Division of Medicaid Office of the Governor State of Mississippi Drug Utilization Review (DUR) Board Meeting



September 7, 2023 at 1:00pm
Woolfolk Building, Room 145
Jackson, MS

Prepared by:



Drug Utilization Review Board

Joseph Austin, MD

Vicksburg Women's Care 100 Maxwell Drive Vicksburg, MS 39180

Term Expires: June 30, 2025

Amy Catherine Baggett, PharmD

Love's Pharmacy of Diamondhead 45000 E Aloha Dr., Suite B Diamondhead, MS 39525 Term Expires: June 30, 2024

Terrence Brown, PharmD

BioScrip Infusion Services

187 Country Place Pkwy, Suite C

Pearl, MS 39208

Term Expires: June 20, 2026

Chrysanthia Davis, PharmD

Omnicare Pharmacy 100 Business Park Dr, Ste D Ridgeland, MS 39157

Term Expires: June 30, 2025

Tanya Fitts, MD (Chair)

Lafayette Pediatric Clinic 1300 Access Road, Suite 400

Oxford, MS 38655

Term Expires: June 30, 2024

Dena Jackson, MD

King's Daughters Specialty Clinic 940 Brookway Blvd

Brookhaven, MS 39601

Term Expires: June 30, 2026

Jahanzeb Khan, MD

University Hospital 2500 N. State Street Jackson, MS 39216

Term Expires: June 30, 2024

Holly R. Moore, PharmD

Anderson Regional Medical Center 2124 14th Street

Meridian, MS 39301

Term Expires: June 30, 2026

Kristi Phelps, RPh

Burnham Drugs 12500 Hwy 57

Vancleave, MS 39565

Term Expires: June 30, 2026

Joshua Pierce, PharmD

McGuffee Drugs 102 Main St.

Magee, MS 39111

Term Expires: June 30, 2024

Bobbie West, MD

MEA Medical Clinic 342 Gilchrist Drive

Pearl, MS 39208

Term Expires: June 30, 2025

2023 DUR Board Meeting Dates

March 2, 2023 June 15, 2023 September 7, 2023 December 7, 2023 As with any analysis, great efforts are made to ensure that the information reported in this document is accurate. The most recent administrative claims data available are being used at the time the reports are generated, which includes the most recent adjudication history. As a result, values may vary between reporting periods and between DUR Board meetings, reflecting updated reversals and claims adjustments.

Unless otherwise indicated, all MS-DUR analyses are conducted for the entire Mississippi Medicaid program including beneficiaries receiving services through the Medicaid fee-for-service (FFS) and the Mississippi Medicaid Coordinated Care Organizations (CCOs). When dollar figures are reported, the reported dollar figures represent reimbursement amounts paid to providers and are not representative of final Medicaid costs after rebates. Any reported enrollment data presented are unofficial and are only for general information purposes for the DUR Board.

Please refer to the Mississippi Division of Medicaid website for the current official Universal Preferred Drug List (PDL).

http://www.medicaid.ms.gov/providers/pharmacy/preferred-drug-list/

MISSISSIPPI DIVISION OF MEDICAID OFFICE OF THE GOVERNOR DRUG UTILIZATION REVIEW BOARD AGENDA

September 7, 2023

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September 7, 2023; December 7, 2023	
Deptember 7, 2023, Detember 7, 2023	

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID DRUG UTILIZATION REVIEW (DUR) BOARD MINUTES OF THE JUNE 15, 2023 MEETING

DUR Board Roster: State Fiscal Year 2023	Sep 2022	Dec 2022	Mar 2023	Jun 2023
(July 1, 2022 – June 30, 2023)				
Joseph Austin, MD	✓	✓		✓
Lauren Bloodworth, PharmD				
Terrence Brown, PharmD	✓	✓	✓	✓
Patrick Bynum, MD	✓	✓		
Chrysanthia Davis, PharmD	✓	✓	✓ (√
Tanya Fitts, MD	✓			✓
Jahanzeb Khan, MD	✓	✓	✓	✓
Ray Montalvo, MD	✓		✓ ✓	
Holly Moore, PharmD	✓	✓	✓	✓
Kristi Phelps, RPh	✓	✓	✓	
Joshua Pierce, PharmD	V	✓		✓
Bobbie West, MD	✓		✓	
TOTAL PRESENT**	11	8	7	7

^{**} Total Present may not be reflected by individual members marked as present above due to members who either resigned or whose terms expired being removed from the list.

Also Present:

Division of Medicaid (DOM) Staff:

Terri Kirby, RPH, CPM, Pharmacy Director; Dennis Smith, RPH, DUR Coordinator; Gail McCorkle, RPH, Clinical Pharmacist; Chris Yount, MA, PMP-Office of Policy; Sue Reno, RN, Program Integrity; Vanessa Banks, RN, Program Integrity;

University of Mississippi School of Pharmacy - MS-DUR Staff:

Eric Pittman, PharmD, MS-DUR Project Director; Claire Lin, Graduate Student; Arman Arabshomali, Graduate Student; Alfred Eriakha, Graduate Student;

Change Healthcare Staff:

Paige Clayton, PharmD, On-Site Clinical Pharmacist; Shannon Hardwick, RPH, CPC Pharmacist;

Coordinated Care Organization (CCO) Staff:

Jenni Grantham, PharmD, Director of Pharmacy, Magnolia Health; Heather Odem, PharmD, Director of Pharmacy - Mississippi, UnitedHealthcare Community & State; Trina Stewart, PharmD, Pharmacy Manager, Molina Healthcare;

Gainwell Staff:

Tricia Banks, PharmD, MS Pharmacy Services Manager; Lew Ann Snow, RN, Advisor Business Analyst;

Alliant Health Staff:

Catherine Brett, MD, Quality Director, MS UM/QIO; Buddy Ogletree, PharmD, Pharmacist;

Visitors:

Cathy Prine-Eagle, Merck; Shawn Headley, Gilead; Michele Shirley, Indivior; Paula Whatley, Novo Nordisk; Keanna Dandridge, Novartis; Chandler Douglas, Capital Resources; Scott Roberson, Alkermes; Bridget Gipson, UCB; Jody Ray, SCA.

Call to Order/Welcome:

Dr. Brown called the meeting to order at 1:06 pm.

OLD BUSINESS:

Dr. Moore moved to approve the minutes from the December 2022 DUR Board Meeting, seconded by Dr. Pierce, and unanimously approved by the DUR Board.

Resource Utilization Review:

Dr. Pittman presented the resource utilization report for March 2023. Dr. Pittman noted that MS-DUR continues to experience data transfer issues with the encounter claims from Gainwell. DOM is working to resolve those issues.

NEW BUSINESS:

Update on MS-DUR Educational Interventions:

Dr. Pittman provided an overview of all DUR mailings and educational notices that occurred between February 2023 – May 2023. He also provided members with a proposed mailing on the preventive use of low-dose aspirin in pregnant beneficiaries at risk of preeclampsia. This mailing will be sent to over 3,400 providers that rendered pregnancy-related care to a Medicaid beneficiary during the previous year. The Board also recommended the educational mailing be distributed to pharmacists through pharmacy professional organizations.

Special Analysis Projects:

Adolescent Vaccines

Mississippi has traditionally performed well when it comes to childhood vaccination rates, particularly regarding vaccinations required for school attendance. With vaccinations that are not required for school attendance, Mississippi often lags behind other states. Efforts are ongoing to improve vaccination rates. This report examined trends in Tdap, meningococcal, and HPV vaccinations among Medicaid beneficiaries. Opportunities exist for the further advancement of vaccination rates in our state.

The following recommendation was presented:

 DOM is encouraged to consider using this study as evidence to explore possible efforts or policy changes to promote increasing rates for the meningococcal, Tdap, and HPV vaccines.

Following discussion, Dr. Fitts made a motion to accept the recommendation, seconded by Dr. Pierce, and unanimously approved by the Board.

GLP-1 Trends

Dr. Pittman presented a report that examined healthcare utilization pre- and post-GLP-1 initiation for those beneficiaries initiated on a GLP-1 without the presence of a diabetes diagnosis in claims data. An interrupted time series study design was utilized to examine this impact. The ITS model demonstrated that the initiation of GLP-1s resulted in a significant increase in pharmacy and total healthcare costs immediately after initiation, but over the 12 months post initiation, pharmacy and total healthcare costs significantly decreased monthly. By the end of the 12-month post initiation period, a comparison of actual costs to the counterfactual estimates showed that although pharmacy costs were elevated, medical costs decreased resulting in a total healthcare cost that was only slightly higher than the counterfactual estimate. The Board also reviewed overall prescribing trends for GLP-1s between June 2022 and March 2023. A substantial increase in prescribing was noted across the entire class, including an increase in the number of non-preferred agents. Additionally, the Board had the opportunity to provide input on the proposed prior authorization criteria for select covered obesity medications set to go into effect July 1, 2023.

The following recommendations were presented:

- 1. DOM is encouraged to implement steps that promote the use of preferred GLP-1 agonists to combat the increase of prescribing of non-preferred agents.
- DOM is encouraged to consider implementing a DUR+ (electronic PA) rule that
 promotes the utilization of GLP-1 agonists for appropriate diagnoses, based on FDA
 approval.
- Due to the potential positive impact on medical and total healthcare costs, DOM is encouraged to consider allowing non-diabetic patients who are stable on preferred GLP-1 agents to continue therapy.

Following a robust discussion, Dr. Davis made a motion to accept the recommendations, seconded by Dr. Fitts, and unanimously approved by the Board.

FDA Drug Safety Updates:

Dr. Pittman updated the Board on FDA drug safety communications that were published between December 2022 – February 2023.

Pharmacy Program Update:

Ms. Kirby provided a pharmacy program update highlighting the following items:

- The names of new members to the Board have been submitted to the Governor's Office. Ms. Kirby took the opportunity to commend all the current members that were completing their terms with the Board.
- DOM is in the midst of transitioning to multiple new vendors that provide pharmacy-related services.
- DOM is moving toward implementing a single PBA (pharmacy benefit administrator). This transition is set to take place July 2024.
- DOM submitted a waiver to CMS that will allow DOM to pay pharmacists for medication management services for members enrolled in the Elderly and Disabled Waiver Program beginning January 2024.

Next Meeting Information:

The next Board meeting is scheduled for September 7, 2023.

Dr. Brown adjourned the meeting at 2:49 pm

Submitted,

Eric Pittman, PharmD
Evidence-Based DUR Initiative, MS-DUR

Meeting Location: Woolfolk Building, 501 North West Street, Conference Room 145, Jackson, MS 39201, unless otherwise noted by the corresponding date of the meeting listed below.

Contact Information: Office of Pharmacy:

Chris Yount, 601-359-5253: Christopher.yount@medicaid.ms.gov, or Jessica Tyson, 601-359-5253; Jessica.Tyson@medicaid.ms.gov

Notice details:

State Agency: MS Division of Medicaid

Public Body: Drug Utilization Board (DUR) Meeting

Subject: Quarterly Meeting

Dates and Times:

2023 dates:

• March 2, 2023 (1-3pm; Room 117, Woolfolk Building)

• June 15, 2023 (1-3pm; Room 145)

• September 7, 2023 (1-3pm; Room 145)

• December 7, 2023 (1-3pm; Room 145)

Description: The Mississippi Division of Medicaid's Drug Utilization Review (DUR) Board is a quality assurance body which seeks to assure appropriate drug therapy to include optimal beneficiary outcomes and appropriate education for physicians, pharmacists, and the beneficiary. The Drug Utilization Review (DUR) Board is composed of twelve participating physicians and pharmacists who are active MS Medicaid providers and in good standing with their representative organizations.

The Board reviews utilization of drug therapy and evaluates the long-term success of the treatments.

The Drug Utilization Review (DUR) Board meets quarterly.

Meetings

Meetings will be held at 1:00 pm in Woolfolk Building Room 145 unless otherwise noted. 2023 dates are as follows:

- March 2, 2023 (Room 117, Woolfolk Building);
- June 15, 2023 (Room 145, Woolfolk Building);
- Sept. 7, 2023 (Room 145, Woolfolk Building),
- Dec. 7, 2023 (Room 145, Woolfolk Building)

All meetings will be live with no virtual options.

<u>Important Updates</u>: Beginning October 1, 2021, pharmaceutical and industry members, vendors, and general public must register to attend. Registration will open thirty (30) days prior to the meeting date. Registration will close at 12pm (noon) the day before the meeting. Public speaking is not allowed at DUR meetings unless called on by the Board.

<u>Parking</u>: parking may be found on the perimeter of the Woolfolk Building, on the north side of the Woolfolk Building located at the old Wright and Ferguson building (yellow/brown building), and at either the Division of Medicaid and First Baptist Church main parking lots at the corner of High Street and North President Street. *Guests may not park in the Woolfolk Building parking garage or in any parking space marked "Reserved"*.

CLICK HERE to register online for the June 15, 2023 MS-DUR Board meeting!

NOTE: Registration is **required** for all pharmaceutical industry and advocacy representatives to be able to attend DUR Board meetings.





Resource Utilization Review

	TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS January 1, 2023 through June 30, 2023								
			Jan-23	Feb-23	Mar-23	Apr-23	May-23	Jun-23	
To	otal enr	rollment	895,883	898,922	902,451	904,956	907,167	907,022	
D	ual-elig	ibles	166,779	166,870	167,167	167,245	167,390	167,270	
Pl	narmac	y benefits	785,703	788,746	792,136	794,461	796,383	796,098	
	LTC		15,539	15,603	15,713	15,679	15,623	15,330	
	,	FFS	50.4%	50.0%	49.9%	49.5%	49.3%	49.0%	
	% N	MSCAN-UHC	19.2%	19.4%	19.4%	19.5%	19.6%	19.8%	
	PLAN	MSCAN-Magnolia	19.9%	20.0%	20.0%	20.1%	20.1%	20.2%	
	1	MSCAN-Molina	10.5%	10.6%	10.7%	10.9%	11.0%	11.0%	

	TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS											
January 1, 2023 through June 30, 2023												
Jan-23 Feb-23 Mar-23 Apr-23 May-23 Jun-23												
# Rx Fills	FFS	193,449	179,863	200,704	182,628	191,012	174,090					
# Rx Fills / Bene	FFS	0.5	0.5	0.5	0.5	0.5	0.4					
\$ Paid Rx	FFS	\$24,851,088	\$24,374,325	\$26,599,117	\$24,461,791	\$27,333,484	\$26,517,385					
\$/Rx Fill	FFS	\$128.46	\$135.52	\$132.53	\$133.94	\$143.10	\$152.32					
\$/Bene	FFS	\$62.76	\$61.81	\$67.29	\$62.20	\$69.62	\$67.98					

NOTE: Paid amounts represent amount reported on claims as paid to the pharmacy. These amounts do not reflect final actual costs after rebates, etc.

In April 2021, UHC changed their claims reporting procedure, and the estimates presented in these tables may be slightly higher than the amount actually paid by UHC

^{**}Incomplete claim information for all MSCAN programs for the reporting period

TABLE C: TOP 10 DRUG CATEGORIES BY NUMBER OF CLAIMS IN JUN 2023 (FFS)

Category	Month Year	Rank Volume	# RXs	\$ Paid	# Unique Benes
contraceptives	Jun 2023	1	7,424	\$431,049	6,113
	May 2023	2	7,555	\$440,379	6,132
	Apr 2023	2	6,997	\$389,316	5,789
CNS stimulants	Jun 2023	2	6,837	\$1,075,326	5,499
	May 2023	1	7,999	\$1,248,335	6,468
	Apr 2023	1	8,172	\$1,283,199	6,771
SSRI antidepressants	Jun 2023	3	6,316	\$84,428	5,289
	May 2023	3	6,683	\$92,214	5,532
	Apr 2023	3	6,370	\$77,007	5,356
nonsteroidal anti-inflammatory agents	Jun 2023	4	5,613	\$84,038	5,032
	May 2023	4	5,867	\$87,467	5,289
	Apr 2023	4	5,642	\$72,707	5,119
vitamins	Jun 2023	5	5,026	\$46,771	3,583
	May 2023	6	5,036	\$47,407	3,607
	Apr 2023	7	4,503	\$40,662	3,362
atypical antipsychotics	Jun 2023	6	4,404	\$1,071,680	3,327
	May 2023	7	4,748	\$1,102,057	3,542
	Apr 2023	6	4,515	\$1,042,028	3,387
proton pump inhibitors	Jun 2023	7	4,229	\$130,474	3,596
	May 2023	8	4,300	\$129,787	3,652
	Apr 2023	9	4,046	\$116,307	3,480
narcotic analgesic combinations	Jun 2023	8	3,824	\$218,614	3,363
	May 2023	11	3,977	\$229,181	3,442
	Apr 2023	12	3,773	\$211,007	3,355
aminopenicillins	Jun 2023	9	3,693	\$50,233	3,512
	May 2023	5	5,473	\$75,953	5,223
	Apr 2023	5	5,417	\$74,296	5,179
adrenergic bronchodilators	Jun 2023	10	3,656	\$280,227	2,925
	May 2023	9	4,272	\$293,522	3,477
	Apr 2023	8	4,372	\$293,306	3,544

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN JUN 2023 (FFS)

