source or Collection Instrument (Reference) S.25.;**

**Level of Analysis S.26.;**

Facility

**Care Setting S.27.;**

Home Health
Post Acute/Long Term Care Facility: Nursing Home/Skilled Nursing Facility
Post Acute/Long Term Care Facility: Inpatient Rehabilitation Facility
Post Acute/Long Term Care Facility: Long Term Acute Care

**Composite Performance Measure S.28.;**

N/A

# Drug Regimen Review Measure Justification Form

## *Project Title:*

IMPACT Act of 2014 Cross-Setting Quality Measure: Drug Regimen Review

## *Project Overview:*

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 was signed into law on October 6, 2014.[1] This Act requires Post-Acute Care (PAC) providers to report standardized patient assessment data and quality measure data to the Secretary of the Department of Health and Human Services.

The Centers for Medicare & Medicaid Services (CMS) is working to ensure that data elements within PAC assessment instruments are standardized and interoperable. Current federal assessment instruments are setting-specific and contain assessment items with varying concepts, definitions, and measurement scales. The move towards standardized assessment data elements facilitates cross-setting data collection, quality measurement, outcome comparison, and interoperable data exchange.

The Centers for Medicare & Medicaid Services (CMS) has contracted with Abt Associates and RTI International to develop a cross-setting PAC measure for the quality measure domain - medication reconciliation. The contract names are Development and Maintenance of Symptom Management Measures (contract number HHSM-500-2013-13015I) and Outcome and Assessment Information Set (OASIS) Quality Measure Development and Maintenance Project (contract number HHSM -500-2013-13001I, Task Order HHSM-500T0002). As part of its measure development process, CMS asks contractors to convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure contractors during measure development and maintenance.

In this measure, medication reconciliation and drug regimen review are defined as:

Medication reconciliation - the process of comparing the medications a patient is taking (and should be taking) with newly ordered medications in order to identify and resolve discrepancies. (Reference: The Joint Commission, National Patient Safety Goals).

Drug Regimen review - a review of all medications the patient 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. (Reference: Home Health Conditions of Participation §484.55c) .

[1] https://www.govtrack.us/congress/bills/113/hr4994

## *Date:*

Information included is current on September 18th, 2015.

## *Measure Name*

Drug Regimen Review Conducted with Follow-Up for Identified Issues

## *Type of Measure*

Process

## *Importance*

### 1a—Opportunity for Improvement

**1a.1. This is a Measure of Process: Drug Regimen Review**

### 1a.2.—Linkage

**1a.2.1 Rationale N/A as "not a health outcome or PRO, skip to 1a.3"**

### 1a.3.—Linkage

Medication review in post-acute care is generally considered to include medication reconciliation for all medications and medication review for high risk medications. As a process measure, medication reconciliation and medication review for high risk medications are expected to reduce re-hospitalizations, reduce adverse events related to medications and improve health outcomes.

**1a.3.1. Source of Systematic Review**
Clinical Practice Guideline (CPG) recommendation – complete sections 1a.4, and 1a.7

US Preventive Services Task Force Recommendation – complete sections 1a.5 and 1a.7

Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, AHRQ Evidence Practice Center) – complete sections 1a.6 and 1a.7

Other – complete section 1a.8

### 1a.4.—Clinical Practice Guideline Recommendation

**1a.4.1. Guideline Citation**
A review of CPGs using the search terms "medication education" returned more than 2000 CPGs which were focused on disease (e.g., medication education for persons with diabetes)

but not in general for persons living in the community or specific to post-acute care settings.

A search for the term “medication review” returned disease- and condition-specific guidelines with one relevant guideline: “Improving medication management in older adult clients” designed for nursing home residents: Bergman-Evans B. Improving medication management for older adult clients. Iowa City (IA): University of Iowa College of Nursing, John A. Harford Foundation Center of Geriatric Nursing Excellence; 2012 May. 31 p. [117 references].

There were no similar guidelines specific to community dwelling older people (for home health care) or those requiring rehabilitation (IRF, LTCH), although these general strategies would apply to all post-acute care settings.

