

Policy Evaluation: Short-Acting Opioid Quantity Limits

Research Questions:

1. Since implementation of 7-day quantity limits for short-acting opioids, has the number of patients prescribed opioids for more than 7 days decreased?
2. Have there been changes in type of opioids prescribed (long- vs. short-acting) or average daily dose of prescribed opioids?
3. Has the number of patients with risk factors for overdose and long-term opioid use decreased since implementation of short-acting opioid quantity limits?
4. Has there been an increase in emergency department visits or hospitalizations for patients with denied opioid claims?
5. Has there been an increase in naloxone prescribing for patients claims for opioids?

Conclusions:

1. Proportion of patients with a 7 days' supply of opioids
 - The total number of patients with paid or denied claims for opioids decreased from 4916 patients in the 6 months before the policy implementation to 4279 in the 6 months after implementation of days' supply limits.
 - More patients had a denied claim (and no subsequent paid claims) for an opioid after implementation of these limits (18.2% vs. 7.4% before implementation).
 - A slightly larger proportion of patients had paid opioid claims for less than 7 days (67.5% of patients compared to 61.8% prior to implementation).
2. Type of opioids prescribed (long- vs. short-acting)
 - In patients with a claim for a short-acting opioid, over 98% of patients had claims for only short-acting opioids over a 90-day period. Few patients are prescribed combination use with a short-acting and long-acting opioid.
3. Daily dose
 - Overall, the average dose in morphine milligram equivalents (MME) per day was unchanged in the 6 months before and after the policy implementation.
 - About 60% of prescriptions were written for less than 30 MME per day and less than 2% of patients were prescribed greater than 90 MME per day.
4. Risk factors for overdose
 - In the overall population, the proportion of patients with use of concomitant sedating prescriptions for more than 14 days decreased in the 6 months after the policy implementation (from 7.6% to 2.8%).
 - There was a slight decrease in patients on high-dose opioids (>90 MME daily) from 20% to 18%, but other risk factors for overdose remained relatively unchanged. About 4% of patients prescribed opioids had a diagnosis of opioid use disorder (OUD), 22% had any type of substance use disorder, and 1% (n=42) had a recent overdose in the prior 90 days.

5. Emergency department (ED) visits and hospitalizations
 - In patients prescribed an opioid, the total number of all-cause ED visits was similar in the 6 months before and after implementation of days' supply limits. Approximately 44% of patients had an ED visit during this period and 19% were hospitalized. About half of all visits occurred following an opioid prescription. In the 6 months before the policy implementation, 2185 patients accounted for 4933 ED visits (average 2.25 visits per patient). A similar number of visits occurred in the 6 months following the policy implementation (4149 ED visits in 1903 patients; average 2.18 ED visits per patient).
 - Similar trends were observed for hospitalizations with the total number of hospitalizations remaining unchanged after the policy implementation.
6. Naloxone prescribing
 - The proportion of patients with claims for naloxone in the 90 days after the first opioid prescription remained small (about 1% of patients). However, this analysis did not evaluate prior history of naloxone prescriptions.

Recommendations:

- Modify criteria of current high-risk opioid retroDUR program to include patients who may be paying cash for chronic opioid prescriptions and patients with a diagnosis of substance abuse or history of overdose. Notify providers about risk mitigation strategies and opportunities to improve care (**Appendix 2**).
- Update renewal criteria for both short-acting and long-acting prior authorization criteria to include an assessment of opioid use disorder to comply with new state minimum standards.

Background:

The Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act was signed into law on October 24, 2018.¹ This law requires state Medicaid programs to have drug utilization review safety edits for opioid refills and an automated claims review process to identify refills in excess of state defined limits, monitor concurrent prescribing of opioids with benzodiazepines or antipsychotics, and require managed care plans to have these processes in place by October 1, 2019.¹ In accordance with these state defined limits, FFS criteria were updated to limit use of short-acting opioids to 7 days per prescription, 90 MME daily, and 2 prescriptions every 90 days. Quantities in excess of days' supply limits can be approved if prior authorization (PA) criteria are met. Current criteria require documentation of improvement in pain or function, evaluation of the Prescription Drug Monitoring Program (PDMP), urine drug screen, and assessment of risk factors for overdose including use of concurrent sedatives before long-term use of opioids can be approved.

