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

MISSISSIPPI DIVISION OF
MEDICAID

September 17, 2020 at 1:00pm

ZOOM Meeting

Jackson, MS

Prepared by:

MS | DUR Evidence-Based DUR Initiative
The University of Mississippi School of Pharmacy

Drug Utilization Review Board

Lauren Bloodworth, PharmD (Chair)
University of MS School of Pharmacy
201D Faser Hall
University, MS 38677
Term Expires: June 30, 2021

Beverly Bryant, MD
UMMC, School of Medicine
2500 North State Street
Jackson, MS 39216
Term Expires: June 30, 2021

Rhonda Dunaway, RPh
Coastal Family Health Center
9113 Hwy 49 Suite 200
Gulfport, MS 39503
Term Expires: December 31, 2020

Tanya Fitts, MD
Lafayette Pediatric Clinic
1300 Access Road, Suite 400
Oxford, MS 38655
Term Expires: June 30, 2021

Ray Montalvo, MD
KDMC Specialty Clinic
940 Brookway Boulevard
Brookhaven, MS 39601
Term Expires: December 31, 2020

Holly R. Moore, PharmD
Anderson Regional Medical Center
2124 14th Street
Meridian, MS 39301
Term Expires: December 31, 2020

Janet Ricks, DO
UMMC, Family Medicine
2500 North State Street
Jackson, MS 39216
Term Expires: June 30, 2021

Dennis Smith, RPh
Polk's Discount Drugs
1031 Star Rd
Brandon, MS 39042
Term Expires: December 31, 2020

Cheryl Sudduth, RPh
Funderburk's Pharmacy
134 West Commerce Street
Hernando, MS 38632
Term Expires: June 30, 2022

James Taylor, PharmD
North MS Medical Center
830 S. Gloster Street
Tupelo, MS 38801
Term Expires: June 30, 2022

Alan Torrey, MD
Merit Health Medical Group
Pain Management
2080 South Frontage Road
Vicksburg, MS 39180
Term Expires: June 30, 2022

2020 DUR Board Meeting Dates

March 19, 2020
June 11, 2020
September 17, 2020
December 3, 2020

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 two 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 17, 2020

Welcome

Old Business

Resource Utilization Review

Follow-up and Discussion from the Board

New Business

Pharmacy Program Update Terri Kirby, RPh

Next Meeting Information
Remaining 2020 Date: December 3

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE JUNE 11, 2020 MEETING

DUR Board Roster: State Fiscal Year 2020 (July 1, 2019- June 30, 2020)	Sep 2019	Dec 2019	Mar 2020	Jun 2020
Lauren Bloodworth, PharmD	✓	✓	✓	✓
Beverly Bryant, MD	✓	✓	✓	✓
Rhonda Dunaway, RPh	✓	✓		✓
Tanya Fitts, MD		✓	✓	✓
Ray Montalvo, MD (Chair)	✓	✓	✓	✓
Holly Moore, PharmD	✓	✓	✓	✓
Janet Ricks, DO			✓	✓
Dennis Smith, RPh	✓	✓	✓	✓
Cheryl Sudduth, RPh	✓	✓		✓
James Taylor, PharmD	✓		✓	✓
Alan Torrey, MD	✓		✓	✓
Veda Vedanarayanan, MD	✓			
TOTAL PRESENT	**10**	**8**	**9**	**11**

Also Present:

Division of Medicaid (DOM) Staff:
Terri Kirby, RPh, CPM, Pharmacy Director; Cindy Noble, PharmD, MPH, DUR Coordinator; Gail McCorkle, RPh, Clinical Pharmacist; Carlos Latorre, MD, Medical Director; Drew Snyder, JD, Executive Director; Sue Reno, RN, Program Integrity; Jessica Tyson, OMAP;

University of Mississippi School of Pharmacy - MS-DUR Staff:
Eric Pittman, PharmD, MS-DUR Project Director; Kaustuv Bhattacharya, PhD, Research Assistant Professor - CPMM;

Conduent Staff:
Lew Anne Snow, RN, BSN, Pharmacy Services Sr. Analyst, Mississippi Medicaid Project;

Change Healthcare Staff:
Paige Clayton, PharmD, On-Site Clinical Pharmacist; Shannon Hardwick, RPh, CPC Pharmacist;

Alliant Health Staff:
Buddy Ogletree, PharmD, Clinical Pharmacist; Catherine Brett, MD, Clinical Director;

MedeAnalytics:
Chris Bryan, Account Manager, Client Services; Felicia Lobrano, RN, BSN, Senior Business Analyst;

Coordinated Care Organization (CCO) Staff:
Heather Odem, PharmD, Director of Pharmacy - Mississippi, UnitedHealthcare Community & State; Jenni Grantham, PharmD, Director of Pharmacy, Magnolia Health; Mike Todaro, PharmD, Vice President Pharmacy Operations, Magnolia Health; Trina Stewart, PharmD, Pharmacy Manager, Molina Healthcare;

Visitors:
Mandy Schnelten, Jazz Pharmaceuticals; Judith Clark, Consultant; Sharon Pennington, MS CAM; Spencer Sullivan, MS CAM; Kayla Douglas, MS CAM; Michael Chen, Aimmune Therapeutics; Michelle Shirley, Indivior; David Large, Biohaven Pharmaceuticals; Lorien Stringer, Avanir Pharmaceuticals; Robert Firnberg, Gilead; Phil Hecht, Abbvie; Mycah Wilson, Genentech; Sonya Powell, Janssen; Gene Wingo, Biogen; Stephanie Arnold, Greenwich Biosciences; Nole Mangine, Allergan/Abbvie; Gibby Rodriguez, Indivior; Brad Leiser, Mylan; Brad Clay, Novartis; Jeff Knappen, Spark; Brent Young, Global Blood Therapeutics; Mike Peoples, Lilly; Bruce Wallace, Azurity.

Call to Order:
Dr. Pittman called the meeting to order at 1:02pm and welcomed everyone to the meeting via Zoom.

OLD BUSINESS:

Dr. Bloodworth moved to approve the minutes from the March2020 DUR Board Meeting, seconded by Dr. Torrey, and unanimously approved by the DUR Board.

Resource Utilization Review:
Dr. Pittman presented the resource utilization report for January 2020 – March 2020. No abnormal shifts in drug categories were noted.

Feedback and Discussion from Board:
Dr. Pittman followed-up with the Board on their request to rerun the human immunodeficiency virus (HIV) antiretroviral (ARV) adherence data that was presented at the March 2020 Board meeting to include beneficiaries less than 18 years. When the analysis was rerun, only 13 additional beneficiaries were identified. This additional data did not change the overall adherence numbers reported at the March 2020 Board meeting.

NEW BUSINESS:

Update on MS-DUR Educational Interventions:
Dr. Pittman provided an overview of all DUR mailings that occurred March 2020 – May 2020. He pointed out the downward trend in the number of beneficiaries classified as provider shopping. MS-DUR also conducted a one-time mailing in May 2020 to providers that had prescribed tricyclic antidepressants to beneficiaries age < 25 years during the previous 6 months alerting them to the new age edit that is scheduled for implementation August 2020. This letter was mailed to 507 prescribers addressing 1,220 beneficiaries.

Special Analysis Projects:
Sickle Cell Disease and New Pharmacologic Agents
Dr. Sharon Pennington with the MS Center for Advanced Medicine (MS CAM) presented to the Board an overview of sickle cell disease and pharmacotherapy options. Dr. Pittman followed Dr. Pennington and presented results from MS-DUR's analysis of sickle cell disease in MS Medicaid. MS-DUR's report also included a forecast of potential candidates for treatment with either crizanlizumab (Adakveo) or voxelotor (Oxbryta). Following a robust discussion, the subsequent recommendations were proposed:

1. DOM should create manual prior authorization criteria for crizanlizumab and voxelotor for review/approval of appropriate use of these products.

2. The pharmacy programs (FFS and MCOs) should provide patient education on the role of hydroxyurea and encourage greater utilization among beneficiaries with sickle cell disease.

3. MS-DUR should expand the analysis to stratify sickle cell-related hospitalizations by the use of medications (hydroxyurea, Endari, or no preventive medications).

Dr. Torrey motioned to approve the recommendations, seconded by Dr. Fitts, and unanimously approved by the Board.

Cytokine and CAM Antagonist Utilization
Dr. Pittman presented an overview report of the utilization of the agents in the cytokine and cell-adhesion molecule (CAM) antagonist category. Prescribing trends were analyzed, and the presence of target diagnosis information was noted. The cytokine and CAM antagonist class experienced a 20.7% increase in utilization from January 2018 until December 2019. This increase was largely due to a 33% increase in claims for Humira®. Although tumor necrosis factor (TNF) inhibitors can be used to treat a broad array of disease states, target diagnosis information was absent in claims data for approximately 18-20% of new starts of Humira® and Enbrel® during the study period. Following a robust discussion by the board, the subsequent recommendations were presented:

1. DOM should implement an electronic PA edit to add a diagnosis check for utilization of TNF inhibitors in the Cytokine & CAM antagonists' category.

2. MS-DUR should continue to monitor this category of drugs to determine whether future step-therapy requirements would be appropriate, especially with the advent of biosimilar alternatives in this therapeutic category.

Dr. Bloodworth motioned to approve the recommendations, seconded by Ms. Dunaway, and unanimously approved by the Board.

Hepatitis C Treatment Overview

Dr. Pittman presented an overview of Hepatitis C treatment among Medicaid beneficiaries since the introduction of direct acting antivirals (DAAs) in 2013. Descriptive characteristics of beneficiaries treated, pharmacologic regimens prescribed, and completion rates were presented. MS Medicaid treated 1345 beneficiaries with DAA therapy since 2013. Overall completion rates for DAA therapy across all pharmacy programs since 2013 was at 89.7%. Overall completion rates since Q4 2016 increased to 92% across all pharmacy programs with the utilization of patient management programs across all pharmacy plans. It was noted that although few beneficiaries were impacted, one area with frequent suboptimal completion rates was among those beneficiaries that switched pharmacy programs during DAA therapy. When examining beneficiaries requiring liver transplants, it appeared that treatment with DAA therapy reduced the proportion of Hep C positive beneficiaries receiving liver transplant during the study period**.** After discussion from the Board, the following recommendation was presented by MS-DUR:

1. MS-DUR recommended DOM restrict beneficiaries from switching pharmacy programs while taking DAA therapy if possible or develop some type of hand-off process for beneficiaries switching pharmacy programs to ensure continuity of care.

Dr. Bloodworth motioned to approve the recommendation, seconded by Dr. Fitts, and unanimously approved by the Board.

FDA Drug Safety Updates:

Dr. Pittman presented FDA drug safety communications for April 2020 – June 2020.

Pharmacy Program Update:

Ms. Kirby informed the Board that DOM is waiving prescription and medical copays when providers indicate treatment is for COVID-19 related treatment. She encouraged providers and pharmacists to be on the lookout for a notification of these changes. Ms. Kirby also informed the Board that the tricyclic antidepressant age edit recommended by the DUR Board would be implemented on August 1, 2020. Ms. Kirby acknowledged the DUR Board members completing their terms of service June 2020 (Ms. Rhonda Dunaway, Dr. Ray Montalvo, Dr. Holly Moore, and Mr. Dennis Smith). Dr. Veda Vedanarayanan also turned in his resignation from the Board. Ms. Kirby announced the upcoming retirement of Dr. Cindy Noble, DUR Coordinator, at the end of

June 2020 and recognized Dr. Noble for receiving the Hall of Fame Award by the Mississippi Pharmacist's Association.