**1a.4.2. Specific Guideline**

**“Outcome 2: Decrease Polypharmacy**

*Assessment*

Nurse practitioners, physician assistants, and or physicians will review and record the total number of routine and as needed medications at each periodic visit. The creatinine clearance level will be calculated on admission, with changes in condition, and at least annually. *(Evidence Grade = C-1).*

*Assessment Action*

The Cockcroft Gault Score (see Appendix B in the original guideline document) and laboratory results will be used to determine dosing. Major Drug Guides and prescribing references provide medication dosing guidelines for initial as well as individualized suggestions based on disease severity and therapeutic responses. *(Evidence Grade = C-1).*

*Expected Outcome*

- The number of scheduled and as needed (prn) medications will not increase and medications will be congruent with diagnoses with no duplications present. Goal: 9 or fewer scheduled medications with number of administrations no more than 3 different times daily. Example; with 7 different meds: 4 given one time daily and 3 twice daily. The regimen could be 5 meds at 9 am, 2 at noon, and 3 at hour of sleep.
- Medication doses will be appropriate for age/renal/hepatic status of older adults. *(Evidence Grade = C-1)* .

**Outcome 3: Avoid Adverse Drug Reactions (ADRs)**

*Assessment*

The resident's record and physical exam will be used to verify adverse drug reactions occurring in the time from the last periodic exam. (*Evidence Grade = D*).

*Assessment Action*

- Medications identified as resulting in adverse drug reactions including reactions or ER/hospitalizations will be adjusted or discontinued based on overall plan of care. (*Evidence Grade = C-1*) .
- Monitoring guidelines will be individualized and in place for high risk medications: insulin, digoxin, warfarin, anti-psychotics. (*Evidence Grade = C-1*) .

*Expected Outcome*

No adverse drug reactions, no drugs ordered to treat side effects or adverse reactions, and no hospitalizations or ED visits resulting from adverse drug reactions. (*Evidence Grade = C-1*).

**Outcome 4: Decrease Inappropriate Prescribing**
*Assessment*

The current Medication Administration Record will be compared to the Beers list, Centers for Medicare & Medicaid Services (CMS) guidelines, and the facility pharmacist's recommendations to ascertain appropriateness of current medication regimen. (*Evidence Grade = B-1*).

*Assessment Action*

- Medications found to be in conflict with the Beers list, CMS guidelines, and/or facility pharmacist's recommendations should be discontinued or adjusted unless compelling evidence exists for continuance. (*Evidence Grade = B-1*).
- The Beers list, CMS guidelines, and/or facility pharmacist's recommendations should be used when planning medication initiation, reviewing established medication regimens, or making changes in the medication regimen. (*Evidence Grade = C-1*).

*Expected Outcome*

No inappropriate prescribing as evidenced by the medication regimen which contains no drugs in conflict with the Beers lists, CMS guidelines, and/or pharmacist recommendations. (*Evidence Grade = C-1*).

**1a.4.3. Grade**

**Definitions:**

**Rating Scheme for Strength of Evidence**

**A1** = Evidence from well-designed meta-analysis or well done systematic review with results that consistently support a specific action (e.g., assessment, intervention, or treatment)

**A2** = Evidence from one or more randomized controlled trials with consistent results

**B1** = Evidence from a high quality evidence-based practice guideline

**B2** = Evidence from one or more quasi-experimental studies with consistent results

**C1** = Evidence from observational studies with consistent results (e.g., correlational descriptive studies)

**C2** = Inconsistent evidence from observational studies or controlled trials

**D** = Evidence from expert opinion, multiple case reports, or national consensus reports

1a.4.4. Grades and Associated Definitions

N/A

**1a.4.5. Methodology Citation**
N/A

**1a.4.6. Quantity, Quality, and Consistency**
No → report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7.

**1a.5.—United States Preventative Services Task Force Recommendation**
There were no recommendations from the USPSTF.

**1a.5.1. Recommendation Citation**

**1a.5.2. Specific Recommendation**

**1a.5.3. Grade**

**1a.5.4. Grades and Associated Definitions**

**1a.5.5. Methodology Citation**

## 1a.6.—Other Systematic Review of the Body of Evidence

### 1a.6.1. Review Citation
Chhabra, P. T., et al. (2012). "Medication reconciliation during the transition to and from long-term care settings: a systematic review." Res Social Adm Pharm 8(1): 60-75.

### 1a.6.2. Methodology Citation
Methodology for evidence review and grading not specified in the publication.

## 1a.7.—Findings from Systematic Review of Body of the Evidence Supporting the Measure

### 1a.7.1. Specifics Addressed in Evidence Review
Medication reconciliation by a pharmacist at the time of transition into a long term care setting (nursing homes, skilled nursing facilities, residential care facilities, assisted living facilities, homes for the aged, and hospice care). The study did not separate findings per setting; rather, combining all “long term care settings” and included SNF.

