Ohio Opioid Prescription Guideline Evaluation:
Second Quarterly Report
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INTRODUCTION

Ohio, like many other states and the nation as a whole, has witnessed an epidemic of opioid-related adverse events and deaths over the past 10 to 15 years. As understanding of the health risks associated with use of prescription opioids became better known, states and regulatory authorities initiated steps to reduce this risk. With leadership from Governor Kasich, Ohio took action to address the health risks arising from prescription opioid use. In May 2011, the legislature passed, and the Governor signed into law, HB 93, known widely as the "pill mill" bill. This bill tightened regulations regarding prescribing of opioids and enhanced the ability of the Ohio Automated Rx Reporting System (OARRS) to monitor prescribing of opioids. In October 2011, the Governor's Cabinet Opiates Action Team (GCOAT) was formed. A month later the GCOAT Professional Education Workgroup was created. In May 2012, the GCOAT Professional Education Workgroup took the important step of releasing the Ohio Emergency and Acute Care Facility Opioids and Other Controlled Substances (OOCS) Prescribing Guidelines. The GCOAT Professional Education Workgroup continued to meet and consider how best to reduce the health risk associated with prescription opioid use.

The Workgroup has broad representation from professional licensing boards, state agencies, state professional associations, practicing pain and palliative care physicians, and state and federal public health agencies. One of its central aims was to develop and implement "one set of guidelines for ALL prescribers of opioids for chronic, non-terminal pain." In May 2013, the Workgroup released the Guidelines, with a "trigger point" of 80 mg/day MED. This trigger point was not intended to be considered a legal limit or a restriction. Rather, it was intended to provide a point of reference for physicians and other providers to take note of the dosage being prescribed. After a three-month period of education and training, starting in September 2013, the Guideline was implemented in January 1, 2014.

To learn as much as possible about the use and impact of the Guideline on opioid dosing patterns, the Workgroup commissioned an evaluation of the Guideline. This evaluation is being conducted by Dr. Thomas Wickizer under contract between the Ohio Department of Aging and The Ohio State University. This report is the second to be prepared under that contract and updates the first report by adding data for the second quarter of Guideline implementation (April 1, 2014 through June 30, 2014). In addition to reports documenting temporal changes in opioid dosing related to the Guideline metrics,

a statewide physician survey is to be conducted in late autumn of 2014. The purpose of that survey is to assess physician attitudes regarding the prescribing of opioids for management of non-cancer chronic pain and to evaluate physician knowledge and use of the Guideline, as well as its perceived impact

METHODS

The Professional Education Workgroup, with assistance from Dr. Wickizer, constructed 10 metrics that form the basis of the evaluation. Data needed to address these 10 metrics is being provided by OARRS. The metrics are best viewed as process measures related to dosing patterns and are listed below.

- % of prescribers of **controlled substances** *registered* with OARRS
- % of prescribers of **opioids** *registered* with OARRS
- % of prescribers of **tranquilizers** *registered* with OARRS
- % of registered prescribers of **controlled substances** *using* OARRS
- % of registered prescribers of **opioids** *using* OARRS
- % of registered prescribers of **tranquilizers** *using* OARRS
- Proportion of patients at 80 mg/day MED and above who have had at least one OARRS inquiry over a 12-month period by a prescriber or pharmacist
- Number and % of patients prescribed both sedatives (hypnotics) and opioids
- % of prescriptions filled with a quantity of 120 or more capsules or pills per prescription
- Average MED per prescription

We obtained OARRS data to address each of the above metrics. A listing of the specific drugs included in the OARRS data base is shown in an appendix to this report. Readers should note the data in OARRS pertain to prescriptions filled in Ohio for Ohio residents. Prescriptions filled through mail order and sent out of state are not tracked through OARRS. Physicians and other prescribers of opioids (e.g. dentists) working in the Veteran's Administration (VA) system or in the military health care system can register with OARRS and check on prescriptions, but they do not report on drugs dispensed at these facilities. The findings presented in the report are in graphical form and cover the time period beginning either in 2008 or 2010 through June 30, 2014 (quarter 2 of Guideline implementation), depending on the specific metric. Quarterly OARRS data were provided for each of the above metrics. To simplify the presentation of results, the quarterly data were averaged over two-

quarter periods beginning with the start of the time series through the end of 2013. After 2013 (post Guideline implementation), the data are shown on a quarterly basis. For example, if a metric had data beginning January 1, 2008, that metric would have two data points for 2008, one representing the average value of the metric for the first two quarters, the second representing the average value for quarters three and four of 2008.

