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September 18, 2018

Ms. Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-10675
P.O. Box 8013
Baltimore, MD 21244-8013

Dear Administrator Verma,

Thank you for the opportunity to comment on *CMS-10675; Evaluation of the CMS Quality Improvement Organizations: Medication Safety and Adverse Drug Event Prevention.*

Our organization, the American Health Quality Association (AHQA), represents the Quality Innovation Network-Quality Improvement Organizations (QIN-QIOs) and their quality improvement partners throughout the United States, Puerto Rico, the Virgin Islands, and the outer Pacific Islands. Our association's goal is to make health care better, safer, and available at a lower cost.

As an organization representing the QIN-QIOs and their quality improvement partners, we are invested in ensuring that the evaluation methodology utilized accurately assesses the QIN-QIO program. We support CMS's efforts to evaluate the effectiveness of this task and believe that we have a shared desire for a high-quality, accurate assessment.

Below are our comments regarding selected elements of the proposed evaluation methodology.

1. **Attribution of Quality Improvement Performance**
   When appropriate, we support public health efforts to attribute health care impact to responsible parties. However, it will be incredibly difficult to attribute quality improvement performance to the QIN-QIOs due to the very nature, purpose, and scope of the QIN-QIO program. The QIN-QIO program is a long-term, collaborative quality improvement effort. The nature of this work is to maximize and celebrate the contributions of our community partners and not to promote recognition for a QIN-QIO's individual contributions. Quality improvement efforts have not been performed in a controlled or semi-controlled research environment and were not designed or intended to control for confounding factors that may interfere with or enhance the QIN-QIO's impact on performance.

   Additionally, in our experience, it is difficult for providers to first identify the QIN-QIO in their state and then separate the work that is led by the QIN-QIO from similar work that is led by other partner organizations.

For example, in 2014 the QIO program was restructured into the QIN-QIO program. Even though four years have passed since that transition, we have found that many local health care organizations are still confused by the program name change.

Survey participants that partner with a QIN-QIO may also be uncertain about which projects can be attributed to the QIN-QIO and which projects can be attributed to other organizations because the work is done collaboratively; many of the same partners are involved in multiple projects.

To account for these distinctions, we recommend including a short explanatory definition of the QIN-QIO program in the survey. We also recommend including a list of the QIN-QIOs and local QIOs that providers may be working with, which would help survey participants identify the partners that participants should take into account as they complete the survey.

2. Attribution of Medication Safety Performance

Similarly, we believe it will be incredibly difficult to attribute medication safety performance to the QIN-QIOs. For example, there are currently two other CMS quality improvement programs, the Hospital Improvement Innovation Networks (HIINs) and End-Stage Renal Disease (ESRD) Networks, that are working to improve medication safety—both have similar goals and work collaboratively with the QIN-QIOs. At least one QIN-QIO co-leads coordination of care communities with a HIIN, and much of the medication safety work takes place in those communities.

A related concern is that QIN-QIOs may also be impacting medication safety performance indirectly. For example, a QIN-QIO might be working through a state pharmacy agency or school of pharmacy to educate pharmacists and students about medication safety; however, the recipients of the education would likely not be aware of the role or influence of the QIN-QIO. This impact will be virtually impossible to measure through the proposed methodology.

It is also unclear how CMS will determine whether any organizations or resources cited by survey participants had anything to do with the participants' work with the QIN-QIO medication safety task (per questions 6 & 7 in draft survey). For example, in some instances, the providers may have acquired and used the resources on their own; in other instances, the QIN-QIO may have promoted the resources that the provider decided to use.

Lastly, while it is understandable that CMS would want to know which resources are most valuable to providers, it is unclear how the percentage of value of each resource relates to attribution to the QIN-QIO. We are also concerned that asking the respondent to allocate percentages to up to 30 entities to total 100% may place an undue burden on the provider. A Likert scale for each entity/program would be less challenging to complete and may be easier to interpret.

3. Defining and Selecting the Survey Participants

While the Federal Register clearly states whom the survey will be sent to, we are concerned that the focus population is too limited and not inclusive of the QIN-QIO partners invested in this task.

