# UPDATE ON THE USE OF CODEINE AND TRAMADOL IN MISSISSIPPI MEDICAID

## BACKGROUND

In April 2017, the US Food and Drug Administration (FDA) issued a notice restricting the use of codeine and tramadol medications in children. The new FDA drug safety announcement stated they were adding the following to the labeling of these products:[1]

- FDA's strongest warning, called a *Contraindication*, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

Prior to the publication of this notice by the FDA, the Mississippi Division of Medicaid (DOM) Universal Preferred Drug List (UPDL) did not include any minimum age restrictions on the use of codeine and tramadol medications.

At the November 2017 DUR Board meeting an analysis of prescription claims for codeine and tramadol products during calendar year 2016 was presented (Table 1). Members recommended implementation of prior authorization (PA) criteria for beneficiaries < 18 years of age prescribed codeine and tramadol products. Educational letters informing providers of this safety edit were distributed in January 2018 to any provider who was identified as prescribing codeine or tramadol products to beneficiaries < 18 years of age within six months of the mailing. A total of 1,067 letters were distributed. The electronic prior authorization safety edit was implemented in the pharmacy point of sale system (POS) in February 2018.

This report provides an update on tramadol and codeine prescribing in this population.

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[1] U.S. Food and Drug Administration. FDA MedWatch Codeine and Tramadol Medicines: Drug Safety Communication Restricting Use in Children, Recommending Against Use in Breastfeeding Women. April 20, 2017. https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm (Accessed August 2018).

## METHODS

A retrospective analysis was conducted using Mississippi Medicaid pharmacy and medical claims from all pharmacy programs for the period from January 2016 to June 2018. A yearly comparison in prescribing of codeine and tramadol products was done for the periods April through June of 2016, 2017, and 2018 in order to provide comparable data for each year.

