**Attachment 4: CMS Response to Public Comments Received for CMS-10675**

The Centers for Medicare and Medicaid Services (CMS) received three comments from a general member of the public, a health professional, and a professional association for Quality Improvement Organizations related to CMS-10675. This is the reconciliation of those comments.

**Comment #1:**

CMS received a comment from an anonymous member of the public concerned that government actions to encourage greater oversight of prescriptions for opioids by providers has severe consequences for people suffering from chronic pain. The commenter asked for a repeal of Centers for Disease Control and Prevention (CDC) guidelines to allow pain management providers "to correctly treat their patients." Several citations were included for news stories and reports related to differences between opioids obtained illicitly and by prescription with respect to causes of the opioid epidemic, as well as stories about the suffering of people living with chronic pain.

**Response:**

**CMS thanks the commenter for discussing some of the challenges faced by individuals with chronic pain conditions and the importance of appropriate pain management medication use. We would like to clarify that this Federal Register announcement supports an evaluation of the Quality Innovation Network-Quality Improvement Organization (QIN-QIO) Program activities related to preventing adverse drug events of high-risk medications, such as opioid overdose, and will not impact access to or insurance coverage of opioid medication.**

**The QIN-QIO program aligns with CMS and the Department of Health and Human Services (HHS) goals and strategies related to pain management. HHS has established the Pain Management Best Practices Inter-Agency Task Force to identify best practices and issue recommendations that address gaps or inconsistencies for managing chronic and acute pain (https://www.hhs.gov/ash/advisory-committees/pain/index.html). One of the strategic aims of this group is to: "Advance the practice of pain management to enable access to high-quality, evidence-based pain care that reduces the burden of pain for individuals, families, and society while also reducing the inappropriate use of opioids and opioid-related harms." We have forwarded your comment to this Task Force, who will also be accepting public comments on their recommendations.**

**Comment #2:**

CMS received comments from a family nurse practitioner and mental health consultant asking for support of a bill introduced to the Senate (S.2908). According to the comment, the bill calls for an increase in the number and types of practitioners (including nurse practitioners and physician assistants) who can be "waivered to prescribe buprenorphine to decrease the number of patients using opioid medications." The commenter explains

this would be accomplished through expanding the use of electronic prior authorization in Medicare Part D, which is currently restricted to physicians. The comment states that this restriction currently limits the number of patients who can receive care using alternatives to opioids for acute and chronic pain.

**Response:**

**CMS thanks the commenter for sharing this proposed legislation. We would like to clarify that this Federal Register announcement supports an evaluation of the QIN-QIO Program activities related to preventing adverse drug events of high-risk medications, such as opioid overdose, and is not intended to support proposed legislative bills.**

**Comment #3:**

CMS received comments from a professional association that represents Quality Improvement Organizations (QIOs). Similar comments were received informally from a QIN-QIO and during a "Think Tank" meeting with several QIN-QIOs. The comments submitted to the docket noted "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." The commenters shared observations and recommendations on the proposed sample for the survey and methods for attributing changes in healthcare practices to the QIO program, as well as suggesting other additions to the survey.

With respect to the survey sample, one concern mentioned was that the sample was not representative of all settings and professional types that have been recruited across QIN-QIOs, such as "home health, social work, care transitions nurses, EMS, and non-medical home care, to name a few". A second concern was about including nursing homes in the sample; although these facilities were the settings for a large volume of technical assistance (TA) provided for increasing medication safety and adverse drug event (ADE) prevention, QIN-QIOs also recruited nursing homes for a different task. Commenters speculated that survey participants may confuse the TA provided for these tasks. They also noted "Nursing homes are over-burdened with surveys, QAPI, composite measures, and National Healthcare Safety Network (NHSN) reporting, not-withstanding the enormous burden of staff turnover."

The comments about the attribution methods included concerns that it may be difficult for participants to distinguish TA provided by the QIN-QIOs from other information sources because the program frequently collaborates with other CMS programs as well as state and local initiatives. Another concern was about the attribution measure, which required participants to enter percentages representing how helpful they found each resource they use to prevent ADEs. Commenters believed this process would be too confusing and suggested using 5-point scales for each resource instead.

Other helpful recommendations were to add a definition of ADE in the introduction, and to include other quality improvement activities or practices to a question that asks about use of best practices to prevent ADEs.

**Response:**

**CMS greatly appreciates the input and observations from the commenters. The recommendation to expand the sample to include all settings and professionals recruited for the program was considered in earlier plans, but we concluded it was not possible to develop a comparison group across each group. We therefore assessed administrative records to discern the types of providers most commonly recruited and found there was a high volume of community-based pharmacies and physician practices. However, we expanded the sample to include nurse practitioners and physician assistants working in physician practices based on the input. We also agree with the concerns expressed about using nursing homes in the survey, and for these reasons have removed nursing homes from the sample.**

**To address concerns about the attribution methods raised in the comments, we reached out to the QIOs to obtain the names by which they would be recognized by participants (e.g., local QIO name, campaign name, etc.) to ensure the QIO program can be distinguished from other resources. We also asked for the names of the partnering programs or organizations, which can be used to adjust analysis if participants identify QIO activities but not the name of the QIO. The recommendation to use 5-point scales to rate the helpfulness of each resource instead of assigning a percentage was tested for a similar question in the survey of nursing home administrators (OMB control number 0938-1330). The results showed that participants could manage both methods of assigning attribution and that responses were highly correlated. However, in pretests of the current survey instrument we observed that the percentage method was slightly more challenging than in the nursing home survey, partly because pharmacists and physicians tend to use more sources of information than did nursing home administrators. For these reasons, we changed the responses for this question to a qualitative scale rating for each resource.**

**Finally, as recommended in the comments, we added a definition of ADE in the introduction to the survey instrument and added more best practices to the question asking about activities or practices to reduce ADEs. These changes were tested in the survey pretests.**