As discussed in our first report, it is unrealistic to expect substantial change in the metrics during the initial period of Guideline implementation. In addition, other contemporaneous changes have been occurring, e.g., media reports of health risks associated with prescription opioid use that may have influenced dosing patterns independent of the Guideline. Though desirable, it was not feasible to design this evaluation with a formal, external comparison group. Instead, we rely on a time series of data, extending back several years prior to Guideline implementation to assess trends in opioid dosing over time. Subsequent reports will capture more of the opioid dosing experience statewide and will include additional analyses of selected subgroups of opioid users or of different regions of the state. This information, combined with important information to be gathered through the statewide physician survey, should provide useful insights, though not necessarily definitive conclusions, regarding the impact of the Ohio Prescription Opioid Guideline.

RESULTS

We begin by examining the changes in numbers of persons prescribed opioids. The data shown in Figure 1 depict the number of patients who were prescribed at least one opioid in the past 12 months starting in 2008. As shown, there was an initial increase in the number of patients prescribed opioids in 2008 and 2009, then a leveling off, then beginning in 2013 a decrease. The number of patients prescribed opioids remained unchanged during the second quarter of Guideline implementation.

Metric Related to Percentage of Prescribers Registered on OARRS

An important goal of Ohio's effort to address its prescription opioid problem was to have prescribers of controlled substances and opioids registered on OARRS. Figure 2 shows changes over time in the percentage of prescribers of controlled substances, opioids and tranquilizers registered on OARRS. As shown, there was a substantial increase in the percentage of prescribers registered on OARRS (see appendix for listing of specific drugs tracked through OARRS). During the second quarter of Guideline implementation, the favorable trend in OARRS registration continued, with half the

prescribers of tranquillizers registered and over 40% of the prescribers of controlled substances and opioids registered.