Miscellaneous:
2020 Meeting Dates/Times
September 17, 2020
December 3, 2020
**Meeting times will remain at 1 pm.*

Next Meeting Information:
Dr. Pittman announced that the next meeting of the DUR Board will take place on September 17, 2020 at 1pm.

Dr. Bloodworth motioned to adjourn the meeting at 2:50 pm, seconded by Mr. Smith, and unanimously approved by the Board.

Submitted,

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

Meeting Location: Woolfolk Building, 501 North West Street, Conference Room 145, Jackson, MS 39201. Update: Due to COVID-19 pandemic, meeting will be held virtually.

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

Date and Time: June 11, 2020 at 1PM. Meeting will be held virtually.

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.


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PUBLIC MEETING NOTICES
Mississippi Public Meeting Notices
NOTICE DETAILS
NOTICE DETAILS
State Agency: Division of Medicaid
Public Body: Division of Medicaid
Title: Drug Utilization Review Board Meeting
Subject: Drug Utilization Review Board
Date and Time: 6/11/2020 1:00:00 PM
Description:
The Mississippi Division of Medicaid Drug Utilization Review Board is a quality assurance body whi
ch seeks to assure appropriate drug therapy.
Back
MEETING LOCATION
501 North West Street
Jackson MS 39201
Map this!
CONTACT INFORMATION
DOM Pharmacy Bureau
6013595253
dompharmacybureau@medicaid.ms.gov
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DFA Meeting notification 2020.docx
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Resource Utilizaton Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS
January 1, 2020 through June 30, 2020

			Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20
Total enrollment			692,441	690,462	687,911	695,265	700,203	705,213
Dual-eligibles			164,238	164,514	164,855	164,842	164,615	164,165
Pharmacy benefits			580,925	578,454	575,381	582,317	587,161	592,134
	LTC		17,097	17,063	16,982	16,725	16,364	15,943
	PLAN %	**FFS**	24.9%	25.1%	25.0%	25.9%	25.7%	24.9%
		MSCAN-UHC	29.2%	29.3%	29.4%	29.2%	29.3%	29.7%
		MSCAN-Magnolia	33.8%	33.5%	33.5%	32.9%	32.8%	32.9%
		MSCAN-Molina	12.1%	12.1%	12.1%	12.0%	12.2%	12.5%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS
January 1, 2020 through June 30, 2020

		Jan-20	Feb-20	Mar-20	Apr-20	May-20	Jun-20
# Rx Fills	**FFS**	110,452	106,472	105,206	86,130	85,565	92,717
	MSCAN-UHC	164,940	159,385	161,849	125,377	121,275	132,540
	MSCAN-Mag	211,771	201,398	192,002	151,397	146,425	156,164
	MSCAN-Mol	47,462	46,383	43,961	32,572	32,472	36,702
# Rx Fills / Bene	**FFS**	0.8	0.7	0.7	0.6	0.6	0.6
	MSCAN-UHC	1.0	0.9	1.0	0.7	0.7	0.8
	MSCAN-Mag	1.1	1.0	1.0	0.8	0.8	0.8
	MSCAN-Mol	0.7	0.7	0.6	0.5	0.5	0.5
$ Paid Rx	**FFS**	$12,651,963	$11,406,954	$12,389,139	$10,953,725	$10,486,179	$11,250,968
	MSCAN-UHC	$14,558,843	$13,934,588	$15,602,724	$13,652,606	$12,632,719	$13,860,855
	MSCAN-Mag	$19,528,097	$18,228,081	$19,162,858	$17,447,459	$16,504,826	$17,198,199
	MSCAN-Mol	$3,458,445	$3,451,184	$3,730,180	$3,255,359	$2,991,883	$3,410,314
$ /Rx Fill	**FFS**	$114.55	$107.14	$117.76	$127.18	$122.55	$121.35
	MSCAN-UHC	$88.27	$87.43	$96.40	$108.89	$104.17	$104.58
	MSCAN-Mag	$92.21	$90.51	$99.81	$115.24	$112.72	$110.13
	MSCAN-Mol	$72.87	$74.41	$84.85	$99.94	$92.14	$92.92
$ /Bene	**FFS**	$87.47	$78.56	$86.13	$72.63	$69.49	$76.31
	MSCAN-UHC	$85.83	$82.22	$92.24	$80.29	$73.43	$78.82
	MSCAN-Mag	$99.45	$94.06	$99.42	$91.07	$85.70	$88.28
	MSCAN-Mol	$49.20	$49.31	$53.58	$46.59	$41.77	$46.07

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

TABLE C: TOP 10 DRUG CATEGORIES BY NUMBER OF CLAIMS IN JUN 2020 (FFS AND CCOs)

Category	Month Year	Rank Volume	# RXs	$ Paid	# Unique Benes
CNS stimulants	Jun 2020	1	19,334	$3,680,983	16,624
	May 2020	1	19,266	$3,677,601	16,721
	Apr 2020	1	20,874	$4,091,078	17,994
atypical antipsychotics	Jun 2020	2	13,659	$3,988,454	11,431
	May 2020	2	13,117	$3,606,650	11,221
	Apr 2020	2	13,621	$3,821,065	11,466
antihistamines	Jun 2020	3	13,002	$194,120	12,091
	May 2020	3	11,956	$178,169	11,176
	Apr 2020	3	13,205	$195,661	12,337
nonsteroidal anti-inflammatory agents	Jun 2020	4	12,939	$189,268	12,237
	May 2020	6	11,137	$164,261	10,558
	Apr 2020	9	10,134	$154,567	9,576
narcotic analgesic combinations	Jun 2020	5	12,877	$582,917	11,667
	May 2020	5	11,483	$534,447	10,517
	Apr 2020	10	10,088	$550,697	9,162
SSRI antidepressants	Jun 2020	6	12,306	$149,776	11,321
	May 2020	4	11,630	$142,380	10,793
	Apr 2020	5	11,963	$148,098	10,991
proton pump inhibitors	Jun 2020	7	11,724	$446,879	11,135
	May 2020	7	11,079	$406,250	10,563
	Apr 2020	6	11,278	$427,529	10,707
adrenergic bronchodilators	Jun 2020	8	11,634	$625,173	9,780
	May 2020	8	10,822	$550,179	9,103
	Apr 2020	4	12,635	$614,053	10,635
antiadrenergic agents, centrally acting	Jun 2020	9	10,252	$233,861	9,222
	May 2020	9	9,994	$227,080	9,036
	Apr 2020	7	10,392	$241,437	9,379
gamma-aminobutyric acid analogs	Jun 2020	10	9,640	$428,864	8,855
	May 2020	10	9,096	$520,207	8,429
	Apr 2020	11	9,339	$551,282	8,507

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN JUN 2020 (FFS AND CCOs)

Category	Month Year	Rank Paid Amt	# RXs	$ Paid	# Unique Benes
atypical antipsychotics	Jun 2020	1	13,659	$3,988,454	11,431
	May 2020	2	13,117	$3,606,650	11,221
	Apr 2020	2	13,621	$3,821,065	11,466
CNS stimulants	Jun 2020	2	19,334	$3,680,983	16,624
	May 2020	1	19,266	$3,677,601	16,721
	Apr 2020	1	20,874	$4,091,078	17,994
insulin	Jun 2020	3	5,122	$2,474,614	3,801
	May 2020	4	4,974	$2,407,929	3,723
	Apr 2020	4	5,086	$2,492,705	3,774
antiviral combinations	Jun 2020	4	813	$2,438,123	739
	May 2020	3	780	$2,452,437	714
	Apr 2020	3	853	$2,738,040	764
antirheumatics	Jun 2020	5	958	$2,074,033	850
	May 2020	5	903	$1,745,652	816
	Apr 2020	5	965	$1,981,464	866
factor for bleeding disorders	Jun 2020	6	104	$1,509,611	78
	May 2020	6	92	$1,354,341	76
	Apr 2020	6	92	$1,401,327	77
interleukin inhibitors	Jun 2020	7	224	$1,405,890	201
	May 2020	8	189	$1,046,427	169
	Apr 2020	7	214	$1,297,617	180
bronchodilator combinations	Jun 2020	8	3,861	$1,062,967	3,468
	May 2020	9	3,802	$1,034,520	3,428
	Apr 2020	8	3,923	$1,058,993	3,553
CFTR combinations	Jun 2020	9	49	$967,439	44
	May 2020	7	54	$1,057,949	48
	Apr 2020	9	51	$945,827	48
TNF alpha inhibitors	Jun 2020	10	149	$807,110	134
	May 2020	10	142	$778,040	134
	Apr 2020	12	138	$759,352	124

TABLE E: TOP 25 DRUG MOLECULES
BY NUMBER OF CLAIMS IN JUN 2020 (FFS and CCOs)

Drug Molecule Therapeutic Category	May 2020 # Claims	Jun 2020 # Claims	Jun 2020 $ Paid	Jun 2020 # Unique Benes
albuterol / adrenergic bronchodilators	10,353	11,010	$440,166	9,331
montelukast / leukotriene modifiers	8,987	9,098	$139,423	8,795
gabapentin / gamma-aminobutyric acid analogs	7,718	8,226	$130,687	7,589
acetaminophen-hydrocodone / narcotic analgesic combinations	7,267	8,223	$110,989	7,648
amoxicillin / aminopenicillins	5,343	7,014	$88,008	6,848
cetirizine / antihistamines	6,011	6,316	$84,642	6,134
clonidine / antiadrenergic agents, centrally acting	6,092	6,255	$106,938	5,787
amlodipine / calcium channel blocking agents	5,566	5,887	$65,099	5,548
lisdexamfetamine / CNS stimulants	5,801	5,738	$1,793,169	5,570
omeprazole / proton pump inhibitors	5,482	5,694	$63,509	5,511
ibuprofen / nonsteroidal anti-inflammatory agents	4,656	5,676	$70,298	5,504
fluticasone nasal / nasal steroids	5,048	5,287	$83,517	5,189
amphetamine-dextroamphetamine / CNS stimulants	4,903	4,953	$206,485	4,279
methylphenidate / CNS stimulants	4,778	4,894	$883,588	4,346
azithromycin / macrolides	3,433	4,515	$72,724	4,389
triamcinolone topical / topical steroids	3,883	4,508	$81,616	4,352
sertraline / SSRI antidepressants	4,128	4,418	$52,687	4,062
atorvastatin / HMG-CoA reductase inhibitors (statins)	4,172	4,332	$52,684	4,039
guanfacine / antiadrenergic agents, centrally acting	3,880	3,975	$126,496	3,727
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	3,285	3,775	$56,405	3,554
mupirocin topical / topical antibiotics	3,073	3,711	$57,522	3,622
metformin / biguanides	3,559	3,692	$42,453	3,450
ondansetron / 5HT3 receptor antagonists	3,152	3,594	$51,142	3,422
lisinopril / angiotensin converting enzyme (ACE) inhibitors	3,392	3,585	$34,639	3,359
sulfamethoxazole-trimethoprim / sulfonamides	2,958	3,573	$64,879	3,490

