

BACKGROUND

Treatment guidelines call for use of Suboxone®/Subutex® (referred to as Suboxone® in poster) in an induction phase to safely suppress opioid withdrawal; a stabilization phase where the minimum dose necessary is used to keep the patient in treatment; a maintenance phase to prevent opioid withdrawal symptoms, suppress opioid cravings, and greatly attenuate the use of self-administered opioids; and a medically supervised withdrawal phase where the dose is slowly tapered. In order to promote appropriate use of Suboxone® the Mississippi Division of Medicaid implemented a treatment protocol edit.

OBJECTIVES

The major objectives of the protocol were to encourage step therapy with dose reduction over time and to limit cumulative length of time patients can remain on therapy. The new protocol was not intended to reduce access to Suboxone® therapy.

PRACTICE DESCRIPTION

Analyses conducted during development of the new treatment protocol found that only a small percentage of beneficiaries required initial daily doses greater than 24mg/day (Table 1).

Table 1: Product Dosage Strength by Starting Daily Dose

(Patients starting therapy between 10/1/2010 and 9/30/2011)

Starting Daily Dose	Dosage Strength				Total
	2 MG	2 - 0.5 MG	8 MG	8 - 2 MG	
2 mg/day	1	1	0	0	2 (1%)
4 mg/day	1	1	0	0	2 (1%)
6 mg/day	0	1	0	0	1 (0%)
8 mg/day	0	0	2	21	23 (10%)
16 mg/day	0	0	6	171	177 (74%)
24 mg/day	0	0	4	27	31 (13%)
32 mg/day	0	0	0	2	2 (1%)
Total	2 (1%)	3 (1%)	12 (5%)	221 (93%)	238

ACKNOWLEDGMENTS/DISCLOSURES

The work reported was conducted by the MS-DUR program in the Center for Pharmaceutical Marketing and Management as part of the retrospective drug use analysis activities conducted under contract with the Mississippi Division of Medicaid. The views expressed are those of the authors and do not necessarily reflect those of Mississippi Division of Medicaid or the University of Mississippi.

After consultation with addictionologists and a detailed analyses of Suboxone® treatment patterns, a new treatment protocol was developed. The key criteria include:

- Limited to treatment of opioid dependence only.
- Maximum doses for three stages of therapy are:
 - 24 mg/day for 1 month (the highest effective dose recommended in prescription information)
 - 16 mg/day for next 4 months, and
 - 8 mg/day for remainder of therapy.
- Cumulative 24 months of coverage.
- Refill gap of 60+ days is considered to be discontinuation and requires a restart.
- Beneficiaries are only allowed one restart.
- Use of opioid products is strictly limited.

MS-DUR mailed educational materials to prescribers and pharmacies explaining the new protocol and how to manage potential prior authorization issues. The protocol was implemented through the electronic prior authorization (EPA) system beginning September 1, 2012.

OUTCOMES

EPA denials were monitored for the first six months after implementation. Prescribers and pharmacies having repeated problems with denials were contacted for further education.

The most frequent reason for denial of claims was the absence of an appropriate diagnosis code(s) being found in prior medical claims or submitted by the pharmacy at the time of claim adjudication.

As shown in Figure 1, reduction in daily dose did occur after implementation of the new criteria. The percentage of prescriptions filled with a daily dose of 8mg/day or less significantly increased and the percentage filled with a daily dose of 16mg/day significantly decreased. Prescribing of daily doses of 20 or 24mg/day also reduced.

As shown in Figure 2, the reduction in daily dosing was achieved without reducing access to Suboxone therapy. The number of prescriptions per month actually rose in the three months after implementation of the new protocol. In December 2012, a major shift of beneficiaries to managed care took place; resulting in the majority of Suboxone® patients moving out of the FFS program. However, after this shift, the number of prescriptions per month was relatively stable, indicating access was not reduced.

INITIAL START OF THERAPY*

- Month 1: Step 1 Up to 24mg/day
- Months 2 - 5: Step 2 Up to 16mg/day
- Remaining Months: Step 3 Up to 8mg/day

RE-START OF THERAPY*
Only 1 re-start permitted (Refill gap of 60+ days considered a discontinuation of therapy that required a restart in treatment)

- Months 1 - 2: Step 1 Up to 16mg/day
- Remaining Months: Step 2 Up to 8mg/day

Cumulative 24 months maximum coverage -- Only 1 re-start permitted

- Suboxone®/Subutex® only approved for opioid dependence – ICD-9 codes 304.0x, 304.7x, 305.5x required to be found in medical claims or written on prescription and entered by pharmacist with prescription claim.
- Subutex® only approved for use during pregnancy – ICD-9 codes V22.xx, V23.xx required to be found in medical claims or written on prescription and entered by pharmacist with prescription claim.
- All Suboxone®/Subutex® prescribers must have current XDEA number.

