# BUPRENORPHINE/NALOXONE THERAPY DOM CLINICAL GUIDELINES AND RECOMMENDED CHANGES

## BACKGROUND

In September 2012, the Division of Medicaid (DOM) implemented criteria through electronic prior authorization (PA) and the pharmacy point-of-sale (POS) systems for managing use of buprenorphine/naloxone (Suboxone®) and buprenorphine (Subutex®) for the treatment of opioid dependence. The criteria were developed after a thorough review of other state Medicaid and commercial payer guidelines and in consultation with licensed prescribers of buprenorphine/naloxone and an addictionologist. DOM's goals were to alleviate the burden of a manual PA for prescribers by including the criteria in electronic PA and to provide adequate access to therapy while assuring appropriate use that would be cost-effective to the state. At the July, 2016 meeting of the DUR Board, MS-DUR reviewed the criteria and provided an analysis of buprenorphine/naloxone utilization patterns since the Sept 2012 implementation.

Previous information during DUR meetings highlighted:
1) major efforts directed by the Department of Health and Human Services (HHS)[1], the Centers for Disease Control (CDC)[2], the Food and Drug Administration (FDA)[3], and a multitude of professional associations and other health agencies to address the opioid abuse "epidemic" and focus attention to the increased need for drug abuse prevention and treatment efforts.
2) the increased use of medication assisted treatment (MAT) for opioid use disorders as an integral component of addressing opioid addiction. Existing evidence shows that MAT is under-utilized.

- MAT is the use of medications in combination with counseling and behavioral therapies to provide a comprehensive patient approach to the treatment of substance use disorders, including opioid use disorders.
- Currently, there are four MAT medications approved by the FDA for the treatment of opioid dependence: methadone, buprenorphine, buprenorphine/naloxone and naltrexone.
- Buprenorphine-based MAT is governed by the Controlled Substances Act (CSA), as amended by the Drug Addiction Treatment Act of 2000 (DATA 2000). Pursuant to DATA 2000 and recent amendments, practitioners may obtain a waiver to prescribe buprenorphine for treatment of opioid use disorder. Initially, they may treat up to 30 patients at a time. After one year they may file a request to treat up to 100 patients at a time and after another year they can request to treat up to 275 patients at a time. Only physicians may be authorized to prescribe buprenorphine for the treatment of opioid use disorder

Section 303 of the Comprehensive Addiction and Recovery Act (CARA), signed into law by President Obama in July 2016, made several changes to the law regarding office-based opioid addiction treatment with buprenorphine which expands prescribing privileges to nurse practitioners (NPs) and physician

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[1] ASPE Issue Brief: Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths. https://aspe.hhs.gov/pdf-report/opioid-abuse-us-and-hhs-actions-address-opioid-drug-related-overdoses-and-deaths

[2] CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. http://www.cdc.gov/media/modules/dpk/2016/dpk-pod/rr6501e1er-ebook.pdf

[3] Food and Drug Administration. Fact Sheet – FDA Opioids Action Plan. http://www.fda.gov/NewsEvents/Newsroom/FactSheets/ucm484714.htm

assistants (PAs) once they have received a waiver to prescribe buprenorphine. Specific details regarding training for NPs and PAs are currently underway.

With the increased focus on MAT and the need to treat opioid abuse more effectively, the restrictions often used to manage utilization of buprenorphine/naloxone treatment are being challenged. In March, 2016, the Centers for Medicare and Medicaid Services (CMS) issued a final ruling on how the Mental Health Parity and Addiction Equity Act of 2008 applied to Medicaid programs. In the ruling, CMS stated that no financial requirement or treatment limitation could be applied to mental health or substance use disorder related services that is more restrictive than the "predominant" financial requirement or treatment limitation of that type applied to "substantially all" medical/surgical benefits. Life-time limits for buprenorphine/naloxone therapy were cited as an example of unacceptable limitations.

During the July DUR Board Meeting, MS-DUR presented study results indicating the current maintenance dose level may be lower than providers are prescribing and that the 24-month life-time limit on therapy was potentially a barrier for only a small percentage of beneficiaries. This report provides additional information on the effect of cash prescriptions obtained from Mississippi's Prescription Drug Monitoring Program (MS PMP) on doses prescribed and the number of beneficiaries reaching the 24-month limit on therapy coverage.