Category	Month Year	Rank Paid Amt	# RXs	\$ Paid	# Unique Benes
interleukin inhibitors	Jun 2023	1	460	\$2,869,230	279
	May 2023	1	464	\$2,675,533	254
	Apr 2023	1	412	\$2,585,162	237
factor for bleeding disorders	Jun 2023	2	107	\$1,696,416	74
	May 2023	3	111	\$1,652,617	84
	Apr 2023	2	111	\$1,635,499	85
antirheumatics	Jun 2023	3	237	\$1,469,839	171
	May 2023	2	252	\$1,772,664	167
	Apr 2023	3	230	\$1,456,615	162
antiviral combinations	Jun 2023	4	302	\$1,278,976	248
	May 2023	6	298	\$1,118,974	231
	Apr 2023	6	277	\$1,019,465	222
CNS stimulants	Jun 2023	5	6,837	\$1,075,326	5,499
	May 2023	4	7,999	\$1,248,335	6,468
	Apr 2023	4	8,172	\$1,283,199	6,771
atypical antipsychotics	Jun 2023	6	4,404	\$1,071,680	3,327
	May 2023	7	4,748	\$1,102,057	3,542
	Apr 2023	5	4,515	\$1,042,028	3,387
CFTR combinations	Jun 2023	7	54	\$1,027,825	39
	May 2023	5	59	\$1,216,374	37
	Apr 2023	7	44	\$865,518	35
selective immunosuppressants	Jun 2023	8	187	\$943,178	138
	May 2023	9	185	\$925,021	132
	Apr 2023	8	169	\$820,468	120
GLP-1 receptor agonists	Jun 2023	9	867	\$759,496	713
	May 2023	11	902	\$801,617	708
	Apr 2023	10	770	\$687,864	622
insulin	Jun 2023	10	2,012	\$749,549	1,311
	May 2023	12	2,131	\$798,146	1,365
	Apr 2023	9	1,985	\$752,471	1,287

TABLE E: TOP 25 DRUG MOLECULES BY NUMBER OF CLAIMS IN JUN 2023 (FFS)

Drug Molecule Therapeutic Category	May 2023 # Claims	Jun 2023 # Claims	Jun 2023 \$ Paid	Jun 2023 # Unique Benes
amoxicillin / aminopenicillins	5,444	3,656	\$49,575	3,478
albuterol / adrenergic bronchodilators	3,964	3,288	\$177,244	2,702
ondansetron / 5HT3 receptor antagonists	3,450	2,763	\$41,028	2,565
gabapentin / gamma-aminobutyric acid analogs	2,677	2,697	\$42,088	2,151
ergocalciferol / vitamins	2,600	2,636	\$23,077	1,988
ibuprofen / nonsteroidal anti-inflammatory agents	2,625	2,474	\$31,262	2,307
sertraline / SSRI antidepressants	2,585	2,448	\$32,385	2,011
azithromycin / macrolides	3,765	2,326	\$35,749	2,201
amlodipine / calcium channel blocking agents	2,321	2,306	\$27,910	1,899
acetaminophen-hydrocodone / narcotic analgesic combinations	2,420	2,299	\$33,714	2,102
montelukast / leukotriene modifiers	2,564	2,252	\$33,585	2,038
amphetamine-dextroamphetamine / CNS stimulants	2,424	2,235	\$87,197	1,845
ethinyl estradiol-norgestimate / contraceptives	2,361	2,200	\$34,128	1,927
medroxyprogesterone / progestins	2,031	2,031	\$71,415	1,952
fluconazole / azole antifungals	1,921	1,985	\$25,807	1,783
fluticasone nasal / nasal steroids	2,587	1,941	\$32,646	1,840
methylphenidate / CNS stimulants	2,332	1,922	\$385,314	1,564
pantoprazole / proton pump inhibitors	1,843	1,823	\$23,046	1,525
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	2,335	1,817	\$39,149	1,714
triamcinolone topical / topical steroids	1,730	1,809	\$31,961	1,627
clonidine / antiadrenergic agents, centrally acting	1,892	1,755	\$22,045	1,529
omeprazole / proton pump inhibitors	1,808	1,744	\$21,637	1,562
ethinyl estradiol-norelgestromin / contraceptives	1,698	1,716	\$199,413	1,270
folic acid / vitamins	1,725	1,698	\$12,949	1,173
atorvastatin / HMG-CoA reductase inhibitors (statins)	1,758	1,684	\$19,462	1,290

TABLE F: TOP 25 DRUG MOLECULES BY DOLLARS PAID IN JUN 2023 (FFS)

Drug Molecule Therapeutic Category	May 2023 \$ Paid	Jun 2023 \$ Paid	Jun 2023 # Claims	Jun 2023 # Unique Benes
adalimumab / antirheumatics	\$1,962,659	\$1,662,712	166	105
dupilumab / interleukin inhibitors	\$1,258,110	\$1,144,378	323	201
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	\$1,095,711	\$1,027,825	54	39
emicizumab / factor for bleeding disorders	\$827,298	\$910,494	32	25
ustekinumab / interleukin inhibitors	\$653,025	\$844,471	37	19
bictegravir/emtricitabine/tenofovir / antiviral combinations	\$619,002	\$698,536	143	119
corticotropin / corticotropin	\$42,714	\$555,229	8	3
ixekizumab / interleukin inhibitors	\$428,717	\$441,372	56	32
everolimus / selective immunosuppressants	\$384,715	\$437,193	23	16
paliperidone / atypical antipsychotics	\$437,240	\$434,708	149	124
lisdexamfetamine / CNS stimulants	\$482,181	\$424,458	1,205	1,073
cannabidiol / miscellaneous anticonvulsants	\$401,885	\$391,482	119	80
methylphenidate / CNS stimulants	\$447,547	\$385,314	1,922	1,564
dulaglutide / GLP-1 receptor agonists	\$368,107	\$368,866	423	354
liraglutide / GLP-1 receptor agonists	\$341,005	\$301,463	346	290
insulin glargine / insulin	\$315,453	\$298,149	701	594
aripiprazole / atypical antipsychotics	\$287,614	\$293,384	1,232	1,010
anti-inhibitor coagulant complex / factor for bleeding disorders	\$0	\$280,080	2	1
coagulation factor ix / factor for bleeding disorders	\$207,897	\$269,454	15	5
empagliflozin / SGLT-2 inhibitors	\$224,395	\$263,697	338	277
somatropin / growth hormones	\$307,629	\$261,719	53	43
cysteamine / miscellaneous uncategorized agents	\$132,407	\$238,325	3	2
apixaban / factor Xa inhibitors	\$247,698	\$234,022	580	419
dapagliflozin / SGLT-2 inhibitors	\$243,823	\$216,033	282	242
ethinyl estradiol-norelgestromin / contraceptives	\$201,700	\$199,413	1,716	1,270

TABLE G: TOP 25 DRUG MOLECULES BY CHANGE IN NUMBER OF CLAIMS FROM APR 2023 TO JUN 2023 (FFS)

Drug Molecule	Apr 2023 # Claims	May 2023 # Claims	Jun 2023 # Claims	Jun 2023 \$ Paid	Jun 2023 # Unique Benes
ergocalciferol / vitamins	2,314	2,600	2,636	\$23,077	1,988
triamcinolone topical / topical steroids	1,523	1,730	1,809	\$31,961	1,627
fluconazole / azole antifungals	1,760	1,921	1,985	\$25,807	1,783
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	331	455	553	\$135,873	482
ethinyl estradiol-norelgestromin / contraceptives	1,514	1,698	1,716	\$199,413	1,270
mupirocin topical / topical antibiotics	1,025	1,140	1,225	\$18,997	1,147
medroxyprogesterone / progestins	1,857	2,031	2,031	\$71,415	1,952
ofloxacin otic / otic anti-infectives	200	261	352	\$8,705	327
folic acid / vitamins	1,552	1,725	1,698	\$12,949	1,173
nitrofurantoin / urinary anti-infectives	939	1,013	1,054	\$41,545	989
amlodipine / calcium channel blocking agents	2,192	2,321	2,306	\$27,910	1,899
pantoprazole / proton pump inhibitors	1,711	1,843	1,823	\$23,046	1,525
potassium chloride / minerals and electrolytes	832	858	941	\$17,477	733
losartan / angiotensin II inhibitors	860	932	967	\$12,081	835
dulaglutide / GLP-1 receptor agonists	319	420	423	\$368,866	354
duloxetine / SSNRI antidepressants	551	628	639	\$9,714	523
metronidazole / miscellaneous antibiotics	1,593	1,718	1,675	\$22,325	1,578
hydrocortisone/neomycin/polymyxin b otic / otic steroids with anti-infectives	119	138	197	\$11,652	187
doxycycline / tetracyclines	1,013	1,099	1,089	\$18,142	1,017
metformin / biguanides	1,395	1,515	1,470	\$15,553	1,197
buspirone / miscellaneous anxiolytics, sedatives and hypnotics	1,324	1,409	1,398	\$18,364	1,211
diclofenac / nonsteroidal anti-inflammatory agents	515	572	589	\$9,750	536
mometasone topical / topical steroids	236	299	308	\$6,896	278
trazodone / phenylpiperazine antidepressants	1,284	1,338	1,355	\$16,033	1,124
mirtazapine / tetracyclic antidepressants	326	360	393	\$5,613	310

TABLE H: TOP 25 DRUG MOLECULES BY CHANGE IN AMOUNT PAID FROM APR 2023 TO JUN 2023 (FFS)

Drug Molecule	Apr 2023 \$ Paid	May 2023 \$ Paid	Jun 2023 \$ Paid	Jun 2023 # Claims	Jun 2023 # Unique Benes
corticotropin / corticotropin	\$85,423	\$42,714	\$555,229	8	3
emicizumab / factor for bleeding disorders	\$651,632	\$827,298	\$910,494	32	25
bictegravir/emtricitabine/tenofovir / antiviral combinations	\$461,043	\$619,002	\$698,536	143	119
adalimumab / antirheumatics	\$1,461,922	\$1,962,659	\$1,662,712	166	105
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	\$827,109	\$1,095,711	\$1,027,825	54	39
eteplirsen / miscellaneous uncategorized agents	\$0	\$640,079	\$185,623	2	2
ustekinumab / interleukin inhibitors	\$686,200	\$653,025	\$844,471	37	19
tipiracil-trifluridine / antineoplastic combinations	\$0	\$42,517	\$154,465	9	3
dupilumab / interleukin inhibitors	\$1,019,318	\$1,258,110	\$1,144,378	323	201
lenalidomide / other immunosuppressants	\$58,351	\$145,905	\$169,246	9	5
dulaglutide / GLP-1 receptor agonists	\$284,353	\$368,107	\$368,866	423	354
regorafenib / multikinase inhibitors	\$28,982	\$72,375	\$101,256	6	3
everolimus / selective immunosuppressants	\$375,979	\$384,715	\$437,193	23	16
asciminib / BCR-ABL tyrosine kinase inhibitors	\$0	\$20,117	\$60,350	3	1
cannabidiol / miscellaneous anticonvulsants	\$331,305	\$401,885	\$391,482	119	80
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	\$82,324	\$114,478	\$135,873	553	482
coagulation factor ix / factor for bleeding disorders	\$217,245	\$207,897	\$269,454	15	5
cabozantinib / multikinase inhibitors	\$25,042	\$61,001	\$75,136	3	2
immune globulin intravenous and subcutaneous / immune globulins	\$140,089	\$246,534	\$189,501	17	9
ofatumumab / CD20 monoclonal antibodies	\$0	\$0	\$49,007	2	1
paliperidone / atypical antipsychotics	\$386,279	\$437,240	\$434,708	149	124
ponatinib / multikinase inhibitors	\$20,134	\$28,019	\$68,294	4	2
ixekizumab / interleukin inhibitors	\$395,604	\$428,717	\$441,372	56	32
teduglutide / miscellaneous GI agents	\$88,424	\$176,849	\$132,636	3	2
treprostinil / agents for pulmonary hypertension	\$25,489	\$12,744	\$69,373	4	2

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > \$1 BY PERCENT CHANGE IN AMOUNT PAID PER UNIT APR 2023 TO JUN 2023 (FFS)

Drug Product Therapeutic Category	Jun 2023 # Claims	Jun 2023 \$ Paid	Jun 2023 Avr. Paid Per Rx	Jun 2023 Avr. Units Per Rx	Apr 2023 Paid Per Unit	May 2023 Paid Per Unit	Jun 2023 Paid Per Unit	Percent Change
dexmethylphenidate 20 mg capsule, extended release / CNS stimulants (Y)	148	\$9,681	\$65.42	29	\$1.42	\$1.63	\$1.83	29.2%
ethinyl estradiol-norethindrone with iron 20 mcg-1 mg capsule / contraceptives (Y)	102	\$7,915	\$77.60	41	\$1.25	\$1.35	\$1.50	20.1%
Jardiance (empagliflozin) 10 mg tablet / SGLT-2 inhibitors (Y)	163	\$126,505	\$776.10	41	\$17.79	\$18.00	\$18.36	3.2%
Jardiance (empagliflozin) 25 mg tablet / SGLT-2 inhibitors (Y)	175	\$137,192	\$783.95	40	\$17.85	\$18.19	\$18.35	2.8%
Biktarvy (bictegravir/emtricitabine/tenofovir) 50 mg-200 mg-25 mg tablet / antiviral combinations (Y)	143	\$698,536	\$4,884.87	38	\$113.20	\$111.86	\$115.00	1.6%
Farxiga (dapagliflozin) 10 mg tablet / SGLT-2 inhibitors (Y)	229	\$179,384	\$783.34	42	\$17.58	\$17.80	\$17.80	1.3%
QuilliChew ER (methylphenidate) 30 mg/24 hr tablet, chewable, extended release / CNS stimulants (Y)	215	\$80,712	\$375.40	31	\$11.72	\$11.53	\$11.83	1.0%
Suboxone (buprenorphine-naloxone) 8 mg-2 mg film / narcotic analgesic combinations (Y)	380	\$158,256	\$416.46	47	\$8.55	\$8.61	\$8.62	0.8%
Vyvanse (lisdexamfetamine) 40 mg capsule / CNS stimulants (N)	260	\$92,503	\$355.78	30	\$11.45	\$11.41	\$11.52	0.6%
Vyvanse (lisdexamfetamine) 30 mg capsule / CNS stimulants (N)	203	\$71,013	\$349.82	30	\$11.44	\$11.33	\$11.51	0.6%
Vyvanse (lisdexamfetamine) 70 mg capsule / CNS stimulants (N)	156	\$55,736	\$357.28	30	\$11.52	\$11.43	\$11.53	0.1%
methylphenidate 36 mg/24 hr tablet, extended release / CNS stimulants (Y)	164	\$8,580	\$52.31	36	\$1.07	\$1.08	\$1.07	(0.1%)
Eliquis (apixaban) 2.5 mg tablet / factor Xa inhibitors (Y)	103	\$36,551	\$354.86	42	\$8.74	\$8.71	\$8.73	(0.2%)

Products are only included if 100 or more fills in last month and average cost per unit in reference month was >= \$1.

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > \$1 BY PERCENT CHANGE IN AMOUNT PAID PER UNIT APR 2023 TO JUN 2023 (FFS)

Drug Product Therapeutic Category	Jun 2023 # Claims	Jun 2023 \$ Paid	Jun 2023 Avr. Paid Per Rx	Jun 2023 Avr. Units Per Rx	Apr 2023 Paid Per Unit	May 2023 Paid Per Unit	Jun 2023 Paid Per Unit	Percent Change
dexmethylphenidate 10 mg capsule, extended release / CNS stimulants (Y)	225	\$9,750	\$43.33	30	\$1.08	\$1.07	\$1.08	(0.2%)
QuilliChew ER (methylphenidate) 40 mg/24 hr tablet, chewable, extended release / CNS stimulants (Y)	140	\$51,147	\$365.34	30	\$11.82	\$11.84	\$11.80	(0.2%)

Products are only included if 100 or more fills in last month and average cost per unit in reference month was >= \$1.

New Business

Special Analysis Projects

MISSISSIPPI DIVISION OF MEDICAID

MS-DUR INTERVENTION / EDUCATIONAL INITIATIVE UPDATE

June 2023 - July 2023

Ongoing Intervention(s):

		PPING FOR OP		COMITANT U AND ANTIPS		
Month	Prescribers	Pharms	Month	Prescribers	Benes	
WOITH	Mailed	Mailed	Addressed	WIOIILII	Mailed	Addressed
22-Aug	3	2	5	22-Aug	48	58
22-Sep	2	1	3	22-Sep	49	56
22-Oct	3	2	5	22-Oct	34	39
22-Nov	2	2	4	22-Nov	41	43
22-Dec	3	3	6	22-Dec	27	28
23-Jan	1	1	2	23-Jan	19	19
23-Feb	4	4	8	23-Feb	14	17
23-Mar	4	2	6	23-Mar	16	16
23-Apr	2	2	4	23-Apr	9	10
23-May	6	7	13	23-May	37	40
23-Jun	3	4	7	22-Jun	19	21
23-Jul	1	1	2	22-Jul	4	4

Note: December 2022 - April 2023 mailings, data for all CCOs was not included due to issues receiving encounter claims.

May 2023 - encounter data for MAG incomplete.

June and July 2023 - FFS claims only

PMP Data for Mississippi Medicaid Beneficiaries: Background and Trends

BACKGROUND

The Mississippi Prescription Monitoring Program (MS PMP) is an electronic tracking program managed by the Mississippi Board of Pharmacy (MBOP) to aid practitioners and dispensers in providing proper pharmaceutical care relating to controlled substances. It also serves as a tool for regulatory agencies and authorized law enforcement to identify potential inappropriate use of controlled substance prescription medication. Bamboo Health is the current data warehouse contractor for the MS PMP. The Mississippi Division of Medicaid (DOM) has a Memorandum of Understanding with the MBOP that allows MS-DUR to obtain MS PMP data for all beneficiaries enrolled in Medicaid each month.

Submission or reporting of dispensing information is mandatory and required by the MBOP for any entity dispensing controlled substances in or into the state of Mississippi, except for the dispensing of controlled substance drugs by a veterinarian residing in the State of Mississippi. Dispensing is tracked for all controlled substances listed in Schedule II, III, IV or V and specific noncontrolled substances identified by the MBOP. Currently the only noncontrolled substance required to be reported is gabapentin.

Pharmacies and dispensing practitioners are required to submit data every 24 hours or the next business day. If no dispensing has occurred, a zero report must be submitted for the reporting period.

