

TO: Centers for Medicare and Medicaid Services (CMS)

FROM: OutcomesMTM, a Cardinal Health Company

SUBJECT: Comments regarding CMS-10396 Medication Therapy Management Program—
Standardized Format (OMB control number 0938-1154)

DATE: June 12, 2021

OutcomesMTM appreciates the opportunity to comment on the Standardized Format and would like to offer points of consideration and recommendations on several proposed modifications to the format.

General Comments

- Please provide a style guide that can be utilized to generate the standardized format including, but not limited to font type, font size, pagination, header and footer sizing and margins. This style guide should ideally include a template file in Word or OpenOffice format and an FAQ document by August 1, 2021, to allow sufficient time for changes to be seamlessly implemented by January 1, 2022. We expect the style guide to be similar as the one provided with the previous Standardized Format template in August of 2017.

Page 2 (Cover Letter)

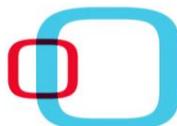
- We support removal of the salutation based on beneficiary feedback specific to diversity and inclusion safeguards and sensitivities.
- In the cover letter, the order of the Medication List and the Recommended To-Do List does not match the order in which the two lists are in the template itself. We recommend changing the bulleted list to match the order of the standardized format (e.g., Recommended To-Do List then Medication List).
- Please clarify if TTY is a required element of the Standardized Format and where it should be placed within the letter information.
- We recommend changing the word “doctors” to the word “healthcare providers” within the statement, “I look forward to working with you and your doctors to make sure your medications work well for you.” Many patients receive care from healthcare providers that are not doctors, such as physician assistants and nurse practitioners.

Page 3 (Recommended To-Do List)

- Please specify the desired content of the “My To-Do List” when no items are identified by the CMR provider.
- Please clarify if a bulleted list in the “What I should do:” section is required or if free text is allowed. We would suggest a bulleted list be optional.

Page 4 (How to Safely Dispose of Unused Prescription Medications)

- Please specify the data source that should be utilized to populate the location of two or more drug take back sites that are available in the community where the enrollee resides as defined in 42 CFR422.111(J) 4. To the best of our knowledge, no government agency is currently publishing the source database for public utilization.
- Further, it is very likely a significant subset of beneficiaries live in a community without one or more drug take back sites. We seek clarifying guidance for CMS’s expectation for the definition of community (e.g., within x miles of the patient’s zip code) as well as what to do when two drug take back sites are unavailable within a beneficiary’s community.



Page 5 (Medication List)

- We ask for clarification on the desired selection for the prescriber field when an over-the-counter medication is recorded. Previous guidance requires inserting “Self” within the prescriber field of an over-the-counter medication.
- We are supportive of the proposed changes to streamline the medication list and anticipate widespread positive provider and patient response to the proposed format of the Medication List.
- Please confirm that the “How I take it” portion of the Medication List would follow the same expectations as the “How I use it” section found in the Personal Medication List or if medication strength is still needed even if it is included in the medication name. Further, please clarify if the expectation is for this section to include the directions as prescribed by the beneficiary’s provider or if it should state how the beneficiary is actually taking the medication when the beneficiary isn’t taking the medication as prescribed.
- OutcomesMTM recommends combining the sections titled “Allergies” and “Side effects I have had.” Based on patient feedback, we do not believe two separate sections adds value for beneficiaries. Additionally, the distinction between an allergy and sensitivity that leads to a side effect may be challenging for a beneficiary to discern. The separate boxes as written in the new template could result in beneficiary frustration as side effects are often categorized as allergies from a patient perspective. Lastly, the separation increases documentation burden for providers.
 - For example, a patient may categorize stomach pain from hydrocodone as an allergy. If the healthcare professional explicitly designates this in the side effect section, the patient may express dissatisfaction which could lead to member grievances.

Sincerely,



Dani Markus, PharmD, MBA
Vice President of Product and Quality
OutcomesMTM

OutcomesMTM, a Cardinal Health company

Outcomes[®] Incorporated, doing business as OutcomesMTM, is the national leader in the design, delivery and administration of Medication Therapy Management (MTM) programs. Our team is committed to leveraging local relationships among pharmacists, patients and prescribers, along with innovative technology to help achieve optimal health outcomes. We administer more than 360 MTM programs for Medicare plan sponsors, Managed Medicaid organizations, commercial plans, pharmacy benefit managers and employer groups. MTM services in our programs are delivered and documented by our nationwide network of pharmacists and their support staff in retail pharmacies, physician clinics and long-term care organizations.