TABLE F: TOP 25 DRUG MOLECULES
BY DOLLARS PAID IN JUN 2020 (FFS and CCOs)

Drug Molecule Therapeutic Category	May 2020 $ Paid	Jun 2020 $ Paid	Jun 2020 # Claims	Jun 2020 # Unique Benes
adalimumab / antirheumatics	$1,597,416	$1,819,257	272	236
lisdexamfetamine / CNS stimulants	$1,818,409	$1,793,169	5,738	5,570
paliperidone / atypical antipsychotics	$1,352,228	$1,560,369	644	562
bictegravir/emtricitabine/tenofovir / antiviral combinations	$1,009,738	$1,038,515	311	291
aripiprazole / atypical antipsychotics	$842,594	$956,317	3,461	3,139
insulin glargine / insulin	$839,223	$888,798	1,909	1,820
methylphenidate / CNS stimulants	$861,466	$883,588	4,894	4,346
etanercept / TNF alpha inhibitors	$653,310	$661,458	125	112
emicizumab / factor for bleeding disorders	$453,608	$646,679	28	19
somatropin / growth hormones	$493,685	$610,944	145	132
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	$624,308	$575,508	28	25
insulin aspart / insulin	$548,912	$574,457	1,347	1,268
dexmethylphenidate / CNS stimulants	$537,720	$543,139	2,392	1,981
lurasidone / atypical antipsychotics	$520,180	$521,836	383	362
budesonide-formoterol / bronchodilator combinations	$491,880	$501,238	1,590	1,524
liraglutide / GLP-1 receptor agonists	$471,345	$488,469	610	587
lacosamide / miscellaneous anticonvulsants	$466,124	$487,256	541	484
ustekinumab / interleukin inhibitors	$213,309	$481,570	25	24
insulin detemir / insulin	$459,343	$477,924	863	813
cobicistat/elvitegravir/emtricitabine/tenofov / antiviral combinations	$515,466	$472,132	139	135
hydroxyprogesterone / progestins	$397,481	$465,180	144	129
albuterol / adrenergic bronchodilators	$409,965	$440,166	11,010	9,331
dupilumab / interleukin inhibitors	$346,249	$436,272	140	121
buprenorphine-naloxone / narcotic analgesic combinations	$383,508	$420,871	1,344	1,101
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	$227,977	$410,446	1,665	1,645

TABLE G: TOP 25 DRUG MOLECULES
BY CHANGE IN NUMBER OF CLAIMS FROM APR 2020 TO JUN 2020 (FFS and CCOs)

Drug Molecule	Apr 2020 # Claims	May 2020 # Claims	Jun 2020 # Claims	Jun 2020 $ Paid	Jun 2020 # Unique Benes
acetaminophen-hydrocodone / narcotic analgesic combinations	6,125	7,267	8,223	$110,989	7,648
amoxicillin / aminopenicillins	5,214	5,343	7,014	$88,008	6,848
ibuprofen / nonsteroidal anti-inflammatory agents	4,175	4,656	5,676	$70,298	5,504
mupirocin topical / topical antibiotics	2,496	3,073	3,711	$57,522	3,622
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	661	922	1,665	$410,446	1,645
sulfamethoxazole-trimethoprim / sulfonamides	2,715	2,958	3,573	$64,879	3,490
triamcinolone topical / topical steroids	3,659	3,883	4,508	$81,616	4,352
cephalexin / first generation cephalosporins	1,750	2,011	2,516	$42,115	2,472
ondansetron / 5HT3 receptor antagonists	2,940	3,152	3,594	$51,142	3,422
metronidazole / miscellaneous antibiotics	1,864	1,925	2,513	$28,285	2,423
clindamycin / lincomycin derivatives	1,553	1,865	2,145	$57,948	2,072
methylprednisolone / glucocorticoids	1,044	1,257	1,543	$22,499	1,524
naproxen / nonsteroidal anti-inflammatory agents	1,789	1,972	2,270	$42,941	2,206
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	3,303	3,285	3,775	$56,405	3,554
acetaminophen-oxycodone / narcotic analgesic combinations	2,048	2,277	2,441	$40,888	2,291
chlorhexidine topical / antiseptic and germicides	356	574	746	$8,259	731
azithromycin / macrolides	4,131	3,433	4,515	$72,724	4,389
gabapentin / gamma-aminobutyric acid analogs	7,868	7,718	8,226	$130,687	7,589
famotidine / H2 antagonists	2,093	2,245	2,436	$95,846	2,294
hydrocortisone topical / topical steroids	1,514	1,510	1,848	$42,646	1,795
ofloxacin otic / otic anti-infectives	227	298	557	$17,969	543
ketorolac / nonsteroidal anti-inflammatory agents	480	625	801	$20,292	790
cyclobenzaprine / skeletal muscle relaxants	2,497	2,608	2,813	$28,179	2,693
prednisolone / glucocorticoids	1,452	1,418	1,764	$30,408	1,710
fluconazole / azole antifungals	2,582	2,583	2,894	$39,583	2,730

TABLE H: TOP 25 DRUG MOLECULES
BY CHANGE IN AMOUNT PAID FROM APR 2020 TO JUN 2020 (FFS and CCOs)

Drug Molecule	Apr 2020 $ Paid	May 2020 $ Paid	Jun 2020 $ Paid	Jun 2020 # Claims	Jun 2020 # Unique Benes
ciprofloxacin-dexamethasone otic / otic steroids with anti-infectives	$163,337	$227,977	$410,446	1,665	1,645
emicizumab / factor for bleeding disorders	$423,317	$453,608	$646,679	28	19
ustekinumab / interleukin inhibitors	$342,468	$213,309	$481,570	25	24
cysteamine / miscellaneous uncategorized agents	$60,853	$170,337	$182,556	3	3
adalimumab / antirheumatics	$1,727,056	$1,597,416	$1,819,257	272	236
paliperidone / atypical antipsychotics	$1,470,473	$1,352,228	$1,560,369	644	562
canakinumab / interleukin inhibitors	$163,848	$180,222	$229,387	11	10
aripiprazole / atypical antipsychotics	$898,247	$842,594	$956,317	3,461	3,139
interferon gamma-1b / interferons	$115,272	$230,536	$172,906	3	3
somatropin / growth hormones	$554,221	$493,685	$610,944	145	132
antihemophilic factor / factor for bleeding disorders	$245,692	$296,873	$300,459	15	11
epinephrine / adrenergic bronchodilators	$108,330	$113,142	$159,187	549	547
immune globulin intravenous / immune globulins	$79,128	$121,018	$128,528	9	7
sacubitril-valsartan / angiotensin receptor blockers and neprilysin inhibitors	$223,091	$230,232	$271,162	487	447
dasatinib / BCR-ABL tyrosine kinase inhibitors	$83,777	$74,593	$126,439	9	7
dimethyl fumarate / selective immunosuppressants	$99,413	$115,982	$140,834	17	16
teduglutide / miscellaneous GI agents	$121,528	$81,019	$162,036	4	4
infliximab / TNF alpha inhibitors	$69,535	$50,752	$108,430	16	14
lenvatinib / multikinase inhibitors	$38,158	$38,158	$76,317	4	4
tucatinib / HER2 inhibitors	$0	$18,508	$37,017	2	1
carglumic acid / miscellaneous uncategorized agents	$0	$12,298	$36,894	3	3
leuprolide / antineoplastic hormones	$118,799	$169,311	$154,919	30	28
sunitinib / multikinase inhibitors	$0	$0	$36,103	2	2
glatiramer / other immunostimulants	$70,530	$85,493	$102,937	25	22
dupilumab / interleukin inhibitors	$404,569	$346,249	$436,272	140	121

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 2020 TO JUN 2020 (FFS and CCOs)

Drug Product Therapeutic Category	Jun 2020 # Claims	Jun 2020 $ Paid	Jun 2020 Avr. Paid Per Rx	Jun 2020 Avr. Units Per Rx	Apr 2020 Paid Per Unit	May 2020 Paid Per Unit	Jun 2020 Paid Per Unit	Percent Change
amphetamine-dextroamphetamine 20 mg capsule, extended release / CNS stimulants (P)	535	$32,764	$61.24	31	$1.53	$1.47	$1.63	6.4%
buprenorphine-naloxone 8 mg-2 mg film / narcotic analgesic combinations (N)	621	$143,431	$230.97	47	$4.46	$4.57	$4.60	3.2%
Tradjenta (linagliptin) 5 mg tablet / dipeptidyl peptidase 4 inhibitors (P)	221	$121,670	$550.54	39	$14.22	$14.17	$14.45	1.6%
dexmethylphenidate 15 mg capsule, extended release / CNS stimulants (N)	111	$12,086	$108.88	30	$3.17	$3.03	$3.22	1.6%
Xarelto (rivaroxaban) 20 mg tablet / factor Xa inhibitors (P)	379	$173,704	$458.32	31	$14.37	$14.77	$14.58	1.5%
Entresto (sacubitril-valsartan) 97 mg-103 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	154	$88,741	$576.24	64	$8.49	$8.54	$8.61	1.4%
Aptensio XR (methylphenidate) (40/60 release) 40 mg/24 hr capsule, extended release / CNS stimulants (P)	102	$25,507	$250.07	30	$7.85	$7.92	$7.96	1.3%
Vyvanse (lisdexamfetamine) 30 mg tablet, chewable / CNS stimulants (P)	154	$48,391	$314.23	30	$10.01	$10.05	$10.14	1.3%
Entresto (sacubitril-valsartan) 24 mg-26 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (P)	169	$90,715	$536.78	61	$8.53	$8.66	$8.61	1.0%
Focalin XR (dexmethylphenidate) 20 mg capsule, extended release / CNS stimulants (P)	249	$97,494	$391.54	30	$12.42	$12.40	$12.53	0.9%
Janumet (metformin-sitagliptin) 1000 mg-50 mg tablet / antidiabetic combinations (P)	116	$68,889	$593.87	80	$7.34	$7.32	$7.40	0.8%
Latuda (lurasidone) 80 mg tablet / atypical antipsychotics (N)	119	$160,800	$1,351.26	33	$40.35	$40.67	$40.67	0.8%
Jardiance (empagliflozin) 25 mg tablet / SGLT-2 inhibitors (P)	283	$199,530	$705.05	41	$16.38	$16.17	$16.50	0.7%

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 2020 TO JUN 2020 (FFS and CCOs)

Drug Product Therapeutic Category	Jun 2020 # Claims	Jun 2020 $ Paid	Jun 2020 Avr. Paid Per Rx	Jun 2020 Avr. Units Per Rx	Apr 2020 Paid Per Unit	May 2020 Paid Per Unit	Jun 2020 Paid Per Unit	Percent Change
atomoxetine 25 mg capsule / CNS stimulants (P)	177	$12,857	$72.64	31	$1.98	$1.96	$2.00	0.6%
Xulane (ethinyl estradiol-norelgestromin) 35 mcg-150 mcg/24 hr film, extended release / contraceptives (P)	1,281	$176,384	$137.69	4	$37.93	$37.88	$38.13	0.5%

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 2020 – AUGUST 2020

Ongoing Intervention(s):