Figure 1. Patients prescribed at least one opioid during the past 12 months

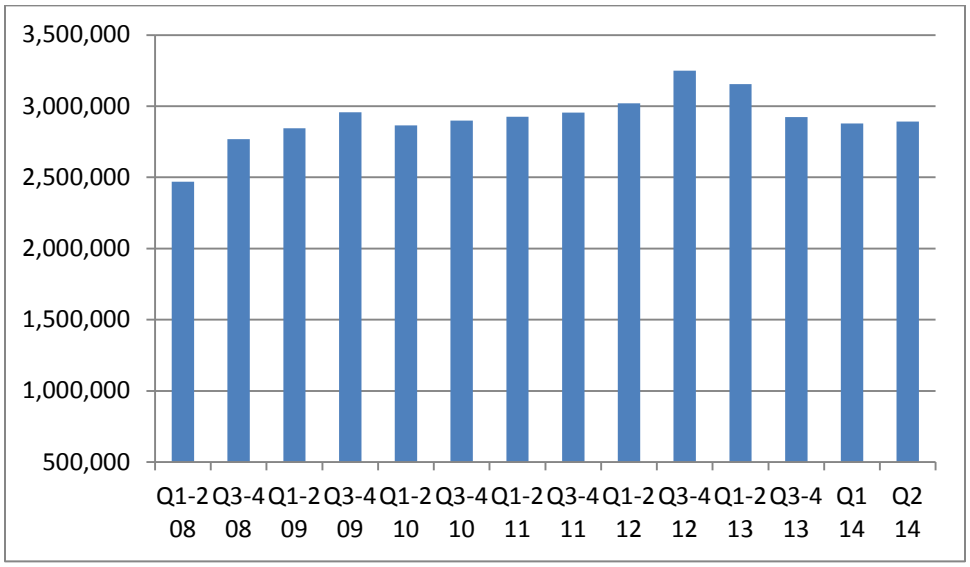
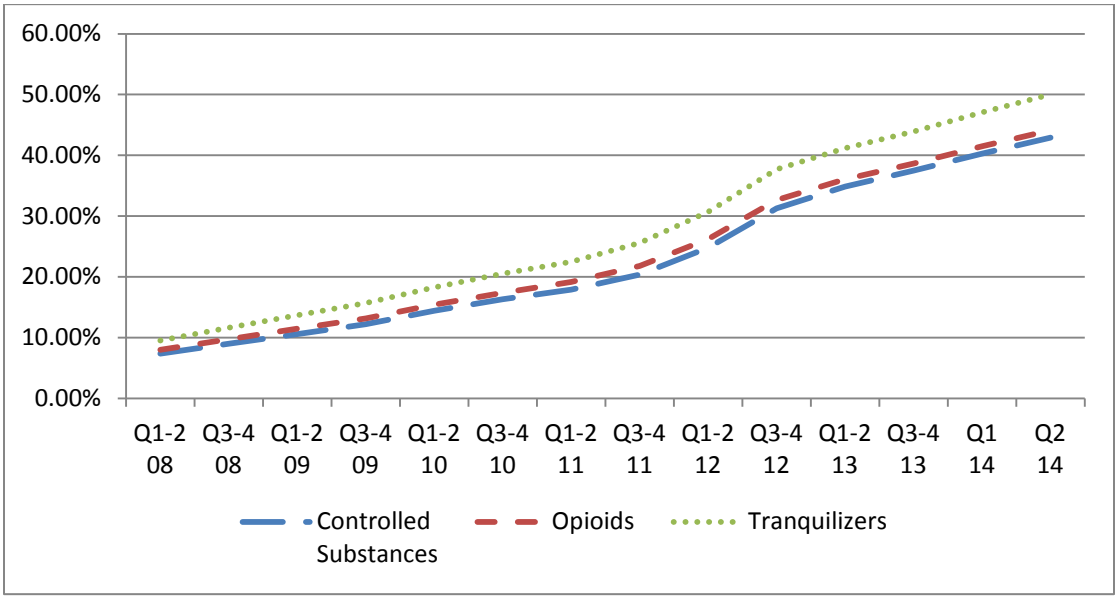
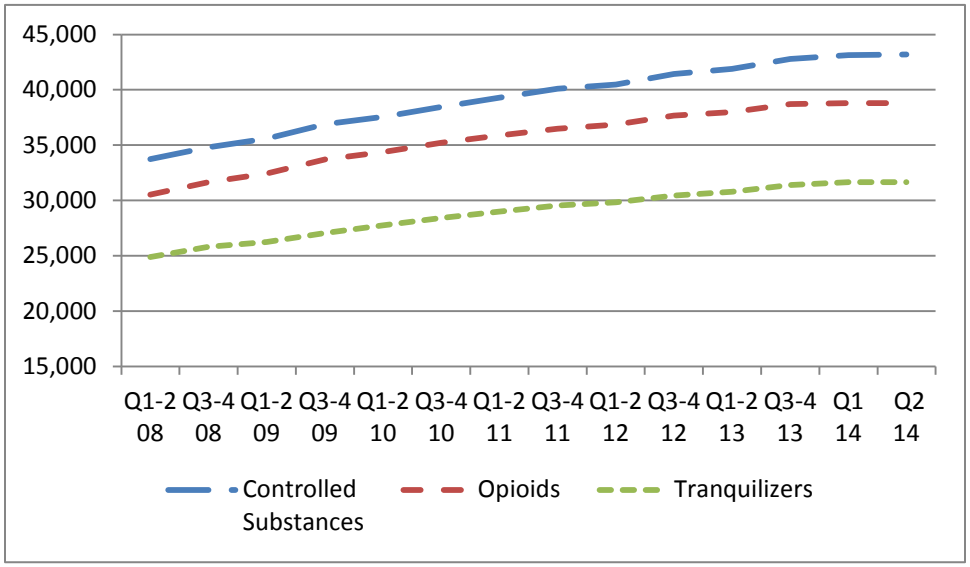


Figure 2. Percentage of prescribers registered on OARRS



This increase is all the more impressive when one considers the increase in the number of prescribers over this time period shown in Figure 3.

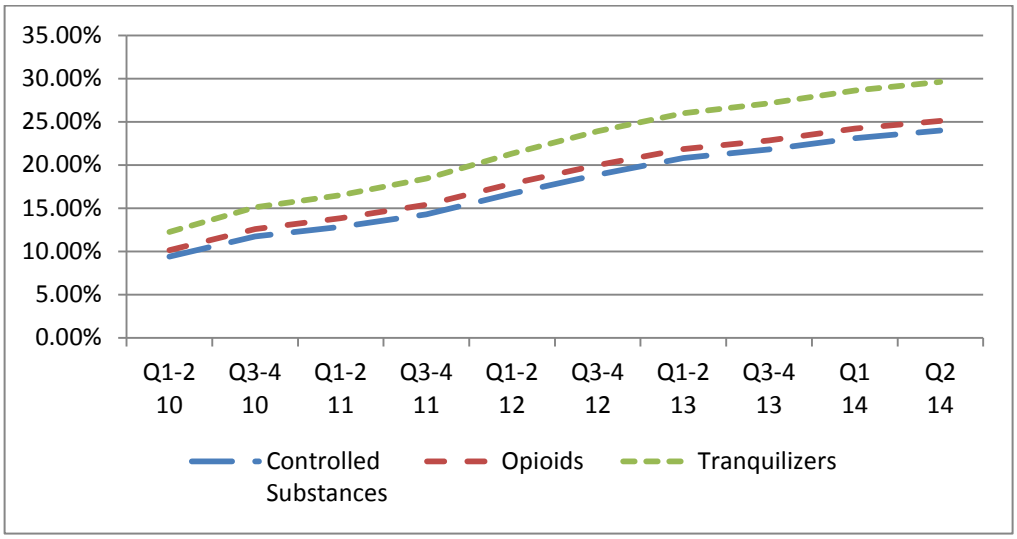
Figure 3. Changes in number of prescribers