Challenges to Implementing a State Prescription Drug Monitoring Program

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act was signed into law (Pub. L. No. 115-271) on October 24, 2018, as a bipartisan effort to address the nation's opioid epidemic.² Section 5042(a) of the SUPPORT Act requires all States to establish a qualified prescription drug monitoring program that ensures that providers have access to information about current and previous opioid prescriptions and other controlled substances at the time of an encounter.³

Identifying Patients Longitudinally. In June 2021, the Centers for Medicare & Medicaid Services presented "A Report to Congress: State Challenges and Best Practices Implementing PDMP Requirements Under Section 5042 of the SUPPORT Act". In the report, patient matching was identified as a major problem faced by state programs.

"States identified patient matching as the largest challenge faced by PDMPs across the country. Patients with common names, misspelled names, multiple names, and multiple entries create challenges in patient identification within one system, but even more so across multiple systems. Each State employs its own patient-matching algorithms; as a

result, even contiguous States employ different strategies to match patients who may be dispensed prescriptions for controlled substances across State lines. In fact, patient-matching algorithms vary across the entire PDMP ecosystem, where PDMPs, pharmacy information systems, electronic health records, and other intermediaries apply a different approach to matching and linking patient records. This challenge is compounded by variations in data content, format, and quality collected by pharmacies and clinicians. Different pharmacies throughout the State may not have the same information on a patient, for example, yet each pharmacy reports on that patient to the same PDMP, creating a situation where the PDMP must reconcile multiple records for the same patient to one longitudinal record.¹⁷

A 2016 survey of Maryland providers also reported patient identification as a barrier to effective use of their state PMP.⁵ Among providers who were registered users of the Maryland PMP, 75% reported that multiple IDs for patients was a barrier to using the PMP in their practice.

The accuracy of data related to the drug dispensed (i.e. date prescription is filled, NDC, quantity dispensed, days supply, etc.) are very accurate for transactions reported to the MS PMP. However, in addition to the problems noted in the CMS report, there are some limitations to the MS PMP currently required reporting fields that can affect the accuracy of reports done at the individual patient or prescriber level. MS PMP data are reported to Bamboo Health, the data warehousing agent, using the American Society for Automation in Pharmacy (ASAP) 4.2B format specification. The MBOP specifies which fields are required and not required, but accepted if submitted.

At the current time, Mississippi pharmacies and dispensing practitioners are required to report patient name, address, date of birth and gender. As discussed in the CMS report, the accuracy of these fields is determined by how the information was entered into the pharmacy or medical system submitting the data. Any variations in how these fields were entered by practitioners will affect the ability of the MS PMP system to correctly match claims for an individual patient. The ASAP specification provides for additional fields that can be used to identify patients such as entering driver's license number, social security number and other types of identification. However, these fields are not required and are typically not submitted by practitioners.

Identifying pharmacies and prescribers. Pharmacies and prescribing physicians are identified using DEA numbers that are required fields. Pharmacies are also required to enter their store name, address, and phone. However, the specific name submitted is determined by the pharmacy system performing the data submission and can change over time. The only required prescriber identifier is the DEA number. Prescriber names, phone numbers, and NPI numbers are not required. Although it is not a large problem, when pharmacies enter new prescriptions into their management systems, they occasionally may select the wrong prescriber when inputting prescription data. The management system then provides the DEA number for the prescriber selected. MS-DUR has conducted physician educational mailings related to opioid prescribing and has, on several occasions, received phone calls from providers saying they had not written prescriptions attributed to them.

Classifying payer type. Another challenge affecting MS-DUR retrospective reviews is how the payment source is recorded in data submitted to the MS PMP. The ASAP standards require that pharmacies and dispensing providers classify the payment source as one of the following eight categories: private pay (cash), Medicaid, Medicare, commercial insurance, military installations and VA, workers' compensation, Indian nations, or other. Each pharmacy management system will have a file for storing information about insurance payers and the RXBIN code from the patient's insurance plan is used to identify the payer to be used for payment. Information in this file specifies the type of payer. Medicaid managed care organizations are sometimes classified as "commercial insurer" in these internal databases since this is their primary business. This frequently results in miscoding of payer type in the PMP data.

MS-DUR Procedure for Use of MS-PMP Data

Each month, MS-DUR submits a request file of all beneficiaries enrolled in Medicaid to Bamboo Health's secure file transfer (SFTP) server and later receives an extract file containing all prescriptions filled for persons listed in the request file. These data are evaluated to determine the validity of the claims matched to each beneficiary.

The procedure used by MS-DUR to process extract files received from Bamboo Health includes the following steps:

- imports the records in the extract file,
- excludes prescriptions not filled during the reporting month,
- excludes prescriptions associated with beneficiaries not having full pharmacy benefits (e.g., dual eligibles, family planning waiver, etc.)
- excludes prescriptions for medications not included in the required list of drugs to be reported to MS PMP,
- validates the prescription claims matched to each Medicaid beneficiary, and
- incorporates claims for beneficiaries where the match is considered to be valid to the data files used for DUR reports and research projects.

Validation of the matching of claims to beneficiaries is done by comparing PMP claims and DOM claims for the reporting month. DOM paid claims for PMP monitored drugs are extracted for beneficiaries enrolled during the reporting period and added to the PMP claims received from Bamboo Health. The claims-match for a beneficiary is considered to be valid if:

- All PMP claims coded as paid by Medicaid match a DOM claim,
- All DOM claims match a PMP claim regardless of the payer type coded, excluding cash paid claims.

This report provides an overview of the validation results and prescribing trends for the three-year period July 2019 through June 2022.

RESULTS

Table 1 shows the total number of beneficiary months and how many beneficiary months were associated with DOM claims and PMP claims for drugs required to be reported to the MS PMP. NOTE this table includes data for all beneficiaries enrolled each month BEFORE exclusion of dual eligibles. An individual beneficiary can be enrolled for 1-3 months each quarter and thus the number of beneficiary months is not the same as the number of unique beneficiaries. Figure 1 shows the percentage of beneficiary months where the beneficiary had one or more DOM or PMP claims graphically. Key findings include:

- As will be discussed in greater detail in later results, beneficiaries consistently had more PMP claims than just those paid for by Medicaid.
- The percentage of beneficiary months having PMP claims closely parallels the percentage having DOM claims.
- Both the percentage having PMP claims and the percentage having DOM claims drop significantly at the beginning of COVID but have slowly risen to slightly less than pre-COVID levels.

Table 1: Beneficiary Months* and Claims for reportable Drugs by Quarter (Only includes beneficiaries with full pharmacy benefits)												
					(Quarter of Mon	thly Enrollmen	t				
	2019-Q3	2019-Q4	2020-Q1	2020-Q2	2020-Q3	2020-Q4	2021-Q1	2021-Q2	2021-Q3	2021-Q4	2022-Q1	2022-Q2
Total beneficiary months* with full pharmacy benefits	1,520,509	1,510,975	1,499,919	1,534,067	1,601,344	1,659,227	1,707,310	1,743,675	1,776,821	1,816,829	1,841,816	1,857,358
Llad DOM claims for remembels during**	106,022	102,582	105,599	89,031	98,478	102,279	103,224	108,458	113,424	122,151	122,197	118,678
Had DOM claim for reportable drugs**	7.0%	6.8%	7.0%	5.8%	6.1%	6.2%	6.0%	6.2%	6.4%	6.7%	6.6%	6.4%
Had PMP claim**	121,640	118,754	122,356	105,312	116,086	120,444	121,980	128,266	135,119	146,688	147,702	144,195
	8.0%	7.9%	8.2%	6.9%	7.2%	7.3%	7.1%	7.4%	7.6%	8.1%	8.0%	7.8%

^{*} PMP match validation uses monthly data for all beneficiaries enrolled in Medicaid that month. Individual beneficiaries may have multiple "beneficiary months" in a quarter.

^{*} Includes all DOM data and PMP data before MS-DUR validity check.

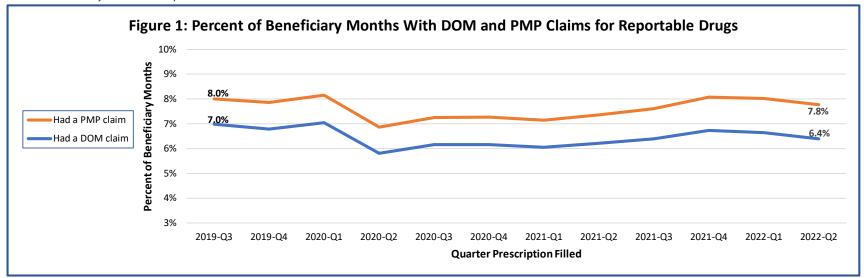


Table 2 shows the number of beneficiary months for beneficiaries with full pharmacy benefits and how many beneficiaries were determined to have a valid match among PMP and DOM claims. The initial data request submitted to Bamboo Health covered the period June 2019 through September 2021. The percentage of beneficiary months considered valid each quarter was slightly under 90% for almost all of this period. Recent monthly requests have resulted in a slightly better match rate. The current rate of beneficiary months being classified as valid runs over 93%. It is important to note that these results indicate that the current patient algorithm being used by the MS PMP system may result in invalid matches for approximately 7% of inquiries.

Table 2: Beneficiary Months* Considered to Have Valid PMP Match by Quarter (Only includes beneficiaries with full pharmacy benefits)												
					C	Quarter of Mon	thly Enrollment	:				
	2019-Q3	2019-Q4	2020-Q1	2020-Q2	2020-Q3	2020-Q4	2021-Q1	2021-Q2	2021-Q3	2021-Q4	2022-Q1	2022-Q2
All beneficiary months* with claims for reportable drugs	121,640	118,754	122,356	105,312	116,086	120,444	121,980	128,266	135,119	146,688	147,702	144,195
Beneficiary months with claims for reportable drugs												
FAILING PMP match validity criteria:												
All DOM claims did not match a PMP claim (if	10,866	11,021	11,111	10,432	11,147	11,396	11,956	8,996	7,562	7,572	7,668	6,733
< 3 all must match; 3+ all but 1 must match)	8.9%	9.3%	9.1%	9.9%	9.6%	9.5%	9.8%	7.0%	5.6%	5.2%	5.2%	4.7%
All PMP Medicaid paid claims did not match a	2,985	2,640	2,513	2,266	2,366	2,833	3,747	4,287	5,449	5,885	5,972	5,424
DOM claim	2.5%	2.2%	2.1%	2.2%	2.0%	2.4%	3.1%	3.3%	4.0%	4.0%	4.0%	3.8%
Beneficiary months with claims AND PMP match	109,336	106,390	109,997	93,678	103,767	107,812	108,766	117,748	125,692	136,850	137,699	135,073
considered VALID	89.9%	89.6%	89.9%	89.0%	89.4%	89.5%	89.2%	91.8%	93.0%	93.3%	93.2%	93.7%

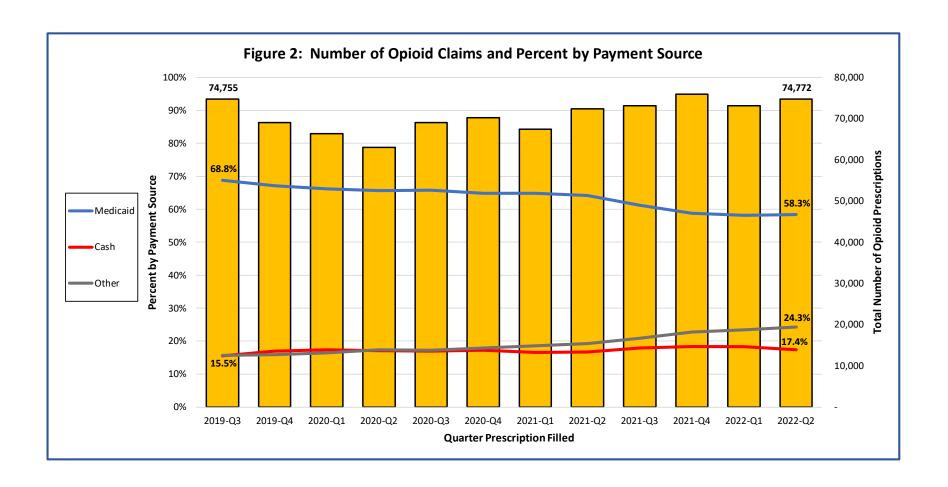
^{*} PMP match validation uses monthly data for all beneficiaries enrolled in Medicaid that month and having full pharmacy benefits. Individual beneficiaries may have multiple "beneficiary months" in a quarter.

Table 3 shows the total number of claims and the percentages paid by Medicaid, cash, and other sources for all reportable drugs and for opioids. Figure 2 shows the results for opioids in a graphic format. As was seen in Table 1, the total number of claims for all reported drugs and for opioids dropped significantly during COVID but has slowly returned to pre-COVID levels. Over the study period, there has been a shift in the payment sources for MS PMP reportable drugs. The percentage of opioid prescriptions paid for by Medicaid has slowly declined from 68.8% in Q3 of 2019 to 58.3% in Q2 of 2022. During this period, there was a slight increase in the percentage of opioid prescriptions paid for with cash (15.5% to 17.4%) and a marked increase in the percentage of prescriptions paid for by other payers (15.7% to 24.3%). As shown in the footnotes for Table 3, in Q2 of 2022, the 24.3% of payments by other sources consisted of 16.6% other insurance, 7.2% unknown payer type, 0.2% Indian nations, 0.2% military/VA, and 0.1% workers' compensation.

Table 3: Reportable Drug Claims and Opioid Claims* by Quarter (Only includes claims for beneficiaries with full pharmacy benefits)												
		Quarter of Monthly Enrollment										
	2019-Q3	2019-Q4	2020-Q1	2020-Q2	2020-Q3	2020-Q4	2021-Q1	2021-Q2	2021-Q3	2021-Q4	2022-Q1	2022-Q2
Claims for all reportable drugs												
Total	206,072	203,827	203,463	179,616	194,577	201,772	200,384	208,317	212,972	223,442	221,069	217,053
Daid hu Madisaid	169,697	167,530	166,988	145,190	157,161	162,592	162,085	164,542	163,809	168,319	166,587	161,992
Paid by Medicaid	82.3%	82.2%	82.1%	80.8%	80.8%	80.6%	80.9%	79.0%	76.9%	75.3%	75.4%	74.6%
Deid ferwith and	16,653	17,086	17,433	15,892	17,241	17,657	16,948	18,892	20,658	22,342	21,964	21,217
Paid for with cash	8.1%	8.4%	8.6%	8.8%	8.9%	8.8%	8.5%	9.1%	9.7%	10.0%	9.9%	9.8%
Daid hu athar incurance ar unknown accurac**	19,722	19,211	19,042	18,534	20,175	21,523	21,351	24,883	28,505	32,781	32,518	33,844
Paid by other insurance or unknown source**	9.6%	9.4%	9.4%	10.3%	10.4%	10.7%	10.7%	11.9%	13.4%	14.7%	14.7%	15.6%
Opioid claims				<u> </u>					<u>.</u>	<u> </u>		
Total	74,755	69,023	66,320	63,039	69,020	70,174	67,384	72,390	73,119	75,916	73,134	74,772
Paid by Medicaid	51,454	46,357	43,881	41,353	45,412	45,524	43,733	46,409	44,744	44,626	42,529	43,618
Paid by Medicaid	68.8%	67.2%	66.2%	65.6%	65.8%	64.9%	64.9%	64.1%	61.2%	58.8%	58.2%	58.3%
Deid ferrorish each	11,578	11,740	11,551	10,757	11,746	12,127	11,125	12,080	13,086	13,972	13,433	12,995
Paid for with cash	15.5%	17.0%	17.4%	17.1%	17.0%	17.3%	16.5%	16.7%	17.9%	18.4%	18.4%	17.4%
Paid by other insurance or unknown source**	11,723	10,926	10,888	10,929	11,862	12,523	12,526	13,901	15,289	17,318	17,172	18,159
raid by other insurance of unknown source	15.7%	15.8%	16.4%	17.3%	17.2%	17.8%	18.6%	19.2%	20.9%	22.8%	23.5%	24.3%

^{*} Includes all claims paid by DOM and all non-Medicaid PMP claims for beneficiaries with full pharmacy benefits and valid PMP match.

^{**} Includes, in order of percentage in Q2022-02, insurance (16.6%), unknown (7.2%), Indian nation (0.2%), military/VA (0.1%), and workers' comp (0.1%).



CONCLUSIONS

The major conclusions from our analysis of the PMP data received from requests made about beneficiaries enrolled each month include:

- Approximately 7% of patient inquiries each month resulted in what were considered to be invalid or questionable linkages to claims.
- Except for the period during the height of COVID, the total number of claims for reportable drugs and for opioids has remained somewhat constant during the three-year period examined.
- There has been a shift in payment source for these prescription claims with a decrease in payments by Medicaid and an almost equally large increase in payment by other payers.
- The use of cash payments has increased slightly among Medicaid beneficiaries, but the primary shift has been to other types of insurance.
- Approximately 42% of opioid claims for individuals enrolled in Medicaid are paid by a source other than Medicaid.

This last conclusion is perhaps one of the most significant with respect to attempts to make state Medicaid agencies accountable for opioid use among their beneficiaries. With only 58% of opioid prescriptions being processed by Medicaid, it is extremely difficult, if not impossible, for Medicaid agencies to adequately control opioid use among their beneficiaries using traditional prospective and retrospective DUR activities. It is important for state Medicaid agencies to have consistent access to PMP data for DUR purposes. Without these data, abuse detection and intervention programs will only have knowledge about 58% of opioid claims.

RECOMMENDATIONS

- DOM is encouraged to use PMP data cautiously to identify potential misuse. Invalid linkages of claims to beneficiaries and errors in recording prescriber identification can contribute to false positives in programs designed to detect misuse. Retrospective DUR reports can use PMP to better identify patients potentially at risk, but DOM will need to evaluate each case carefully to avoid acting on false positives.
- 2. DOM and others should encourage MS PMP to include unique patient identifiers as required fields, if possible, to reduce the problems with patient linkages to claims.