As of July 31, 2018, QIN-QIOs across the nation have recruited 8,125 settings, per the requirements of Task C.3.6 in the 11th Scope of Work (SOW) contract. These settings "provide medication related

care to Medicare beneficiaries using three or more medications including one of the following high-risk medications: anticoagulants, diabetic agents, and opioids" and include "but [are] not limited to physicians, pharmacist, pharmacies, medical practices, hospitals, [and] nursing homes." Per CMS-10675, "The survey will . . . provide estimates of the attribution of the QIN-QIO program for improving ADE prevention, and reported impact of the QIN-QIO program from the perspective of healthcare providers." If, as described above, the survey will be sent only to community-based pharmacists, primary care providers (PCPs), and nursing home administrators or directors of nursing in nursing homes, it will miss a large proportion of C.3.6-recruited settings and make it difficult to estimate a true attribution of QIN-QIO work on ADE prevention. The targeted audience of survey respondents as defined per CMS-10675 may also result in oversampling nursing home providers.

For example, when reviewing the survey and survey questions, community-based pharmacists are equated with or limited to "retail" pharmacies. However, this categorization does not accurately represent the breadth and depth of the role of pharmacists in QIN-QIO quality improvement partnerships. QIN-QIOs partner with many more pharmacists than just those in the retail pharmacy setting. For example, they partner with pharmacists that play active roles in ambulatory care clinics, anticoagulation clinics, diabetes management clinics, pain management clinics, and academic settings. These community-based pharmacists are not included in the proposed target population.

The decision to target only primary care providers poses similar limitations. The QIN-QIOs also reach out to endocrinologists, surgeons, and other specialists who prescribe high-risk medications and can impact medication safety.

When working across the care continuum, QIN-QIOs have also developed strong partnerships with home health agencies, the Area Agencies on Aging, and other critical community-based organizations. These groups are especially important as we strive to develop safe medication practices at home; however, these groups are not listed as targeted groups to survey.

To ensure an accurate sampling of QIN-QIO providers, we recommend that all providers and settings listed in the QIN-QIO scope of work be included in the sample population. The scope of work reads "community healthcare providers and practitioners including but not limited to physicians, pharmacist, pharmacies, medical practices hospitals, nursing homes," and "retail pharmacies, ambulatory pharmacies, hospital pharmacies and long term care pharmacies and clinical pharmacists who are providing care in an ambulatory or long term care setting," and "work with national pharmacy collaborations, local schools of pharmacy and national pharmacy organizations, and patient advocates." The "not limited to" includes home health, social work, care transitions nurses, EMS, and non-medical home care, to name a few.

A potential source for identifying a representative sample of QIN-QIO partners for the survey is the Access database managed by the QIN National Coordinating Center (NCC). This database includes records of all recruited settings across the medication safety task and not just those specified in the Federal Register.

Additionally, because the QIN-QIOs work with people in a wide variety of roles across these care settings (e.g., administrative staff, allied health providers, physicians, etc.) the main point of contact for the QIN-QIO may be the front-line staff. However, the survey instrument CMS-10675_APP_A_Survey Instrument_06-18-18_508.pdf states: "if technician or office/practice manager STOP survey, else proceed." Technicians and front-line staff may be interacting with the QIN-QIO in lieu of the "prescriber" or "clinician." Likewise, the "prescriber" or "clinician" may delegate a survey to front-line staff who do not know the QIN-QIO. Therefore, we recommend that technicians and front-line staff not be excluded if they are collaborating with the QIO. Before excluding their participation, discern whether the technician or member of front-line staff is only designated to complete the survey or if a relationship between the QIO and the individual completing the survey exists. Additionally, we recommend providing guidance to the practitioner/survey participant site as to who should complete the survey. If the survey isn't completed by the appropriate person, the data collected may not accurately reflect the partnership with the QIN-QIO.

Lastly, pharmacy collaboration is often represented by an individual at the corporate level of a chain who disseminates the information, not via a direct collaboration with the local pharmacist. Consequently, local pharmacists may not attribute any quality improvement work to the QIN. Therefore, we recommend that the IEC ask the QIN-QIO staff for the appropriate contact person when surveying chain pharmacies.

4. Defining the Control Group

The Federal Register states: "The perceived influence on quality improvement efforts will be quantified and, along with econometric modeling methods, will be used to assess program attribution."