Opiate use restriction:

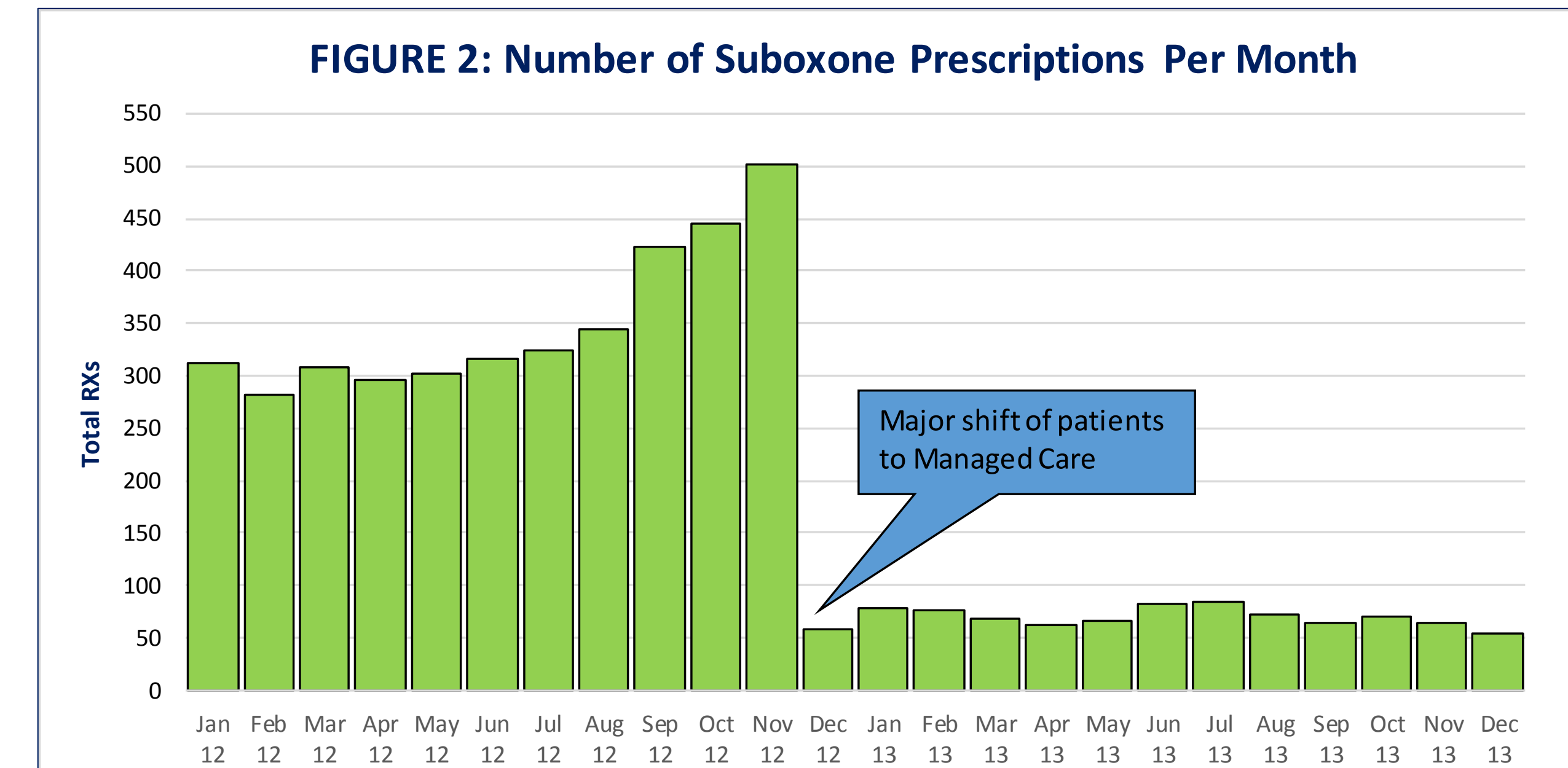
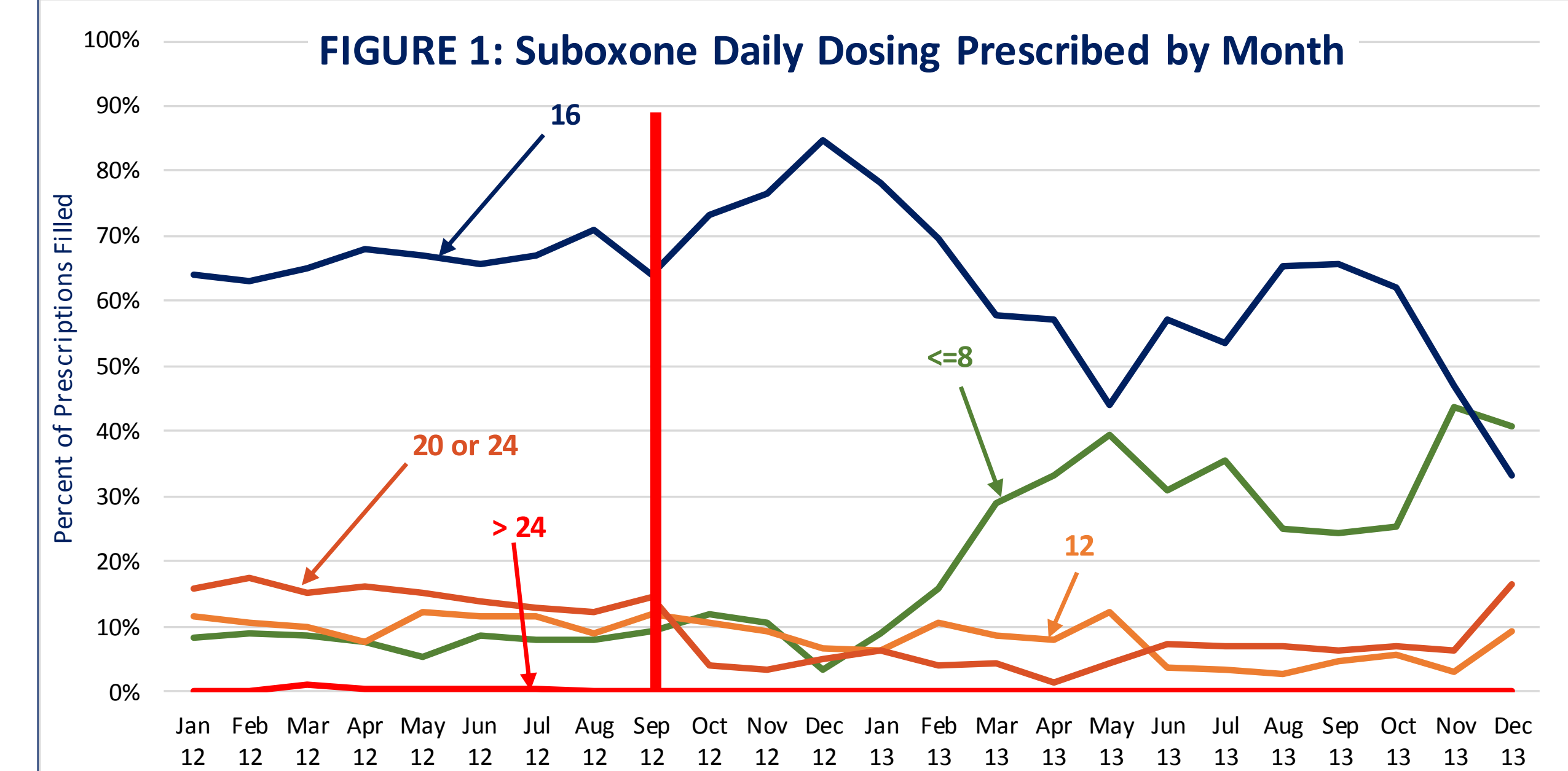
- Beneficiaries cannot have prescription for more than 5 day supply of opiate while on Suboxone®/Subutex® therapy.
- Cumulative maximum of 10 days of opiate treatment while on Suboxone®/Subutex® therapy.
- Medicaid claims are electronically reviewed for opiate use. Physicians and pharmacists are encouraged to use Prescription Monitoring Program (PMP) to monitor opiate use paid for by cash or other payers.

Trouble Shooting Rejections:

- Claim denied no diagnosis for opioid dependence or for pregnancy (Subutex® use) found**
Solution: Physician should write diagnosis code on prescription and pharmacy should enter diagnosis code on pharmacy claim and call Medicaid PA unit if claim is still rejected for lack of diagnosis.
- Maximum daily dose exceeded for current step in therapy**
Solution: Limits at each step in therapy are absolute. Beneficiary may pay for additional pills.
- Beneficiary has claim for > 5 days of opiate use in last 30 days**
Solution: Refill for Suboxone®/Subutex® cannot be processed until 30 days after opiate prescription was filled.
- Beneficiary has more than 10 days total opiate supply while on Suboxone®/Subutex® therapy**
Solution: Manual PA required from physician for appeal with medical justification for restarting or continuing treatment.

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Revision: 11/20/2013

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Copies of this Summary Sheet are available at: www.pharmacy.olemiss.edu/cpm/misurresourcesforproviders.html



CONCLUSIONS

The Suboxone® protocol implemented by DOM provided a good method for encouraging appropriate treatment patterns and appropriate utilization while not restricting access to this therapy.

