# CMS-10675 Attachment 3

# Crosswalk for Changes to Survey Instrument for Adverse Drug Events

| **Section**  | **Type of Change** | **Rationale for Change** |
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| Introduction and Informed Consent | Added definition of adverse drug events (ADE) | Recommendation from comments received during the 60-day public notice  |
| Introduction and Informed Consent | Started a new paragraph | To improve readability of the introduction and informed consent. |
| PRA Disclosure Statement | Changed “[Insert Time (hours or minutes)]” to “10-20 minutes” | To improve clarity of instructions. |
| Screener  | S1 – Changed question from identifying industry to identifying state | Given the sample source, all participants will pass the industry question. It was changed to identify state for verification of the sample. |
| Screener | S2 – Separated “*Physician Assistant*” and “*Nurse Practitione*r” response options | To more accurately collect response options. |
| Screener | S2 – Deleted “Behavioral Health Clinician (e.g. therapist, clinical psychologist, counselor, social worker)” response option | To more accurately recruit the intended survey participants based on the inclusion/exclusion criteria. |
| Screener | S2 – Deleted “*Nursing Home Administrator*” and “*Director of Nursing*” options. | To more accurately recruit the intended survey participants based on the inclusion/exclusion criteria. |
| Screener | S3 – Changed response option *“pharmacy”* to *“hospital pharmacy”* (end survey) and *“community or retail pharmacy”* (continue with survey). | To more accurately recruit the intended survey participants based on the inclusion/exclusion criteria. |
| Screener | S3 –– Removed response options related to nursing homes. | Based on feedback from QIN-QIO stakeholders, the survey will no longer include nursing home administrators as participants. |
| Screener | S3 – Added “Community retail pharmacy” to response options. | To more accurately recruit the intended survey participants based on the inclusion/exclusion criteria. |
| Screener | S4 – Changed phrase *“how many staff”* to *“how many providers.”* | To ensure that we are obtaining the same information about all the practices we are assessing. |
| Screener | S4 – Removed references to nursing homes.  | Based on feedback from QIN-QIO stakeholders, the survey will no longer include nursing home administrators as participants. As a result, we removed references to nursing home and long-term care facilities throughout the survey. |
| Screener | S4 – Indicated changes to *“staff”* through following criteria: *[INSERT “providers” IF S3 = “Physician’s office or group practice” OR “pharmacists” IF S3 = “Community or Retail Pharmacy”]*  | To accurately collect information based on respondent’s status. |
| Screener | S4 – Changed *“Pharmacy”* to read as *“Community or retail pharmacy”.* | To more accurately recruit the intended survey participants based on the inclusion/exclusion criteria. |
| Screener | S5 – Changed question to read *“Is the [INSERT “practice” or “pharmacy]” depending on participant’s setting] where you primarily work part of any of the following?”* | To obtain more thorough responses based on survey pretests of participants’ settings. |
| Screener | S5 – Provided the following response options: *[SINGLE PUNCH PER ITEM] [RANDOMIZE ITEMS]]**[ITEMS]**[IF S3 = “Physician’s office or group practice”] Network of practices**[IF S3 = “Community or retail pharmacy”] Corporate chain**[IF S3 = “Community or retail pharmacy”] Pharmacy co-op**[ALL] Health system* | To more accurately collect data. |
| Screener | S6, S7, S8 – Removed *“facility”* as part of work environment option*.* | This change reflects removing nursing homes from the sample. |
| I. Quality Improvement Initiatives | Q1 – Changed the question wording from *“has your facility worked on any”* to *“has your practice or pharmacy begun or continued working on any.”* | To obtain whether facilities were working on new efforts or continuing to work on existing QI efforts related to ADEs. |
| I. Quality Improvement Initiatives | Q1 – Changed the response options from *“Yes/No”* to *“Yes, began new QI activities; Yes, Continued existing QI activities; No, haven’t worked on QI activities.”* Inserted the parenthetical *(QI)* after the phrase *“quality improvement”* in the question text. | To obtain whether facilities were working on new efforts or continuing to work on existing QI efforts related to ADEs. |