PROVIDER SHOPPING FOR OPIOIDS (≥4 Prescribers AND ≥4 Pharmacies)			
Month	**Prescribers Mailed**	**Pharmacies Mailed**	**Benes Addressed**
19-Sep	18	14	32
19-Oct	18	14	32
19-Nov	13	12	27
19-Dec	14	9	23
20-Jan	15	12	27
20-Feb	8	6	14
20-Mar	7	4	11
20-Apr	4	3	7
20-May	3	4	7
20-Jun	9	5	14
20-Jul	6	5	11
19-Aug	9	4	13

OPIOID PRESCRIBING TRENDS IN MISSISSIPPI MEDICAID

BACKGROUND

The opioid epidemic and its devastating impacts have led to extensive changes in the way opioids are prescribed across the United States. Mississippi Medicaid DUR has been involved in assessing multiple opioid-related quality measures and implementing various DUR initiatives over the past several years. In 2016 the Centers for Disease Control and Prevention (CDC) published the CDC Guidelines for Prescribing Opioids for Chronic Pain.[1] At the April 2016 DUR Board meeting, the Board reviewed the CDC guidelines along with Medicaid claims data analysis and made several recommendations for the prescribing of opioids. Over the next several years the Mississippi Division of Medicaid (DOM) carefully developed criteria based on those DUR Board recommendations. As an initial step, in late 2016 MS-DUR began conducting multiple patient-specific provider notices focused on educating prescribers on the CDC guidelines. In August 2019, DOM implemented four Opioid Initiatives in response to the DUR Board's recommendations which aligned with the CDC's guidelines, the Mississippi State Board of Medical Licensure prescribing regulations, the Governor's Opioid and Heroin Task Force recommendations, and Medicaid requirements under section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and the Communities Act (SUPPORT Act).[1–4]

The four Opioid Initiatives implemented were:

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.

MS-DUR analyzed opioid claims for the period from January 2018 through June 2020 to examine prescribing trends related to CDC Guidelines and DOM's Opioid Initiatives among Medicaid beneficiaries.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid administrative claims data from January 2018 to June 2020. 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.

RESULTS

Table 1: All opioid prescriptions were analyzed and classified as short-acting or long-acting opioids based on CDC's Injury Center list of NDCs prescription data and morphine milligram equivalent (MME) conversion factor information (https://www.cdc.gov/drugoverdose/resources/data.html). 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 2017 to June 2020 were excluded from this analysis.

TABLE 1. Trends in Opioid Prescriptions in Mississippi Medicaid January 2018 - June 2020									
Month filled	Total opioid Rx	Number of benes with opioids	Percentage of benes on SA opioids among all opioid Rx	Short-acting (SA) opioid users			Long-acting (LA) opioid users		
				Number of benes	New starts	Percentage of new starts among SA opioid users	Number of benes	New starts	Percentage of new starts among LA opioid users
2018-01	19,021	16,888	88.8%	16,636	6,606	39.7%	609	16	2.6%
2018-02	17,911	16,001	89.3%	15,756	7,721	49.0%	580	48	8.3%
2018-03	18,541	16,383	88.4%	16,144	6,997	43.3%	576	17	3.0%
2018-04	17,553	15,581	88.8%	15,364	6,472	42.1%	543	15	2.8%
2018-05	17,922	15,682	87.5%	15,479	6,447	41.6%	522	13	2.5%
2018-06	17,692	15,696	88.7%	15,497	6,690	43.2%	511	16	3.1%
2018-07	17,401	15,448	88.8%	15,265	6,504	42.6%	496	8	1.6%
2018-08	17,923	15,561	86.8%	15,371	6,590	42.9%	490	15	3.1%
2018-09	15,783	14,114	89.4%	13,930	5,594	40.2%	466	13	2.8%
2018-10	16,970	14,921	87.9%	14,734	6,097	41.4%	479	15	3.1%
2018-11	15,763	13,856	87.9%	13,671	6,118	44.8%	463	40	8.6%
2018-12	14,711	13,126	89.2%	12,957	5,578	43.1%	450	34	7.6%
2019-01	15,617	13,790	88.3%	13,630	2,522	18.5%	432	36	8.3%
2019-02	14,279	12,755	89.3%	12,597	1,883	14.9%	412	6	1.5%
2019-03	14,676	13,153	89.6%	13,000	2,011	15.5%	427	12	2.8%
2019-04	14,740	13,118	89.0%	12,965	2,169	16.7%	421	9	2.1%
2019-05	14,705	12,977	88.2%	12,834	2,058	16.0%	411	10	2.4%
2019-06	13,778	12,487	90.6%	12,338	2,062	16.7%	384	6	1.6%
2019-07	14,905	13,185	88.5%	13,036	2,220	17.0%	388	10	2.6%
2019-08	13,062	11,589	88.7%	11,438	2,138	18.7%	341	5	1.5%
2019-09	12,370	11,139	90.0%	10,995	2,051	18.7%	330	6	1.8%
2019-10	12,635	11,305	89.5%	11,168	2,216	19.8%	323	2	0.6%
2019-11	11,235	10,233	91.1%	10,103	1,971	19.5%	300	4	1.3%
2019-12	11,378	10,291	90.4%	10,168	2,072	20.4%	284	2	0.7%
2020-01	11,793	10,558	89.5%	10,443	2,361	22.6%	273	4	1.5%
2020-02	10,713	9,738	90.9%	9,623	2,185	22.7%	256	6	2.3%
2020-03	10,175	9,099	89.4%	8,983	1,947	21.7%	260	8	3.1%
2020-04	8,658	7,746	89.5%	7,622	1,462	19.2%	261	1	0.4%
2020-05	9,962	8,951	89.9%	8,828	1,879	21.3%	253	3	1.2%
2020-06	11,255	10,060	89.4%	9,951	2,446	24.6%	255	8	3.1%

Note: Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from Jan 2017 to June 2020 were excluded.
Red line indicates when Medicaid Opioid Initiatives we implemented.

From Table 1:

- Total number of opioid prescription fills consistently trended down until May 2020.
- The percentage of beneficiaries taking SA opioids was approximately 90% after the Opioid Initiatives were implemented.
- A minimal number of beneficiaries were initiated on LA opioids. This number continued to decrease after the Opioid Initiatives were implemented.

Table 2: Among new starts, beneficiaries with short-acting opioid prescriptions were identified. Prescriptions were classified into different categories based on prescription days of supply (1 to 3, 4 to 7, 8 to 15, 16 to 29 and 30+ days). Based on the Opioid Initiative regarding days supply for initial SA opioid fills, new starts who either had more than 2 prescriptions for 7-day supply each or prescriptions with day supply lasting more than 7 day were flagged as beneficiaries exceeding the fill limit.

TABLE 2. Trends in Days Supply Prescribed to New Starts of Short-Acting (SA) Opioids in Mississippi Medicaid January 2018 - June 2020

Month filled	New starts of SA opioid fills	Days supply filled					Percentage of new starts exceeding fill limit*
		Percentage of new starts with corresponding days supply					
		1 to 3	4 to 7	8 to15	16 to 29	30+	
2018-01	6,606	41.8%	39.2%	12.0%	2.5%	4.5%	18.9%
2018-02	7,721	40.4%	33.2%	11.7%	4.5%	10.1%	26.3%
2018-03	6,997	45.0%	35.7%	11.5%	2.5%	5.3%	19.2%
2018-04	6,472	45.8%	34.2%	11.6%	2.9%	5.5%	19.9%
2018-05	6,447	46.5%	34.2%	10.9%	3.0%	5.5%	19.3%
2018-06	6,690	45.3%	36.8%	10.5%	2.5%	4.9%	17.9%
2018-07	6,504	47.5%	37.0%	8.6%	2.3%	4.5%	15.4%
2018-08	6,590	47.4%	37.5%	8.5%	2.0%	4.6%	15.0%
2018-09	5,594	48.3%	37.0%	8.7%	2.1%	3.8%	14.6%
2018-10	6,097	47.4%	38.0%	8.5%	2.2%	3.9%	14.6%
2018-11	6,118	44.1%	35.8%	8.6%	3.4%	8.1%	20.1%
2018-12	5,578	43.8%	36.8%	9.2%	3.2%	7.0%	19.3%
2019-01	2,522	37.4%	27.8%	9.6%	6.6%	18.8%	34.9%
2019-02	1,883	43.1%	33.3%	8.9%	4.5%	10.2%	23.6%
2019-03	2,011	44.8%	33.3%	10.4%	3.8%	7.8%	21.8%
2019-04	2,169	45.8%	33.4%	9.5%	3.2%	8.0%	20.7%
2019-05	2,058	45.6%	35.7%	8.0%	2.4%	8.3%	18.6%
2019-06	2,062	46.7%	34.9%	8.5%	2.9%	7.0%	18.4%
2019-07	2,220	46.9%	34.6%	8.6%	2.6%	7.2%	18.3%
2019-08	2,138	50.8%	46.1%	1.5%	0.6%	1.0%	2.9%
2019-09	2,051	49.3%	44.9%	1.7%	1.1%	3.1%	5.7%
2019-10	2,216	49.2%	43.2%	2.5%	1.6%	3.5%	7.4%
2019-11	1,971	48.8%	45.5%	1.5%	0.9%	3.3%	5.6%
2019-12	2,072	48.1%	46.8%	1.4%	0.8%	2.8%	5.0%
2020-01	2,361	50.2%	43.8%	1.6%	1.1%	3.3%	6.0%
2020-02	2,185	48.1%	44.7%	1.9%	1.4%	4.0%	6.9%
2020-03	1,947	46.9%	45.3%	1.8%	1.8%	4.2%	7.5%
2020-04	1,462	44.9%	46.7%	2.1%	1.8%	4.4%	8.3%
2020-05	1,879	47.0%	46.8%	2.0%	0.7%	3.4%	6.1%
2020-06	2,446	50.4%	45.3%	1.4%	0.7%	2.2%	4.2%

Note: Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from Jan 2017 to June 2020 were excluded.
* '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.
Red line indicates when Medicaid Opioid Initiatives we implemented.

From Table 2:

- The percent of new start claims for 7 days or less has remained above 90% since implementation of the Opioid Initiatives.
- The percentage of new starts exceeding the fill limit has averaged only 6.3% since implementation of the Opioid Initiatives.

Table 3: All opioid prescriptions (excluding cancer and sickle cell patients) were included in this analysis. MME daily dose was calculated for individual and/or cumulative opioid prescriptions for beneficiaries during the study period. Beneficiaries with MME $\geq$ 90 mg were flagged. In instances

where the High MME (≥ 90 MG) event spanned over multiple months for a beneficiary, the High MME was attributed to the month in which the first day of high MME use occurred.