### 1a.7.2. Grade
Grade not described or specified in the systematic review.

### 1a.7.3. Grades and Associated Definitions
N/A—see 1a.7.2.

### 1a.7.4. Time Period
2000 to 2010.

### 1a.7.5. Number and Type of Study Designs
7 studies total with 4 from the United States: one RCT, three quasi-experimental studies.

### 1a.7.6. Overall Quality of Evidence
Authors note biases in all 4 studies from the US, particularly the lack of randomization.

### 1a.7.7. Estimates of Benefit
Pharmacist involvement in medication reconciliation was found to have a positive effect on patient outcome of mortality with no effect or a small effect (if any) on Emergency Department (ED) visits and hospital readmissions.

### 1a.7.8. Benefits Over Harms
No harms were studied.

### 1a.7.9. Provide for Each New Study

## 1a.8.—Other Source of Evidence

### 1a.8.1. Process Used
Literature search of PubMed and Google Scholar.

**1a.8.2. Citation**
Medication review in post-acute care is generally considered to include medication reconciliation and medication review for high risk medications. The general issue of medication review is included below, noting that there is much less research and evidence in this area.

**Medication reconciliation** is a well-supported practice with specific points in the care process noted as particularly high risk. Hospital discharge is one high risk time point with evidence that there are high levels of discrepancy. [1;2] In fact, there is evidence that 50% of patients experience a clinically important medication error after hospital discharge.[3] Specific to skilled nursing facilities, there is evidence that medication discrepancies occur in three out of four SNF admissions.[4]

There is evidence that medication reconciliation is effective at identifying medication discrepancy and potential harm but the impact on clinical outcomes (e.g. reduced rehospitalizations) is limited.[5] In part this is due to the complex reasons behind rehospitalizations and that many medication reconciliation studies simply identify the issue without collecting data on the outcomes. Despite this lack of strong evidence on patient outcomes, medication reconciliation is a requirement of accrediting organizations (e.g. The Joint Commission) and a key element in strategies to improve the quality of care transition programs.[6]

There is no evidence on medication reconciliation at the transition points within post-acute care sites (e.g. from SNF to home health care) but there is no reason to think that medication reconciliation would be better between post-acute care sites as compared to hospital to post-acute care settings.

Specific to home health care, there is evidence that there is substantial medication discrepancies following hospital stay[7] and that 38% of home health care patients are prescribed potentially inappropriate medications.[8] For skilled nursing facility residents, there is one research study that reported that 21% of patients were prescribed at least one high risk medication prior to a hospitalization.[9] There was no research found for IRF and LTCHs on medication reconciliation, potentially inappropriate medications or high risk medications.

**High risk medications** have been identified by the Institute for Safe Medication Practices (ISMP) as "high alert" medications or those that "bear a heightened risk of causing significant patient harm when they are used in error." The ISMP lists medications for community and ambulatory home care on their web site: http://ismp.org/communityRx/tools/ambulatoryhighalert.asp ISMP recommends patient education as one strategy to improve safe use of these medications.

CMS has identified high risk medications for the elderly through their work with the Part D Medicare benefit. These drugs were identified through the National Committee for Quality Assurance through the Healthcare Effectiveness Data and Information Set (HEDIS). The

drug list is available here:
http://www.ncqa.org/HEDISQualityMeasurement/HEDISMeasures/HEDIS2015/HEDIS2015NDCLicense/HEDIS2015FinalNDCLists.aspx

Thus there is evidence that medication review in post-acute care settings focuses on high risk medications as a priority.

**Communication at transitions of care:** There is evidence that medication information is not always transmitted between hospitals and rehabilitation facilities[10], including for patients on high risk medications (i.e. Coumadin)[11]. There is evidence that a Quality Improvement process can be effective at improving the medication information transmitted from hospital to sub-acute facilities through increased training and improvements in the infrastructure (health IT) to support the change process.[12]

**Medication review in general:** There is very limited evidence on medication review in general for post-acute care settings. However, medication discrepancies upon hospital to skilled nursing facility transitions concluded that medication discrepancies occurred in nearly three out of four SNF admissions from hospitals. Further discrepancies of one in five were noted upon medications prescribed upon admission[4]. There are reports from two studies that used pharmacists for medication review. [13;14] The RCT found no differences in mortality or hospitalizations for those who received the pharmacist directed medication review intervention.[13] One RCT from home health care focused on nurse-led medication review (among other interventions) for persons with hypertension reported improvement in blood pressure control.[15]