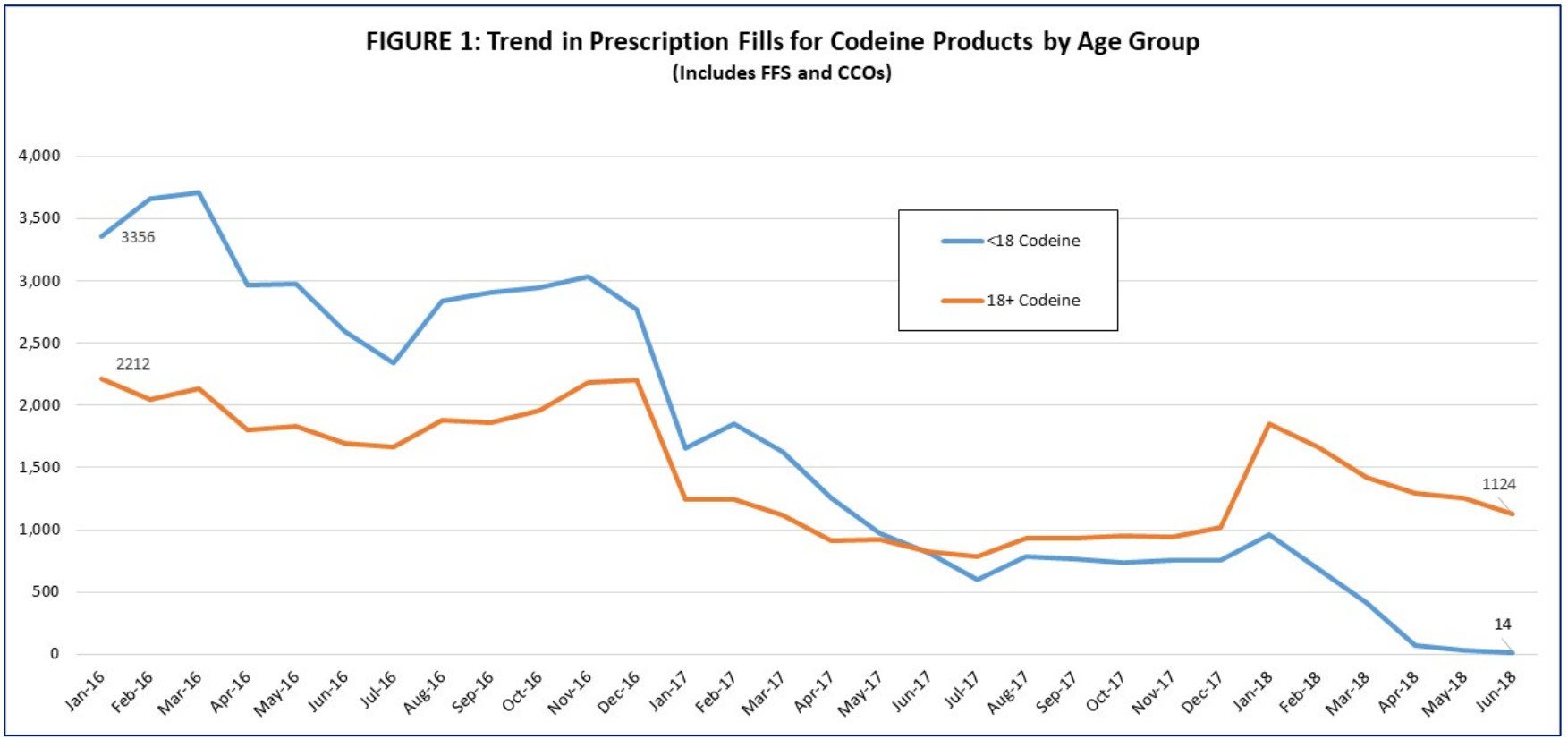
## RESULTS

Table 1 shows the results from the annual comparison in prescribing of codeine and tramadol products during April through June timeframe for each year. Prescribing for beneficiaries under age 18 began decreasing after the FDA safety notice. After the electronic prior authorization was implemented in February 2018, prescribing of these products in this age group decreased to almost zero prescriptions.

**TABLE 1: Beneficiaries Filling Codeine and Tramadol Prescriptions**
**(Includes FFS and CCOs)**

| Age at Time of Prescription | April - June 2016 | | | | |
|---|---|---|---|---|---|
| | Enrolled | Codeine | | Tramadol | |
| 0 to 5 | 153,498 | 1,260 | 0.8% | 0 | 0.0% |
| 6 to 11 | 147,016 | 1,757 | 1.2% | 2 | 0.0% |
| 12 to 17 | 121,692 | 994 | 0.8% | 103 | 0.1% |
| 18 to 44 | 166,047 | 1685 | 1.0% | 868 | 0.5% |
| 45+ | 190,685 | 520 | 0.3% | 555 | 0.3% |
| Total | 778,938 | 6216 | 0.8% | 1528 | 0.2% |
| **Age at Time of Prescription** | **April - June 2017** | | | | |
| | Enrolled | Codeine | | Tramadol | |
| 0 to 5 | 149,235 | 797 | 0.5% | 1 | 0.0% |
| 6 to 11 | 142,321 | 1,299 | 0.9% | 5 | 0.0% |
| 12 to 17 | 119,979 | 799 | 0.7% | 108 | 0.1% |
| 18 to 44 | 163,051 | 1632 | 1.0% | 836 | 0.5% |
| 45+ | 191,542 | 576 | 0.3% | 727 | 0.4% |
| Total | 766,128 | 5103 | 0.7% | 1677 | 0.2% |
| **Age at Time of Prescription** | **April - June 2018** | | | | |
| | Enrolled | Codeine | | Tramadol | |
| 0 to 5 | 142,307 | 6 | 0.0% | 0 | 0.0% |
| 6 to 11 | 134,682 | 19 | 0.0% | 0 | 0.0% |
| 12 to 17 | 116,624 | 31 | 0.0% | 0 | 0.0% |
| 18 to 44 | 154,227 | 1105 | 0.7% | 602 | 0.4% |
| 45+ | 189,713 | 434 | 0.2% | 486 | 0.3% |
| Total | 737,553 | 1595 | 0.2% | 1088 | 0.1% |

Figures 1 and 2 depict the number of monthly codeine and tramadol prescription claims by age group. These graphs clearly show the decline that began after the FDA safety notice and the rapid drop after the educational mailing and POS edit in 2018.