Metric Related to Prescriber Use of OARRS

A second set of metrics developed to assess the Guideline pertained to use of OARRS by prescribers. In order to use OARRS, a prescriber has to be registered. Figure 2 showed the growth in prescribers registered with OARRS. Figure 4 shows changes over time in the percentage of registered prescribers using OARRS. More specifically, the percentage values shown in Figure 4 represent the number of prescribers who wrote at least one prescription for one of the three drug categories shown in the figure and who queried OARRS in the past 12 months, as a percentage of all prescribers who wrote at least one prescription for a drug within one of the three drug categories during the past 12 months. As shown, there was a steady and substantial increase in the percentage of registered prescribers using OARRS. The favorable trend shown in Figure 4 persisted through the second quarter of Guideline implementation. Though difficult to detect from Figure 4, the percentage of prescribers using OARRS increased by one to two percentage points during the second quarter of Guideline implementation.

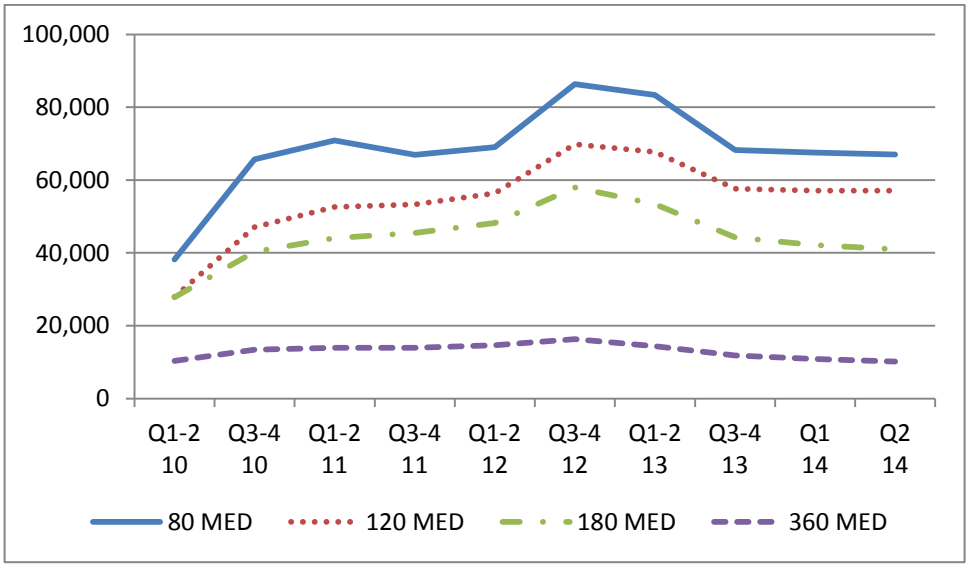
Figure 4. Changes in registered prescribers using OARRS



Metric related to the percentage of patients at or above 80 mg/day MED who had at least one OARRS inquiry over the past 12 months

Eighty (80) mg/day MED is the "pause point" for opioid prescribers incorporated in the Guideline, and it therefore is of interest to assess what proportion of patients at or above that threshold level were subject to one or more OARRS inquiries in the past 12 months. It is useful to begin by assessing the change over time in the number of patients who reached or exceeded this threshold level in the past 12 months. Figure 5 shows the results of this analysis, with the observation period beginning in 2010. As shown, the number of persons at or above 80 mg MED increased substantially from 2010 through 2012, then began to moderate or decline. The general pattern was similar for the four MED categories, except the MED category 360 mg MED, which included substantially fewer patients. As shown in Figure 5, in 2010 there were approximately 40,000 patients in Ohio that were prescribed opioids reaching a level of 80 mg MED or more in any 90-day period within the past year. This figure rose to almost 90,000 by the end of 2012 and then began to decline. By the end of the second quarter of 2014 this figure was approximately 67,000, a 25% decrease from the earlier 2012 figure.