**Clinical practice guidelines**: A review of CPGs using the search terms "medication education" returned more than 2000 CPGs which were focused on disease (e.g. medication education for persons with diabetes) but not in general for persons living in the community or specific to post-acute care settings. A search for the term "medication review" returned disease- and condition-specific guidelines with one relevant guideline: "Improving medication management in older adult clients" designed for nursing home residents. This guideline recommends: decreasing polypharmacy (C1 evidence: Evidence from observational studies with consistent results [e.g., correlational descriptive studies]; avoiding adverse drug reactions (C1 evidence); and decreasing inappropriate prescribing (C1 evidence). There were no similar guidelines specific to community dwelling older people (for home health care) or those requiring rehabilitation (IRF, LTAC), although these general strategies would apply to all post-acute care settings.

Reference List


(1) Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med* 2005;165:1842–1847.

(2) Wong JD, Bajcar JM, Wong GG et al. Medication reconciliation at hospital discharge: evaluating discrepancies. *Ann Pharmacother* 2008;42:1373–1379.

(3) Kripalani S, Roumie CL, Dalal AK et al. Effect of a pharmacist intervention on clinically important medication errors after hospital discharge: a randomized trial. *Ann Intern Med* 2012;157:1–10.

(4) Tjia J, Bonner A, Briesacher BA, McGee S, Terrill E, Miller K. Medication discrepancies upon hospital to skilled nursing facility transitions. *J Gen Intern Med* 2009;24:630–635.

(5) Lehnbom EC, Stewart MJ, Manias E, Westbrook JI. Impact of medication reconciliation and review on clinical outcomes. *Ann Pharmacother* 2014;48:1298–1312.

(6) Oakes SL, Gillespie SM, Ye Y et al. Transitional care of the long-term care patient. *Clin Geriatr Med* 2011;27:259–271.

(7) Mager DD, Madigan EA. Medication use among older adults in a home care setting. *Home Healthc Nurse* 2010;28:14–21.

(8) Bao Y, Shao H, Bishop TF, Schackman BR, Bruce ML. Inappropriate Medication in a National Sample of US Elderly Patients Receiving Home Health Care. *J Gen Intern Med* 2011.

(9) Stevenson DG, Dusetzina SB, O'Malley AJ et al. High-risk medication use by nursing home residents before and after hospitalization. *Med Care* 2014;52:884–890.

(10) Gandara E, Moniz T, Ungar J et al. Communication and information deficits in patients discharged to rehabilitation facilities: an evaluation of five acute care hospitals. *J Hosp Med* 2009;4:E28–E33.

(11) Gandara E, Moniz TT, Ungar J et al. Deficits in discharge documentation in patients transferred to rehabilitation facilities on anticoagulation: results of a systemwide evaluation. *Jt Comm J Qual Patient Saf* 2008;34:460–463.

(12) Gandara E, Ungar J, Lee J, Chan-Macrae M, O'Malley T, Schnipper JL. Discharge documentation of patients discharged to subacute facilities: a three-year quality improvement process across an integrated health care system. *Jt Comm J Qual Patient Saf* 2010;36:243–251.

(13) Barker A, Barlis P, Berlowitz D, Page K, Jackson B, Lim WK. Pharmacist directed home medication reviews in patients with chronic heart failure: a randomised clinical trial. *Int J Cardiol* 2012;159:139-143.

(14) Pherson EC, Shermock KM, Efird LE et al. Development and implementation of a postdischarge home-based medication management service. *Am J Health Syst Pharm* 2014;71:1576-1583.

(15) Pezzin LE, Feldman PH, Mongoven JM, McDonald MV, Gerber LM, Peng TR. Improving blood pressure control: results of home-based post-acute care interventions. *J Gen Intern Med* 2011;26:280–286.

### 1b.—Evidence to Support Measure Focus

**1b.1. Rationale**
Because of the high prevalence of and potential medication errors among post-acute care patients and because there are best practices and regulatory standards that are associated with high quality care, reporting is beneficial for quality standards as the morbidity associated with incorrect medication regimen may be substantial.