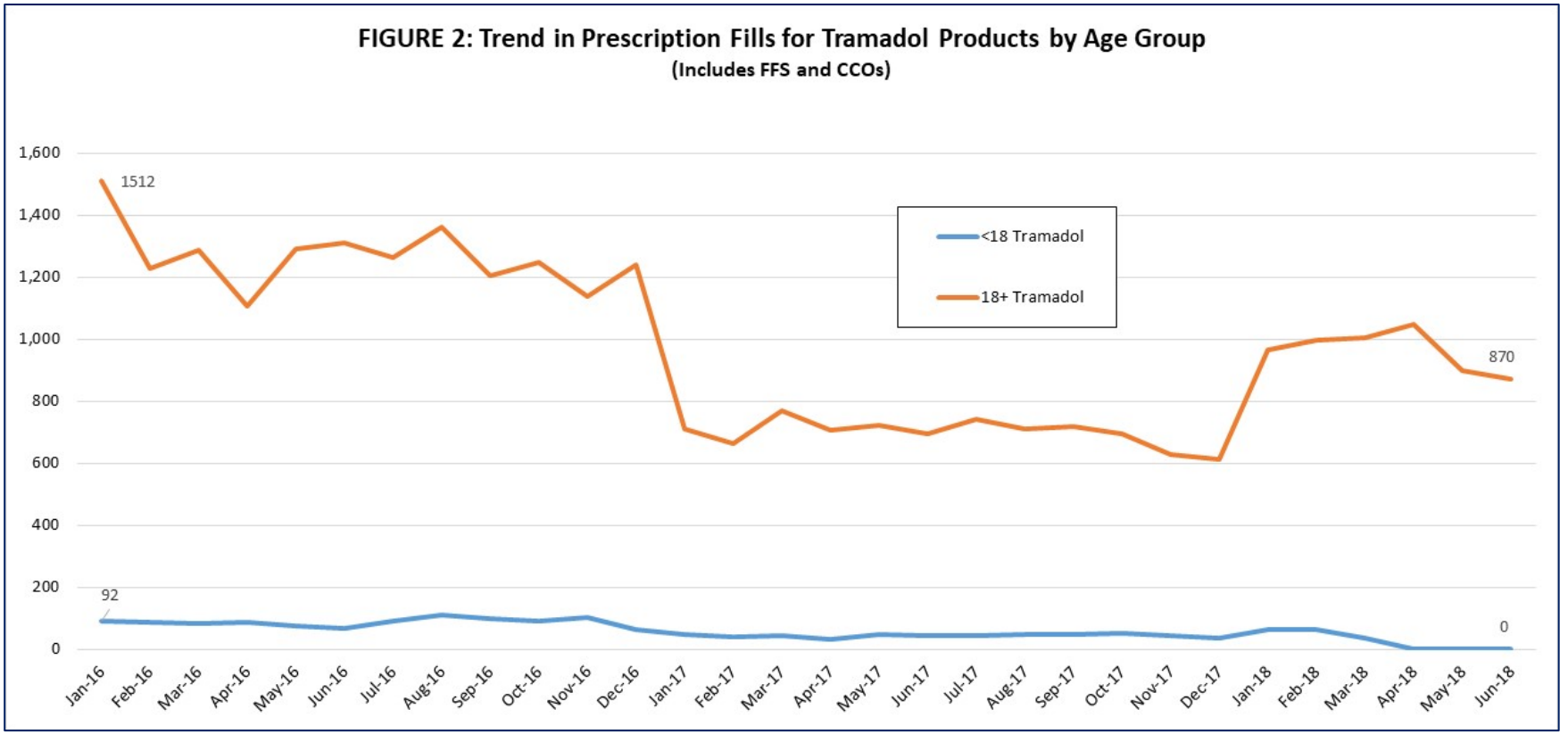


FIGURE 2: Trend in Prescription Fills for Tramadol Products by Age Group
(Includes FFS and CCOs)
1,600
1,400
1,200
1,000
800
600
400
200
0
1512
870
92
0
<18 Tramadol
18+ Tramadol
Jan-16
Feb-16
Mar-16
Apr-16
May-16
Jun-16
Jul-16
Aug-16
Sep-16
Oct-16
Nov-16
Dec-16
Jan-17
Feb-17
Mar-17
Apr-17
May-17
Jun-17
Jul-17
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Jan-18
Feb-18
Mar-18
Apr-18
May-18
Jun-18

## CONCLUSIONS

Implementation of a POS SMART PA clinical edit has basically eliminated prescribing of codeine and tramadol products for beneficiaries less than age 18 years.