TABLE 3. Trends in High Morphine Milligram Equivalent (MME) Daily Dose Among Medicaid Beneficiaries January 2018 - June 2020

Month filled	Total opioid Rx	Number of benes with opioids	Number of benes with MME ≥ 90 mg*	Percentage of benes with MME ≥ 90 mg*
2018-01	19,021	16,888	174	1.0%
2018-02	17,911	16,001	187	1.2%
2018-03	18,541	16,383	250	1.5%
2018-04	17,553	15,581	199	1.3%
2018-05	17,922	15,682	219	1.4%
2018-06	17,692	15,696	195	1.2%
2018-07	17,401	15,448	240	1.6%
2018-08	17,923	15,561	232	1.5%
2018-09	15,783	14,114	183	1.3%
2018-10	16,970	14,921	233	1.6%
2018-11	15,763	13,856	185	1.3%
2018-12	14,711	13,126	234	1.8%
2019-01	15,617	13,790	203	1.5%
2019-02	14,279	12,755	243	1.9%
2019-03	14,676	13,153	277	2.1%
2019-04	14,740	13,118	213	1.6%
2019-05	14,705	12,977	168	1.3%
2019-06	13,778	12,487	157	1.3%
2019-07	14,905	13,185	170	1.3%
2019-08	13,062	11,589	117	1.0%
2019-09	12,370	11,139	97	0.9%
2019-10	12,635	11,305	120	1.1%
2019-11	11,235	10,233	115	1.1%
2019-12	11,378	10,291	130	1.3%
2020-01	11,793	10,558	110	1.0%
2020-02	10,713	9,738	90	0.9%
2020-03	10,175	9,099	116	1.3%
2020-04	8,658	7,746	87	1.1%
2020-05	9,962	8,951	102	1.1%
2020-06	11,255	10,060	81	0.8%

Note: Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from Jan 2017 to June 2020 were excluded.
*Beneficiaries with individual and/or cumulative daily sum of all opioid prescriptions with high MME (≥ 90 mg) were identified and attributed to the month of the first day of high MME use.
Red line indicates when Medicaid Opioid Initiatives we implemented.

For Table 3:

- The percentage of beneficiaries with MME ≥ 90 mg decreased to an average of 1.1% monthly after the implementation of the Opioid Initiatives.

Table 4: All opioid prescriptions were included for this analysis. Cancer and sickle cell disease patients were NOT excluded. 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.

TABLE 4. Trends in Concomitant Use of Benzodiazepenes and Opioids Among Medicaid Beneficiaries January 2018 - June 2020

Month filled	Total opioid Rx	Number of benes with opioids	Concomitant BZD Use	
			Number of benes with concomitant BZD use	Percentage of benes with concomitant BZD use
2018-01	22,693	19,886	2,278	11.5%
2018-02	21,441	18,926	2,185	11.5%
2018-03	22,276	19,439	2,014	10.4%
2018-04	21,197	18,598	2,006	10.8%
2018-05	21,618	18,660	1,922	10.3%
2018-06	21,323	18,658	1,818	9.7%
2018-07	21,016	18,384	1,647	9.0%
2018-08	21,661	18,571	1,681	9.1%
2018-09	19,183	16,963	1,543	9.1%
2018-10	20,547	17,810	1,538	8.6%
2018-11	19,155	16,601	1,351	8.1%
2018-12	18,027	15,842	1,229	7.8%
2019-01	19,056	16,584	1,272	7.7%
2019-02	17,521	15,445	1,101	7.1%
2019-03	17,944	15,850	1,089	6.9%
2019-04	17,969	15,756	1,039	6.6%
2019-05	17,945	15,608	973	6.2%
2019-06	16,726	14,967	854	5.7%
2019-07	18,096	15,785	912	5.8%
2019-08	16,021	13,976	583	4.2%
2019-09	15,187	13,495	562	4.2%
2019-10	15,556	13,662	539	3.9%
2019-11	13,952	12,469	472	3.8%
2019-12	14,095	12,502	395	3.2%
2020-01	14,592	12,832	482	3.8%
2020-02	13,274	11,902	424	3.6%
2020-03	12,755	11,194	397	3.5%
2020-04	11,067	9,699	416	4.3%
2020-05	12,454	10,997	419	3.8%
2020-06	13,821	12,157	433	3.6%

Note: Beneficiaries with a diagnosis for either cancer or sickle cell disease anytime from Jan 2017 to June 2020 were NOT excluded.
Red line indicates when Medicaid Opioid Initiatives we implemented.

From Table 4:

- The percentage of beneficiaries with concomitant opioid and benzodiazepine use has dropped to an average of 3.8% since the implementation of the Opioid Initiatives.

In addition to conducting analyses specifically aimed at assessing the impact of the Opioid Initiatives for this report, MS-DUR also runs 2 quality measures which DOM annually reports to CMS that are directly impacted by the Opioid Initiatives. The "Concurrent Use of Opioids and Benzodiazepines" (COB-AD) measure was developed by the Pharmacy Quality Alliance. The COB-AD assesses the percentage of beneficiaries who are taking opioids that have concurrent use of benzodiazepines for 30 or more days.

TABLE 5: COB-AD Concurrent Use of Opioids and Benzodiazepines

Mississippi Medicaid January 1, 2019 - December 31, 2019
Includes all Medicaid Benefiaries Meeting Inclusion Criteria
- DOES NOT include CHIP -

Beneficiary		Denominator	Numerator	Rate
TOTAL		12,559	937	7.5%
Age	18 - 65	12,523	932	7.4%
	65+	36	5	13.9%
Gender	Female	8,937	682	7.6%
	Male	3,622	255	7.0%
Race	Caucasian	4,601	507	11.0%
	Afr. Amer.	6,656	340	5.1%
	Amer. Indian	24	1	4.2%
	Hispanic	36	4	11.1%
	Other	1,242	85	6.8%
Pharmacy Program	FFS	1,951	176	9.0%
	UHC	4,624	309	6.7%
	MAG	5,412	436	8.1%
	MOL	572	16	2.8%

Table 5 shows the COB-AD quality measure rates for CY 2019 for all Mississippi Medicaid beneficiaries meeting the inclusion criteria for the denominator. The overall rate within Mississippi Medicaid was 7.5%. This shows a continued significant decrease for this measure compared to prior years reported (20.0% for CY 2017, 13.7% for CY 2018 and 7.5% for CY 2019).

The "Use of Opioids at High Dosage in Persons Without Cancer" (OHD-AD) was developed by the Pharmacy Quality Alliance and added to the Medicaid Adult Core Set in 2016. The OHD-AD assesses the potentially inappropriate prescribing of opioids at average morphine milligram equivalents (MME) of 90 or more for treatment periods of 90 or more days.

Table 6 shows the OHD-AD quality measure rates for CY 2019 for all Mississippi Medicaid beneficiaries meeting the inclusion criteria for the denominator. The overall rate within Mississippi Medicaid was 1.7% which was significantly lower than the rate of 2.5% for CY 2018.

TABLE 6: Use of Opioids at High Dosage in Persons Without Cancer *Includes all Medicaid Beneficiaries Meeting Inclusion Criteria* *Mississippi Medicaid January 1, 2019 - December 31, 2019* *Includes Medicaid ONLY - No CHIP*				
Beneficiary		**Denominator**	**Numerator**	**Rate**
TOTAL		11,112	190	1.7%
Age	18 - 65	11,083	190	1.7%
	65+	29	0	0.0%
Gender	Female	7,884	111	1.4%
	Male	3,228	79	2.4%
Race	Caucasian	4,088	126	3.1%
	Afr. Amer.	5,896	48	0.8%
	Amer. Indian	23	0	0.0%
	Hispanic	28	1	3.6%
	Other	1,077	15	1.4%
Pharmacy Program	FFS	1,686	41	2.4%
	UHC	4,152	71	1.7%
	MAG	4,811	73	1.5%
	MOL	463	5	1.1%

CONCLUSIONS

Working with prescribers to appropriately prescribe opioids is a process that Medicaid has been working on for several years. With the implementation of DOM's Opioid Initiatives in 2019, a major step was taken toward regulating the appropriate prescribing of opioids for Medicaid beneficiaries. This study provides data demonstrating that prescribing trends for opioids are moving in a positive direction. Although significant progress has been made, the opioid epidemic fight continues. Assessing the impact of COVID-19 on the prescribing of opioids is an area that warrants further study.

RECOMMENDATIONS

1. DOM should continue monitoring trends in opioid prescribing related to the Opioid Initiatives and explore other metrics for measuring appropriate opioid prescribing.

2. MS-DUR, at the direction of DOM, should explore the impacts of COVID-19 on the prescribing of opioids.

References:

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2. Prescribing Regulation Tools | Mississippi State Board of Medical Licensure. Accessed August 13, 2020. https://www.msbml.ms.gov/PR_Tools

3. Governor's Opioid and Heroin Study Taskforce. Stand Up, Mississippi. Accessed August 13, 2020. https://standupms.org/governors-opioid-and-heroin-study-taskforce/

4. State Guidance for Implementation of Medicaid Drug Utilization Review (DUR) provisions included in Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (P.L. 115-271). Accessed August 13, 2020. https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf

SEDATIVE HYPNOTICS

BACKGROUND

Insomnia can be defined as an inability to initiate or maintain sleep associated with daytime impairment that is not attributed to inadequate opportunities to sleep.[1,2] Insomnia is a common condition for which adults seek treatment with prevalence typically ranging from 10-30% of the population, with some estimates as high as 50-60%.[3,4] Sleep is essential for normal physiological and psychological functioning. Multiple factors (age, comorbid physical symptoms, comorbid psychiatric conditions, medication side effects, and poor sleep habits) can influence the amount and quality of sleep an individual receives.[5] The economic burden associated with insomnia has been estimated as high as $16 billion annually in direct costs and up to $75-100 billion annually in indirect costs.[6]

According to the International Classification of Sleep Disorders, Third Edition, insomnia can be classified as either short-term or chronic.[1] Short-term insomnia is the most common type of insomnia and usually lasts less than one month.[5] Chronic insomnia is defined as insomnia that persists for at least 3 months at a frequency of at least three times per week.[1] Chronic insomnia is associated with a significant impact on overall health and quality of life.

Treatment options for insomnia include both non-pharmacologic and pharmacologic therapies. Non-pharmacologic therapy centered around cognitive behavioral therapy (CBT) which includes psychological and behavioral interventions is often the initial recommended treatment.[7–10] CBT involves addressing root causes of insomnia and developing behaviors that promote sleep such as good sleep hygiene. Addressing comorbid conditions that commonly cause insomnia is also essential.