**1b.2. Performance Scores**

**1b.3. Summary of Data Indicating Opportunity**

**1b.4. and 1b.5. Disparities**

### 1c.—High Priority

**1c.1. Demonstrated High-Priority Aspect of Health Care**
IMPACT Act; severity of patient/societal consequences of poor quality; making care safer by reducing harm caused in the delivery of care; and promoting effective communication **and coordination of care.**

**1c.3. Epidemiologic or Resource Use Data**

**1c.4. Citations**

**1c.5. Patient-Reported Outcome Performance Measure (PRO-PM)**
N/A

## *Scientific Acceptability*

### 1.—Data Sample Description

**1.1. What Type of Data was Used for Testing?**

**1.2. Identify the Specific Dataset**

**1.3. What are the Dates of the Data Used in Testing?**

**1.4. What Levels of Analysis Were Tested?**

**1.5. How Many and Which Measured Entities Were Included in the Testing and Analysis?**

**1.6. How Many and Which Patients Were Included in the Testing and Analysis?**

**1.7. Sample Differences, if Applicable**

**2a.2—Reliability Testing**

**2a2.1. Level of Reliability Testing**

**2a2.2. Method of Reliability Testing**

**2a2.3. Statistical Results from Reliability Testing**

**2a2.4. Interpretation**

**2b2—Validity Testing**

**2b2.1. Level of Validity Testing**

**2b2.2. Method of Validity Testing**

**2b2.3. Statistical Results from Validity Testing**

**2b2.4. Interpretation**

**2b3—Exclusions Analysis**

**2b3.1. Method of Testing Exclusions**

**2b3.2. Statistical Results From Testing Exclusions**

**2b3.3. Interpretation**

**2b4—Risk Adjustment or Stratification**

**2b4.1. Method of controlling for differences**

**2b4.2. Rationale why Risk Adjustment is not Needed**

**2b4.3. Conceptual, Clinical, and Statistical Methods**

**2b4.4. Statistical Results**

**2b4.5. Method Used to Develop the Statistical Model or Stratification Approach**

**2b4.6. Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R2)**

**2b4.7. Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic)**

**2b4.8. Statistical Risk Model Calibration—Risk decile plots or calibration curves**

**2b4.9. Results of Risk stratification Analysis**

**2b4.10. Interpretation**

**2b4.11. Optional Additional Testing for Risk Adjustment**

**2b5—Identification of statistically significant and clinically meaningful differences**

**2b5.1. Method for determining**

**2b5.2. Statistical Results**

**2b5.3. Interpretation**

**2b6—Comparability of performance scores**

**2b6.1. Method of testing conducted to demonstrate comparability**

**2b6.2. Statistical Results**

**2b6.3. Interpretation**

## *Feasibility*

**3a.1. How are the data elements needed to compute measure scores generated; Generated or "collected" by and used by healthcare personnel.**

**3b.1. Are the data elements needed for the measure as specified available electronically; All data elements are in defined fields in electronic clinical data.**

**3b.3. If this is an eMeasure, provide a summary of the feasibility assessment;**
N/A

**3c.1. Describe what you have learned or modified as a result of testing;**
Have not tested yet.

**3c.2. Describe any fees, licensing, or other requirements;**
N/A

## *Usability and Use*

### 4.1—Current and Planned Use

**4a.1. Program, sponsor, purpose, geographic area, accountable entities, patients;**
IMPACT Act driven for CMS PAC settings; HH; IRF; LTCH; SNF.

**4a.2. If not publicly reported or used for accountability, reasons**
Data for measure may start TBD.

**4a.3. If not, provide a credible plan for implementation**
Item testing to begin TBD with possible revision of HH; IRF; LTCH; SNF assessment instruments' data sets to enable commencement of data collection on TBD.

**4b.1. Progress on improvement**
N/A, initial endorsement.

**4b.2. If no improvement was demonstrated, what are the reasons**
N/A

## *Related and Competing Measures*

### 5—Relation to Other NQF-Endorsed Measures

None; purpose of IMPACT Act is to standardize to other PAC settings.

**5.1a. The measure titles and NQF numbers are listed here**

**5.1b. If the measures are not NQF-endorsed, indicate the measure title**

### 5a—Harmonization

**5a.1. Are the measure specifications completely harmonized**

**5a.2. If not completely harmonized, identify the differences rationale, and impact**

### 5b—Competing measures

**5b.1 Describe why this measure is superior to competing measures**

## *Additional Information*

### Co.1.—Measure Steward Point of Contact

**Co.1.1. Organization**
CMS

**Co.1.2. First Name**
Tara

**Co.1.3. Last Name**
McMullen, PhD

**Co.1.4. Email Address**
McMullen, Tara L. (CMS/CCSQ) <Tara.McMullen@cms.hhs.gov>

**Co.1.5. Phone Number**
410.786.8425

### Co.2.—Developer Point of Contact (indicate if same as Measure Steward Point of Contact

**Co.2.1. Organization**
Abt Associates / RTI Inc.

**Co.2.2. First Name**
Nicole

**Co.2.3. Last Name**
Keane, MSN, RN

**Co.2.4. Email Address**
Nicole_Keane@abtassoc.com

**Co.2.5. Phone Number**
617.520.3074

## Ad.1. Workgroup/Expert Panel Involved in Measure Development;

DRR TEP held July 29th, 2015.