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Updated Opioid Guidelines and Utilization Trends

BACKGROUND

As the opioid epidemic spread across the US, opioid dispensing rates continued to climb throughout the early 2000s. In 2012, annual opioid dispensing in the US reached its highest point with over 255 million prescriptions dispensed that year equating to a rate of 81.3 prescriptions per 100 persons. Beginning 2013, the annual dispensing rate across the US began decreasing and continued this steady trajectory through 2020.1 Throughout that entire period, however, Mississippi continued to have higher opioid dispensing rates compared to the national average.¹ To help combat the opioid epidemic, federal and state agencies across the US enacted policies and regulations with the goal of curtailing inappropriate opioid prescribing. In 2016 the Centers for Disease Control and Prevention (CDC) released their Guideline for Prescribing Opioids for Chronic Pain.² This guideline, along with the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)³, served as the cornerstone in the development of opioid initiatives by state Medicaid programs across the US. The Mississippi Division of Medicaid (DOM) was one of the first Medicaid programs in the nation to address the CDC's Guideline and implemented four opioid initiatives in 2019 to align with the Guideline (Figure 1). In advance of implementing the opioid initiatives in 2019, MS-DUR conducted multiple provider educational mailings around opioid prescribing to prepare prescribers for these upcoming changes. An additional mechanism utilized by DOM to manage opioid prescribing is quantity limits in the Universal Preferred Drug List.⁴ (see Attachment A)

FIGURE 1: Mississippi Medicaid Opioid Initiatives

- 1. New opioid prescriptions (first opioid fill within 90 days) for opiate-naïve patients must be for short-acting (SA) opioid.*
- 2. For new starts (first opioid fill within 90 days) a SA opioid can be filled for a maximum of two 7-day supplies in a 30 day period. Use of SA opioids for longer periods will require a manual PA.*
- 3. Any prescriptions (whether individual and/or cumulative daily sum of all prescriptions for the patient) with a Morphine Equivalent Daily Dose (MEDD) of ≥ 90 will require a manual PA with documentation that the benefits outweigh the risks and that the patient has been counseled about the risks of overdose and death.*

(* Patients with a diagnosis of cancer or sickle-cell disease are exempt from the 3 edits above.)

4. Concomitant use of opioids and benzodiazepines should require a manual PA.

To allow for the short-term treatment of pre-procedure anxiety or other short-term anxiety, a prescription for up to 2 units of a solid oral dosage form of a benzodiazepine can be overridden at the point-of-sale by the dispensing pharmacist based upon his/her clinical judgment and consultation with the prescriber. A maximum of two, 2-unit prescriptions may be overridden in a 60 day period. Prospective DUR billing directions can be found on DOM's website.

In the fall of 2022, the CDC issued an update to their Guideline for Prescribing Opioids for Chronic Pain.⁵ Figure 2 displays a crosswalk comparing the 2016 and 2022 Guidelines.

FIGURE 2: CDC Opioid Guideline Crosswalk

	CDC Opioid Guidelin	ne Crosswalk
	2016 CDC Guideline*	2022 CDC Guideline**
	Determining Whether or Not to I	
1	Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).	nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider opioid therapy for acute pain if benefits are anticipated to outweigh risks to the patient. Before prescribing opioid therapy for acute pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy (recommendation category: B; evidence type: 3).
2	Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate (recommendation category: A, evidence type 3).	Nonopioid therapies are preferred for subacute and chronic pain. Clinicians should maximize use of nonpharmacologic and nonopioid pharmacologic therapies as appropriate for the specific condition and patient and only consider initiating opioid therapy if expected benefits for pain and function are anticipated to outweigh risks to the patient. Before starting opioid therapy for subacute or chronic pain, clinicians should discuss with patients the realistic benefits and known risks of opioid therapy, should work with patients to establish treatment goals for pain and function, and should consider how opioid therapy will be discontinued if benefits do not outweigh risks (recommendation category: A; evidence type: 2).
	Selecting Opioids and Determ	
3	When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long acting (ER/LA) opioids (recommendation category: A, evidence type: 4).	When starting opioid therapy for acute, subacute, or chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release and long-acting (ER/LA) opioids (recommendation category: A; evidence type: 4).
4	When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to =50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to =90 MME/day or carefully justify a decision to titrate dosage to =90 MME/day (recommendation category: A, evidence type: 3).	dosage, should carefully evaluate individual benefits and risks when

5	Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (recommendation category: A, evidence type: 3).	For patients already receiving opioid therapy, clinicians should carefully weigh benefits and risks and exercise care when changing opioid dosage. If benefits outweigh risks of continued opioid therapy, clinicians should work closely with patients to optimize nonopioid therapies while continuing opioid therapy. If benefits do not outweigh risks of continued opioid therapy, clinicians should optimize other therapies and work closely with patients to gradually taper to lower dosages or, if warranted based on the individual circumstances of the patient, appropriately taper and discontinue opioids. Unless there are indications of a life-threatening issue such as warning signs of impending overdose (e.g., confusion, sedation, or slurred speech), opioid therapy should not be discontinued abruptly, and clinicians should not rapidly reduce opioid dosages from higher dosages (recommendation category: B; evidence type: 4).
	Deciding Duration of initial Opioid Prescri	 intion and Conducting Follow-Up
	Long-term opioid use often begins with treatment of acute pain.	When opioids are needed for acute pain, clinicians should prescribe
6	When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should	no greater quantity than needed for the expected duration of pain severe enough to require opioids (recommendation category: A; evidence type: 4).
7	Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids (recommendation category: A, evidence type: 4).	Clinicians should evaluate benefits and risks with patients within 1–4 weeks of starting opioid therapy for subacute or chronic pain or of dosage escalation. Clinicians should regularly reevaluate benefits and risks of continued opioid therapy with patients (recommendation category: A; evidence type: 4).
	Assessing Risk and Addressing Pote	ntial Harms of Opioid Use
8	Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (=50 MME/day), or concurrent benzodiazepine use, are present (recommendation category: A, evidence type: 4).	Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk for opioid-related harms and discuss risk with patients. Clinicians should work with patients to incorporate into the management plan strategies to mitigate risk, including offering naloxone (recommendation category: A; evidence type: 4).

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		Clinicians should review the patient's history of controlled substance	When prescribing initial opioid therapy for acute, subacute, or
		prescriptions using state prescription drug monitoring program	chronic pain, and periodically during opioid therapy for chronic pain,
		(PDMP) data to determine whether the patient is receiving opioid	clinicians should review the patient's history of controlled substance
	9	dosages or dangerous combinations that put him or her at high risk	prescriptions using state prescription drug monitoring program
	9	for overdose. Clinicians should review PDMP data when starting	(PDMP) data to determine whether the patient is receiving opioid
		opioid therapy for chronic pain and periodically during opioid therapy	dosages or combinations that put the patient at high risk for
		for chronic pain, ranging from every prescription to every 3 months	overdose (recommendation category: B; evidence type: 4).
		(recommendation category: A, evidence type: 4).	
		When prescribing opioids for chronic pain, clinicians should use urine	When prescribing opioids for subacute or chronic pain, clinicians
		drug testing before starting opioid therapy and consider urine drug	should consider the benefits and risks of toxicology testing to assess
	10	testing at least annually to assess for prescribed medications as well	for prescribed medications as well as other prescribed and
		as other controlled prescription drugs and illicit drugs	nonprescribed controlled substances (recommendation category: B;
		(recommendation category: B, evidence type: 4).	evidence type: 4).
		Clinicians should avoid prescribing opioid pain medication and	Clinicians should use particular caution when prescribing opioid pain
		benzodiazepines concurrently whenever possible (recommendation	medication and benzodiazepines concurrently and consider whether
	11	category: A, evidence type: 3).	benefits outweigh risks of concurrent prescribing of opioids and other
			central nervous system depressants (recommendation category: B;
			evidence type: 3).
		Clinicians should offer or arrange evidence-based treatment (usually	Clinicians should offer or arrange treatment with evidence-based
		medication-assisted treatment with buprenorphine or methadone in	medications to treat patients with opioid use disorder. Detoxification
	12	combination with behavioral therapies) for patients with opioid use	on its own, without medications for opioid use disorder, is not
	12	disorder (recommendation category: A, evidence type: 2).	recommended for opioid use disorder because of increased risks for
			resuming drug use, overdose, and overdose death (recommendation
L			category: A; evidence type: 1).

Notes: Recommendation categories (on basis of evidence type, balance between desirable and undesirable effects, values and preferences, and resource allocation [cost]).

Category A recommendation: Applies to all persons; most patients should receive the recommended course of action.

· Category B recommendation: Individual decision-making needed; different choices will be appropriate for different patients. Clinicians help patients arrive at a decision consistent with patient values and preferences and specific clinical situations.

Evidence types: (on basis of study design and as a function of limitations in study design or implementation, imprecision of estimates, variability in findings, indirectness of evidence, publication bias, magnitude of treatment effects, dose-response gradient, and constellation of plausible biases that could change effects).

- Type 1 evidence: Randomized clinical trials or overwhelming evidence from observational studies.
- · Type 2 evidence: Randomized clinical trials with important limitations, or exceptionally strong evidence from observational studies.
- · Type 3 evidence: Observational studies or randomized clinical trials with notable limitations.
- · Type 4 evidence: Clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations.

^{*} Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

^{**} Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

Rationale noted by the CDC for the guideline update include: evidence on the misapplication of the 2016 Guideline, risk/benefits of different opioid tapering strategies, opioid access challenges for patients, abrupt discontinuation of opioids, new data comparing the effectiveness of opioid and nonopioid medications in the treatment of long-term pain, characteristics of initial opioid prescribing associated with subsequent long-term use, and data showing the small number of opioids used for postoperative pain compared to the quantities prescribed.

The goal of this project is to describe recent opioid prescribing trends among Medicaid beneficiaries and determine whether any changes to DOM's policies related to opioids should be considered in light of the recent CDC Guideline update.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid administrative claims data from January 2019 to June 2022. The analysis included data from the Fee-for-Service (FFS) program and the Coordinated Care Organizations (CCOs) which include Magnolia Health (MAG), Molina Healthcare (MOL), and UnitedHealthcare (UHC). All opioid claims during the study period were identified in pharmacy claims data and monthly trends in prescription-related factors were analyzed. All opioid prescriptions were analyzed and classified as short-acting or long-acting opioids based and morphine equivalent daily dosing (MEDD) was calculated. The first prescription was identified as the index opioid prescription. Beneficiaries were identified as new starts if they did not have an opioid prescription in the 90-day period prior to the index opioid prescription. Opioid prescriptions for beneficiaries with a diagnosis for cancer or sickle cell disease from January 2018 to June 2022 were excluded from all analyses except where noted.

RESULTS

A total of 151,165 beneficiaries, excluding those with a cancer or sickle cell diagnosis, had prescription claims for opioids between January 1, 2019 and June 30, 2022. The majority of those with opioid claims were Black (55%), female (72.5%), and were 18-50 years of age (60.8%). Magnolia had the most beneficiaries with opioid claims during the study period followed by UnitedHealthcare. (Table 1)

TABLE 1. Demographics of Beneficiaries with Opioid Prescription Claims	
in Mississippi Medicaid	
January 1, 2019 - June 30, 2022	

		Number of beneficiaries	Percentage
Total		151,165	100.0%
	White	56,582	37.4%
Race	Black	83,164	55.0%
Nace	Hispanic	1,763	1.2%
	Other	9,656	6.4%
Gender*	Male	41,501	27.5%
Gender	Female	109,661	72.5%
	0-17	41,215	27.3%
	18-30	52,870	35.0%
Age	31-50	38,952	25.8%
	51-64	18,007	11.9%
	65+	121	0.1%
	FFS	32,169	21.3%
Plan	UHC	46,549	30.8%
rian	MAG	49,013	32.4%
	MOL	23,434	15.5%

Notes: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina;

The plan and age of each beneficiary was calculated based on the first date of any opioid prescription claim during the study period.

Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from January 2018 to June 2022 were excluded.

From Table 2:

- As the number of Medicaid beneficiaries with full pharmacy benefits grew, the percentage of those with opioid claims slowly decreased after the opioid initiatives were implemented to a mean of 1.9% monthly.
- The first opioid initiative implemented states that **New opioid prescriptions for opiate- naïve patients must be for short-acting (SA) opioids.** Table 2 shows that **98.6%** of new starts after implementation of the opioid initiatives were for short-acting opioids. This percentage was the same in the months preceding the implementation of the opioid initiatives. It should be noted that MS-DUR began provider education on the new opioid initiatives well before implementation occurred.

^{* 3} beneficiaries had missing variable data.

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2021-04 583,252 11,150 1.9% 12,655 5,100 40.3% 5,026 98.5%	
2021-05 587,829 11,076 1.9% 12,375 5,032 40.7% 4,975 98.9% 5	-
2021-06 592,735 11,603 2.0% 13,212 5,338 40.4% 5,258 98.5% {	
2021-07 596,945 11,110 1.9% 12,616 5,015 39.8% 4,953 98.8% 2021-08 601,415 10,581 1.8% 11,865 4,627 39.0% 4,569 98.7%	
2021-08 601,415 10,581 1.8% 11,865 4,627 39.0% 4,569 98.7% 5001-09 604,914 11,039 1.8% 12,426 5,056 40.7% 4,998 98.9% 5001,415 10,581 1.8% 501,415 10,581	
2021-10 608,303 11,017 1.8% 12,381 5,074 41.0% 5,007 98.7%	
2021-10 006,505 11,017 1.8% 12,581 3,074 41.0% 3,007 98.7% C	
2021-12 614,320 10,831 1.8% 12,355 4,851 39.3% 4,795 98.8% 5	
2022-01 617,905 10,174 1.6% 11,416 4,500 39.4% 4,432 98.5%	
2022-02 620,177 10,087 1.6% 11,188 4,483 40.1% 4,413 98.4%	
2022-03 622,986 11,030 1.8% 12,530 5,279 42.1% 5,188 98.3% 9	
2022-04 625,341 10,729 1.7% 11,984 5,042 42.1% 4,958 98.3% 8	1.6%
2022-05 627,914 10,642 1.7% 11,939 4,941 41.4% 4,864 98.4%	1.6%
2022-06 630,303 11,004 1.7% 12,364 5,178 41.9% 5,092 98.3%	1.6% 1.7% 1.7%

^{*}Exclusion: beneficiaries without full pharmacy claims or enrolled in Medicare and Medicaid

Note: Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from January 2018 to June 2022 were excluded.

Red line indicates when Medicaid Opioid Initiatives were implemented.

From Table 3:

- Initiative #2 states, For new starts (first opioid fill within 90 days) a SA opioid can be filled for a maximum of two 7-day supplies in a 30 day period.
- After the implementation of the opioid initiatives, 97.1% of SA opioid new start claims were for ≤ 7 days which is a substantial change compared to 87.6% during the period prior to implementation of the opioid initiatives.

TABLE 3. Trends in Days Supply Prescribed to New Starts of Short-Acting (SA) Opioids in Mississippi Medicaid January 1, 2019 - June 30, 2022

	Days supply filled					Percentage of	
Month filled	New starts of SA opioid fills	Percentage	new starts exceeding fill				
		1 to 7	8 to 15	16 to 29	30+	limit*	
2019-01	5,735	85.3%	7.9%	2.0%	4.8%	14.7%	
2019-02	5,015	84.5%	8.0%	2.4%	5.0%	15.5%	
2019-03	5,537	85.8%	8.2%	2.0%	4.1%	14.2%	
2019-04	5,676	85.7%	7.9%	2.1%	4.3%	14.3%	
2019-05	5,451	86.6%	7.6%	1.6%	4.1%	13.4%	
2019-06	5,461	86.2%	7.9%	2.0%	4.0%	13.9%	
2019-07	5,928	87.9%	7.1%	1.5%	3.5%	12.1%	
2019-08	5,450	98.3%	0.8%	0.3%	0.6%	1.7%	
2019-09	5,110	97.2%	1.0%	0.5%	1.2%	2.8%	
2019-10	5,294	96.6%	1.2%	0.6%	1.7%	3.4%	
2019-11	4,664	96.9%	1.0%	0.4%	1.8%	3.2%	
2019-12	4,790	97.5%	0.7%	0.4%	1.3%	2.5%	
2020-01	5,048	97.0%	1.0%	0.5%	1.5%	3.1%	
2020-02	4,645	96.6%	1.0%	0.5%	1.8%	3.4%	
2020-03	4,045	95.8%	1.1%	0.9%	2.2%	4.2%	
2020-04	2,835	95.5%	1.2%	1.0%	2.4%	4.5%	
2020-05	3,980	96.9%	1.1%	0.3%	1.7%	3.1%	
2020-06	4,998	97.8%	0.8%	0.2%	1.2%	2.2%	
2020-07	4,917	97.7%	0.8%	0.2%	1.2%	2.3%	
2020-08	4,880	98.0%	0.8%	0.2%	1.0%	2.1%	
2020-09	4,938	97.6%	0.8%	0.3%	1.3%	2.4%	
2020-10	5,077	97.5%	0.7%	0.5%	1.2%	2.5%	
2020-11	4,732	97.3%	0.8%	0.5%	1.4%	2.8%	
2020-12	4,731	96.9%	0.7%	0.6%	1.9%	3.1%	
2021-01	4,625	96.9%	0.9%	0.5%	1.7%	3.2%	
2021-02	4,232	96.5%	1.1%	0.6%	1.9%	3.5%	
2021-03	5,203	97.1%	0.9%	0.4%	1.6%	2.9%	
2021-04	5,026	97.2%	0.9%	0.5%	1.4%	2.8%	
2021-05	4,975	97.5%	0.6%	0.4%	1.4%	2.5%	
2021-06	5,258	97.6%	0.8%	0.3%	1.3%	2.4%	
2021-07	4,953	97.6%	0.6%	0.4%	1.4%	2.5%	
2021-08	4,569	97.3%	0.9%	0.4%	1.4%	2.7%	
2021-09	4,998	97.4%	0.7%	0.4%	1.5%	2.7%	
2021-10	5,007	97.4%	0.8%	0.4%	1.4%	2.7%	
2021-11	4,726	97.5%	0.8%	0.4%	1.3%	2.6%	
2021-12	4,795	97.4%	0.9%	0.4%	1.4%	2.6%	
2022-01	4,432	97.6%	0.6%	0.3%	1.5%	2.4%	
2022-02	4,413	96.8%	0.9%	0.6%	1.8%	3.3%	
2022-03	5,188	95.7%	0.9%	0.9%	2.5%	4.4%	
2022-04	4,958	95.9%	0.9%	0.7%	2.4%	4.1%	
2022-05	4,864	97.1%	0.7%	0.5%	1.8%	2.9%	
2022-06	5,092	96.9%	0.9%	0.4%	1.8%	3.1%	

Note: Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from January 2018 to June 2022 were excluded.