PHARMACOTHERAPY

Pharmacologic agents utilized in the treatment of insomnia can be broadly categorized into benzodiazepines (BZD) and nonbenzodiazepines (non-BZD). Under the current MS Medicaid Universal Preferred Drug List, agents for the treatment of insomnia are listed as “Sedative Hypnotics”. (Figure 1)

FIGURE 1: Medicaid Preferred Drug List – Sedative Hypnotics v.2020.3

THERAPEUTIC DRUG CLASS	PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
SEDATIVE HYPNOTICS			
	BENZODIAZEPINES SmartPA		
	estazolam flurazepam temazepam (15mg and 30mg)	DALMANE (flurazepam) DAYVIGO (lemborexant)NR DORAL (quazepam) HALCION (triazolam) quazepam RESTORIL (temazepam) temazepam (7.5mg and 22.5mg) triazolam	Single source benzodiazepines and barbiturates are NOT covered – NO PA's will be issued for these drugs. **MS DOM Opioid Initiative** • Concomitant use of Opioids and Benzodiazepines Criteria details found here **Quantity Limit – CUMULATIVE**
			Quantity limit per rolling days for all strengths. *SmartPA will allow an early refill override for one dose or therapy change per year.* • **31 units/31 days** - all strengths **Triazolam – CUMULATIVE** Quantity limit per rolling days for all strengths • **10 units/31 days** • **60 units/365 days**
	OTHERS SmartPA		
	zaleplon zolpidem	AMBIEN (zolpidem) AMBIEN CR (zolpidem) BELSOMRA (suvorexant) doxepin EDLUAR (zolpidem) eszopiclone HETLIOZ (tasimelteon) INTERMEZZO (zolpidem) LUNESTA (eszopiclone) ramelteon ROZEREM (ramelteon) SILENOR (doxepin) SONATA (zaleplon) zolpidem ER zolpidem SL ZOLPIMIST (zolpidem)	**Quantity Limit – CUMULATIVE** Quantity limit per rolling days for all strengths. *SmartPA will allow an early refill override for one dose or therapy change per year.* • **31 units/31 days** • **1 canister/31 days** – Zolpimist & male • **1 canister/62 days –** Zolpimist & female **Gender and Dose Limit for zolpidem** • **Female** - Ambien 5mg, Ambien CR 6.25mg, Intermezzo 1.75 mg • **Male** – all zolpidem strengths **Non-Preferred Criteria** • Have tried 2 different preferred agents in the past 6 months **Hetlioz**

There are five benzodiazepines that are only indicated for use as sedative hypnotics for the treatment of insomnia: estazolam, flurazepam (Dalmane®), quazepam (Doral®), temazepam (Restoril®), and triazolam (Halcion®). Temazepam and triazolam are **only** indicated for short-term treatment of insomnia (generally 7-10 days), however, short-term use is recommended for all benzodiazepines.[11–15] Additionally, benzodiazepines contain a warning related to the failure of insomnia to remit after 7 to 10 days of treatment and the potential presence of other illnesses that should be evaluated. (Figure 2)

Figure 2: Benzodiazepine Warning

Warnings

Because sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. **The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated.** Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative-hypnotic drugs. Because some of the important adverse effects of sedative-hypnotics appear to be dose related (see PRECAUTIONS and DOSAGE AND ADMINISTRATION), it is important to use the smallest possible effective dose, especially in the elderly.

Nonbenzodiazepines approved for use in the treatment of insomnia include nonbenzodiazepine receptor agonists (BzRA or Z Drugs), melatonin agonists, low-dose form of sedating antidepressant (doxepin), and orexin receptor antagonists. In addition to those agents FDA-approved for use as sedative hypnotics, non-FDA approved agents have been utilized in the management of insomnia such as other BZDs, antidepressants, antipsychotics, and analgesics. Although not FDA-approved, there is evidence supporting the use of low-dose trazodone in the management of insomnia.[16] Figure 3 provides an overview of agents FDA-approved in the treatment of insomnia along with their duration of action.

Figure 3: Agents FDA-Approved for the Management of Insomnia[5,17]

Drug	Usual Adult Dose	Indication	Duration of Action
BENZODIAZEPINES:			
estazolam	1 to 2 mg	sleep onset or maintenance	intermediate
flurazepam (Dalmane)	15 to 30 mg	sleep onset or maintenance	long
quazepam (Doral)	7.5 to 15 mg	sleep onset or maintenance	long
temazepam (Restoril)	7.5 to 30 mg	sleep onset or maintenance	intermediate
triazolam (Halcion)	0.125 to 0.25 mg	sleep onset	short
NONBENZODIAZEPINES:			
Nonbenzodiazepine benzodiazepine receptor agonists (BzRAs or Z Drugs):			
eszopiclone (Lunesta)	1 to 3 mg	sleep onset or maintenance	intermediate
zaleplon (Sonata)	5 to 20 mg	sleep onset	short
zolpidem (Ambien, Edular, Zolpimist)	5 to 10 mg	sleep onset or maintenance	short
zolpidem extended release (Ambien CR)	6.25 to 12.5 mg	sleep onset or maintenance	intermediate
zolpidem middle of the night (Intermezzo)	1.75 to 3.5 mg	sleep maintenance	short
Melatonin receptor agonist:			
ramelteon (Rozerem)	8 mg	sleep onset	short
tasimelteon (Hetlioz)	20mg	non-24 hr sleep/wake cycle	short
Low-dose antidepressant:			
doxepin (Silenor)	3 to 6 mg	sleep maintenance	long
Orexin receptor antagonists:			
lemborexant (Dayvigo)	5 to 10 mg	sleep onset or maintenance	long
suvorexant (Belsomra)	10 to 20 mg	sleep onset or maintenance	intermediate

TREATMENT RECOMMENDATIONS

Short-term insomnia treatment involves identifying and addressing the stressor involved in sleep disturbance. When short-term insomnia is severe, a trial of a short or intermediate acting benzodiazepine receptor agonist for two to four weeks is often recommended.[5] When insomnia persists and transitions into chronic insomnia, a combination approach of CBT and pharmacologic therapy is the primary treatment approach recommended.[5,7,10]

In 2017 the American Academy of Sleep Medicine published the Clinical Practice Guideline for the Pharmacologic Treatment of Chronic Insomnia in Adults.[10] The recommendations were rated from STRONG (one that clinicians should, under most circumstances, always be following when pharmacologic treatment is indicated) to WEAK (one that reflects a lower degree of certainty in the appropriateness of the patient-care strategy and requires that the clinician use his/her clinical knowledge and experience, and refer to the individual patient's values and preferences to determine the best course of action). Figure 4 displays a summary of the clinical practice recommendations.

Figure 4: Summary of Clinical Practice Recommendations[10]

Treatment	Recommendation	Direction and Strength of Recommendation	Quality of Evidence	Benefits and Harms Assessment	Patients' Values and Preferences Assessment
Orexin receptor agonists					
Suvorexant This recommendation is based on trials of 10, 15/20, and 20 mg doses of suvorexant.	We suggest that clinicians use suvorexant as a treatment for sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Low	Benefits outweigh harms	The majority of patients would use this treatment (over no treatment), but many would not.
BZD receptor agonists					
Eszopiclone This recommendation is based on trials of 2 mg and 3 mg doses of eszopiclone.	We suggest that clinicians use eszopiclone as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Very low	Benefits outweigh harms	The majority of patients would use this treatment (over no treatment), but many would not.
Zaleplon This recommendation is based on trials of 10 mg doses of zaleplon.	We suggest that clinicians use zaleplon as a treatment for sleep onset insomnia (versus no treatment) in adults.	WEAK	Low	Benefits outweigh harms	The majority of patients would use this treatment (over no treatment), but many would not.
Zolpidem This recommendation is based on trials of 10 mg doses of zolpidem.	We suggest that clinicians use zolpidem as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Very low	Benefits outweigh harms	The majority of patients would use this treatment (over no treatment), but many would not.
Benzodiazepines					
Triazolam This recommendation is based on trials of 0.25 mg doses of triazolam.	We suggest that clinicians use triazolam as a treatment for sleep onset insomnia (versus no treatment) in adults.	WEAK	High	Benefits approx equal to harms	The majority of patients would use this treatment (over no treatment), but many would not.
Temazepam This recommendation is based on trials of 15 mg doses of temazepam.	We suggest that clinicians use temazepam as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Moderate	Benefits outweigh harms	The majority of patients would use this treatment (over no treatment), but many would not.
Melatonin agonists					
Ramelteon This recommendation is based on trials of 8 mg doses of ramelteon.	We suggest that clinicians use ramelteon as a treatment for sleep onset insomnia (versus no treatment) in adults.	WEAK	Very low	Benefits outweigh harms	The majority of patients would use this treatment (over no treatment), but many would not.
Heterocyclics					
Doxepin This recommendation is based on trials of 3 mg and 6 mg doses of doxepin.	We suggest that clinicians use doxepin as a treatment for sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Low	Benefits outweigh harms	The majority of patients would use this treatment (over no treatment), but many would not.
Trazodone This recommendation is based on trials of 50 mg doses of trazodone.	We suggest that clinicians not use trazodone as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Moderate	Harms outweigh benefits	The majority of patients would use this treatment (over no treatment), but many would not.
Anticonvulsants					
Tiagabine This recommendation is based on trials of 4 mg doses of tiagabine.	We suggest that clinicians not use tiagabine as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Very low	Harms outweigh benefits	The majority of patients would not use this treatment (over no treatment), but many would.
Over-the-counter preparations					
Diphenhydramine This recommendation is based on trials of 50 mg doses of diphenhydramine.	We suggest that clinicians not use diphenhydramine as a treatment for sleep onset and sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Low	Benefits approx equal to harms	The majority of patients would not use this treatment (over no treatment), but many would.
Melatonin This recommendation is based on trials of 2 mg doses of melatonin.	We suggest that clinicians not use melatonin as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Very low	Benefits approx equal to harms	The majority of patients would use this treatment (over no treatment), but many would not.
L-tryptophan This recommendation is based on trials of 250 mg doses of tryptophan.	We suggest that clinicians not use tryptophan as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults.	WEAK	High	Harms outweigh benefits	The majority of patients would use this treatment (over no treatment), but many would not.
Valerian This recommendation is based on trials of variable dosages of valerian and valerian-hops combination.	We suggest that clinicians not use valerian as a treatment for sleep onset or sleep maintenance insomnia (versus no treatment) in adults.	WEAK	Low	Benefits approx equal to harms	The majority of patients would not use this treatment (over no treatment), but many would.

approx = approximately.

The guideline noted multiple difficulties and limitations related to the development of meaningful clinical guidelines. These limitations lead to a relatively low level in quality of evidence for the vast majority of recommendations. With the significant risks of sedation and related complications associated with the use of hypnotic agents, clinicians are encouraged to prescribe the lowest dose

for the shortest duration possible, conduct appropriate patient counseling and maintain diligent monitoring of individuals prescribed hypnotic agents.[10]

DOM and MS-DUR have undertaken multiple initiatives involving sedative hypnotics in recent years. Based on recommendations from the DUR Board in 2015, DOM implemented quantity limits for triazolam as indicated on the current UPDL. (Figure 1) At the September 2016 DUR Board meeting, MS-DUR recommended the implementation of further quantity limits on temazepam (quantity limit of 10 day supply per month, cumulative quantity limit of 60 days within a 365-day period). No action was taken at that time due to a lack of therapeutic alternatives available. Additionally, as part of the DOM's Opioid Initiative that was implemented in 2019, concomitant use of opioids and benzodiazepines was restricted.

Recently the Centers for Medicare and Medicaid Services (CMS) released proposed rule changes to the minimum standards for Medicaid State Drug Utilization Review. Included as part of the proposed rule changes is the following language around concomitant use of opioids and sedatives, " *We also would like to remind states that section 1927(g)(1) of the Act also currently supports including other potentially harmful opioid interactions as* ***additional prospective or retrospective reviews in state DUR programs, such as opioids and central nervous system (CNS) depressants, including alcohol or sedatives. We fully support states including such additional opioid interactions or contraindications in prospective or retrospective reviews as part of a comprehensive DUR program***."[18] In conjunction with this proposed rule change, the CMS Medicaid DUR Annual Report for Federal Fiscal Year (FFY) 2019 included for the first time a question related to DUR activities involving the monitoring of concomitant use of opioids and sedatives.

With the changing landscape in the treatment of insomnia, the approval of new therapeutic agents, and updated CMS guidance around sedatives hypnotics, MS-DUR conducted an updated review of the utilization of sedative hypnotics in the treatment of insomnia.

