Part D Enhanced Medication Therapy Management Model

Encounter Data Specification Plan - Consolidated Responses to Public Comment

Using SNOMED CT Codes

Q1. How should plan participants proceed to get new SNOMED codes created for an activity that does not yet have a SNOMED code or has a SNOMED code that is not found in the MTM subset?

A1. Plan sponsors have two options for situations in which they cannot identify a SNOMED CT code in the forthcoming enhanced MTM value sets.

a. Search the SNOMED CT database of codes, and identify and use a SNOMED CT code that is not included in an enhanced MTM value set.
b. If a suitable code cannot be found, enter the code ZZZZZ in the Encounter Code field and a text description of the activity in the Encounter Code Description field.

To request that a new SNOMED CT code be created, sponsors should complete the form on the Pharmacy HIT Collaborative's website: http://www.pharmacyhit.org/index.php/online-request-for-mtm-snomed-ct-code. While SNOMED CT codes are being considered for addition to the UMLS, sponsors must still submit quarterly encounter data files using the options listed above.

Q2. Will CMS offer trainings to participating plan sponsors and MTM providers on proper coding of enhanced MTM-related activities using the SNOMED system?

A2. Yes, once the final Enhanced MTM Encounter Data Specification Plan is released, CMS plans to conduct a SNOMED training webinar for all participating plan sponsors. More information about this webinar will be released in the future. CMS will also release an Enhanced MTM Encounter Data Companion Guide, which will contain additional information on all the coding systems that must be used to submit enhanced MTM encounter data.

Q3. How will CMS ensure that plans are aware of changes to the Enhanced MTM encounter data specifications? It is important that notifications are sent out promptly—and in advance, when feasible—to ensure that plan participants can plan accordingly.

A3. Sponsors will be given adequate advanced notice of changes to the enhanced MTM encounter data element specifications and required reports. Notices of changes will be posted as memoranda via the Health Plan Messaging System (HPMS).

Q4. When will CMS release the Companion Guide? This is essential to support participating plans as they develop processes for data submission.

A4. CMS intends to issue the Enhanced MTM Data Companion Guide to participants by the end of August 2016.

Timeframe and Resources Necessary to Fully Implement SNOMED CT Coding

Q5. How will plan participants be able to develop infrastructure to facilitate reporting and map existing data to SNOMED CT codes by the reporting deadline in 2017? Additionally, what is CMS doing to promote standardization of reporting—not only within participants, but also across participating plans?

A5. CMS recognizes that participating sponsors may not all be at the same levels of readiness regarding the use of health IT in tracking medication usage and patient outcomes.[1] The proposed dataset specifications allow participating sponsors flexibility in aligning their own data and reporting systems with the enhanced MTM encounter data reporting requirements. CMS expects participating sponsors to submit encounter data that are appropriately detailed and comprehensive, and will work with sponsors as they move towards full readiness.

CMS appreciates that various external stakeholders have already made significant efforts to promote a standardized use of SNOMED CT codes. For example, the Pharmacy Health IT Collaborative has produced several guidance documents that will help sponsors begin to map encounters into SNOMED CT codes. We expect that sponsors, CMS, and industry/professional organizations will collaborate toward this goal over time, so that best practices can be documented and shared to improve the experience. We recognize that developing sponsors' ability to map current data and text fields to SNOMED CT codes will be an ongoing process.

In the beginning of the model, starting with the first data submission due by July 31, 2017, sponsors can use the enhanced MTM SNOMED CT value sets as a guide, and can choose whether to use those codes or other codes the plan deems appropriate for the services being provided. For codes that the plan cannot find in the dataset, they can rely on the "ZZZZZZ" code for "other codes," describing them appropriately in their submission. This built-in flexibility will allow CMS to analyze the "Other" (ZZZZZZ) codes provided; this analysis will be used to update the enhanced MTM SNOMED CT value sets and to help promote SNOMED CT standardization.

[1] See CMS/PQA Webinar, "PQA Quality Forum: "The Changing Landscape of Pharmacy HIT", April 28, 2016. Available online at http://pqaalliance.org/images/uploads/files/Apr%202016%20Quality%20Forum_The%20Changing%20Landscape%20of%20Pharmacy%20HIT_Wilkins_Spiro_Owen.pdf.

Flexibility to Capture Proposed Enhanced MTM Program Activities

Q6. How will CMS' enhanced MTM encounter data submission process accommodate participating plans that lack the ability to monitor all of a beneficiary's medical services? For example, a participating plan may be able to document and report that a consultative MTM engagement was delivered by a pharmacist to a beneficiary; however, the participating plan may not have insight to that beneficiary's current patient condition status (e.g., stable), or if there was a transition from acute care to self-care.

A6. CMS expects participating sponsors' encounter data submissions to, ultimately, capture as many, or as few, types of services as the sponsors are providing. Communication between sponsors and CMS, and the sharing of best practices and other insights during the life of the model, can help sponsors become better able to report all relevant encounters.

The specification plan does not make any recommendations as to the kinds of data infrastructure or internal monitoring capabilities sponsors should have. There may be variability among proposed enhanced MTM programs with regard to what types of interventions and outcomes can be documented, but the encounter data specifications require sponsors to report, to the extent that they are able, on the services they provide and the encounters surrounding these services.