Red line indicates when Medicaid Opioid Initiatives were implemented.

^{* &#}x27;Fill limit' was determined based on PA edit specification (August 2019) of maximum two 7-day fills for new starts of SA opioids. Benes represented in this category either had more than two 7-day fills or had fills for more than 7 days of supply.

Table 4 displays trends in morphine equivalent daily dosing (MEDD) and includes all Medicaid opioid claims for those with full pharmacy benefits during the study period excluding those with a cancer or sickle cell diagnosis. MEDD is a term that can be interchanged with morphine milligram equivalents (MME); however, MEDD is the terminology used by DOM. The CDC Opioid Guideline lists a vast body of evidence supporting the dose-dependent association between MEDD and an increased risk in the development of opioid use disorder (OUD) and an increased risk of overdose deaths.⁵ Furthermore, there is also little evidence of added benefit in reducing pain symptoms at doses of above 50 MEDD.⁵

MEDD was calculated for individual and/or cumulative opioid prescription claims filled through Medicaid for beneficiaries during the study period. Beneficiaries with MEDD \geq 90 mg were flagged. In instances where the High MEDD (\geq 90 mg) event spanned over multiple months for a beneficiary, the High MEDD was attributed to the month in which the first day of high MEDD use occurred.

- Initiative #3 states, Any prescriptions (whether individual and/or cumulative daily sum of all prescriptions for the patient) with a Morphine Equivalent Daily Dose (MEDD) of ≥ 90 will require a manual PA.
- The percentage of beneficiaries with MEDD \geq 90 mg decreased to a mean of 1.1% monthly after the implementation of the Opioid Initiatives.
- Again, this metric did not change substantially compared to the period just prior to implementation. This is due in part to the fact that in September 2016, MS-DUR began sending out targeted monthly educational letters to prescribers with patients having a high MEDD. This mailing continued until the implementation of the opioid initiatives.

TABLE 4. Trends in High Morphine Equivalent Daily Dose (MEDD)

Among Medicaid Beneficiaries

January 1, 2019 - June 30, 2022

Month filled	Total opioid Rx	Number of benes with opioids	Number of benes with MEDD ≥ 90 mg*	Percentage of benes with MEDD ≥ 90 mg*
2019-01	16,263	14,287	155	1.1%
2019-02	14,948	13,328	244	1.8%
2019-03	15,373	13,722	267	1.9%
2019-04	15,466	13,699	212	1.5%
2019-05	15,529	13,571	165	1.2%
2019-06	14,555	13,128	149	1.1%
2019-07	15,823	13,903	165	1.2%
2019-08	13,975	12,344	113	0.9%
2019-09	13,284	11,911	94	0.8%
2019-10	13,651	12,069	117	1.0%
2019-11	12,239	11,058	110	1.0%
2019-12	12,352	11.069	133	1.2%
2020-01	12.839	11,385	112	1.0%
2020-02	11.668	10.541	90	0.9%
2020-03	11,271	9,982	120	1.2%
2020-04	9,791	8,628	85	1.0%
2020-05	11,020	9.840	114	1.2%
2020-06	12,494	11,024	90	0.8%
2020-07	12,524	11,073	116	1.0%
2020-08	12,295	10,985	104	0.9%
2020-09	12,397	11,107	93	0.8%
2020-10	12,776	11,348	121	1.1%
2020-11	12,066	10,853	94	0.9%
2020-12	12,547	10,986	144	1.3%
2021-01	11.809	10,576	98	0.9%
2021-02	11,024	10,065	63	0.6%
2021-03	12,938	11,469	138	1.2%
2021-04	12,655	11,150	105	0.9%
2021-05	12,375	11,076	143	1.3%
2021-06	13.212	11.603	126	1.1%
2021-07	12,616	11,110	148	1.3%
2021-08	11,865	10,581	109	1.0%
2021-09	12,426	11,039	111	1.0%
2021-10	12,381	11,017	123	1.1%
2021-11	11,994	10,705	108	1.0%
2021-12	12,355	10,831	157	1.4%
2022-01	11,416	10,174	106	1.0%
2022-02	11,188	10,087	86	0.9%
2022-03	12,530	11,030	166	1.5%
2022-03	11,984	10,729	140	1.3%
2022-04	11,984	10,729	146	1.4%
2022-05	12,364	11,004	137	1.2%

Note: Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from June 2018 to June 2022 were excluded.

Red line indicates when Medicaid Opioid Initiatives were implemented.

^{*}Beneficiaries with individual and/or cumulative daily sum of all opioid prescriptions with high MEDD (≥ 90 mg) were identified and attributed to the month of the first day of high MEDD use.

Table 5 displays trends in the concomitant use of benzodiazepines and opioids. Concomitant use of benzodiazepines and opioids was defined as at least one overlapping day of use between the drug classes. Concomitant use for the beneficiary was attributed to the month of first day of overlapping use. For this analysis, all opioid prescription claims were included. The was no exclusion for cancer and sickle cell diagnosis.

- Initiative #4 states, Concomitant use of opioids and benzodiazepines should require a manual PA.
- The percentage of beneficiaries with concomitant benzodiazepine and opioid use has dropped to a mean of 3.7% since the implementation of the opioid initiatives.
- Similar to the approach taken with High MEDD prescribing, MS-DUR began a monthly
 educational mailing in September 2017 targeting prescribers with patients receiving
 benzodiazepines and opioids concomitantly. This mailing also continued until the
 implementation of the opioid initiatives.

In May 2021, MS-DUR began a new mailing targeting the concomitant prescribing of opioids and antipsychotics among Medicaid beneficiaries. This mailing was initiated due requirements that were added to CMS' Minimum Standards in Medicaid State Drug Utilization Review. The intention of the mailing is to encourage the coordination of care for both psychiatric and pain disorders in beneficiaries taking antipsychotic and opioid medications concurrently. Table 6 displays those trends.

- This mailing was not intended to decrease the concomitant prescribing of antipsychotics and opioids. Rather, it was intended to make providers aware and encourage the coordination of care for psychiatric and pain disorders.
- There was no decrease in the concomitant prescribing of antipsychotics and opioids after the initiation of the educational mailing.

TABLE 5. Trends in Concomitant Use of Benzodiazepines and Opioids
Among Medicaid Beneficiaries
January 1, 2019 - June 30, 2022

			Concomita	nt BZD Use
Month filled	Total opioid Rx	Number of benes with opioids	Number of benes with concomitant BZD use	Percentage of benes with concomitant BZD use
2019-01	20,102	17,422	1,289	7.4%
2019-02	18,577	16,357	1,158	7.1%
2019-03	19,050	16,758	1,144	6.8%
2019-04	19,128	16,700	1,095	6.6%
2019-05	19,207	16,581	1,021	6.2%
2019-06	17,946	15,985	904	5.7%
2019-07	19,474	16,885	971	5.8%
2019-08	17,401	15,124	652	4.3%
2019-09	16,516	14,624	626	4.3%
2019-10	17,017	14,807	605	4.1%
2019-11	15,369	13,662	524	3.8%
2019-12	15,559	13,696	452	3.3%
2020-01	16,148	14,098	540	3.8%
2020-02	14,752	13,148	482	3.7%
2020-03	14,371	12,511	468	3.7%
2020-04	12,724	11,020	481	4.4%
2020-05	14,093	12,390	499	4.0%
2020-06	15,694	13,648	539	3.9%
2020-07	15,717	13,720	530	3.9%
2020-08	15,402	13,578	502	3.7%
2020-09	15,461	13,701	487	3.6%
2020-10	15,946	13,963	489	3.5%
2020-11	14,982	13,313	480	3.6%
2020-12	15,632	13,502	458	3.4%
2021-01	14,758	13,062	474	3.6%
2021-02	13,810	12,447	452	3.6%
2021-03	16,079	14,054	464	3.3%
2021-04	15,642	13,625	515	3.8%
2021-05	15,355	13,558	497	3.7%
2021-06	16,311	14,136	539	3.8%
2021-07	15,620	13,557	509	3.8%
2021-08	14,655	12,909	499	3.9%
2021-09	15,262	13,398	482	3.6%
2021-10	15,278	13,418	504	3.8%
2021-11	14,787	13,015	483	3.7%
2021-12	15,239	13,150	513	3.9%
2022-01	14,081	12,391	496	4.0%
2022-02	13,771	12,270	445	3.6%
2022-03	15,231	13,249	459	3.5%
2022-04	14,682	12,957	500	3.9%
2022-05	14,517	12,819	457	3.6%
2022-06	14,966	13,161	504	3.8%

Note: Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from January 2018 to June 2022 were **NOT** excluded.

Red line indicates when Medicaid Opioid Initiatives were implemented.

TABLE 6. Trends in Concomitant Use of Antipsychotics and Opioids
Among Medicaid Beneficiaries
January 1, 2019 - June 30, 2022

			Concomitant Antipsychotic U	
Month filled	Total opioid Rx	Number of benes with opioids	Number of benes with concomitant antipsychotic use	Percentage of benes with concomitant antipsychotic use
2019-01	20,102	17,422	816	4.7%
2019-02	18,577	16,357	865	5.3%
2019-03	19,050	16,758	830	5.0%
2019-04	19,128	16,700	899	5.4%
2019-05	19,207	16,581	894	5.4%
2019-06	17,946	15,985	864	5.4%
2019-07	19,474	16,885	896	5.3%
2019-08	17,401	15,124	801	5.3%
2019-09	16,516	14,624	818	5.6%
2019-10	17,017	14,807	775	5.2%
2019-11	15,369	13,662	704	5.2%
2019-12	15,559	13,696	686	5.0%
2020-01	16,148	14,098	758	5.4%
2020-02	14,752	13,148	661	5.0%
2020-03	14,371	12,511	677	5.4%
2020-04	12,724	11,020	625	5.7%
2020-05	14,093	12,390	701	5.7%
2020-06	15,694	13,648	751	5.5%
2020-07	15,717	13,720	714	5.2%
2020-08	15,402	13,578	704	5.2%
2020-09	15,461	13,701	706	5.2%
2020-10	15,946	13,963	707	5.1%
2020-11	14,982	13,313	715	5.4%
2020-12	15,632	13,502	706	5.2%
2021-01	14,758	13,062	777	5.9%
2021-02	13,810	12,447	691	5.6%
2021-03	16,079	14,054	749	5.3%
2021-04	15,642	13,625	816	6.0%
2021-05	15,355	13,558	758	5.6%
2021-06	16,311	14,136	814	5.8%
2021-07	15,620	13,557	748	5.5%
2021-08	14,655	12,909	794	6.2%
2021-09	15,262	13,398	805	6.0%
2021-10	15,278	13,418	738	5.5%
2021-11	14,787	13,015	745	5.7%
2021-12	15,239	13,150	745	5.7%
2022-01	14,081	12,391	717	5.8%
2022-02	13,771	12,270	673	5.5%
2022-03	15,231	13,249	759	5.7%
2022-04	14,682	12,957	698	5.4%
2022-05	14,517	12,819	721	5.6%
2022-06	14,966	13,161	715	5.4%

Note: Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from January 2018 to June 2022 were **NOT** excluded.

Red line indicates when Medicaid Opioid Initiatives were implemented.

Blue line indicates when the Concomitant Opioids and Antipsychotics mailing began.

CONCLUSIONS

Recognizing the need to establish a national guideline on pain management to combat the opioid epidemic, the CDC issued guidance in 2016 for the prescribing of opioids for chronic pain. This guidance ushered in sweeping regulatory and policy changes across the US targeting opioid prescribing. In 2019, Mississippi Medicaid implemented their Opioid Initiatives based on the CDC's recommendations and the SUPPORT Act requirements. Criteria implemented by DOM effectively altered prescribing patterns to comply with the Opioid Initiatives. Medicaid also utilizes quantity limits to manage opioid use, however, little evidence supports the use of quantity limits. An alternative approach to using quantity limits could be the use of cumulative MEDD limits. With the CDC's updated 2022 Guideline's purpose to 'provide voluntary clinical practice recommendations for clinicians that should not be used as inflexible standards of care,' DOM should reevaluate their opioid prescribing guidelines. The challenge is to find a regulatory balance that encourages appropriate prescribing of opioids without restricting access to these medications for patients with legitimate needs.

RECOMMENDATIONS

- DOM is encouraged to seek input from the DUR Board on current Medicaid policies related to opioid prescribing and the updated 2022 CDC Guideline for Prescribing Opioids in Chronic Pain.
- 2. DOM is encouraged to explore the possibility of replacing quantity limit criteria for opioids with cumulative MEDD criteria.



MISSISSIPPI DIVISION OF MEDICAID UNIVERSAL PREFERRED DRUG LIST

EFFECTIVE 09/01/2023 Version 2023.7 Updated:08/23/2023

(For All Medicaid, MSCAN and CHIP Beneficiaries)

Gainwell Technologies' DUR+ process is a proprietary electronic prior authorization system used for Medicaid fee for service claims. MSCAN plans may/may not -have electronic PA functionality. However, they must adhere to Medicaid's PA criteria.

HERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
	SHORT ACTING DUR+		
NALGESICS, OPIOID-	acetaminophen/codeine benzhydrocodone/APAP codeine dihydrocodeine/APAP/caffeine ENDOCET (oxycodone/APAP) hydrocodone/APAP hydromorphone morphine oxycodone capsules oxycodone liquid oxycodone liquid oxycodone/APAP oxycodone/APAP oxycodone/apaprin oxycodone/ibuprofen pentazocine/APAP tramadol tramadol/APAP	ABSTRAL (fentanyl) ACTIQ (fentanyl) APADAZ (benzhydrocodone/APAP) butalbital/APAP/caffeine/codeine butalbital/ASA/caffeine/codeine butorphanol tartrate (nasal) DEMEROL (meperidine) DILAUDID (hydromorphone) DVORAH (dihydrocodeine/ APAP/caffeine) fentanyl FENTORA (fentanyl) FIORICET W/ CODEINE (butalbital/APAP/caffeine/codeine) FIORINAL W/ CODEINE (butalbital/ASA/caffeine/codeine) hydrocodone/ibuprofen IBUDONE (hydrocodone/ibuprofen) LAZANDA NASAL SPRAY (fentanyl) levorphanol LORCET (hydrocodone/APAP) LORTAB (hydrocodone/APAP) MAGNACET (oxycodone/APAP) meperidine solution meperidine tablet	MS DOM Opioid Initiative Short-Acting Opioids Long-Acting Opioids Morphine Equivalent Daily Dose Concomitant use of Opioids and Benzodiazepines Criteria details found here Minimum Age Limit 18 years – tramadol and codeine products Quantity Limit Applicable quantity limit in 31 rolling days 62 tablets – butalbital/codeine combinations, codeine, dihydrocodeine combinations, fentanyl, hydromorphone, levorphanol, meperidine, morphine, oxycodone, oxycodone/ibuprofen, oxymorphone, pentazocine, tapentadol, tramadol 62 tablets CUMULATIVE – hydrocodone combinations,
		NALOCET (oxycodone/APAP) NORCO (hydrocodone/APAP) NUCYNTA (tapentadol)	oxycodone combinations • 186 tablets –butalbital/APAP 300, butalbital/APAP 325, butalbital/ASA 325
		ONSOLIS (fentanyl) OPANA (oxymorphone) OXAYDO (oxycodone) oxymorphone	 5mL (2 x 2.5 bottles) – butorphanol nasal 180 mL CUMULATIVE – oxycodone liquids
		pentazocine/naloxone PERCOCET (oxycodone/APAP)	280 mL CUMULATIVE – Qdolo



MISSISSIPPI DIVISION OF MEDICAID UNIVERSAL PREFERRED DRUG LIST

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THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA	
ANALGESICS, OPIOID-	ALGESICS, OPIOID- SHORT ACTING DUR+			
		PERCODAN (oxycodone/ASA) PRIMLEV (oxycodone/APAP) PROLATE (oxycodone/APAP) QDOLO (tramadol) REPREXAINE (hydrocodone/ibuprofen) ROXICET (oxycodone/acetaminophen) ROXICODONE (oxycodone) ROXYBOND (oxycodone) SEGLENTIS (tramadol/celecoxib) SUBSYS (fentanyl) SYNALGOS-DC (dihydrocodeine/aspirin/caffeine) TYLENOL W/CODEINE (APAP/codeine) TYLOX (oxycodone/APAP) ULTRACET (tramadol/APAP) ULTRAM (tramadol) VICODIN (hydrocodone/APAP) VICOPROFEN (hydrocodone/ibuprofen) XODOL (hydrocodone/APAP) ZAMICET (hydrocodone/APAP) ZOLVIT (hydrocodone/APAP) ZYDONE (hydrocodone/APAP)		



MISSISSIPPI DIVISION OF MEDICAID UNIVERSAL PREFERRED DRUG LIST

EFFECTIVE 09/01/2023 Version 2023.7 Updated:08/23/2023

(For All Medicaid, MSCAN and CHIP Beneficiaries)