In order to satisfy requirements for the SUPPORT Act, several other initiatives were implemented at the same time. Prior authorization was implemented for all long-acting opioid formulations. A retroDUR provider fax program targeted patients on concomitant sedatives and opioids. Faxes were sent to providers if their patient received an opioid and another sedative from different providers. A second retroDUR initiative involved profile review of patients who received opioids in excess of state defined quantity limits (e.g., more than 90 MME per day, more than one type of opioid, combination benzodiazepine use, multiple early refills, etc). For both retroDUR programs, providers were notified regarding potential risks with included suggestions for care coordination and mitigation strategies. In many cases, these initiatives overlap with short-acting opioid quantity limits, and patients may have been included in multiple programs. It is difficult to determine which program may have had the most impact on changes in opioid prescribing. In 2021, several additional changes were made to the SUPPORT Act which require the state to set minimum standards for monitoring in several new areas.² Areas of focus include monitoring for patients with a diagnosis of OUD prescribed subsequent opioids and assessment of patients at high risk for overdose.²

Methods:

This is a before-and-after analysis evaluating patients with a prescription for a short-acting opioid in the 6 months before and after implementation of the days' supply limits on 10/1/2019. The index event (IE) was classified as the first paid or denied FFS claim for a short-acting opioid in the reporting period (PDL class: opioids, short-acting). Denied claims were included based on error codes in **Table A1** and any denied claims with error codes associated with **Table A2** were excluded (see **Appendix 1**). If patients had both a paid and denied claim on the same date, the claim was classified as a paid IE. Patients were then categorized according to the duration of opioid use paid for by FFS in the 90 days following the IE. Patients with Medicare (benefit packages BMM, BMD, MED) or limited drug coverage (benefit packages CWM, MND, SMF, SMB) were excluded from the analysis. Patients with less than 75% Medicaid eligibility in the 6 months before or 3 months after the index event were excluded in order to ensure complete data was captured for included patients.

The following definitions and timeframes were used for this analysis:

- Duration of opioid therapy was defined using the cumulative days' supply from paid FFS opioid claims and was evaluated in the 3 months following the IE. The IE was included in days' supply calculations.
- Type of opioid was defined according to PDL class (short-term and long-term).
- Daily dose was defined based on average morphine milligram equivalents (MME) per day.
- New start patients were classified as patients with no opioid use (short or long-acting) in the 90 days before the IE. Patients with a prior history of opioid use were defined as patients with paid opioid claims (FFS or CCO) in this same timeframe.
- Prescriber type was identified using the primary provider specialty.
- Risk factors for overdose
 - Concurrent prescribing of sedating medications was evaluated in the 30 days before and after the IE. Because opioids are often prescribed for short durations, patients with concurrent sedative prescribing were defined based on duration of overlapping therapy: either 2 consecutive days in overlapping therapy, or more than 14 days of overlapping therapy with no more than a 4 day gap in concomitant use. Sedating medications included in the analysis were categorized by type of medication and included the following classes:
 - Muscle relaxants, oral
 - Sedatives
 - Benzodiazepines
 - Antipsychotics, 2nd gen
 - Select antiepileptics: gabapentin (HSN 008831), pregabalin (HSN 026470), phenobarbital (HSN 001561)
 - Cumulative average opioid dose greater than 90 MME per day
 - Claims for both a short and long-acting opioid in the 90 days following the IE
 - Diagnosis of opioid (ICD-10: F11x) or other substance abuse, dependence or use (ICD-10: F10x-F19x) was identified based on medical claims in the 2 years before the IE. Diagnosis history may be incomplete for patients who were recently enrolled in Medicaid.
 - Diagnosis on any medical claim indicating narcotic or sedative overdose in the 3 months before the IE (see **Appendix 1** for list of included ICD-10 codes)
- Prescriptions for naloxone (HSN 001874) were evaluated in the 7 days before or 90 days after the IE.
- Hospitalizations and ED visits occurring during the study period were identified for patients in the pre-specified populations. Since patients may have had multiple paid or denied claims, visits were categorized according to the most recent paid or denied opioid claim occurring within 90 days before the encounter and grouped into the following categories:
 - 1) visits with a paid opioid claim prior to the event