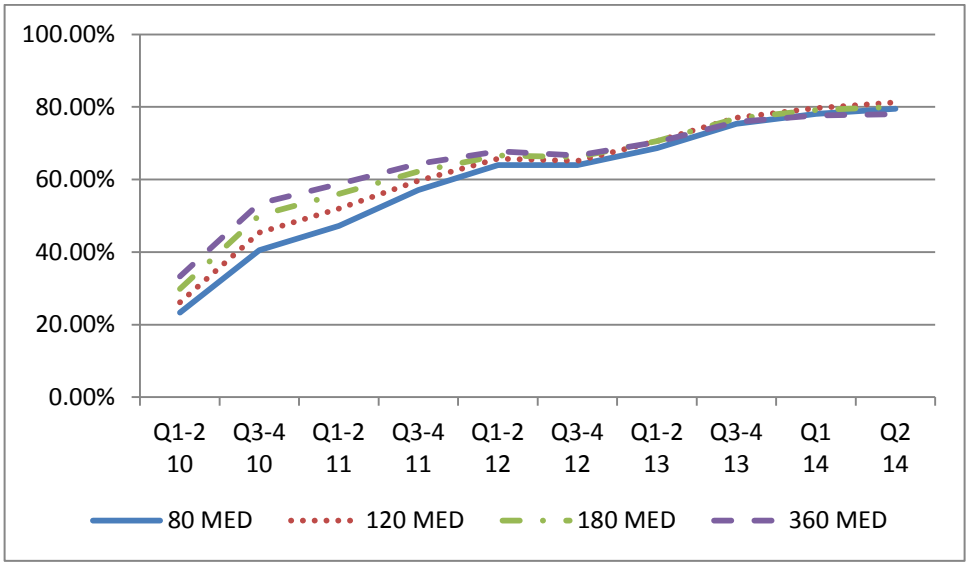
Figure 5. Numbers of patients prescribed 80 mg/day MED or above in any 90-day period in the past 12 months *



* Dose categories are not mutually exclusive and represent doses at or above the value shown. Thus, the line depicting 80 mg/day MED represents all patients prescribed an opioid with 80 mg/day MED or above.

The question of interest for this metric concerns the proportion of patients included in Figure 5 that had at least one OARRS inquiry in the past 12 months? This question is addressed in Figure 6. As shown, there was a marked increase in the percentage of patients having an OARRS inquiry at all MED levels. At the start of 2010, approximately 23% to 33% of the patients had at least one OARRS inquiry by a physician or pharmacist. By the end of quarter 2, 2014, this figure increased to 80%.

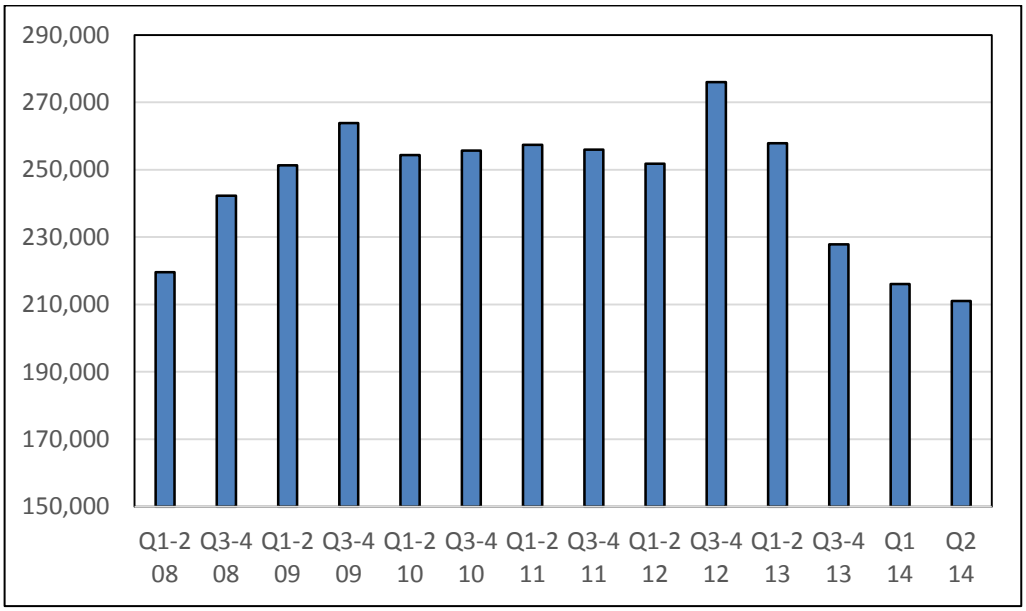
Figure 6. Changes in the percentage of patients prescribed opioids having at least one OARRS inquiry in the past 12 months