| I. Quality Improvement Initiatives | Q3 – Used bold to highlight “your practice/pharmacy”. | To clarify that the question is referring to systematic changes at the institutional level, not based on the individual participant. |
| I. Quality Improvement Initiatives | Q3 – Added response options:* Pharmacist case management for patients with several medications
* Medication management review
* Instituting electronic health record (EHR) or electronic medical record (EMR)-populated notifications of drug interactions and/or allergies
* Educating patients/customers on signs of opioid misuse, abuse, dependence, and addiction
* Teaching patients/customers and family members how to identify and treat an overdose
* Advising patients/customers on the availability of mental health and substance use disorder treatment methods and facilities
* Documenting and monitoring adverse drug event rates within your patients/customers
 | Based on pretest results, multiple participants recommended including these additional response options. |
| I. Quality Improvement Initiatives | Q3 – Option A: Changed *“screening data”* to *“Screening or review of data, reports or graphs.”* | Preferred labelling. |
| I. Quality Improvement Initiatives | Q3 – Option I: Changed *“substance”* to *“opioid.”* | To clarify intent of question. |
| I. Quality Improvement Initiatives | Q3 – Option N: Changed *“Educate… on signs of opioid misuse, abuse, dependence, and addiction”* to *“Educating…on opioid guidelines”* | Original specification wasn’t in this contract work |
| I. Quality Improvement Initiatives | Q3 – Option O: Changed *“overdose”* to *“adverse drug events.”* | Not all ADEs are overdoses. |
| I. Quality Improvement Initiatives | Q3 – Option P: *“Advise [patients/ customers] on the availability of mental health and substance use disorder treatment methods and facilities”* to *“Coordinating with hospitals, skilled nursing facilities or other healthcare services around transfers of [patients/ customers] from these facilities.”* | Original specification was not part of the C.3.6 contract or frame/or scope of ADE reduction. We substituted an activity more relevant to the task. |
| I. Quality Improvement Initiatives | Q3 and Q4 – Rephrased both Q3S and Q4 to indicate that *“involving patients and family members”* means *“involving patients and family members in your efforts to improve medication safety.”* | Based on multiple potential meanings of involving patients and family members mentioned during the survey pretests by participants, these items were revised to clarify the intended meaning. |
| I. Quality Improvement Initiatives | Q5 – Removed mentions of *“facility”* and *“nursing homes.”* | Based on feedback from stakeholders, we have removed nursing homes from our sample.  |
| I. Quality Improvement Initiatives | Q5 – Added new responses and wording as detailed in Q3 | Based on recommendations received in comments and pretesting |
| II. Outcome Attribution to QIO  | Q6 – Added an introductory screen stating: *“The next several questions ask about different programs, organizations, and other resources your practice/ pharmacy may have used when developing and implementing quality improvement activities related to preventing and reducing adverse drug events. These questions refer to your efforts since [for practices display ‘January 2015’. For pharmacies display ‘September 2016’.”* | To clarify intent of question. |
| II. Outcome Attribution to QIO  | Q6 – Added timeframe to the question. | Based on pretest results, clarified the timeframe for using the resources.  |
| II. Outcome Attribution to QIO | Q6 – Updated response options. | Based on pretest results, included additional resources that were reported useful by participants. |
| II. Outcome Attribution to QIO | Q6 – For the introduction to the third group of items (information and resources), rephrased to say: *“Did your [practice/pharmacy] use information and resources from any of these organizations in your efforts to promote medication safety or prevent adverse drug events?”* | Modified text to be consistent with the introduction of other items. |
| II. Outcome Attribution to QIO | Q6 – For group 4 of response options, rephrased *“No outside help – staff’s own initiative”* as *“Ideas and initiatives developed by your [practice’s/pharmacy’s] own staff.”* | To clarify existing response option based on the pretest results.  |