2) visits with a denied opioid claim prior to the event

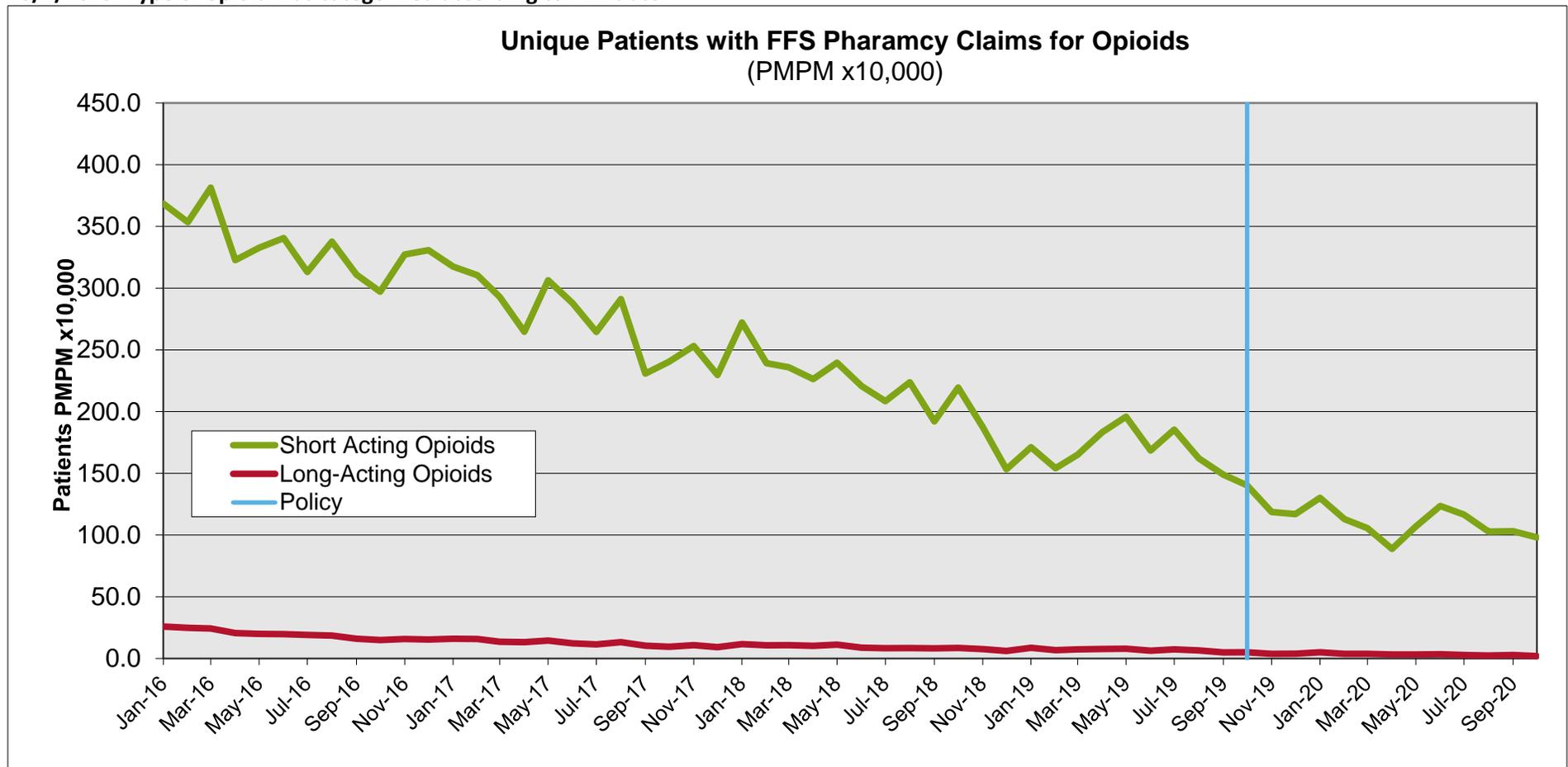
3) visits without an opioid claim within 90 days before the event

If a patient had both a paid and denied claim on the same day, the encounter was categorized as paid. This analysis captures all ED visits or hospitalizations for the patients during the study period, and patients would be counted more than once if they had multiple medical visits. Subsequently, data for this analysis may be more heavily influenced by members with frequent ED visits or hospitalizations.