Metric related to the percentage of patients (at any MED level) prescribed both opioids and sedatives (hypnotics) in the past 12 months

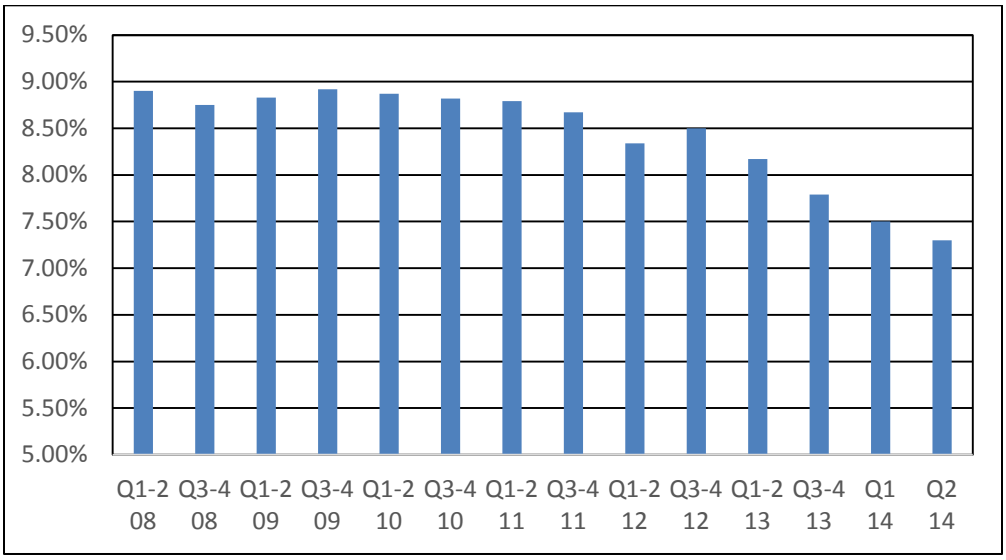
Using opioids and sedatives at the same time heightens health risk and the chances of incurring an adverse event. The Guideline explicitly addresses this and cautions providers about prescribing opioids together with sedatives. Figure 7 presents information on the number of patients for whom both opioids and sedatives were prescribed, starting in 2008. It was not feasible to determine whether a patient received both opioid and sedative prescriptions on the same day. The data shown in Figure 7 represent patients who received an opioid prescription and also received a prescription for a sedative within 90 days before or after the date the opioid prescription was filled. This period is referred to as the "90-day window." The number of patients receiving prescriptions for both opioids and sedatives within the 90-day window first increased, then leveled off and then decreased. The favorable downward trend for opioid and sedative prescribing shown in Figure 7 was maintained through the second quarter of Guideline implementation.

Figure 7. Number of patients prescribed both opioids and sedatives



As part of the analysis performed to assess this metric, we examined changes in the number of patients receiving opioids and sedatives as a percentage of all patients receiving opioids. The results are shown in Figure 8. As shown, approximately 8.5% to 9.0% of the patients who received an opioid prescription over the initial period of observation (2008 through 2011) also received a sedative within the 90-day window. Starting in the latter half of 2012, the percentage figures shown in Figure 8 decline markedly through the second quarter of Guideline implementation. Compared to the first six months of 2008, the percentage of patients receiving both opioids and sedatives declined on a relative basis by 18%. Given the wide health concern about using prescription opioids and sedatives at the same time, this trend is encouraging. By the second quarter of 2014, under the Guideline, only 7.25% of patients prescribed opioids were also prescribed sedatives during the 90-day window.

Figure 8. Percentage of patients prescribed both opioids and sedatives



Metric related to percentage of opioid prescriptions filled with a quantity of 120 or more capsules or pills per prescription in the last 12 months

In general, opioid prescriptions for larger quantities of pills (> 120) raise concern about potential diversion as well as health risk. This metric is intended to track the percentage of prescriptions (solid-dose) having 120 or more capsules or pills during the previous 12 months. The results are shown in Figures 9 and 10, which report the number of opioid prescriptions written in the past 12 months and the percentage of these prescriptions with 120 pills or more, respectively. On an annual basis, 11.3 million opioid prescriptions were written during the first two quarters of observation in 2008. This number increased to 12.7 million (12.4%) during the latter half of 2012 and declined slightly. By the second quarter of Guideline implementation, 12.5 million opioid prescriptions were written on an annual basis.

