Agency Response to Economic Impact Analysis

Board of Medicine Regulations on Prescribing of Opioids

The Board of Medicine and the Department of Health Professions does not concur with the result of the analysis that "there is insufficient data to accurately compare the magnitude of the benefits versus the costs." The focus of the analysis was on the cost of one requirement of regulation, urine drug screens. We believe it failed to fully analyze the personal and societal costs of opioid addiction. It is the position of the agency that reducing the quantity of opioids in our homes and communities has already been shown to have a cost-benefit and will ultimately have a direct benefit in a reduction in opioid misuse and opioid overdose deaths.

1. The agency believes the analysis does not include sufficient data about the current crisis in opioid overdose deaths.

In 2015, there were 811 opioid deaths and in 2016, there were 1,133 – a 40% increase. In a preliminary report from the Department of Criminal Justice Services (DCJS), the number for 2017 is expected to 1,181. The result of the 2017 National Drug Threat Assessment notes that controlled prescription drugs (CPDs) have been linked to the largest number of overdose deaths of any illicit drug class since 2001. For each of these deaths, there are immeasurable costs. For the purpose of an economic analysis, medical malpractice carriers and civil litigants can attribute costs in dollars and cents for each year of life lost.

Yearly direct and indirect costs related to prescription opioids have been estimated (based on studies published since 2010) to be $53.4 billion for nonmedical use of prescription opioids; $55.7 billion for abuse, dependence (i.e., opioid use disorder), and misuse of prescription opioids; and $20.4 billion for direct and indirect costs related to opioid-related overdose alone. While we acknowledge that these are national figures, the EIA has used national data to extrapolate the costs of urine drug screens for Virginians. Copious amounts of data exist in national and state reports on the opioid crisis for which these regulations offer a partial solution.

2. The analysis believes the analysis does not make the connection between the opioid crisis of fentanyl and heroin to the prescribing of opioid pain medication.

One of the primary purposes of these regulations is to reduce the number of persons who enter the pipeline of addiction through a legitimately prescribed opioid. The National Institute on Drug Abuse reports that a study of young, urban injection drug users interviewed in 2008 and 2009 found that 86 percent had used opioid pain relievers nonmedically prior to using heroin, and their initiation into nonmedical use was characterized by three main sources of opioids: family, friends, or personal prescriptions Examining national-level general population heroin data (including those in and not in treatment), nearly 80 percent of heroin users reported using prescription opioids prior to heroin.

The report from DCJS noted that "data from Department of Forensic Sciences (DFS) and Office of the Chief Medical Examiner (OCME) demonstrate that there are still a large number of individuals using prescription opioids non-medically. These individuals are at risk of overdose death through the prescription drugs they are currently using, but they are also at a higher risk of using heroin in the future. Although only a small percentage of individuals who abuse prescription opioids move on to heroin, a high percentage of heroin users report that their first opioid was a prescription drug (https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-abuse-heroin-use/). Additionally, non-medical users of prescription opioids may seek to acquire those drugs illegally, putting themselves at risk of purchasing and using counterfeit pills made with fentanyl and fentanyl analogs."

Data from OCME indicates that between 2013 and 2016, the number of prescription opioid fatalities involving fentanyl and/or heroin increased 69%. In 2016, 37% of prescription opioid fatalities also involved fentanyl and/or heroin. Although illicit fentanyl cases increased 207% between 2015 and 2016, there were almost four times as many heroin cases and four times as many prescription opioid cases that year.

Data from the Virginia Prescription Monitoring Program shows that since the adoption of emergency regulation there has been a drop in morphine milligram equivalents (MME). MME per day is the amount of morphine an opioid dose is equal to, often used to gauge the abuse and overdose potential of the amount of opioid being prescribed at a particular time. The Centers for Disease Control indicate that individuals taking greater than 90 MME/day are at a higher risk of overdose and death. The total number of patients prescribed high dosages declined from 169,145 individuals in the fourth quarter of 2016 to 137,618 individuals in the third quarter of 2017, or an 18.6% decline in individuals receiving greater than 100 MME/day. The data is an indicator of the effectiveness of the emergency regulation being replaced with the proposed regulations for which the EIA was prepared.

Numerous reports in the press have made the connection between the overdose death of a person who was prescribed on opioid following an accident or medical procedure. The intent of this regulation is to require prescribers to prescribe fewer quantities for shorter periods of time and to consider non-pharmacological alternatives or non-opioid medications that have the effect of addressing a patient's pain without the potential for addiction and long-term, costly consequences.

3. The agency believes the analysis has not included sufficient data on cost savings relating to a reduction on opioid prescribing.

For example, this agency provided information from DMAS which experienced a 44% decrease in opioid days-supply and 27% decrease in opioid prescription spending when that agency implemented the CDC guidelines on which these regulations were based, for an annual reduction in drug spending on opioids of approximately $466,000. It is that agency's belief that costs related to an increase in urine drug screens (which have been routinely required by pain management physicians prior to adoption of these regulations) would be more than offset by the decrease in spending on opioid prescriptions, so it would be budget neutral or result in a net cost savings.

Data from the Prescription Monitoring Program show that from the fourth quarter of 2016 to the third quarter of 2017 pain reliever doses declined from 129,797,789 to 77,729,833 which represents a 40.15% decline. It is apparent that the emergency regulations are having a positive effect on the costs of prescription opioids – a cost benefit to consumers and insurers that could be reflected in the EIA.

4. There is an incorrect statement in the analysis about one regulatory requirement.

On pages 3 and 12 of the EIA, it notes that the regulation requires prescribers to query the PMP for all individuals before prescribing an opioid. In fact, the regulation states:
"the prescriber shall perform a history and physical examination appropriate to the complaint, *query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia…"* Section 54.1-2522.1 requires a prescriber to query "at the time of initiating a new course of treat*ment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than seven consecutive days."* While the agency may believe a prescriber should query before prescribing on opioid for any period of time, that is not what the law and regulation require. It is required only if a prescription is being written "to last more than seven consecutive days."