Results:

The number of medicaid patients prescribed opioids has decreased steadily in the past few years (**Figure 1**). The majority of patients have prescriptions for short-acting opioids and relatively few patients are prescribed long-acting opioids.

Figure 1. Per member per month (PMPM) count of patients with a prescription for an opioid from 2016 to present. Policy implementation date was 10/1/2019. Type of opioid was categorized according to PDL class.



Basic patient characteristics at the time of the first opioid claim are shown in **Table 1**. The total number of patients with paid or denied claims for opioids decreased from 4916 patients in the 6 months before the policy implementation to 4279 in the 6 months after implementation of days' supply limits. The majority of prescriptions were for adults (92%) and females (69%). Approximately 32% of patients were white and 34% identified as American Indian or Alaskan Native. Only 2% of patients had a hospital discharge within 7 days prior to the first opioid prescription. Populations were similar in the 6 months before and after the IE.

Table 1: Demographics at the time of the IE.

	Before		After	
N=	4916		4,279	
Age				
<=18	433	9%	338	8%
19-64	4473	91%	3,930	92%
>=65	10	0%	11	0%
Race				
White	1506	31%	1,353	32%
American Indian/Alaskan Native	1628	33%	1,472	34%
Other	387	8%	333	8%
Unknown	1395	28%	1,121	26%
Female	3378	69%	2,951	69%
Inpatient hospital discharge date within 7 days before IE	117	2%	97	2%

After implementation of days' supply edits, patients were allowed to fill 2 prescriptions of up to 7 days without a PA. PA was required for more than 2 prescriptions within a 90 day timeframe or for any single prescription greater than 7 days. After implementation of these limits, there was an increased number of patients with denied claims (shown as patients with 0 days' supply in **Table 2**), and a slight increase in the proportion of patients prescribed opioids for less than 7 days (67.5% compared to 61.8% prior to implementation). Similarly, there was a decreased number of patients with paid opioid prescriptions for more than 14 in the 6 months after the policy implementation (7.7%) compared to the control period (21.5%). Similar trends were observed in patients newly started on opioids and in those with a history of opioid prescribing in the prior 90 days (**Table 2**). Of all patients prescribed opioids in the 6 months following implementation, 77% were patients with no recent opioid use. Of these, 41% of patients with an initial denied prescription and no subsequent paid claims (n=319 of 780 total) were patients with no opioid use in the previous 90 days.

Table 2. Days' Supply in the 90 days following the first opioid claim

	Before		After	
	N=			
	4,916		4,279	
All Patients				
0 days	366	7.4%	780	18.2%
1-7 days	3,039	61.8%	2,888	67.5%
8-14 days	456	9.3%	280	6.5%
>14 days	1,055	21.5%	331	7.7%
	N=	%	N=	%
New Start	3709		3291	
0 days	86	2.3%	319	9.7%
1-7 days	2,782	75.0%	2,661	80.9%
8-14 days	348	9.4%	240	7.3%
>14 days	493	13.3%	71	2.2%
	N=	%	N=	%
Prior Opioid History	1207		988	
0 days	280	23.2%	461	46.7%
1-7 days	257	21.3%	227	23.0%
8-14 days	108	8.9%	40	4.0%
>14 days	562	46.6%	260	26.3%

