CMS-10675 Attachment 3
Crosswalk for Changes to Survey Instrument for Adverse Drug Events

Section	Type of Change	Rationale for Change
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.
	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.
	S2 – Separated "*Physician Assistant*" and "*Nurse Practitione*r" response options	To more accurately collect response options.
	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.
	S2 – Deleted "*Nursing Home Administrator*" and "*Director of Nursing*" options.	To more accurately recruit the intended survey participants based on the inclusion/exclusion criteria.
	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.
	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.
	S3 – Added "Community retail pharmacy" to response options.	To more accurately recruit the intended survey participants based on the inclusion/exclusion criteria.
	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.

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	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.
	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.
	S4 – Changed *"Pharmacy"* to read as *"Community or retail pharmacy"*.	To more accurately recruit the intended survey participants based on the inclusion/exclusion criteria.
	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.
	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.
	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.
	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.

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	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.
	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.
	Q3 – Option A: Changed *"screening data"* to *"Screening or review of data, reports or graphs."*	Preferred labelling.
	Q3 – Option I: Changed *"substance"* to *"opioid."*	To clarify intent of question.
	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
	Q3 – Option O: Changed *"overdose"* to *"adverse drug events."*	Not all ADEs are overdoses.

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	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.
	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.
	Q5 – Removed mentions of *"facility"* and *"nursing homes."*	Based on feedback from stakeholders, we have removed nursing homes from our sample.
	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.
	Q6 – Added timeframe to the question.	Based on pretest results, clarified the timeframe for using the resources.
	Q6 – Updated response options.	Based on pretest results, included additional resources that were reported useful by participants.
	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.

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	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.
	Q6 – Removed nursing home response options.	Based on feedback from stakeholders, we have removed nursing homes from our sample.
	Q6 – Option A: Changed *"QIO Collaborative"* to *"QIO Collaborative or Campaign for Medicine Management."*	To clarify existing response option based on comments from stakeholders.
	Q7 – Highlighted the word *"helpful"* with bold font.	To help clarify what question is assessing based on participant confusion during pretests.
	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.
	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).
	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.
	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.
	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.
	Q11 – Removed mentions of nursing homes.	Reflects decision to remove nursing homes from sample.

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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.
	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.
	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.
	Q19 – Option A: Changed *"Data"* to *"Data, reports or graphs."*	To clarify existing response option based on comments from stakeholders.
	Q20 – Minor wording change from: "*level of engagement in"* to "*level of engagement with."*	To improve the clarity of the sentence.
	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.
	Q21 – Added instruction: *IF QIO EXPERIENCE = 0, ASK Q22. ELSE, SKIP TO FINAL SCREEN.*	Programming instruction to set up respondents for Q22
	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.
	Q22 – Made changes consistent with Q3	