## METHODS

A retrospective analysis was conducted using DOM buprenorphine/naloxone and buprenorphine prescription claims data from the FFS and the two coordinated care organizations (CCO's), United Healthcare (UHC) and Magnolia (MAG) for the period January 1, 2015 through April 30, 2016. Information on buprenorphine and buprenorphine/naloxone prescriptions paid for with cash was extracted from the MS PMP's database and added to the data from Medicaid paid claims.

Maximum daily dosing limits are set for each month of therapy. Since DOM beneficiaries sometimes need multiple partial fills in a month and have compliance gaps (refill gaps < 60 days) between refills, the months of therapy is calculated based on cumulative days supply. For purposes of computing daily dosing each month on therapy, prescription fills were consolidated such that each individual fill represented the dosing for sequential 30-day increments.

## RESULTS

***Table 1: Step Therapy With Maximum Daily Doses for Initial Therapy Starts and Restarts***

Current DOM treatment criteria require dose reduction over time with maximum daily doses established for each month of therapy (month 1, up to 24mg buprenorphine/6mg naloxone per day; months 2-5, up to 16mg/4mg per day; and remaining months, up to 8mg/2mg per day). It is important to note that the month of therapy is determined by cumulative days supply of therapy and not calendar months. This distinction addresses small refill gaps due to noncompliance and multiple partial fills during a calendar month. DOM's current treatment criteria limit the daily dose for maintenance therapy to a maximum of 8mg/2mg. According to the current prescribing information for Suboxone®, for maintenance treatment, the target dosage of Suboxone® sublingual film is usually 16mg/4mg as a single daily dose.

Table 1 shows the number of beneficiaries with an initial start or restart on buprenorphine/naloxone or buprenorphine therapy since January 2015 by daily dose levels each month. Due to the January 1, 2015 implementation of the Universal Preferred Drug List (UPDL) for DOM, this analysis only includes therapy beginning on or after January 1. Doses at or below the criteria maximums are shaded green.

As shown in Table 1, when cash payment prescriptions are included, almost all beneficiaries had maintenance daily doses below 16mg/4mg per day but over half of beneficiaries had daily doses that exceeded the current DOM limit of 8mg/2mg per day. These results indicate that providers usually prescribe within the recommended FDA approved dosage in the labeling. However, the prior authorization process is used by providers or cash payments are used by beneficiaries for prescriptions that exceed the current DOM maintenance dose criteria.

**TABLE 1: Daily Dosing by Month on Therapy for New Starts and Restarts Beginnin After January 1, 2015**

*(FFS and CCOs with PMP Cash Claims Included)*

| DAILY DOSE - NEW STARTS After January 1, 2015 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Therapy Month* | <= 8 mg | | >8 to <= 16 mg | | >16 to <=24 mg | | > 24 mg | | Total Treated |
| 1 | 97 | 12% | 558 | 71% | 123 | 16% | 6 | 1% | 784 |
| 2 | 60 | 11% | 456 | 82% | 36 | 6% | 2 | 0% | 554 |
| 3 | 45 | 10% | 364 | 82% | 31 | 7% | 2 | 0% | 442 |
| 4 | 44 | 13% | 287 | 82% | 19 | 5% | 1 | 0% | 351 |
| 5 | 35 | 12% | 237 | 83% | 11 | 4% | 1 | 0% | 284 |
| 6 | 55 | 24% | 164 | 72% | 10 | 4% | 0 | 0% | 229 |
| 7 | 62 | 34% | 111 | 60% | 11 | 6% | 1 | 1% | 185 |
| 8 | 50 | 33% | 93 | 61% | 9 | 6% | 1 | 1% | 153 |
| 9 | 38 | 30% | 74 | 59% | 11 | 9% | 2 | 2% | 125 |
| 10 | 35 | 34% | 58 | 57% | 8 | 8% | 1 | 1% | 102 |
| 11 | 29 | 36% | 47 | 59% | 3 | 4% | 1 | 1% | 80 |
| 12 | 21 | 38% | 30 | 55% | 3 | 5% | 1 | 2% | 55 |
| 13 | 17 | 41% | 21 | 51% | 3 | 7% | 0 | 0% | 41 |
| 14 | 11 | 39% | 12 | 43% | 5 | 18% | 0 | 0% | 28 |
| 15 | 2 | 13% | 11 | 69% | 3 | 19% | 0 | 0% | 16 |
| 16 | 2 | 25% | 3 | 38% | 3 | 38% | 0 | 0% | 8 |
| 17 | 1 | 33% | 1 | 33% | 1 | 33% | 0 | 0% | 3 |
| 18 | 1 | 50% | 1 | 50% | 0 | 0% | 0 | 0% | 2 |