Because multiple point-of-sale edits were implemented at the same time period, there may be multiple reasons for paid or denied claims. For example, patients may have an initial denied claim if it was billed for greater than 7 days, but receive a subsequent paid claim pharmacy decided to dispense a partial prescription or the provider decreased the prescription quantity. Other patients may have an initial paid claim for less than 7 days, but a have a subsequent denial for another prescription if they continue to be prescribed opioids for longer than 14 days. **Table 3** shows patterns of paid and denied claims for the IE and in the subsequent 90 days. In the 6 months after the implementation of 7 day supply limits, the proportion of patients with an initial paid claim decreased from 90% to 77%. More than half of patients (62%) had only paid claims for opioids indicating they were prescribed within the recommended days' supply limits. Twenty percent of patients had both paid and denied claims, indicating they were impacted by the policy, but had received a paid opioid prescription. Eighteen percent of patients had only denied claims for opioids indicating that while they were prescribed an opioid, it was never paid for by FFS Medicaid. As expected, the proportion of patients with at least one denied claim increased after implementation of the days' supply limits from 7% to 18% for patients without any paid opioid claims and from 12% to 20% in patients with at least one denied claim. The total number of patients with more than one claim for an opioid has decreased over time indicating that prescribers continue to write fewer prescriptions for short-acting opioids (from 1658 patients in the 6 months before to 1518 patients in the 6 months after the policy implementation). In patients with more than one claim, they were more likely to have subsequent denied opioid prescription in the 6 months after implementation of the policy (48% of patients with more than one claim) compared to 22% in the control period.

Table 3. Claim types and prescription characteristics

	Before		After	
	N=	4,916	4,279	
Initial IE (first claim)				
Paid		4,414	90%	3,303 77%
Denied		502	10%	976 23%
FFS Claim types in 90 days after IE				
Paid only		3,938	80%	2,658 62%
Denied only		366	7%	780 18%
Paid and denied		612	12%	841 20%
Last FFS opioid claim in the 90 days after the IE (for patients with >1 claim)				
	N=	1,659		1,518
Paid		1,295	78%	781 51%
Denied		364	22%	737 49%

Table 4 shows the days' supply of opioids paid for by FFS Medicaid within 90 days of an initial claim. In patients with an initial paid claim the proportion of patients with less than 7 days of opioids increased from 68% to 84%. In patients with an initial denied claim, the majority of patients (79%) had no subsequent paid claim. Only a small proportion of patients with an initial denial had subsequent paid claims for less than 7 days (10%), 7 to 14 days (3%) or greater than 14 days (7%).

Table 4. Days' Supply based on the disposition of the initial IE

	Before		After		
Paid IE	N=	4,414	%	3,303	%
1-7 days		3,021	68.4%	2,791	84.5%
8-14 days		450	10.2%	251	7.6%
>14 days		943	21.4%	261	7.9%
Denied IE	N=	502	%	976	%
0 days		366	72.9%	780	79.9%
1-7 days		18	3.6%	97	9.9%
8-14 days		6	1.2%	29	3.0%
>14 days		112	22.3%	70	7.2%

In patients with a claim for a short-acting opioid, over 98% of patients had claims for only short-acting opioids over a 90-day period (**Table 5**). A small proportion of patients were prescribed long-acting opioids or long-acting opioids in combination with a short-acting product. The number of patients prescribed multiple opioid products has decreased since implementation of the policy.

Table 5. Type of opioid prescribed for the IE and in the 90 days after the IE

	Before		After	
	N=	4,916	%	4,279
Short-acting opioid (paid claims)	4,478	91%	3,457	80.8%
Short-acting opioid (single denied claim)	366	7%	780	18.2%
Long-acting opioid only	11	0%	20	0.5%
Rx for both short-and long-acting opioids	61	1%	22	0.5%

Overall, the average dose in morphine milligram equivalents (MME) per day was unchanged in the 6 months before and after the policy implementation (**Table 6**). About 60% of prescriptions were written for less than 30 MME per day and less than 2% of patients were prescribed greater than 90 MME per day. When evaluating dose based on the days' supply, the largest changes after the policy occurred in patients on lower doses. More patients with less than 30 MME per day had denied prescriptions (3.7% before vs. 11.9% after policy implementation) and fewer patients had more than 14 days of opioid therapy paid by Medicaid (14.1% before vs. 4.5% after policy implementation). About 33% of patients before the policy and 34% of patients after the policy had claims with more than one prescription number indicating that these patients had a subsequent opioid prescription written in the following 90 days. Similar trends in daily dose were observed for patients with more than one claim in the 90 days following the IE.