METHODS

A retrospective analysis was conducted using Mississippi Medicaid pharmacy claims for sedative hypnotics and opioids during the study period June 2019 – May 2020. 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). Sedative hypnotics were classified into benzodiazepines indicated for insomnia (estazolam, flurazepam, quazepam, temazepam, and triazolam) and non-benzodiazepines (based on MS-UPDL v2020.3). Low-dose formulations of doxepin (3/6/10 mg) and trazodone (50 and 100 mg) were also evaluated.

Beneficiaries were included if they had at least one pharmacy claim for any sedative hypnotic during the study period. Maximum duration of continuous sedative-hypnotic therapy was evaluated as date of first fill to date of last fill, including days' supply of last fill, allowing for a 15-day refill gap. Concomitant use of sedative hypnotic therapy and opioids was evaluated if a beneficiary had at least one day of overlap between two therapies with duration of concomitant therapy assessed. Demographic characteristics including age at first fill of sedative-hypnotic therapy, gender, race, and health plan at first fill were evaluated. Beneficiaries prescribed both non-benzodiazepines and benzodiazepines were classified based on the drug type of first sedative hypnotic prescribed. Concomitant treatment episodes of sedative hypnotics and opioids were evaluated for physician characteristics. Provider specialty of the second prescribing physician (for either a sedative-hypnotic or an opioid) resulting in a concomitant treatment episode is reported.

RESULTS

Table 1 displays an overall utilization summary of sedative hypnotics by drug type. Of the benzodiazepine agents, temazepam accounted for the vast majority of use (97.9%) among beneficiaries. Low-dose trazodone and zolpidem accounted for 94.8% of non-benzodiazepine use.

TABLE 1. Overall Summary of Medication Utilization by Drug and Drug Type (June 2019 - May 2020)

Benzodiazepines			
Drug	**# of fills**	**# of benes**	**Mean Days Supply**
Temazepam	1,868	510	29.1
Triazolam	10	8	12.9
Estazolam	2	2	30.0
Flurazepam	1	1	30.0
Non-Benzodiazepines			
Drug	**# of fills**	**# of benes**	**Mean Days Supply**
Trazodone*	28,985	7,962	33.0
Zolpidem	6,170	1,465	29.1
Doxepin**	1,057	342	29.7
Zaleplon	285	88	28.4
Eszopiclone	194	53	29.2
Suvorexant	141	22	30.0
Tasimelteon	15	3	30.0
Ramelteon	11	8	30.0

*Trazodone - 50mg and 100mg.
**Doxepin - 3mg, 6mg, and 10 mg

TABLE 2. Demographic Characteristics of Beneficiaries Prescribed Sedative Hypnotic Therapy by Drug Type* (June 2019 - May 2020)

Variable	Benzodiazepines**									Non-benzodiazepines***									Grand Total
	FFS		UHC		Magnolia		Molina		Total	FFS		UHC		Magnolia		Molina		Total	
Age Category (yrs)																			
0-12	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	69	3.5%	123	3.8%	43	1.2%	5	0.6%	240	**240**
13-20	0	0.0%	0	0.0%	2	1.1%	1	2.9%	3	216	10.8%	464	14.5%	255	7.0%	77	10.0%	1,012	**1,015**
21-30	9	8.0%	13	9.8%	15	8.1%	9	26.5%	46	266	13.3%	442	13.8%	561	15.5%	200	26.0%	1,469	**1,515**
31-40	19	16.8%	32	24.1%	40	21.6%	9	26.5%	100	329	16.5%	676	21.1%	867	24.0%	241	31.3%	2,113	**2,213**
41-50	23	20.4%	26	19.5%	39	21.1%	8	23.5%	96	281	14.1%	610	19.0%	705	19.5%	123	16.0%	1,719	**1,815**
51-64	58	51.3%	62	46.6%	88	47.6%	7	20.6%	215	806	40.4%	886	27.6%	1,183	32.7%	124	16.1%	2,999	**3,214**
65+	4	3.5%	0	0.0%	1	0.5%	0	0.0%	5	26	1.3%	7	0.2%	4	0.1%	0	0.0%	37	**42**
Total	***113***		***133***		***185***		***34***		***465***	***1,993***		***3,208***		***3,618***		***770***		***9,589***	***10,054***
Gender																			
Female	77	68.1%	98	73.7%	142	76.8%	26	76.5%	343	1,209	60.7%	2,159	67.3%	2,531	70.0%	570	74.0%	6,469	**6,812**
Male	36	31.9%	35	26.3%	43	23.2%	8	23.5%	122	784	39.3%	1,049	32.7%	1,087	30.0%	200	26.0%	3,120	**3,242**
Total	***113***		***133***		***185***		***34***		***465***	***1,993***		***3,208***		***3,618***		***770***		***9,589***	***10,054***
Race																			
Caucasian	60	53.1%	64	48.1%	82	44.3%	16	47.1%	222	962	48.3%	1,471	45.9%	1,469	40.6%	360	46.8%	4,262	**4,484**
African American	46	40.7%	48	36.1%	81	43.8%	13	38.2%	188	849	42.6%	1,364	42.5%	1,760	48.6%	316	41.0%	4,289	**4,477**
Hispanic	0	0.0%	3	2.3%	1	0.5%	0	0.0%	4	9	0.5%	25	0.8%	15	0.4%	7	0.9%	56	**60**
Other	7	6.2%	18	13.5%	21	11.4%	5	14.7%	51	173	8.7%	348	10.8%	374	10.3%	87	11.3%	982	**1,033**
Total	***113***		***133***		***185***		***34***		***465***	***1,993***		***3,208***		***3,618***		***770***		***9,589***	***10,054***

NOTE: Of the 10,054 beneficiaries, 111 (1.10%) were prescribed both, benzodiazepines and non-benzodiazepines during the study period. For these beneficiaries, date and type of first sedative hypnotic fill was used for classification. Health plan was assessed at the time of first fill of the medication.

*Classification of drug type was based on Mississippi Universal Preferred Drug List (v2020.3)

** Benzodiazepines assessed included estazolam, flurazepam, triazolam, temazepam, and quazepam.

*** Two of the drugs classified under non-benzodiazepines were included based on their dose as follows:
Doxepin - 3mg, 6mg, and 10 mg
Trazodone - 50mg and 100mg.

Table 2 describes demographic characteristics of sedative hypnotic users.

- Beneficiaries aged 51-64 years had the highest sedative hypnotic use across all age groups (Overall 32%).
  - 46.2 % of benzodiazepine use
  - 31.3% of non-benzodiazepine use
- 67.8% of sedative hypnotic use occurred among females.
- Across all sedative hypnotic use, Caucasians and African Americans had nearly identical proportions of use (44.6% for Caucasians and 44.5% for African Americans).
  - However among benzodiazepine use, Caucasians had a higher proportion of use at 47.7% compared to African Americans at 40.4%.

TABLE 3a. Maximum Number of Days of Continuous Therapy* with Benzodiazepines (June 2019 - May 2020)								
Drug	**Maximum Days of Continuous Therapy**							
	1 - 10	**11 - 20**	**21 - 31**	**32 - 62**	**63 - 93**	**94 - 186**	**187 +**	**Total**
Temazepam	13	22	240	93	58	49	35	510
Triazolam	6	0	0	2	0	0	0	8
Estazolam	0	0	1	1	0	0	0	2
Flurazepam	0	0	1	0	0	0	0	1
*Continuous therapy was calculated as date of first fill to date of last fill, including days supply of last fill, allowing for a 15-day refill gap.								
NOTE: Results include all beneficiaries filling a prescription during study period. Beneficiaries may have started therapy before June 2019 and may have started therapy just prior to May 2020 end data for inclusion in the analyses.								

Table 3b. Maximum Number of Days of Continuous Therapy* with Non-benzodiazepines (June 2019 - May 2020)								
Drug	**Maximum Days of Continuous Therapy**							
	1 - 10	**11 - 20**	**21-31**	**32 - 62**	**63 - 93**	**94 - 186**	**187 +**	**Total**
Trazodone	132	214	3,263	1,652	1,183	968	550	7,962
Zolpidem	71	79	546	276	163	194	136	1,465
Doxepin	8	12	177	69	36	27	13	342
Zaleplon	2	6	45	14	10	8	3	88
Eszopiclone	2	1	26	10	3	5	6	53
Suvorexant	0	0	7	3	2	3	7	22
Ramelteon	0	0	7	1	0	0	0	8
Tasimelteon	0	1	1	0	0	0	1	3
*Continuous therapy was calculated as date of first fill to date of last fill, including days supply of last fill, allowing for a 15-day refill gap.								
NOTE: Results include all beneficiaries filling a prescription during study period. Beneficiaries may have started therapy before June 2019 and may have started therapy just prior to May 2020 end data for inclusion in the analyses.								

Considering the maximum number of days of continuous therapy, Tables 3a/b indicate:

- The maximum days supply edit for triazolam appears to be keeping continuous days of therapy low.
- 93.1% of temazepam use is for ≥ 21 days of therapy, with 27.8% of beneficiaries receiving it for ≥ 63 days.
    - In 2016, the DUR Board considered implementing a maximum days supply edit for temazepam similar to that applied to triazolam.
- 95.7% of beneficiaries prescribed trazodone and 89.7% of beneficiaries prescribed zolpidem received them for ≥ 21 days.

CMS is considering updating their minimum standards to include the monitoring of concomitant use of opioids and sedatives. As part of this review of sedative hypnotics, MS-DUR also assessed concomitant use with opioids. Tables 4a/b display the number of beneficiaries and claims with concomitant use.

TABLE 4a. Concomitant Use of Benzodiazepines and Opioids - Benes and Claims by Plan (June 2019 - May 2020)

Drug	FFS		UHC		Magnolia		Molina	
	Benes	Claims	Benes	Claims	Benes	Claims	Benes	Claims
Temazepam	33	46	35	85	37	60	6	10
Triazolam	1	1	1	1	2	2	0	0
Estazolam	0	0	0	0	1	1	0	0

TABLE 4b. Concomitant Use of Non-benzodiazepines and Opioids - Benes and Claims by Plan (June 2019 - May 2020)

Drug	FFS		UHC		Magnolia		Molina	
	Benes	Claims	Benes	Claims	Benes	Claims	Benes	Claims
Trazodone*	468	858	584	1,157	637	1,243	119	170
Zolpidem	180	366	152	421	230	556	22	35
Doxepin**	12	19	23	45	25	43	8	9
Eszopiclone	2	2	6	8	13	21	0	0
Zaleplon	13	31	9	17	9	17	2	4
Suvorexant	0	0	1	1	6	8	0	0
Ramelteon	0	0	1	1	2	5	0	0
Tasimelteon	0	0	0	0	0	0	1	2

*Trazodone - 50mg and 100mg.
**Doxepin - 3mg, 6mg, and 10 mg

- There were a total on 2,641 beneficiary specific concomitant use events during the study period. ** A beneficiary could be represented multiple times if they had concomitant events involving multiple sedative hypnotic drugs.*
    - There were 116 beneficiary specific concomitant events with benzodiazepine sedative hypnotics and opioids.
    - There were 2525 beneficiary specific concomitant events with non-benzodiazepine sedative hypnotics and opioids.