| DAILY DOSE - RESTARTS After January 1, 2015 | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Therapy Month* | <= 8 mg | | >8 to <= 16 mg | | >16 to <=24 mg | | > 24 mg | | Total Treated |
| 1 | 60 | 14% | 308 | 74% | 44 | 11% | 3 | 1% | 415 |
| 2 | 52 | 18% | 211 | 73% | 26 | 9% | 2 | 1% | 291 |
| 3 | 43 | 19% | 167 | 73% | 18 | 8% | 1 | 0% | 229 |
| 4 | 33 | 18% | 136 | 75% | 11 | 6% | 2 | 1% | 182 |
| 5 | 33 | 22% | 107 | 73% | 6 | 4% | 1 | 1% | 147 |
| 6 | 27 | 23% | 80 | 69% | 9 | 8% | 0 | 0% | 116 |
| 7 | 22 | 26% | 58 | 67% | 5 | 6% | 1 | 1% | 86 |
| 8 | 21 | 32% | 40 | 62% | 3 | 5% | 1 | 2% | 65 |
| 9 | 13 | 25% | 34 | 65% | 5 | 10% | 0 | 0% | 52 |
| 10 | 15 | 37% | 23 | 56% | 2 | 5% | 1 | 2% | 41 |
| 11 | 8 | 29% | 18 | 64% | 2 | 7% | 0 | 0% | 28 |
| 12 | 7 | 33% | 14 | 67% | 0 | 0% | 0 | 0% | 21 |
| 13 | 7 | 41% | 10 | 59% | 0 | 0% | 0 | 0% | 17 |
| 14 | 8 | 67% | 4 | 33% | 0 | 0% | 0 | 0% | 12 |
| 15 | 5 | 45% | 5 | 45% | 1 | 9% | 0 | 0% | 11 |
| 16 | 5 | 56% | 3 | 33% | 1 | 11% | 0 | 0% | 9 |
| 17 | 1 | 33% | 1 | 33% | 0 | 0% | 1 | 33% | 3 |
| 18 | 0 | 0% | 0 | 0% | 1 | 100% | 0 | 0% | 1 |
| 19 | 0 | 0% | 0 | 0% | 1 | 100% | 0 | 0% | 1 |
| 20 | 0 | 0% | 0 | 0% | 1 | 100% | 0 | 0% | 1 |
| 21 | 0 | 0% | 0 | 0% | 1 | 100% | 0 | 0% | 1 |
| 22 | 0 | 0% | 0 | 0% | 1 | 100% | 0 | 0% | 1 |
| 23 | 1 | 100% | 0 | 0% | 0 | 0% | 0 | 0% | 1 |

** Maximum daily dose limits are based on 30-day supply increments; therefore therapy month is caluculated as 30-day increments instead of calendar months.*

*NOTE: Green shading indicates approved maximum daily dosing.*

***Table 2: Length of Coverage***

Since the implementation of DOM's criteria, the cumulative number of months that beneficiaries have been on therapy with buprenorphine/naloxone or buprenorphine are represented in Table 2. The number and percentage of beneficiaries remaining on therapy for longer than 24 months increased slightly when cash paid prescriptions were included in the analysis. This indicates that cash paid prescriptions are being used in lieu of prior authorization requests for some beneficiaries to continue treatment.