| II. Outcome Attribution to QIO | Q6 – Removed nursing home response options. | Based on feedback from stakeholders, we have removed nursing homes from our sample. |
| II. Outcome Attribution to QIO | Q6 – Option A: Changed *“QIO Collaborative”* to *“QIO Collaborative or Campaign for Medicine Management.”* | To clarify existing response option based on comments from stakeholders.  |
| II. Outcome Attribution to QIO | Q7 – Highlighted the word *“helpful”* with bold font. | To help clarify what question is assessing based on participant confusion during pretests. |
| II. Outcome Attribution to QIO | Q7 – Switched response from allocating percentages to qualitative scales with all points labeled. | To increase comprehension and reduce burden of response, the response options were modified to a qualitative scale based on multiple participants’ difficulty in answering this question during pretests and suggestions to develop a scale.  |
| II. Outcome Attribution to QIO | Q7 – Changed instructions to reflect qualitative scale: *“in your quality improvement efforts to improve medication safety and reduce adverse drug events;”* and to promote medication safety or prevent adverse drug events *“since [for practices display ‘January 2015’. For pharmacies display ‘September 2016’]”* | Reflects decision to adopt qualitative scale (see above). |
| II. Outcome Attribution to QIO | Q7 – Constructed new set of response options, including both updated versions of old response options and new response options. | To improve clarity of response criteria/more accurately collect data. |
| II. Outcome Attribution to QIO | Q7 and Q7AA – Option A: Changed *“QIO Collaborative”* to *“QIO Collaborative or Campaign for Medicine Management.”* | To clarify existing response option based on comments from stakeholders. |
| II. Outcome Attribution to QIO | Q7AA – Added tie-breaker question. | To provide information on what resource participants found most helpful. |
| III. Non-QIO Practices/ Pharmacies | Q10 – Bolded the phrase “participated in any activities.” | To help clarify the focus of the question based on feedback during pretests. |
| III. Non-QIO Practices/ Pharmacies | Q11 – Removed mentions of nursing homes. | Reflects decision to remove nursing homes from sample. |
| IV. Interaction with the QIN-QIO  | Q14 – Used bold to highlight the type of interaction *“one-on-one or small group meetings.”* | To help clarify the type of interaction based on participant input during pretests. |
| IV. Interaction with the QIN-QIO | Q15 – Used bold to highlight the type of interaction “*Apart from one-on-one exchanges.*” | To clarify the type of interaction based on participant confusion during pretests.  |
| IV. Interaction with the QIN-QIO | Q16 – Used bold to highlight the type of interaction “*meetings with these other healthcare providers or pharmacists.*” | To clarify the type of interaction based on participant confusion during pretests. |
| V. Activities and Resources Provided By QIN-QIO | Q19 – Changed response option D to read: *Technical assistance on using data to monitor potential ADEs or occurrence of ADEs with patients/customers* | Based on participant input during pretests. |
| V. Activities and Resources Provided By QIN-QIO | Q19 – Option A: Changed *“Data”* to *“Data, reports or graphs.”* | To clarify existing response option based on comments from stakeholders. |
| V. Activities and Resources Provided By QIN-QIO | Q20 – Minor wording change from: “*level of engagement in”* to *“level of engagement with.”* | To improve the clarity of the sentence. |
| V. Activities and Resources Provided By QIN-QIO | Q21 – Added an instruction, *“Please provide enough detail so that CMS can understand what type of assistance you would need for this quality improvement area.”* | To clarify the questions instructions and obtain more informative responses. |
| V. Activities and Resources Provided By QIN-QIO | Q21 – Added instruction: *IF QIO EXPERIENCE = 0, ASK Q22. ELSE, SKIP TO FINAL SCREEN.* | Programming instruction to set up respondents for Q22 |
| V. Activities and Resources Provided By QIN-QIO | Added additional question (Q22) for participants not involved with the QIO program to gauge interest in TA provided by QIN-QIO program. | To assess the potential usefulness of instituting the activities identified in Q3 for participants not involved in the QIO program. |
| V. Activities and Resources Provided By QIN-QIO | Q22 – Made changes consistent with Q3 |  |