Table 6. Average Daily Dose of the IE

	Before		After	
	N=	4,916	%	4,279
<= 30 MME/day	2,906	59.1%	2,589	60.5%
31-60 MME/day	1,514	30.8%	1,264	29.5%
61-90 MME/day	405	8.2%	354	8.3%
>= 91 MME/day	91	1.9%	72	1.7%

Patients with several risk factors for overdose were evaluated in patients with paid or denied claims for opioids (**Table 7**). In the overall population, the proportion of patients with use of concomitant sedating prescriptions for more than 14 days decreased in the 6 months after the policy implementation (from 7.6% to 2.8%). It is unclear if this change is due to discontinuation of the opioid or sedative. The majority of patients with concomitant sedating prescriptions occurred in patients prescribed opioids for more than 14 days. Of the 331 patients prescribed more than 14 days of opioids in the 6 months after the policy implementation, approximately 36% (n=119) were prescribed a concomitant sedating medication which is similar to the 6 months prior to policy implementation (376 of 1055 patients, 36%). There was a slight decrease in patients on high-dose opioids (>90 MME daily) from 20% to 18%, but other risk factors for overdose

remained relatively unchanged. **Table 8** examines risk factors in more detail according to days' supply for paid prescriptions in the 90 days following the first opioid claim.

Table 7. Patients with risk factors for overdose in the 90 days following the IE

	N=	Before		After	
		4916	%	4279	%
Concomitant sedative					
>= 2 consecutive days		268	5.5%	131	3.1%
>= 14 days		376	7.6%	121	2.8%
Short and long acting opioid claims		81	1.6%	72	1.7%
Average cumulative daily dose >90 MME for opioid covered days		1006	20.5%	782	18.3%
Diagnosis for opioid use disorder in 90 days prior to IE (F11x)		192	3.9%	167	3.9%
Diagnosis for substance use disorder in 90 days prior to IE (F10x-F19x)		1154	23.5%	961	22.5%
Recent overdose in 90 days prior to IE		42	0.9%	42	1.0%
Number of risk factors (mutually exclusive)					
1		1640	33.4%	1384	32.3%
2		420	8.5%	305	7.1%
3		60	1.2%	39	0.9%
4		7	0.1%	1	0.0%
5		2	0.0%	1	0.0%
Naloxone prescription in 7 days before or after IE		44	0.9%	57	1.3%

After implementation of the days' supply policy, there was a slightly greater number of patients with denied claims only for both short-acting and long-acting opioids (n=20, 0.5% of the total population) compared to the period before the policy implementation (n=2, 0%). Similarly, fewer patients with diagnoses of OUD or any substance use disorder received opioids from Medicaid for longer than 14 days after implementation of days' supply edits (**Table 8**). Opioid use disorder was defined according to ICD-10 codes and included codes for opioid dependence, opioid abuse, and opioid use. In patients with a diagnosis of OUD, patients with prescriptions for more than 14 days decreased from 1.2% (n=61) to 0.4% (n=17) and the proportion of patients who had no paid prescriptions for an opioid despite having a prescription increased from 0.5% (n=24) to 1.0% (n=42). Similar trends were noted in all patients with a diagnosis of any substance use disorder with a greater number of patients with no paid claims for their opioid prescription after implementation of the policy. In patients with an overdose in the past 90 days, there were more patients with 0 to 7 days' supply compared to patients in the 6 months before the policy implementation. While the number of patients with a recent overdose is relatively small (42 patients over 6 months), it is concerning that patients with a recent overdose continue to have prescriptions written for opioids.