Figure 9. Total number of opioid prescriptions written in past 12 months

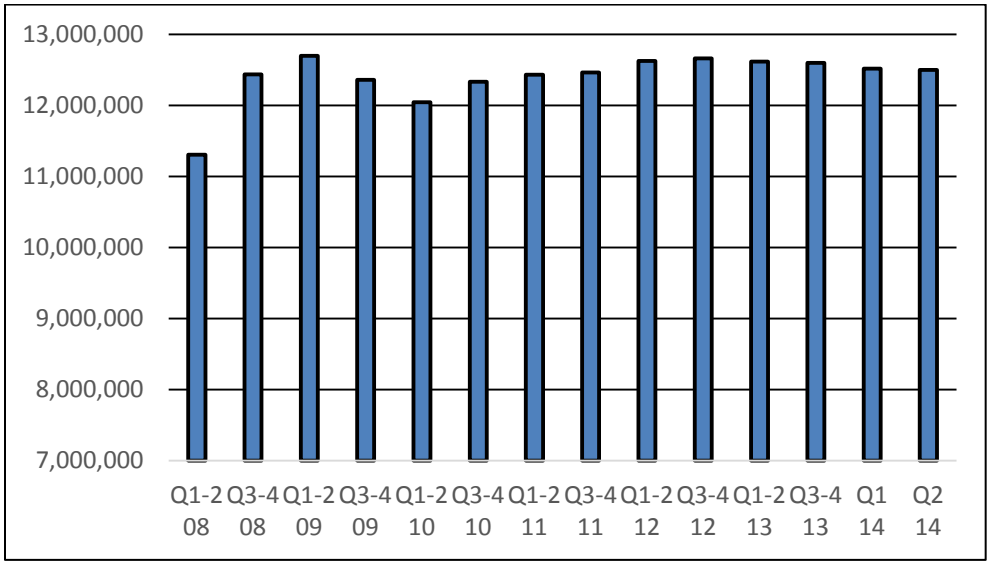


Figure 10 presents information in terms of the percentage of opioid prescriptions having 120 or more capsules or pills. As shown, there was a steady increase (14% to 18%) from 2008 through 2012 in the percentage of opioid prescriptions having 120 or more capsules or pills. The upward trend then leveled off and began to decline slightly through the second quarter of Guideline implementation.

Metric related to average MED per prescription

The final metric included in the Guideline evaluation relates to average MED per prescription. The Guideline includes a pause point at 80 MED per prescription. As shown in Figure 11, average MED per prescription declined over the entire period of observation, though not at a constant rate. The highest MED value was 60 MED observed during the initial six months of 2008. This value declined to approximately 52 MED by the second half of 2011 and remained fairly constant thereafter. A very slight further decline occurred during the first and second quarters of Guideline implementation.