TABLE 5a. Days of Concomitant Use of Benzodiazepines and Opioids (June 2019 - May 2020)					
Drug	Number of claims				
	≤3 days	4 to 7 days	8 to 14 days	15 to 30 days	31+ days
Temazepam	34	36	29	102	0
Triazolam	4	0	0	0	0
Estazolam	0	0	0	1	0

TABLE 5b. Days of Concomitant Use of Non-benzodiazepines and Opioids (June 2019 - May 2020)					
Drug	Number of claims				
	≤3 days	4 to 7 days	8 to 14 days	15 to 30 days	31+ days
Trazodone	590	754	505	1,481	98
Zolpidem	145	298	233	702	0
Doxepin	16	21	16	63	0
Zaleplon	5	12	12	40	0
Eszopiclone	1	7	5	18	0
Ramelteon	0	0	1	5	0
Suvorexant	4	2	0	3	0
Tasimelteon	2	0	0	0	0

*Trazodone - 50mg and 100mg.
**Doxepin - 3mg, 6mg, and 10 mg

From Tables 5a/b it can be determined:

- Of the 206 concomitant opioid/benzodiazepine claims, 103 (50%) were for ≥ 15 days.
- Approximately 47.8% (2410/5039) of concomitant use of non-benzodiazepines and opioids was for ≥15 days.

TABLE 6. Demographic Characteristics of Beneficiaries who had Concomitant Use of Sedative-Hypnotics and Opioids (June 2019 - May 2020)

Variable	Benzodiazepines*									Non-benzodiazepines**									Grand Total†
	FFS		UHC		Magnolia		Molina		Total	FFS		UHC		Magnolia		Molina		Total	
Age Category (yrs)																			
0-12	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	1	0.1%	1	0.1%	0	0.0%	0	0.0%	2	2
13-20	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	16	2.4%	23	3.2%	15	1.8%	6	4.9%	60	60
21-30	3	8.8%	2	5.7%	2	5.1%	0	0.0%	7	62	9.3%	42	5.8%	72	8.8%	24	19.5%	200	207
31-40	5	14.7%	9	25.7%	13	33.3%	1	25.0%	28	130	19.5%	150	20.7%	191	23.3%	37	30.1%	508	536
41-50	8	23.5%	5	14.3%	7	17.9%	1	25.0%	21	140	21.0%	178	24.6%	194	23.6%	30	24.4%	542	563
51-64	15	44.1%	19	54.3%	17	43.6%	2	50.0%	53	280	42.0%	326	45.0%	345	42.0%	26	21.1%	977	1,030
65+	3	8.8%	0	0.0%	0	0.0%	0	0.0%	3	38	5.7%	5	0.7%	4	0.5%	0	0.0%	47	50
Total	***34***		***35***		***39***		***4***		***112***	***667***		***725***		***821***		***123***		***2,336***	***2,448***
Gender																			
Female	21	61.8%	22	62.9%	29	74.4%	2	50.0%	74	441	66.1%	509	70.2%	606	73.8%	91	74.0%	1,647	**1,721**
Male	13	38.2%	13	37.1%	10	25.6%	2	50.0%	38	226	33.9%	216	29.8%	215	26.2%	32	26.0%	689	**727**
Total	***34***		***35***		***39***		***4***		***112***	***667***		***725***		***821***		***123***		***2,336***	***2,448***
Race																			
Caucasian	15	44.1%	15	42.9%	16	41.0%	1	25.0%	47	345	51.7%	339	46.8%	353	43.0%	60	48.8%	1,097	**1,144**
African American	18	52.9%	14	40.0%	19	48.7%	1	25.0%	52	282	42.3%	282	38.9%	386	47.0%	44	35.8%	994	**1,046**
Hispanic	0	0.0%	2	5.7%	0	0.0%	0	0.0%	2	1	0.1%	8	1.1%	2	0.2%	1	0.8%	12	**14**
Other	1	2.9%	4	11.4%	4	10.3%	2	50.0%	11	39	5.8%	96	13.2%	80	9.7%	18	14.6%	233	**244**
Total	***34***		***35***		***39***		***4***		***112***	***667***		***725***		***821***		***123***		***2,336***	***2,448***

* Benzodiazepines assessed included estazolam, flurazepam, triazolam, temazepam, and quazepam.

** Two of the drugs classified under non-benzodiazepines were included based on their dose as follows:
Doxepin - 3mg, 6mg, and 10 mg
Trazodone - 50mg and 100mg.

† 16 beneficiaries were prescribed both benzodiazepines and non-benzodiazepines. These beneficiaries were counted under both drug classes. The grand total is inflated to represent double counting of these beneficiaries. **There were a total of 2432 unique beneficiaries with concomitant use.**

Examining the demographics of concomitant users of sedative hypnotics and opioids:

- A total of 2,432 unique beneficiaries had concomitant events. This means approximately **24.2%** (2,432/10,054) of all beneficiaries that used sedative hypnotics had concomitant use with opioids.
    - Of the 465 beneficiaries prescribed benzodiazepine sedative hypnotics (Table 2), 112 (24.1%) had concomitant use with opioids.
- Similar to all sedative hypnotic users, beneficiaries aged 51-64 years had the highest proportion of concomitant use at 42.1%.
- Females comprised 70.3% of concomitant users.
- Although overall Caucasians made up the largest proportion of concomitant use at 46.7%, African Americans made up the highest proportion of benzodiazepine and opioid concomitant use at 46.4%.

While examining beneficiary characteristics of concomitant users of sedative hypnotics and opioids, MS-DUR reviewed their clinical history for a period of one year prior to the date of first concomitant use.

TABLE 7. Clinical History of Beneficiaries with Concomitant Use of Sedative Hypnotics and Opioids between Jun 2019 - May 2020

Diagnoses	Benzodiazepines (N = 112)		Non-benzodiazepines (N = 2,328)*	
	n	%	n	%
Spinal and Back Pain	69	61.6%	1,476	63.4%
Depression	47	42.0%	1,260	54.1%
Anxiety	64	57.1%	1,214	52.1%
Joint pain	54	48.2%	1,171	50.3%
Chronic Pain	48	42.9%	1,157	49.7%
Muscle Pain	58	51.8%	1,142	49.1%
Abdominal, Pelvic, and Renal Pain	35	31.3%	931	40.0%
Psychiatric Comorbidities**	20	17.9%	550	23.6%
Opioid Use Disorder	17	15.2%	540	23.2%
Substance Use Disorder	19	17.0%	437	18.8%
Cancer	25	22.3%	278	11.9%
Acute pain	7	6.3%	206	8.8%
Alcohol Use Disorder	12	10.7%	202	8.7%

NOTE: Clinical history was assessed in a 1-year period prior to the date of first concomitant use of sedative-hypnotic therapy and opioids.

*Of 2,336 beneficiaries who had concomitant use of non-benzodiapines and opioids, 8 beneficiaries did not have medical claims to assess baseline clinical history.

**Psychiatric comorbidities included schizophrenia, schizotypal, and schizoaffective disorders, delusional disorders, psychotic disorders, manic episode, and bipolar disorder.

- A large proportion of beneficiaries had a history of the following clinical conditions:
  - Spinal/Back Pain
  - Depression
  - Anxiety
  - Joint Pain
  - Chronic Pain
  - Muscle Pain

Provider type associated with the concomitant use of sedative hypnotics and opioids was also assessed.

TABLE 8. Type of Prescriber for Second Prescription Resulting in Concomitant Episodes of Sedative-Hypnotic and Opioid Use (June 2019 - May 2020)

Benzodiazepines				Non-benzodiazepines			
Provider Type	# of Providers	# of Events	# of Benes	Provider Type	# of Providers	# of Events	# of Benes
MD-FP	38	20	17	MD-FP	210	1,073	497
NP-FM	39	20	20	NP-FM	202	754	425
Dentist	13	13	12	MD-IM	104	449	223
MD-IM	22	11	6	NP-Other	86	378	177
NP-Other	16	7	7	Dentist	140	266	229
MD-Hem/Onc	8	6	6	MD-EM	77	195	131
MD-Ortho	4	4	3	MD-Pain	22	143	98
MD-Pain	5	4	4	MD-Other PCP	62	109	81
MD-EM	3	3	3	MD-Ortho	44	79	70
MD-Surg	2	2	2	MD-Hem/Onc	29	63	37
MD-Other PCP	2	1	1	MD-Surg	41	63	52
Other	54	35	35	NP-Other PCP	4	6	4
				Other	534	1,462	846

- MD-FP and NP-FM made up the highest proportion of providers associated with the concomitant prescribing of sedative hypnotics and opioids.

CONCLUSIONS

Although guidelines for prescribing sedative hypnotics exist, the quality of evidence for specific clinical recommendations for pharmacotherapy is limited. However, the guidelines do stress utilizing the lowest dose for the shortest duration possible when prescribing pharmacotherapy. Among Medicaid beneficiaries, trazodone and zolpidem are the most commonly prescribed sedative hypnotics. Among benzodiazepine sedative hypnotics specifically, temazepam is the most commonly prescribed. Approximately 90% or greater of the use of trazodone, zolpidem, and temazepam was for > 21 days of continuous therapy. This may indicate that beneficiaries are remaining on these therapies for extended periods of time. The PDL days supply edits implemented in 2016 for triazolam appear to be effective in limiting the days of continuous therapy for that agent. When examining concomitant use of sedative hypnotics and opioids, 24.3% of all beneficiaries prescribed sedative hypnotics had concomitant use with opioids.

RECOMMENDATIONS

1. DOM should implement provider education around the concomitant use of sedative hypnotics and opioids.

Options for Consideration:

- MS-DUR distribute a one-time letter to all providers that prescribed concomitant sedative hypnotics and opioids to beneficiaries during the previous six months alerting them to the increased risks associated with concomitant use and CMS monitoring recommendations.
- Develop an educational piece to be included in the next DOM Provider Bulletin.

2. DOM should implement DUR review(s) around the concomitant use of sedative hypnotics and opioids.

Options for Consideration:

- Pro-DUR edit – create a pro-DUR edit alerting pharmacists to the risks associated with concomitant use but allowing the pharmacist to bypass.
- Retro-DUR notice – MS-DUR send letters monthly to providers that prescribed concomitant sedative hypnotic/opioid therapy alerting them of the potential dangers.

3. MS-DUR to further evaluate trends and risk factors (racial disparities, comorbidities, prescriber types) associated with long-term use of sedative hypnotics and their concomitant use with opioids.

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FDA DRUG SAFETY COMMUNICATIONS

July 2020 – September 2020

- 8/26/2020 - FDA removes Boxed Warning about risk of leg and foot amputations for the diabetes medicine canagliflozin (Invokana, Invokamet, Invokamet XR)

- 7/23/2020 - FDA recommends health care professionals discuss naloxone with all patients when prescribing opioid pain relievers or medicines to treat opioid use disorder

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 re-appointed 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

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: e-mail, 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.

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

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
COB	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
HB	House Bill
HCPCS/ HEIDIS	Health Plan Employer Data and 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
PDL	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-DUR	Retrospective Drug Utilization Review
RFI	Request for Information
RFP	Request for Proposal
RHC	Rural Health Clinic
SB	Senate Bill
SCHIP	State Child Health Insurance Program
SMART PA	Conduent's Pharmacy Application (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