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THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA	
ANALGESICS, OPIOID	- LONG ACTING DUR+			
	BUTRANS (buprenorphine) fentanyl patches morphine ER tablets •	ARYMO ER (morphine) BELBUCA (buprenorphine) buprenorphine patch CONZIP ER (tramadol) DOLOPHINE (methadone) DURAGESIC (fentanyl) EMBEDA (morphine/naltrexone)	MS DOM Opioid Initiative Short-Acting Opioids Long-Acting Opioids Morphine Equivalent Daily Dose Concomitant use of Opioids and Benzodiazepines Criteria details found here	
		EXALGO (hydromorphone) hydromorphone ER HYSINGLA ER (hydrocodone) KADIAN (morphine) methadone MORPHABOND (morphine) morphine ER capsules MS CONTIN (morphine) NUCYNTA ER (tapentadol) OPANA ER (oxymorphone) oxycodone ER OXYCONTIN (oxycodone) oxymorphone ER RYZOLT (tramadol) tramadol ER ULTRAM ER (tramadol) XARTEMIS XR (oxycodone/APAP) XTAMPZA (oxycodone myristate) ZOHYDRO ER (hydrocodone bitartrate)	Minimum Age Limit 18 years – Butrans, Xartemis XR, Zohydro ER, tramadol products Quantity Limit Applicable quantity limit per rolling days 11 tablets/31 days - Conzip ER, Exalgo ER, Hysingla ER, Ryzolt, Ultram ER 62 tablets/31 days – Arymo ER, Belbuca, Embeda, Kadian, methadone, Morphabond, morphir ER, Nucynta ER, Opana ER, oxycodone ER, Oxycontin, Xtampza ER, Zohydro ER 10 patches/31 days – Duragesic 4 patches/31 days – Butrans 40 tablets/10 days – Xartemis XR Non-Preferred Criteria Have tried 2 different preferred agents in the past 6 months OR Documented diagnosis of cancer	

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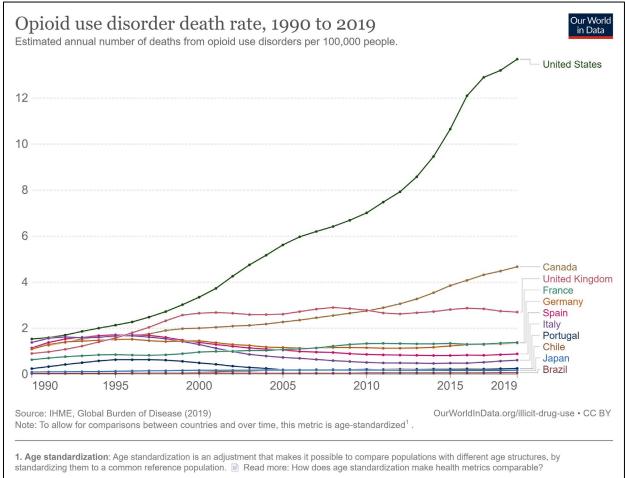
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NALOXONE PRESCRIBING TRENDS AMONG MEDICAID BENEFICIARIES

BACKGROUND

Overdose deaths involving opioids impact the United States more than any other country and are a major health concern. (Figure 1)

FIGURE 1: Opioid Use Disorder Death Rates Around the World¹



Although the rate of opioid prescribing in the US began to decline in 2013², the annual number of opioid-involved overdose deaths has continued to rise since 1999.³ Opioid-involved overdose deaths dramatically rose 61% between 2019 and 2021 to 80,411 deaths annually with 7 out of 10 deaths occurring among men.⁴ This sharp increase in opioid-involved deaths is likely the result of the disruption and stress associated with the COVID pandemic.⁵ (Figure 2) In Mississippi, this upward trend in opioid-involved overdose deaths was even more pronounced. According to data published by the Mississippi State Department of Health (MSDH), overdose deaths due to opioids increased 127% between 2019 and 2021.⁶

National Overdose Deaths Involving Any Opioid*, Number Among All Ages, by Gender, 1999-2021 100,000 Total Female 80,411 Male 80,000 68.630 60,000 49.860 47,600 40,000 21,089 20,000 2009 2006 2008 2010 2012 2013 2011 *Among deaths with drug overdose as the underlying cause, the "any opioid" subcategory was determined by the following ICD-10 multiple cause-of-death codes: natural and semi-synthetic opioids (T40.2), methadone (T40.3), other synthetic opioids (other than methadone) (T40.4), or heroin (T40.1). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2021 on CDC WONDER Online Database, released 1/2023.

FIGURE 2: Overdose Deaths Involving Opioids³

Depression of the respiratory and central nervous systems by opioids is the key factor that contributes to their lethal effects.⁷ Opioid antagonists, such as naloxone, can reverse the effects of opioids and prevent opioid-involved deaths. Naloxone works by competitively binding mu opioid receptors thereby reversing signs of opioid intoxication. ^{8,9} Naloxone is available in intravenous, intramuscular, and intranasal formulations.

Across the US, extensive efforts have been made to increase the accessibility of naloxone for those at risk of opioid overdose. In Mississippi, the Naloxone Standing Order Act was passed in 2017 allowing pharmacists to dispense naloxone without an individual prescription. In December 2022, through the Mississippi Opioid and Substance Use Disorder Program, MSDH began distributing naloxone kits free to individuals upon request. Most recently, the first over-the-counter naloxone nasal spray received FDA approval in March 2023 followed by a second agent in July 2023. Additionally, the Mississippi Division of Medicaid (DOM) has multiple naloxone products listed on their Universal Preferred Drug List (UPDL). (Figure 3)

FIGURE 3: DOM UPDL - OPIATE DEPENDENCE TREATMENTS

MISSISSIPPI DIVISION OF MEDICAID Gainwell Technologies' DUR+ profunctionality. However, they m	EFFECTIVE 08/01/2023 Version 2023.6 Updated:07/28/2023 plans may/may not -have electronic PA					
THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA			
OPIATE DEPENDENCE	OPIATE DEPENDENCE TREATMENTS					
	TREAT	MENT				
	naloxone injection NARCAN NASAL SPRAY (naloxone) KLOXXADO (naloxone)	EVZIO (naloxone) ZIMHI (naloxone)				

Even with extensive efforts to improve naloxone availability, getting naloxone into the hands of individuals needing this life-saving medication can still be a challenge. In 2020, a MS-DUR report examining the prescribing of naloxone to Medicaid beneficiaries considered high-risk for opioid overdose found that < 2% had claims for naloxone during the study period. A recent study by Gravlee et al. examining the accessibility of naloxone across Mississippi found that out of 591 pharmacies surveyed, just over 36% had naloxone available to purchase under the standing order. Furthermore, nearly 41% of pharmacies surveyed reported being unwilling to dispense naloxone under the standing order. The Delta region of the state had the fewest pharmacies with naloxone available to purchase.

This current study aims to describe the utilization of naloxone among Medicaid beneficiaries over a multi-year period.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid administrative claims data for Fee-for-Service (FFS) and the three Coordinated Care Organizations (CCOs) which include Magnolia Health (MAG), Molina Healthcare (MOL), and UnitedHealthcare (UHC) for the period of January 1, 2018, to June 30, 2022 (i.e., study period). Demographic characteristics for beneficiaries prescribed naloxone during the study period were noted. Naloxone use was assessed at a claim level and beneficiary level by pharmacy program across each year of the study period. Only point-of-sale naloxone claims were assessed for this analysis. Furthermore, naloxone utilization among beneficiaries characterized as high-risk for an adverse event associated with opioid use was captured. High-risk events for opioid users identified in this analysis included: high morphine equivalent daily dosing (MEDD), long-term opioid use, prior opioid overdose event, concomitant use of benzodiazepine, concomitant use of antipsychotic, and presence of other high-risk diagnoses. Beneficiaries with a cancer diagnosis were excluded from this part of the analysis. High MEDD was identified by flagging beneficiaries who had any day of opioid use with greater than or

equal to 90 MEDD. Long-term opioid use was defined as the continuous use of opioids with greater than or equal to 50 MEDD for 90 days or more allowing for a 15-day gap during continuous use. Opioid overdose was identified if beneficiaries had any opioid overdose related diagnosis or opioid induced respiratory depression diagnosis in claims data. Concomitant use of benzodiazepines as well as concomitant use of antipsychotics was defined as any concomitant use of opioids and benzodiazepines or opioids and antipsychotics during the study period, respectively. The presence of other high-risk diagnoses included any diagnosis of alcohol dependence, opioid dependence, other substance abuse dependence, and depression. Claims for naloxone were identified using the national drug code (NDC). For each naloxone claim, the provider type was identified. Naloxone prescription rates were calculated at the county level based on the beneficiary's county of residence.

RESULTS

Between January 2018 and June 2022, there were 2,825 naloxone claims for Medicaid beneficiaries. The majority of beneficiaries associated with those claims were black females between the ages of 46-65 years. (Table 1)

TABLE 1. Demographic Characteristics of Beneficiaries Prescribed Naloxone January 1, 2018 - June 30, 2022							
		Pl	an*				
	FFS	UHC	MAG	MOL	Total		
Age (years)							
< 18	17	15	22	11	65		
18 - 45	211	517	355	125	1,208		
46 - 65	260	700	525	65	1,550		
65+	1	1	0	0	2		
Gender团							
Female	320	871	632	131	1,954		
Male	169	362	270	70	871		
Race							
Black	248	569	433	73	1,323		
White	196	517	366	108	1,187		
Other	45	147	103	20	315		

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina

* Plan as of the naloxone fill date

Table 2 displays naloxone utilization by year and pharmacy program.

- There was a 329% increase in the annual number of naloxone claims between 2018 and 2021.
- There was a 315% increase in the annual number of unique beneficiaries with naloxone claims between 2018 and 2021.
- Despite the large percentage increase in naloxone claims during the study period, the number of naloxone claims continues to be low compared to the number of Medicaid beneficiaries receiving opioids. (see Opioid Trends Report)

TABLE 2. Naloxone Utilization Among Beneficiaries Enrolled in Mississippi Medicaid by Year and Pharmacy Program January 1, 2018 - June 30, 2022

		# of	# of Unique
Year	Plan*	Claims	Beneficiaries
2018			
	FFS	36	35
	UHC	87	84
	MAG	109	107
	MOL	0	0
	TOTAL	232	226
2019			
	FFS	53	53
	UHC	157	155
	MAG	177	174
	MOL	27	27
	TOTAL	414	409
2020			
	FFS	88	85
	UHC	207	193
	MAG	233	227
	MOL	47	44
	TOTAL	575	549
2021			
	FFS	155	151
	UHC	510	462
	MAG	254	249
	MOL	76	75
	TOTAL	995	937
2022			
	FFS	157	148
	UHC	272	226
	MAG	129	127
	MOL	51	51
	TOTAL	609	552

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG -

Magnolia; MOL - Molina

^{*} Plan as of the index date of the earliest event

Naloxone use is targeted towards individuals considered high-risk for adverse events associated with opioids. Table 3 displays naloxone utilization among beneficiaries classified as high-risk for adverse opioid events. High-risk events for opioid users identified in this analysis included: high morphine equivalent daily dosing (MEDD \geq 90 MEDD), long-term opioid use, prior opioid overdose event, concomitant use of benzodiazepine, concomitant use of antipsychotic, and presence of other high-risk diagnoses (any diagnosis of alcohol dependence, opioid dependence, other substance abuse dependence, and depression).

- Of the 109,968 beneficiaries identified as having at least one high-risk event during the study period, 2806 had claims for naloxone.
- This equates to 2.55% of Medicaid beneficiaries that were considered high-risk of experiencing an adverse opioid event having had a claim for naloxone between January 1, 2018 and June 30, 2022.

Тл	PLE 2 Nalovono Utilizat	ion Among High	Pick Panaficiaries				
I A	TABLE 3. Naloxone Utilization Among High-Risk Beneficiaries January 1, 2018 - June 30, 2022						
	Juliaury 1, 2	# of benes with	# of high-risk benes with				
Plan	High-risk event type	high-risk event	naloxone claims				
	High MEDD	466	24				
	Long-term opioid use	480	58				
	Opioid overdose	421	16				
FFS	Concomitant use of						
113	benzodiazepine	5,127	116				
	Concomitant use of						
	antipsychotic	4,913	78				
	High-risk diagnosis	17,027	273				
	Total*	28,434	565				
	High MEDD	1,057	78				
	Long-term opioid use	346	75				
	Opioid overdose	455	48				
United	Concomitant use of						
Omica	benzodiazepine	7,483	212				
	Concomitant use of						
	antipsychotic	6,767	142				
	High-risk diagnosis	18,566	546				
	Total*	34,674	1,101				
	High MEDD	1,431	73				
	Long-term opioid use	315	72				
	Opioid overdose	511	37				
Magnolia	Concomitant use of						
	benzodiazepine	8,292	204				
	Concomitant use of						
	antipsychotic	7,930	155				
	High-risk diagnosis	20,890	493				
	Total*	39,369	1,034				
	High MEDD	254	5				
	Long-term opioid use	37	5				
	Opioid overdose	108	6				
Molina	Concomitant use of	4 400					
	benzodiazepine	1,139	18				
	Concomitant use of	4.070					
	antipsychotic	1,079	16				
-	High-risk diagnosis Total*	4,874	56				
	lotal*	7,491	106				

^{*}Sum of columns may not add up to the total reported. Beneficiaries could have multiple high-risk event types.

Table 4 describes the types of providers that prescribed naloxone to beneficiaries during the study period. MS-DUR attempted to quantify the number of naloxone claims originating at pharmacies through MSDH's Naloxone Standing Order. To arrive at this number, any claims associated with the National Provider Identifier (NPI) for any physician listed on the MSDH Naloxone Standing Order during the

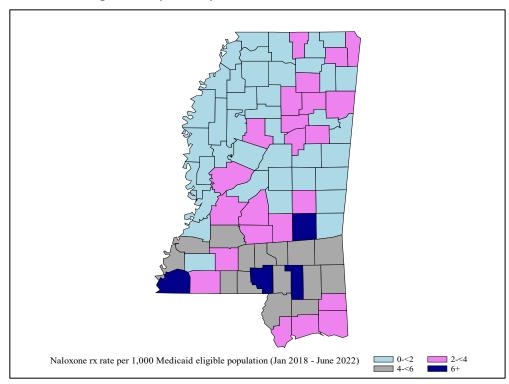
TABLE 4. Number of Naloxone Claims by Prescribing Provider Type January 1, 2018 - June 30, 2022							
		Pla	an				
Provider type	FFS	UHC	MAG	MOL	Total		
Primary care physician	67	158	154	45	424		
Department of Health*	87	209	179	63	538		
Other physicians(specialists)	93	226	131	33	483		
Nurse practitioner	217	606	406	52	1281		
Physician assistant	7	11	10	0	28		
Other provider	12	20	18	7	57		
Unknown	6	3	4	1	14		

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina * Department of Health provider type: Providers associated with the MSDH Naloxone Standing Order

study period was categorized as 'Department of Health' for their provider type. Based on this approach, approximately 19% (538) of naloxone claims could be attributed to the Naloxone Standing Order.

Figure 4 displays a geographic illustration of naloxone prescribing among Medicaid beneficiaries based on the beneficiary's county of residence. Naloxone prescribing rates were calculated as the number of naloxone prescription claims in each county between January 2018 and June 2022 divided by the total number of beneficiaries in that county with Medicaid eligibility multiplied by 1,000. The highest rates of naloxone prescribing were clustered around the southern and coastal counties.

FIGURE 4: Naloxone Prescribing Rates by County



CONCLUSIONS

Opioid-related overdose deaths have risen dramatically across Mississippi and the US in recent years. Naloxone is a safe and effective treatment that can reverse the effects of opioids and prevent deaths. Although many efforts have taken place at both the state and national levels to increase naloxone access, utilization continues to be low. More work needs to be done to decrease stigma and improve access to this life-saving treatment for those at high-risk of experiencing adverse opioid events.

RECOMMENDATIONS

- DOM is encouraged to pursue efforts to increase the utilization of naloxone, especially among those at high-risk of experiencing an adverse opioid event. These efforts could include:
 - a. Conducting an educational intervention targeting pharmacists to increase the availability of naloxone in community pharmacies and improve the rates of dispensing naloxone through MSDH's Naloxone Standing Order.
 - Conducting an educational intervention targeting prescribers to increase their rates
 of prescribing naloxone among Medicaid beneficiaries considered high-risk of
 experiencing an opioid overdose.

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UPDATE ON BUPRENORPHINE PRESCRIBING TRENDS IN MISSISSIPPI MEDICAID

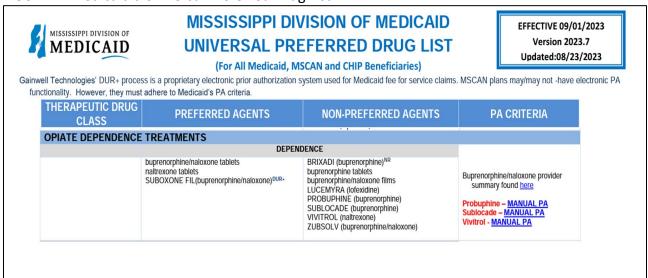
BACKGROUND

A consequence of opioid overprescribing in the US has been a spike in the prevalence of opioid use disorder (OUD). It is estimated that upwards of 6 to 7 million adults in the US currently live with OUD. Opioid use disorder can be described as significant impairments resulting from the chronic use of opioids with diagnostic criteria that may include the use of larger amounts of opioids for longer periods of time than prescribed; craving, strong desire, or urge to use opioids; continued opioid use despite recurrent social interpersonal problems caused by opioids; and exhibiting tolerance or withdrawal.

Medication-assisted treatment (MAT) is the use of medicine in combination with behavioral therapies for the effective treatment of opioid use disorders.³ Buprenorphine products are a major part of MAT in the treatment of OUD. Buprenorphine is a partial opioid agonist available alone or in combination with naloxone. Historically, barriers such as stigma and access have limited the availability of MAT to those in need of treatment.

The Mississippi Division of Medicaid has taken multiple steps to improve access to MAT. Buprenorphine containing products are listed as preferred agents under the Opiate Dependence Treatment category of Medicaid's UPDL with no prior authorization requirements for preferred agents used in the treatment of opioid dependence (Figure 1).⁴ In 2016, the state removed a 24-month maximum length of coverage limit and removed limits on the number of times an individual could restart treatment. DOM has available on its website the "Buprenorphine/Naloxone and Buprenorphine Therapy Coverage" provider summary sheet (Attachment A) to facilitate providers in the prescribing of buprenorphine and buprenorphine/naloxone products.