Figure 10. Percentage of opioid prescriptions with 120 or more capsules or pills

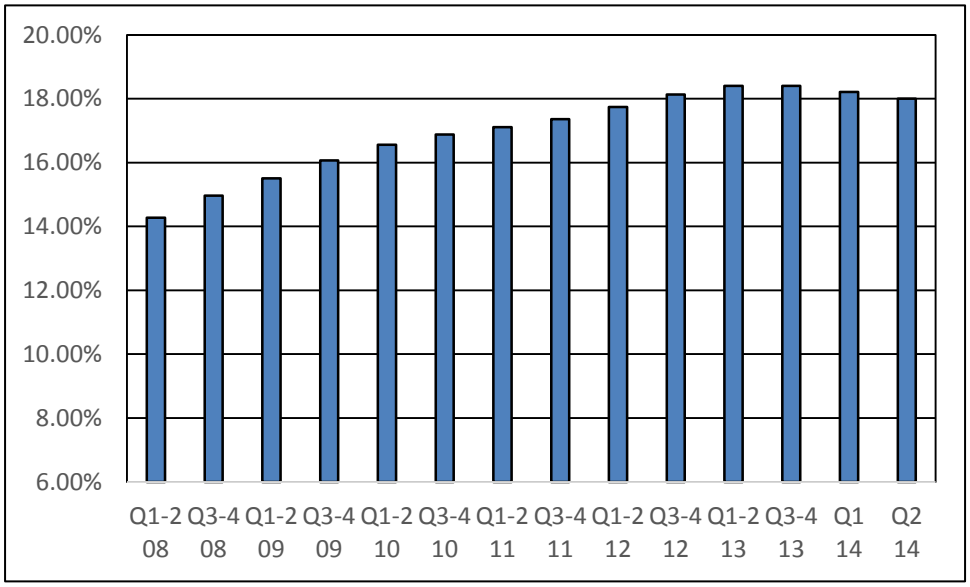
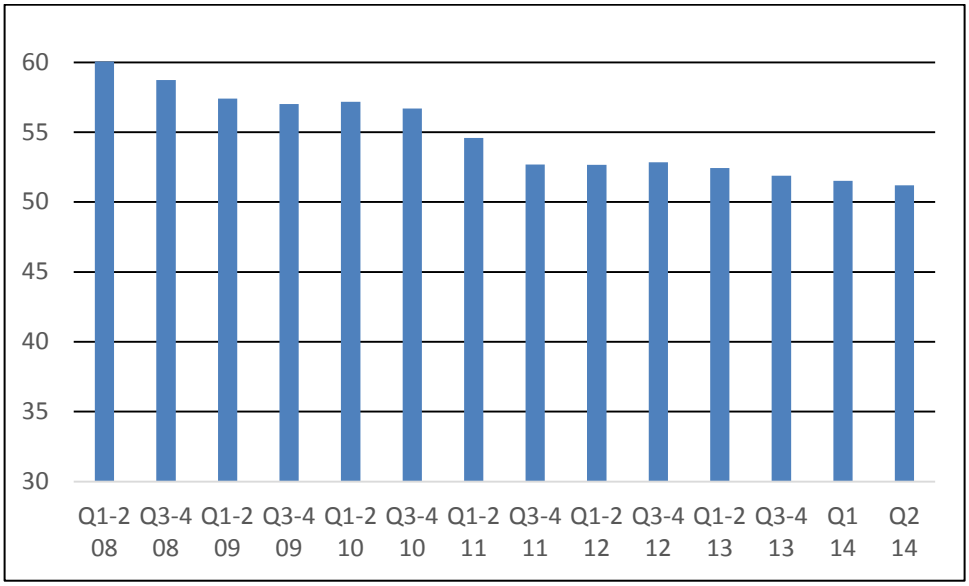


Figure 11. Average MED per prescription



CONCLUSION

This second evaluation report has presented updated information for the second quarter of Guideline implementation (April 1, 2014 to June 30, 2014) on different aspects of opioid dosing related to the metrics developed by the Professional Educational Workgroup. Like the first report, this second report should be considered preliminary in so far as it captures only the early experience of the Guideline. No firm conclusions regarding the Guideline's impact should be made based on the data presented in this report. The findings presented here continue to show small, though favorable, trends in many of the Guideline's metrics through the second Quarter of Guideline implementation.

Appendix

This appendix provides information regarding the definition of controlled substances and lists the specific drugs included in OARRS within three categories: opioids, tranquilizers, and sedative hypnotics.

Controlled Substances – Any drug listed as schedule II, schedule III, schedule IV or schedule V in Ohio Revised Code 3719.41.

Opioids – The following drugs are considered to be opioids:

- Alfentanil
- Buprenorphine
- Butorphanol Tartrate
- Codeine
- Dihydrocodeine
- Fentanyl
- Hydrocodone
- Hydromorphone
- Levomethadyl Acetate
- Levorphanol
- Meperidine
- Methadone (pills not liquid)
- Morphine Sulfate
- Opium Preparations
- Oxycodone
- Oxymorphone
- Pentazocine
- Remifentanil
- Sufentanil Citrate
- Tapentadol
- Tramadol

Tranquilizers – The following drugs are considered to be tranquilizers:

- Alprazolam
- Chlordiazepoxide
- Clonazepam
- Clorazepate
- Diazepam
- Lorazepam
- Meprobamate

- Prazepam
- Quazepam

Sedative Hypnotics – The following drugs are considered to be sedative hypnotics:

- Alprazolam
- Amobarbital
- Barbiturates
- Butabarbital
- Chloral Hydrate
- Chlordiazepoxide
- Clonazepam
- Clorazepate
- Diazepam
- Estazolam
- Eszopiclone
- Ethchlorvynol
- Flurazepam
- Glutethimide
- Halazepam
- Lorazepam
- Mephobarbital
- Meprobamate
- Midazolam
- Oxazepam
- Paraldehyde
- Pentobarbital
- Phenobarbital
- Prazepam
- Quazepam
- Secobarbital
- Temazepam
- Thiopental Sodium
- Triazolam
- Zaleplon
- Zolpidem Tartrate