| TEP Name and Credentials | Organizational Affiliation | Skilled Nursing Facilities | Long Term Care Facilities | Inpatient Rehabilitation Facilities | Home Health | Conflict of Interests |
|---|---|---|---|---|---|---|
| Susan Levy, MD, CMD, AGSF | *Independent Geriatric Medicine Consultant;* *Vice* President – The Society for Post-Acute and Long-Term Care Medicine | X | - | - | - | None |
| Diane Vaughn, RN, C-DONA-LTC, LNHA | *Vice President, Clinical Services* – Benedictine Health System, Duluth, Minnesota; American Health Care Association | X | - | - | - | None |
| W. Gary Erwin, Pharm.D. | *Senior Vice President, Clinical Services* – Omnicare, Inc., Cincinnati, Ohio | X | - | - | - | None |
| Francine Weber, Pharm.D. | *Director of Pharmacy Services* - Helen Hayes Hospital, West Haverstraw, New York | - | - | X | - | None |
| K. Rao Poduri, M.D., FAA PMR | *Professor & Chair and Residency Program Director Medical Director Department of Physical Medicine and Rehabilitation* – University of Rochester Medical Center, Rochester, New York; American Academy of Physical Medicine & Rehabilitation | - | - | X | - | None |

| TEP Name and Credentials | Organizational Affiliation | Skilled Nursing Facilities | Long Term Care Facilities | Inpatient Rehabilitation Facilities | Home Health | Conflict of Interests |
|---|---|---|---|---|---|---|
| Kathleen Boncimino, M.D., M.P.H., C.P.E., | *Medical Director* - Carolinas Rehabilitation Northeast - Carolinas Rehabilitation Department of Physical Medicine & Rehabilitation, Charlotte, NC ; American Medical Providers Rehabilitation Association | - | - | X | - | None |
| Carolyn Winchester, BSN, RN | *Quality Data Coordinator, Regulatory Readiness Manager* - Spartanburg Hospital for Restorative Care, Spartanburg, South Carolina | - | X | - | - | None |
| Chris Marshall, RPh, MBA | *SVP and Chief Pharmacy Officer* – Select Medical, Mechanicsburg, Pennsylvania; American Medical Rehabilitation Providers Association | - | X | - | - | None |
| Susan Yendro, RN, MSN | *Associate Project Director Department of Quality Measurement* – The Joint Commission, Oakbrook Terrace, Illinois | - | X | - | - | None |

| TEP Name and Credentials | Organizational Affiliation | Skilled Nursing Facilities | Long Term Care Facilities | Inpatient Rehabilitation Facilities | Home Health | Conflict of Interests |
|---|---|---|---|---|---|---|
| Melissa O'Connor, PhD, MBA, RN, COS-C | *Assistant Professor*<br>Villanova University, College of Nursing, Claire M. Fagin Fellow (2014-2016), Patricia G. Archbold Scholar (2010-2012) / National Hartford Centers of Gerontological Nursing Excellence, Villanova, Pennsylvania;<br>Eugenie and Joseph Doyle Research Fellow, Visiting Nurse Service of New York | - | - | - | X | None |
| Mary Carr, RN,MPH | *Vice President for Regulatory Affairs* – National Association for Home Care and Hospice | - | - | - | X | None |
| James Summerfelt, M.Ed, MSPT, | *President and CEO* – VNA of Nebraska, Omaha, Nebraska | - | - | - | X | None |
| Consumer | - | - | - | - | - | - |

### Ad.2. Year the Measure Was First Released
TBD

### Ad.3. Month and Year of Most Recent Revision
N/A

### Ad.4. What is your frequency for review/update of this measure?
N/A

### Ad.5. When is your next scheduled review/update for this measure?
N/A

### Ad.6. Copyright Statement
N/A

### Ad.7. Disclaimers
N/A

### Ad.8. Additional Information/Comments