FIGURE 1: Medicaid's Universal Preferred Drug List



Recently, additional steps have been taken to improve access to these medications. In December 2022, the Mainstreaming Addiction Treatment (MAT) Act was signed into law eliminating one of the major hurdles to the access of MAT. This act removed waiver requirements for the prescribing of buprenorphine products.^{5,6} This change improves access to MAT by permitting all practitioners with a current Drug Enforcement Agency (DEA) registration that includes Schedule III authority to prescribe buprenorphine for OUD.

In 2019, MS-DUR presented a report on buprenorphine prescribing trends among Medicaid beneficiaries that was modeled after a report published by the Mississippi State Department of Health titled "Bridging the Treatment Gap: Buprenorphine Prescription Practices in Mississippi, 2021-2017." Those reports highlighted the needs surrounding MAT in Mississippi.

The aim of this current report is to update buprenorphine prescribing data and describe current utilization trends among Medicaid beneficiaries.

METHODS

A retrospective analysis of Mississippi Medicaid beneficiaries was conducted using pharmacy claims for single agent buprenorphine and buprenorphine-naloxone combination products across the Fee-for-Service (FFS) program and the Coordinated Care Organizations (CCOs) which include Magnolia Health (MAG), Molina Healthcare (MOL), and UnitedHealthcare (UHC) from January 1, 2015 to June 30, 2022. Claims for Butrans, Belbucca, and Buprenex products indicated for pain management were excluded from this analysis. The number of prescription fills, unique prescriptions and long-term prescription fills each year were calculated for the entire study period. The number of unique prescriptions was assessed by calculating the number of prescriptions with unique prescription numbers each year. Long-term prescription fills were defined as prescription fills having a days supply of greater than or equal to 30 days. Moreover, the number of unique prescriptions for each year was stratified by gender (male or female), age group (less than or equal to 24 years, 25 to 34 years, 35 to 44 years, 45 to 54 years, 55 to 64 years and greater than or equal to 65 years), and whether the prescription was issued by a Mississippi-based (MS-based) provider.

Additionally, drug-specific utilization from January 1, 2015 to June 30, 2022 was assessed to capture the current trends in buprenorphine use among beneficiaries enrolled in Mississippi Medicaid. The number of prescription fills and number of beneficiaries utilizing buprenorphine was assessed while stratifying by gender and type of drug used (single agent buprenorphine or buprenorphine-naloxone combination).

Furthermore, buprenorphine prescription rates per 1000 Medicaid eligible population was calculated at the county level (based on the beneficiary's county of residence). The number of Medicaid eligible beneficiaries in each county was calculated as the total number of beneficiaries with at least one month of Medicaid eligibility between January 2021 and June 2022. Lastly, the number of unique Mississippi based providers prescribing buprenorphine was calculated at the county level.

RESULTS

Table 1 depicts buprenorphine trends from January 2015 through June 2022.

- The majority of individuals receiving buprenorphine products through Medicaid were females between the ages of 25 and 44 years of age.
- Consistent with trends noted in the December 2019 DUR Board Report, the total number
 of prescription claims for buprenorphine products showed a year-over-year increase
 between 2015 and 2021. This trend also appeared to continue through the first half of
 2022.
- Total Rx Fills increased 157% and Unique Rx Fills (prescriptions with different prescription numbers) increased 142% between 2015 and 2021 in Mississippi Medicaid. These increases are almost identical to the trends reported in the December 2019 DUR Board Report.
- Approximately 67.5% of buprenorphine claims during the study period in Medicaid were for prescription fills of at least 30 days supply. Long-term maintenance treatment with buprenorphine products has been associated with improved outcomes.⁸ The percentage of Medicaid beneficiaries with long-term use stands in stark contrast to the approximate 20% reported for statewide data by the Mississippi State Department of Health in their report published in October 2019. These higher numbers among Medicaid beneficiaries could be attributed to efforts Medicaid has made to remove barriers and improve access to buprenorphine products.

TABLE 1. Buprenorphine Prescriptions in Mississippi Medicaid																
	January 1, 2015 - June 30, 2022 (across all plans)															
Characteristics	2015		2016		2017		2018		2019		2020		2021		2022**	ķ
Rx and Fills	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Total Rx Fills	7,448		7,936		9,977		12,067		14,530		16,887		17,999		9,167	
Unique Rx Fills*	6,706		7,256		9,251		11,303		13,599		16,037		17,228		8,712	
Rx fills for 30 or more days	4,998	67.1%	5,545	69.9%	6,753	67.7%	7,868	65.2%	9,832	67.7%	11,717	69.4%	12,304	68.4%	6,000	65.5%
Total days of supply	190,784		207,980		259,126		310,318		367,696		428,931		462,677		232,987	
Gender																
Female	5,574	74.8%	5,945	74.9%	7,609	76.3%	9,306	77.1%	11,136	76.6%	12,891	76.3%	13,933	77.4%	7,140	77.9%
Male	1,874	25.2%	1,991	25.1%	2,368	23.7%	2,761	22.9%	3,394	23.4%	3,996	23.7%	4,066	22.6%	2,027	22.1%
Age at fill date																
< 24 years	550	7.4%	394	5.0%	410	4.1%	430	3.6%	416	2.9%	405	2.4%	376	2.1%	174	1.9%
25 - 34 years	3,430	46.1%	3,525	44.4%	4,186	42.0%	4,384	36.3%	5,218	35.9%	5,748	34.0%	5,499	30.6%	2,574	28.1%
35 - 44 years	2,193	29.4%	2,672	33.7%	3,457	34.6%	4,268	35.4%	4,976	34.2%	5,963	35.3%	7,080	39.3%	3,722	40.6%
45 - 54 years	858	11.5%	841	10.6%	1,253	12.6%	1,826	15.1%	2,098	14.4%	2,497	14.8%	2,478	13.8%	1,376	15.0%
55 - 64 years	417	5.6%	504	6.4%	671	6.7%	1,158	9.6%	1,816	12.5%	2,267	13.4%	2,545	14.1%	1,311	14.3%
> 65 years	0	0.0%	0	0.0%	0	0.0%	1	0.0%	6	0.0%	7	0.0%	21	0.1%	10	0.1%
Unique Rx Issued by MS																
Providers																
	5,289	71.0%	5.818	73.3%	7.600	76.2%	9,497	78.7%	11,526	79.3%	14.077	83.4%	14.463	80.4%	7,349	80.2%

^{*}Unique Rx calculated based on prescription numbers for claims.

^{**} Numbers for 2022 are through June 2022.

^{***} Rx fills for both buprenorphine and buprenorphine-naloxone were considered for the analysis; claims for Butrans, Belbucca, and Buprenex were excluded from the analysis.

Examining annual prescribing trends in greater detail, claims w and beneficiaries prescribed buprenorphine products were further broken down by gender and drug product (Table 2). Per Mississippi Medicaid policy, oral buprenorphine single-agent products included in this analysis are only approved for use during pregnancy.

- Across all years, there were 96,011 total claims for buprenorphine containing products with 92% of those claims being for combination products.
- Of the 7,697 claims for single agent buprenorphine products, 9.3% (718) were prescribed to 116 male beneficiaries during the study period.

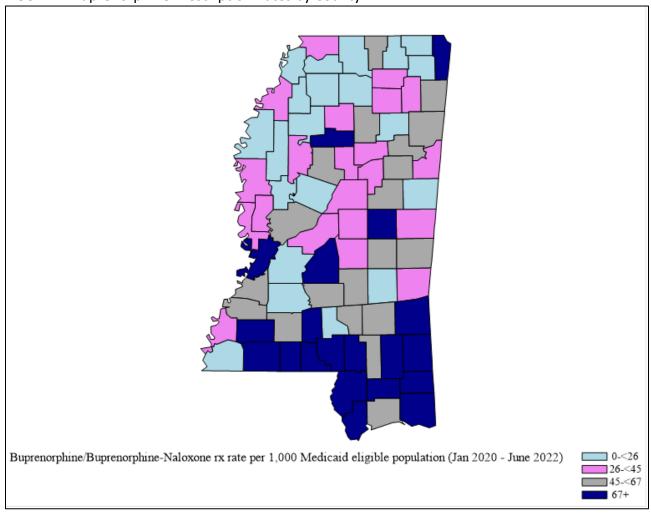
	TABLE 2. Prescription Claims and Beneficiaries by Gender and Drug Type January 1, 2015 - June 30, 2022							
Year	Drug type	Fem	ale	Mal	e	Total		
		#claims	#benes	#claims	#benes	#claims	#benes	
2015	Buprenorphine	636	187	90	19	726	206	
	Buprenorphine-Naloxone	4938	875	1,784	314	6722	1189	
2016	Buprenorphine	750	187	50	17	800	204	
	Buprenorphine-Naloxone	5195	864	1941	306	7136	1170	
2017	Buprenorphine	892	203	37	12	929	215	
	Buprenorphine-Naloxone	6717	949	2331	316	9048	1265	
2018	Buprenorphine	991	226	78	20	1069	246	
	Buprenorphine-Naloxone	8315	1113	2683	359	10998	1472	
2019	Buprenorphine	1051	231	125	27	1176	258	
	Buprenorphine-Naloxone	10085	1207	3269	383	13354	1590	
2020	Buprenorphine	1082	198	147	28	1229	226	
	Buprenorphine-Naloxone	11809	1290	3849	420	15658	1710	
2021	Buprenorphine	1070	186	140	28	1210	214	
	Buprenorphine-Naloxone	12863	1371	3926	435	16789	1806	
2022	Buprenorphine	507	122	51	16	558	138	
	Buprenorphine-Naloxone	6633	1198	1976	383	8609	8609	
All years	Buprenorphine	6979	953	718	116	7697	1069	
	Buprenorphine-Naloxone	66555	3282	21759	1136	88314	4418	

Note - Rx fills for both buprenorphine and buprenorphine-naloxone were considered for the analysis; claims for Butrans, Belbucca, and Buprenex were excluded from the analysis

Figure 2 provides a geographic depiction of beneficiaries prescribed buprenorphine products across Mississippi based on the beneficiary's county of residence. Buprenorphine prescription rates were calculated as the number of buprenorphine prescription claims in each county between January 2020 and June 2022 divided by the total number of beneficiaries in each county with Medicaid eligibility multiplied by 1,000. The categories are broken into quartiles.

- The coastal and southern counties had the highest buprenorphine prescribing rates. Two northern counties, Tishomingo and Grenada, were also among the counties with the highest prescribing rates in the state.
- The northern Delta counties had some of the lowest buprenorphine prescribing rates in the state.

FIGURE 2: Buprenorphine Prescription Rates by County



One of the key issues impacting access to buprenorphine products in the past has been the availability of prescribers licensed to prescribe these products. These limitations can be visualized in a map displaying the number of unique buprenorphine prescribers. Figure 3 displays a map of Mississippi providers associated with buprenorphine claims for Medicaid beneficiaries between January 2020 and June 2022. There are vast areas across the state where very few providers have prescribed buprenorphine products for Medicaid beneficiaries. A total of 64 of the 82 counties in Mississippi had 2 or fewer providers that wrote prescriptions for buprenorphine products for Medicaid beneficiaries during the study period. Thirty-nine counties had no providers that prescribed buprenorphine products during that period. These gaps in buprenorphine prescribing rates across Mississippi further point to the healthcare disparities that some Medicaid beneficiaries face.

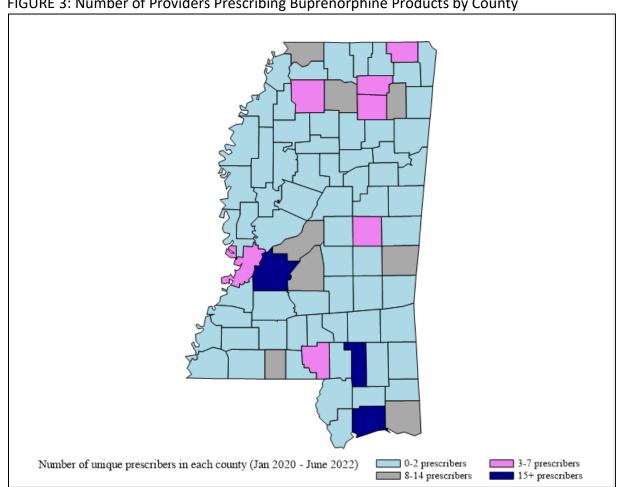


FIGURE 3: Number of Providers Prescribing Buprenorphine Products by County

CONCLUSIONS

The prescribing of buprenorphine products among Medicaid beneficiaries continues to increase. The inclusion of buprenorphine containing products as preferred agents not requiring prior authorization for use in MAT as well as the removal of limits on the length of therapy are steps DOM has taken to improve access to buprenorphine products. With passage of the MAT Act in 2022 removing waiver requirements to prescribe buprenorphine, access to these products should continue to improve.

RECOMMENDATIONS

1. DOM is encouraged to continue working internally and expand their reach to external stakeholders in efforts to improve access to MAT across the state.

Buprenorphine/Naloxone and Buprenorphine



THERAPY GUIDANCE

Provider Summary Sheet

START (first prescription fill in 90 days)

Induction and Stabilization Phase



Maintenance Phase

Months 3 and after



Up to 16mg/day **

- ** Maximum daily doses shown are for use of Suboxone®, the preferred product. If Zubsolv® or Bunavail® are approved for use, equivalent dosing limits will apply. Refer to the Uniform Preferred Drug List for criteria regarding use of non-preferred products. http://www.medicaid.ms.gov/providers/pharmacy/preferred-drug-list
 - Buprenorphine/naloxone and buprenorphine are only approved for opioid dependence. ICD-10 codes that must be found in medical claims or written on prescription and entered by pharmacist with prescription claim (F11.1xx, F11.2xx, F11.90, F19.20 or F19.21).
 - Buprenorphine is only approved for use during pregnancy. Appropriate ICD-10 codes must be
 found in medical claims or written on prescription and entered by pharmacist with prescription
 claim. Appropriate codes can be found at: https://medicaid.ms.gov/wp-content/uploads/2018/09/ICD-10-codes-for-POS-claims-and-SMART-PAs-8.20.18.pdf

Trouble Shooting Rejections:

- Claim denied no diagnoses for opioid dependence or no diagnosis for pregnancy (buprenorphine 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.
- Contact information for PA Units:

Medicaid Fee for Service/Gainwell
 Magnolia Health/Envolve Pharmacy Solutions
 Molina Healthcare/CVS Caremark
 UnitedHealthcare/OptumRx
 Ph: 1-833-660-2402 Fax: 1-866-644-6147
 Ph: 1-866-399-0928 Fax: 1-877-386-4695
 Ph: 1-844-826-4335 Fax: 1-844-312-6371
 Ph: 1-800-310-6826 Fax: 1-866-940-7328

Prepared by:



Copies of this Summary Sheet are available at: https://medicaid.ms.gov/providers/pharmacy/pharmacy-resources/

Revision: 01/23/2023

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FDA DRUG SAFETY COMMUNICATIONS

June 2023 - August

No new safety communications were issued between June-August 2023



August 1, 2023

Dear Americans,

As leaders of the U.S. Food and Drug Administration (FDA) and the Drug Enforcement Administration (DEA), we recognize the important role that prescription stimulants play in the treatment of conditions such as attention-deficit/hyperactivity disorder (ADHD), binge eating disorder, and uncontrollable episodes of deep sleep (narcolepsy). The lack of availability of certain medications in recent months has been understandably frustrating for patients and their families.

Given the interest related to access to these medications, we want to provide an update on the ongoing actions being taken to resolve the shortages of prescription stimulant medications. In addition, we want to acknowledge important issues that will need to be addressed through longer-term coordination by a variety of entities involved in this effort. This is not a problem that the FDA and DEA can solve on our own. We are urging all stakeholders to work together to resolve these shortages as quickly as possible.

The FDA and DEA do not manufacture drugs and cannot require a pharmaceutical company to make a drug, make more of a drug, or change the distribution of a drug. That said, we are working closely with numerous manufacturers, agencies, and others in the supply chain to understand, prevent, and reduce the impact of these shortages.

The current shortage of stimulant medications is the result of many factors. It began last fall due to a manufacturing delay experienced by one drug maker. While this delay has since resolved, we are continuing to experience its effects in combination with record-high prescription rates of stimulant medications. Data show that, from 2012 to 2021, overall dispensing of stimulants (including amphetamine products and other stimulants) increased by 45.5 percent in the United States. According to a U.S. Centers for Disease Control and Prevention report, particularly during 2020–2021, when virtual prescribing was permitted on a widespread basis during the COVID-19 Public Health Emergency, the percentages in certain age groups grew by more than 10 percent. We are calling on key stakeholders, including manufacturers, distributors, pharmacies, and payors, to do all they can to ensure access for patients when a medication is appropriately prescribed. We want to make sure those who need stimulant medications have access. However, it is also an appropriate time to take a closer look at how we can best ensure these drugs are being prescribed thoughtfully and responsibly.

Stimulants are controlled substances with a high potential for abuse, which can lead to addiction and overdose. Therefore, there are limits (also known as quotas) set by DEA for how much of these drugs can be produced. However, for amphetamine medications, in 2022, manufacturers did not produce the full amount that these limits permitted them to make. Based on DEA's internal analysis of inventory, manufacturing, and sales data submitted by manufacturers of amphetamine products, manufacturers only sold approximately 70 percent of their allotted quota

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.gov for the year, and there were approximately 1 billion more doses that they could have produced but did not make or ship. Data for 2023 so far show a similar trend.

We (DEA and the FDA) have called on manufacturers to confirm they are working to increase production to meet their allotted quota amount. If any individual manufacturer does not wish to increase production, we have asked that manufacturer to relinquish their remaining 2023 quota allotment. This would allow DEA to redistribute that allotment to manufacturers that will increase production. DEA is also committed to reviewing and improving our quota process.