According to Surapaneni K M et al.[i], "Contamination bias occurs when members of the 'control' group inadvertently receive the treatment or are exposed to the intervention, thus potentially minimizing the difference in outcomes between the two groups." Additionally, "co-intervention bias occurs when some subjects receive other (unaccounted for) interventions at the same time as that of the study treatment."

Given that over 75% of nursing homes and over 60% of beneficiaries represented by community coalition stakeholders are participating with QIN-QIO programs across the nation, both contamination bias and co-intervention bias are unavoidable.A participant might not identify our work as "attribution of the QIN-QIO program for improving ADE prevention" and be inappropriately placed into the control group and susceptible to contamination bias.

We recommend that participants receiving technical assistance from any QIN task should be excluded from the control group.

5. Role of Pharmacists and Directors of Nursing Homes

The Federal Register states: "We plan to conduct an online survey of 1,200 community-based pharmacists, physicians, and nursing home administrators or directors of nursing in nursing homes. These participants were selected based on their role in prescribing HRM and treating ADEs."

This sample selection rationale is concerning because pharmacists and directors of nursing homes neither prescribe HRM nor treat ADEs. Furthermore, the QIN-QIOs were not tasked to alter prescribing or treating of ADEs. The scope of work reads "The QIN-QIO shall improve medication safety and aim to reduce and prevent adverse drug events by implementing evidence based and or proven best practice strategies and tools" and "this function shall be integrated into the coordination of care work and include, but not be limited to:" learning and action networks, applying interventions, identifying barriers, providing training and education, spreading best practices, promoting beneficiary engagement, etc.

We recommend expanding the scope of the evaluation beyond these 3 clinician types and measuring the activities outlined in the scope of work.

6. **Variation in the Definition of Adverse Drug Event**

The Federal Register defines Adverse Drug Events (ADEs) as "injury resulting from medical intervention related to a drug." However, in our experience, the definition of and terminology used to describe an ADE in practice varies across regions and care settings (e.g., practitioners in the Pacific Northwest have a different practical definition of the term ADE than those in New England). Consequently, we believe that when presented with survey questions about ADEs, participants will likely respond using a non-uniform definition of ADE that may exclude important components of the adverse drug event prevention initiatives coordinated by QIN-QIOs.

Furthermore, the task language in the contract for this work is broad and leaves room for interpretation. The contract requires QIOs to "improve medication safety and aim to reduce and prevent adverse drug events . . . while integrating these activities into the coordination of care work." Because this task language is broad, implementation varies across QIN-QIOs—not all QIN-QIOs are implementing the same initiatives or activities.

To account for these variations, we recommend that the survey include a clear and easily accessible definition of the term ADE. We also recommend that the definition of ADE be expanded to reflect some of the possible "injuries" associated with ADEs. The resulting definition would read as follows: "*An Adverse Drug Event (ADE) is an injury resulting from medical intervention related to a drug. These injuries include: 1) Medication errors 2) Adverse drug reaction 3) Allergic reaction 4) Overdoses*."

In addition, because the task language is so broad, we recommend surveying participants on medication safety improvement activities related to the four injury categories included in the expanded definition above.

7. **Verification of Evaluation Measures**

The IEC indicated on 9/5/18 that "one of the C.3-6 measures *by drug class* was nearly flat for the QIO constituents using claims data"- prompting further evaluation, and that the IEC reference measure is "all-cause readmissions", which showed favorable results.

We would request that the IEC please verify, name, and define the evaluation measure you are attempting to evaluate. This is very important because ONLY C.3-6a measures adverse drug events (ADEs), whereas the measures named *by drug class* measure all-cause harm, and *do NOT* measure ADEs (C.3-6b, C.3-6c, C.3-6d, C.3-6e, C.3-6f, C.3-6g). This would have a tremendous impact on the types of questions that need to be asked. The primary causes of all-cause harm for these measures are sepsis, pneumonia, and diabetes complications, and NOT ADE. The "all-cause readmissions" referenced measure is C.3-4, which is not a part of the ADE task.