Q7. Why did CMS not include beneficiary-specific episode of care identifiers to accommodate situations in which multiple or repeated MTM interventions are necessary to address a beneficiary's medication issue(s)? More than one data point may be necessary to track the impact of model services on the beneficiary.

A7. CMS agrees that more than one MTM intervention may be necessary to influence health outcomes and medication usage for certain enrollees in the model. The encounter-based approach attempts to balance collecting robust data for evaluation and administrative burden on model participants. CMS considered developing an episode-based encounter data structure, but determined that this would impose significant administrative burden on sponsors, providers, and vendors and potentially lead to confusion over how to construct an episode, particularly for chronic issues that span multiple reporting periods. During post-hoc evaluation of encounter data, CMS may construct episodes for evaluative or monitoring purposes.

Q8. Why did CMS choose to require RXCUI codes to be reported for drug-related services, rather than NDC codes? NDCs are already standard on pharmacy claims.

A8. Although pharmacy claims typically include NDC codes, rather than RXCUIs, RXCUIs offer significant advantages over using NDCs alone. RXCUIs offer a standardized, normalized, and

more-intuitive way to represent drugs. NDCs do have value, but the use of RXCUIs aligns more closely with other CMS functions such as formulary submissions. In addition, the list of RXCUIs is relatively efficient compared to NDCs, where several NDCs map to one RXCUI. Technical help and algorithms for associating NDCs to RXCUIs can be found here: https://www.nlm.nih.gov/research/umls/rxnorm/docs/2012/rxnorm_doco_full_2012-1.html.

Q9. Which SNOMED CT codes require the reporting of a drug product identifier?

A9. In the forthcoming Enhanced MTM Encounter Data Validation Plan, which will be released for public comment in the fall of 2016, CMS is planning to release some examples of SNOMED CT codes that are likely to be used for enhanced MTM encounter data reporting and for which an accompanying drug product identifier is expected. However, CMS does not expect to identify an exclusive universe of such SNOMED CT codes, and encourages plans to develop internal protocols to standardize when and what is reported with certain SNOMED CT codes.

Specification of Proposed Monitoring Measures

Q10. Will CMS provide definitions for follow-up periods and "high-risk" patients?

A10. CMS plans to establish full definitions of each monitoring measure that is to be used for internal monitoring in the Enhanced MTM Encounter Data Validation Plan, which will be made publicly available in fall 2016.

Q11. Some of the draft specification measures require CMS to provide Medicare data within a certain timeframe to facilitate accurate reporting. If CMS is unable to provide data within this tight timeframe, can participants use pharmacy claims as an alternative to identify certain health services, such as when a patient is discharged?

A11. Enhanced MTM model monitoring measures will account for availability of claims data to both sponsors and CMS. CMS will release further details on the availability of and process for requesting Medicare claims data in the coming months.

Q12. Will CMS consider replacing the term "compliance" with the preferred term "adherence" throughout the document, to reflect a more patient-centered commitment to and engagement in the medication use process?

A12. CMS agrees that the term “adherence” and not “compliance” should be used when referring to medication-taking behavior. This update will be reflected in the final Enhanced MTM Encounter Data Specification Plan.

Q13. For accepted records that were submitted in error in entirety, should a revised record be submitted with blank data?

A13. While a quarterly encounter data submission window is still open, sponsors can submit an entirely new encounter data file that will replace any previously submitted accepted file. However, if the quarterly file submission window has closed, sponsors should resubmit the erroneous record during the next quarterly file submission window, leaving all fields the same, but changing the version number to “0.” This will cause the incorrect record to be deleted. Record deletion guidance will be added to the final Enhanced MTM Encounter Data Specification Plan.

Q14. Will CMS continue to solicit input from stakeholders, particularly Part D plan sponsors and MTM providers, to ensure practicality and operability of the data submission plan as CMS works to finalize the Enhanced MTM Encounter Data Specification Plan in July 2016?

A14. In addition to the public comment period, CMS will continue to encourage participant and other stakeholder input throughout the model.

Q15. Will CMS monitor and evaluate submitted data on an ongoing basis and make adjustments to the data submission plan as needed as the Enhanced MTM model is rolled out?

A15. CMS will monitor encounter data quality and any issues that sponsors experience with respect to preparing and submitting encounter data. CMS will distribute any new or updated guidance to sponsors as needed throughout the model.

Q16. How long should sponsors monitor each encounter for related outcomes or services (e.g., 120 days after drug therapy problem intervention, until end of calendar year, until end of pilot program, until end of member eligibility), and what methods should be used (e.g., pharmacy claims review)?

A16. Ideally, participating sponsors will track beneficiaries and their encounters until the expected health outcome is achieved, however long that takes. For example, depending on the intervention, 120 days may be too short to detect a difference. Because it is not necessary to

"close out" any beneficiary sequence in the encounter data to make an episode, sponsors are not required to determine an encounter endpoint. CMS expects that plans will continue to monitor many targeted patients throughout the year to determine their ongoing eligibility and need for MTM services.