**TABLE 2: Number and Percentage of Beneficiaries by Total Cumulative Months on Therapy**
**(September 1, 2012 - April 30, 2016)**

| Total Cummulative Months* on Therapy | Medicaid Paid Claims Only | | Medicaid Paid Claims Plus PMP Cash Claims | |
|---|---|---|---|---|
| 6 months or less | 1,267 | 51.5% | 1232 | 50.1% |
| >6 months to 12 months | 552 | 22.5% | 541 | 22.0% |
| >12 months to 18 months | 294 | 12.0% | 311 | 12.6% |
| >18 months to 24 months | 146 | 5.9% | 143 | 5.8% |
| >24 months to 30 months | 92 | 3.7% | 100 | 4.1% |
| >30 months | 107 | 4.4% | 134 | 5.4% |

** Maximum daily dose limits are based on 30-day supply increments; therefore therapy month is calculated as 30-day supply increments instead of calendar months.*

## BOARD ACTION REQUESTED

In light of the national initiatives to have MAT accessible and to ensure that DOM's clinical criteria is compliant with the Mental Health Parity and Addiction Equity Act of 2008, the DUR Board should consider the below recommendations.

**Recommendations**:
The DOM criteria for use of buprenorphine/naloxone and buprenorphine in the treatment of opioid dependence should be modified as follows:

a. **Appropriate Diagnosis** – unchanged
b. **Length of Coverage** – the 24-month maximum length of coverage and limits on restarts should be removed
c. **Step Therapy With Maximum Daily Doses** – change to:
   - Induction and stabilization phase – maximum daily dose of 24 mg/day for up to 2 months
   - Maintenance phase -- maximum daily dose of 16 mg/day
d. **Opioid Use Restriction** – unchanged

**FREE PROVIDER TRAINING AND SUPPORT MATERIALS**
**FOR BECOMING CERTIFIED FOR MAT AND FOR TREATING OPIOID DEPENDENCE**

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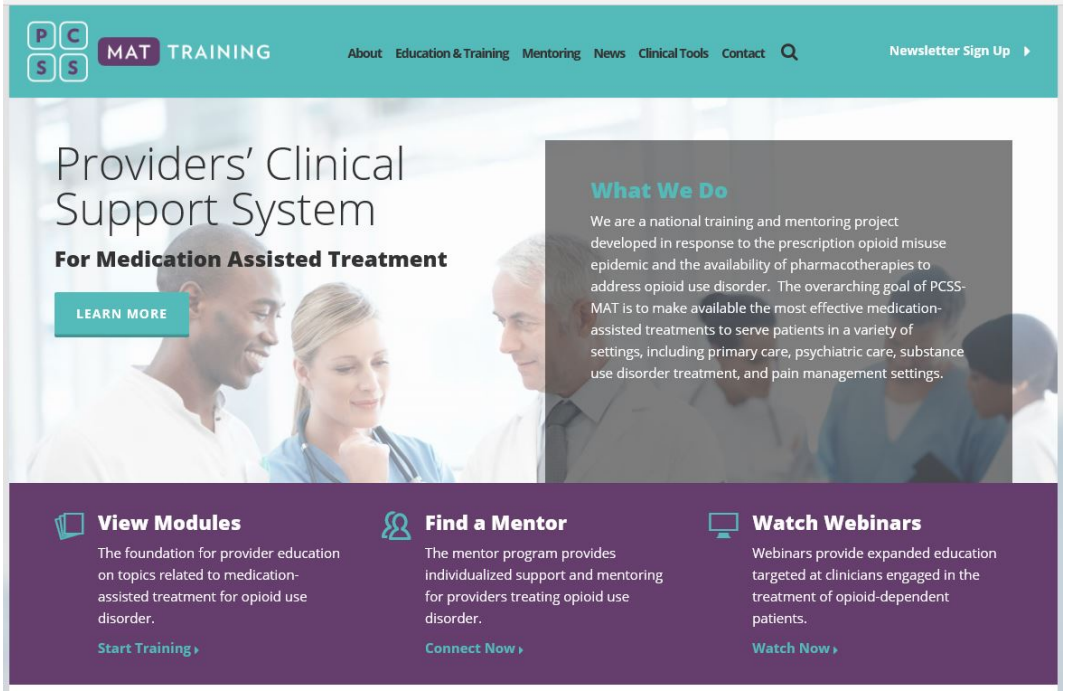


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