Our recommendation would be to verify, name, and define the evaluation measures you are attempting to evaluate and submit for public comment. If you are attempting to evaluate measure C.3-6a, then the ADE questions are potentially in alignment. If you are attempting to evaluate all-cause harm *by drug class*, then all ADE questions are inappropriate. The all-cause harm *by drug class* is resulting from sepsis, pneumonia, diabetes complications, etc. for people *taking* a high-risk medication, and therefore the work is approached differently than an ADE reduction strategy.

8. Assessment of the National Action Plan

Although it was released four years ago, in our experience there is a lack of awareness about the National Action Plan for ADE Prevention (Action Plan) at the provider level. The Action Plan was developed to provide guidance to federal agencies and stakeholders on how to leverage existing programs (such as the QIN-QIO program) and payment models to incentivize ADE monitoring and prevention. It was not developed to directly target the frontline health care practitioner, nor is the Action Plan used at the practitioner level. The end-user for this product was always intended to be federal agencies and similar stakeholders.

Because the Action Plan was not developed to directly target practitioners, it has not been utilized in a coordinated national awareness campaign, unlike other provider-focused resources such as the CDC's Guideline for Prescribing Opioids in Chronic Pain or National Drug Take Back Day.

Health care practitioners may be using some of the resources and best practices referenced in the document (such as AHRQ's blood thinner patient education booklet), however, they are likely unaware that these tools are included in the Action Plan. Similarly, if practitioners are asked about a specific resource or practice, they likely won't understand the connection between the resource or practice and its inclusion in the Action Plan.

Therefore, we do not believe that surveying practitioners about the Action Plan directly (i.e., by name) will accurately assess the Plan's adoption or effectiveness.

An alternative approach may be to inquire about specific best practices identified in the Action Plan to assess their rates of adoption/implementation. Several example questions could include the following: "Do you offer anticoagulant counseling and/or management services at your institution?

If so, do you offer these services to patients on 'warfarin only' or 'all anticoagulants'? Do you document and monitor adverse drug event rates within your institution or practice setting? How long have you been engaged in this practice?"

9. **Purpose of the Evaluation**

The Federal Register states: "The current CIR focuses on evaluating one component of the quality improvement activities of the Quality Innovation Network Quality Improvement Organizations (QIN-QIOs) and is part of a larger evaluation of the overall impact of the QIO program."

We are concerned because currently the survey is designed to assess the execution of the QIO Program rather than the design of the QIO Program, which could reflect poorly on the individual QIN rather than the design.

Therefore, we recommend that the intent of the survey be stated clearly, along with the CMS measure being evaluated and the potential impact of this process, and submitted for public comment. Alternatively, the survey could be redeveloped to assess the design of the program rather than the execution of the program by the QIN.

10. **Medicare Advantage Plans and ADEs**

The Federal Register states: "For the program to improve medication safety and prevent adverse drug events (ADEs), QIN-QIOs provide technical assistance to providers, practitioners, organizations offering Medicare Advantage plans under Medicare Part C, and prescription drug sponsors offering drug plans under Part D. "

However, the current contract does not contain directive language requiring the QIN-QIOs to provide specific or targeted technical assistance to Medicare Advantage plans related to ADEs. The focus of the current contract is the Medicare fee-for-service population. In addition, QIN-QIOs do not have access to Medicare Part C (Advantage) prescription claims, which would be needed to support work in this area. The provision of technical assistance to Medicare Advantage plans is permitted as one of many activities of quality improvement organizations listed in the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). While reference to this provision had been included in the task order language of prior contracts, it was not included in the 11th Scope of Work contract. In fact, it was discovered that Part D data analysis being performed by the NCC inadvertently included data for beneficiaries of Medicare Advantage plans. That data was eventually corrected to exclude Medicare Advantage.

Therefore, we request that this language be removed from the evaluation.

Again, thank you for the opportunity to share this feedback. The QIN-QIOs support CMS in its efforts to define the impact of the QIN-QIO program and welcome the opportunity to discuss ways to measure their impact in this and future scopes of work.

Regards,

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Executive Director

[i] KRISHNA R , MAITHREYI R ,SURAPANENI K M. RESEARCH BIAS: A REVIEW FOR MEDICAL STUDENTS. Journal of Clinical and Diagnostic Research [serial online] 2010 April [cited: 2010 April 5]; 4:2320-2324. http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.610.8597&rep=rep1&type=pdf