The FDA is asking professional groups and healthcare providers to accelerate efforts to support appropriate diagnosis and treatment of ADHD, such as further development of additional clinical guidelines for ADHD in adults. In recognition of this need, FDA <u>awarded a grant</u> to the National Academies of Sciences, Engineering, and Medicine (NASEM) to support a scientific meeting on ADHD in adults and considerations for diagnosis and treatment. FDA also recognizes that further research is needed into the diagnosis and treatment of ADHD and believes that research can help inform the development of alternative treatments and an understanding of the behavioral and societal issues leading to <u>widespread misuse</u> of these medications in certain groups.

FDA has already taken steps to support the development of alternative treatment options. In 2020, for instance, FDA permitted marketing of a game-based digital therapeutic to improve attention function in children with ADHD. This device offers a non-drug option for improving symptoms associated with ADHD in children. There are also non-stimulant medications approved to treat ADHD, including one approved in 2021. Additionally, to address continuing concerns of misuse, addiction and overdose of prescription stimulants, the FDA recently issued a drug safety communication and required updates to the labeling to standardize prescribing information and clearly inform patients, caregivers and healthcare professionals of these risks.

FDA and DEA will continue to do all we can to prevent stimulant drug shortages, limit their impact, and resolve them as quickly as possible. We will consider additional actions to prevent non-medical use and identify efforts to better understand and strengthen the supply chain. We also hope that we can all work together to assure that those who need stimulant medications can get them based on the best clinical knowledge about when they are effective, and avoid them when there is no indication for their use.

We will continue to work together and with all of you to mitigate this drug shortage and provide up to date information.

Sincerely,

Robert M. Califf, M.D.

Rut M Celly

Commissioner of Food and Drugs

U.S. Food and Drug Administration

Anne M. Milgram Administrator

Drug Enforcement Administration

APPENDIX



Division of Medicaid Drug Utilization Review Board By-Laws

Article I. Purpose

The Drug Utilization Review Board (DUR) is a requirement of the Social Security Act, Section 1927. The purpose of the DUR Board is to provide clinical guidance to the Division of Medicaid (DOM) regarding the utilization of pharmaceutical products within the Mississippi Medicaid program. The DUR Board makes recommendations to DOM to promote patient safety and cost effective care in the Mississippi Medicaid program. The DUR Board shall advise DOM with respect to the content of medical criteria and standards for utilization management strategies including prospective drug prior authorization (PA), concurrent patient management, retrospective drug utilization review, and educational intervention programs. DOM retains the authority to accept or reject the recommendations by the DUR Board.

Article II. Membership

Section 1 - Board Composition

- A. The DUR Board will consist of not less than twelve (12) voting members.
- B. The DUR Board voting members will be comprised of at least one-third (1/3), but no more than fifty-one percent (51%), licensed and actively practicing physicians and at least one-third (1/3) licensed and actively practicing pharmacists. Voting members may consist of health care professionals with knowledge/expertise in one or more of the following:
 - 1) Prescribing of drugs,
 - 2) Dispensing and monitoring of drugs,
 - 3) Drug use review, evaluation, and intervention,
 - 4) Medical quality assurance.
- C. Non-voting board members consist of the Division of Medicaid (DOM) Executive Director, Office of Pharmacy pharmacists, DUR Coordinator, the DUR contractor and Medical Director.

Section 2 - Appointment selection methodology

- A. DOM's Office of Pharmacy in consultation with officially recognized state professional healthcare associations recommends potential, qualified new candidates for appointment or reappointment of existing board members to DOM's Executive Director.
- B. Nominations are considered internally and appointments are given final approval by the DOM Executive Director.
- C. Board members are appointed by the Governor of the State of Mississippi, or Governor's designee, pursuant to state law.

Section 3 - Term of Office

- A. All members are appointed for three year terms following a staggered appointment fulfillment as follows: one-third of DUR Board members shall be appointed each term. All subsequent appointments shall be for terms of three years from the expiration date of the previous term.
- B. Members may serve up to three consecutive three-year terms (for a total of nine consecutive years).
- C. Members may serve for either an extended term or a fourth consecutive term at the discretion of the Executive Director and by recommendation of both the DUR Coordinator and Division of Medicaid Office of Pharmacy in the event that no qualified, willing candidate is found in sufficient time. Members, including those filling vacated positions, may be re-appointed by the Executive Director for a subsequent term.
- D. In the event of an unexpected or expected vacancy, the DUR Coordinator and Office of Pharmacy may recommend a qualified replacement candidate to DOM's Executive Director for emergency approval.
- E. The Executive Director shall fill any vacancy before the end of the term, and the person appointed to fill the vacancy shall serve for the remainder of the unexpired term. Members, including those filling vacated positions, may be reappointed by the Executive Director for a subsequent term.

Section 4 - Attendance

- A. Members are required to attend at least fifty percent of the meetings per year. Failure to attend meetings without an explanation of extenuating circumstances will result in the termination of the member's appointment.
- B. Members are asked to give advance notice regarding any planned absences so that a quorum may be determined prior to meetings.

Section 5 - Resignation

A member of the DUR Board may resign by giving a 30 day written advance notice to the DUR Board Chair and DUR Coordinator.

Section 6 - Removal

A member of the DUR Board may be removed by either the DUR Board Chair or majority vote of the DUR Board for good cause. Good cause may be defined as one or more of the following conditions:

- A. Lack of attendance –failure to attend at least 50% of the scheduled DUR meetings shall constitute a resignation by said DUR Board member,
- B. Identified misconduct or wrongdoing during any DUR Board term, or

DUR Bylaws V2= updated 12/06/2018

C. Not disclosing a conflict of interest either upon initial disclosure or throughout the rest of the term.

Section 7 - Board Officers

At the first meeting of the state fiscal year, which constitutes July 1 through June 30, board members shall select two members to serve as Chair and Chair-Elect of the board, respectively. The Chair and Chair-Elect shall both serve one year terms. At the end of the serving year, the Chair-Elect assumes the role of Chair, and a new Chair-Elect will be chosen.

If the persons serving as Chair and Chair-Elect have either previously served as Chair or Chair-Elect, that person may be reelected to either posting.

The Chair-Elect will serve as Chair in absentia of the Chair or by the Chair's request.

Section 8 - Reimbursement

The Division of Medicaid will reimburse DUR Board members for travel related expenses.

Article III. Meetings

Section 1 – Frequency

The DUR Board shall meet at least quarterly, and may meet at other times as necessary for the purpose of conducting business that may be required. The DUR Board Chair, a majority of the members of the board, or the Division of Medicaid Office of Pharmacy and DUR Coordinator, shall maintain the authority of calling DUR meetings.

Section 2 - Regular Meetings

The DUR Board will hold regular quarterly meetings in the city of Jackson, Mississippi. Meetings will occur at the predesignated time and place. Dates for the upcoming year's quarterly meetings will be posted before the first quarterly meeting of the upcoming year.

Section 3 – Special Meetings

The DUR Board may meet at other times other than regular quarterly meetings as deemed necessary and appropriate. The DUR Coordinator and Office of Pharmacy must notify DUR Board members of any special meeting at least two weeks, i.e., ten (10) days, prior to the requested meeting date. Special meetings may be requested by the following officials:

- A. Division of Medicaid Executive Director,
- B. DUR Coordinator and Office of Pharmacy,
- C. DUR Board Chair, or
- D. Majority of DUR Board members via communication to DUR Coordinator and/or DUR Board Chair.

Section 4 - Meeting Notice

DUR Board members will be notified of the location for the meeting a minimum of ten (10) days in advance. Notification may include one or a combination of the following methods: email, fax, or other written communication. DUR Board members are required to keep on file with

DOM Office of Pharmacy his or her address, primary phone number, alternate phone number (i.e., cell), fax number, and email address to which notices and DUR related communications may be submitted.

DUR Bylaws V2= updated 12/06/2018

Meetings may be cancelled due to lack of quorum, severe inclement weather, or other reasons as determined by the DUR Coordinator and Office of Pharmacy. In the event of a cancellation, the DUR Coordinator and DOM Pharmacy staff will communicate with DUR Board members regarding the meeting cancellation as soon as circumstances permit. Notifications shall also be posted with DFA and on DOM's website to ensure that the public is notified of any meeting cancellation.

DUR Board Meetings shall be open to the public and conducted in accordance with state law, specifically the Open Meetings Act. Notice of any meetings held shall be provided at least five (5) days in advance of the date scheduled for the meeting. The notice shall include the date, time, place and purpose for the meeting and shall identify the location of the meeting to the general public.

Section 5 - Meeting Sign-In

All meeting attendees will be required to sign-in at the meeting entrance for DUR meetings. Sign-in sheets will be logged, scanned and transferred to electronic medium for official records. All attendees shall include participant's name and entity represented (as applicable).

Section 6 - Quorum

A simple majority of voting board members shall constitute a quorum and must be present for the transaction of any business of the board. For a fully-appointed 12-person DUR Board as required by state law, seven voting board members constitutes a quorum. If a quorum is not present, the Chair, Chair-Elect or DUR Coordinator maintains the responsibility to conclude meeting proceedings. Meeting minutes shall reflect that a quorum was not present.

Section 7 - Voting

The voting process shall be conducted by the Chair or the Chair-Elect in absentia of the Chair.

All board recommendations shall begin with a motion by a voting board member. The motion may then be seconded by a voting board member. If a recommendation does not receive a second motion, the motion shall not pass. If a recommendation receives a second motion, then the board shall vote on the motion. A motion shall be considered as passed if the motion carries a majority of votes if a quorum of the board is present.

In the event that a motion receives a tie vote in the presence of a quorum, the motion shall not pass. The motion can be brought up for further discussion after which a subsequent motion may be made to vote on the issue again during the same meeting, or a motion can be made to table the issue and discussion until the next quarterly DUR Board meeting.

A vote abstention occurs when a voting member is present for the meeting and the action but has chosen not to vote on the current motion. An abstention is a vote with the majority on the measure. A recusal, on the other hand, is necessitated when a voting member has a conflict of interest or potential pecuniary benefit resulting from a particular measure. In order to properly and completely recuse oneself from a matter, the DUR Board member must leave the room or area where discussions, considerations, or other actions take place

before the matter comes up for discussion. The member must remain absent from the meeting until the vote is concluded. The minutes will state the recusing member left the room before the matter came before the DUR Board and did not return until after the vote.

Section 8 – Minutes

A public body speaks only through its minutes. State law, specifically the Open Meetings Act, requires minutes be kept of all meetings of a public body, whether in open or executive session, showing the following:

- A. Members present or absent,
- B. Date, time and place of meeting,
- C. Accurate recording of any final actions taken,
- D. Record, by individual member, of how s/he voted on any final action, and
- E. Any other information that the public body requests is reflected in the minutes.

The minutes shall be finalized no later than thirty (30) days after the adjournment of the DUR Board meeting and shall be made available for public inspection. DOM Office of Pharmacy posts all DUR Board Minutes on the DUR webpage.

Section 9 - Speakers & Special Topics

DUR Board members may request various healthcare, industry, or specialized professionals to present at DUR meetings regarding a posted topic on an upcoming DUR agenda.

- A. The DUR Board may allow up to 20 minutes for topic presentation by an invited speaker.
- B. DUR Board Members may ask a member of the audience to provide information on a topic being discussed by the Board. Invited participants may be asked to disclose any potential conflicts of interests if applicable. (See Article IV, Section 1).
- C. Members of the audience may not speak unless so designated at the appropriate time by a DUR Board member.
- D. DUR Board Members, both voting and non-voting, maintain speaking privileges at DUR meetings.
- E. Contracted employees of DOM and employees of other DOM vendors are considered members of the audience.

Section 10 - Executive Session

During special circumstances, the DUR Board may go into executive session at the conclusion of normal meeting proceedings; however, all DUR Board meetings must commence as an open meeting. In order for executive session to be called, the following procedure must be followed in accordance with the Open Meetings Act:

- A. A member may <u>move to close</u> the meeting to determine whether board needs to go into executive session; vote in open meeting with vote recorded in minutes, majority rules.
- B. Closed meeting: vote taken on whether to <u>declare</u> executive session, requires 3/5 of all members present.
- C. Board comes back into open session and states statutory reason for executive session. The reason for the executive session shall be recorded in the meeting minutes.
- D. Board members then will go into executive session where action may be taken on stated subject matter only.

E. Minutes must be kept in accordance with the Open Meetings Act.

Section 11 - Conduct of Participants

Pursuant to state law, specifically the Open Meetings Act, the DUR Board may make and enforce reasonable rules and regulations for the conduct of persons attending the DUR meetings. The following is a non-exhaustive list of rules for DUR Board meetings:

- A. Attendees should please remain silent and allow for the efficient transaction of business.
- B. Cell phones should be placed on silent or vibrate.
- C. Laptop computers are discouraged from being utilized during meetings as frequent typing may distract board members.
- D. Food and drink are not allowed in the meeting room.
- E. Security is provided by the state. Guests not following proper decorum may be asked to leave by security.

Article IV. Public Participation

Section 1 - Disclosure of Persons Appearing Before DUR Board

The DUR Board may ask individuals appearing before the board to disclose either in writing or verbally their relationship, as applicable, including but not limited to pharmaceutical companies or special interest groups. Any such disclosures should be recorded as a matter of public record in the documented meeting minutes.

Article V. Conflicts of Interest

DUR Board members are expected to maintain the highest professional, ethical standards. A conflict of interest may exist when a DUR Board member maintains a financial/pecuniary, personal, or professional interest that may compete or interfere with the DUR Board member's ability to act in a fair, impartial manner while acting in the best interests of the Division of Medicaid and the beneficiaries that it serves.

As such, DUR Board members are required to complete and submit annually a Conflict of Interest disclosure statement with the DOM Office of Pharmacy and DUR Coordinator. Statements shall be maintained by the Office of Pharmacy. Members have an ongoing responsibility to update and revise said statements, disclosing any new conflicts of interest to the DUR Coordinator and DOM Office of Pharmacy.

It is the sole responsibility and requirement of each board member to review the agenda of each forthcoming board meeting to determine any if any potential conflicts of interest exist. If so, an aforementioned Disclosure statement must be updated indicating the conflict of interest. The board member should notify the Chair or Chair-Elect of the conflict of interest prior to the meeting.

A DUR Board member shall recuse himself/herself from any vote, action, or discussion pertaining to any product or product class if there is documentation stating an actual or perceived conflict of interest. Please refer to the procedure outlined in Article III, Section 7.

Article VI. Confidentiality

DUR Board members are required to safeguard all confidential and proprietary information, including but not limited to pricing information, which is disclosed by the Mississippi Division of Medicaid for purposes of conducting DUR Board activities. Any provider or patient specific information discussed by the DUR Board shall also be kept strictly confidential in accordance with state and federal law.

Article VII. Amendments

Proposed Amendments of By-Laws

- A. Proposed amendments must be submitted to the DUR Coordinator at least thirty (30) days prior to the next scheduled DUR meeting and the proposed amendments will be disseminated to the DUR Board en masse for consideration at said DUR Board meeting.
- B. Proposed amendments will be distributed to board members no less than five (5) business days prior to next DUR Board meeting.
- C. Proposed amendments will be initiated by the Chair, or the Chair-Elect in absentia of the Chair, prior to Next Meeting Information announcements.
- D. Proposed amendments will be voted upon at the next scheduled DUR Board meeting. If majority of DUR Board votes to ratify amendment, the amendment will take effect immediately at the conclusion of the meeting.

MS-DUR BOARD COMMON ABBREVIATIONS

	1
AWP	Any Willing Provider, Average
	Wholesale Price
BENE	Beneficiary
CAH	Critical Access Hospital
CCO	Coordinated Care Organization
CDC	Centers for Disease Control
CHIP	Children's Health Insurance
	Program
CMS	Center for Medicare and Medicaid
	Services
СОВ	Coordination of Benefits
CPC	Complex Pharmaceutical Care
DME	Durable Medical Equipment
DOC	Department of Corrections
DOM	Division of Medicaid
DUR	Drug Utilization Review
EOB	Explanation of Benefits
EPSDT	Early and Periodic Screening,
	Diagnosis and Treatment
FA	Fiscal Agent
FFS	Fee For Service
FPW	Family Planning Waiver
FQHC	Federally Qualified Health Clinic
FY	Fiscal Year
НВ	House Bill
HCPCS/	Health Plan Employer Data and
HEIDIS	Information Set
HHS	Department of Health and Human
	Services
HIPAA	Health Insurance Portability and
	Accountability
IDD	Intellectual and Developmental
	Disabilities
LTC	Long Term Care
MAG	Magnolia Health
MEDD	Morphine Equivalent Daily Dose
MOL	Molina Healthcare
MPR	Medication Possession Ratio
MSCAN	Mississippi Coordinated Access
	Network
MSDH	Mississippi State Department of
	Health
NADAC	National Average Drug Acquisition
	Cost

NDC	National Drug Code
P&T	Pharmacy and Therapeutics
PA	Prior Authorization
PBM	Pharmacy Benefit Manager
PDC	Proportion of Days Covered
PDC	•
	Preferred Drug List
PI	Program Integrity
PIP	Performance Improvement
	Program
POS	Point of Sale, Place of Service,
	Point of Service
Pro-DUR	Prospective Drug Use Review
OTC	Over the Counter
QI	Quality Indicator
QIO	Quality Improvement Organization
QM	Quality Management
RA	Remittance Advise
REOMB	Recipient's Explanation of Medicaid
	Benefits
Retro-	Retrospective Drug Utilization
DUR	Review
RFI	Request for Information
RFP	Request for Proposal
RHC	Rural Health Clinic
SB	Senate Bill
SCHIP	State Child Health Insurance
	Program
SMART	Conduent's Pharmacy Application
PA	(SmartPA) is a proprietary
	electronic prior authorization
	system used for Medicaid fee for
	service claims
SPA	State Plan Amendment
UHC	United Healthcare
UM/QIO	Utilization Management and
	Quality Improvement Organization
UPDL	Universal Preferred Drug List
UR	Utilization Review
VFC	Vaccines for Children
WAC	Wholesale Acquisition Cost
WIC	Women, Infants, Children
340B	Federal Drug Discount Program
3400	I reactat brug biscoulit Program