Table 8. Risk factors for overdose based on days' supply

	Before		After		
	N=	4916	%	4279	%
Short and long acting opioid claims		81	1.6%	72	1.7%
0 days		2	0.0%	20	0.5%
1-7 days		2	0.0%	6	0.1%
7-14 days		2	0.0%	3	0.1%
>14 days		75	1.5%	43	1.0%
Patients with average cumulative daily dose >90 MME for opioid covered days		1006	20.5%	782	18.3%
0 days		0	0.0%	0	0.0%
1-7 days		955	19.4%	767	17.9%
7-14 days		11	0.2%	1	0.0%
>14 days		40	0.8%	14	0.3%
Diagnosis for opioid use disorder in 90 days prior to IE (ICD-10: F11x)		192	3.9%	167	3.9%
0 days		24	0.5%	42	1.0%
1-7 days		92	1.9%	96	2.2%
7-14 days		15	0.3%	12	0.3%
>14 days		61	1.2%	17	0.4%
Diagnosis for substance use disorder in 90 days prior to IE (ICD-10: F10x-F19x)		1154	23.5%	961	22.5%
0 days		84	1.7%	168	3.9%
1-7 days		677	13.8%	648	15.1%
7-14 days		114	2.3%	78	1.8%
>14 days		279	5.7%	67	1.6%
Recent overdose in 90 days prior to IE		42	0.9%	42	1.0%
0 days		5	0.1%	12	0.3%
1-7 days		15	0.3%	23	0.5%
7-14 days		8	0.2%	2	0.0%
>14 days		14	0.3%	5	0.1%
Naloxone prescription in 7 days before or after IE		44	0.9%	57	1.3%
0 days		4	0.1%	13	0.3%
1-7 days		13	0.3%	29	0.7%
7-14 days		3	0.1%	5	0.1%
>14 days		24	0.5%	10	0.2%

Provider specialty for the initial opioid claim is shown in **Table 9**. For the majority of patients, the first prescription in the reporting period was prescribed from a family provider (15%), physician assistant (12%), emergency room provider (10%), obstetrics and gynecology specialist (10%), or family nurse practitioner (9%). Overall, the proportion of patients receiving opioid claims from each specialty was similar in the 6 months before and after the implementation of days' supply limits. For almost all specialties, there were a greater number of patients who had no opioids paid by FFS and fewer patients with paid opioid prescriptions of more than 14 days after the policy implementation.

Table 9. Top 20 prescriber specialties associated with the IE

	N=	Before		After	
		4,916	%	4,279	%
1 Family Practitioner	682	13.9%	652	15.2%	
2 Physician Assistants	642	13.1%	508	11.9%	
3 Emergency Med Practitioner	486	9.9%	442	10.3%	
4 Obstetrics & Gynecology	468	9.5%	426	10.0%	
5 Family Nurse Practitioner	395	8.0%	367	8.6%	
6 Gen. Dentistry Practitioner	369	7.5%	289	6.8%	
7 Internist	298	6.1%	266	6.2%	
8 Dentist (Default Spec)	175	3.6%	190	4.4%	
9 Oral Surgeon	192	3.9%	134	3.1%	
10 Orthopedic Surgeon	165	3.4%	154	3.6%	
11 General Surgeon	127	2.6%	123	2.9%	
12 Nurse Practitioner (default Spec)	118	2.4%	102	2.4%	
13 Advance Practice Nurse	104	2.1%	62	1.4%	
14 Physician (Default Spec)	57	1.2%	62	1.4%	
15 Certified Nurse Midwife	60	1.2%	46	1.1%	
16 Otologist, Laryngologist, Rhinologist	63	1.3%	37	0.9%	
17 Physical Medicine and Rehabilitation Practitioner	39	0.8%	39	0.9%	
18 Urologist	37	0.8%	32	0.7%	
19 UNKNOWN	54	1.1%	8	0.2%	
20 Pediatrics	32	0.7%	28	0.7%	

In total, 1621 patients had at least one denied claim in the 6 months after implementation of days' supply limitations compared to 978 patients in the 6 months prior to implementation. Approximately 32% of these patients had a subsequent paid claim within 30 days and another 6% of patients had a paid claim within 90 days. However, most patients who received a denial had no paid claims (62%) or prior authorization requested (60%) in the 90 days after their denial (increased from 50% and 47% in the period before the policy implementation, respectively). Upon evaluation of prior opioid history, 42% of patients with a denied claim were new start patients.

Table 10. Outcomes for patients with any denied claim in the 90 days after the IE. In order to avoid counting patients multiple times, the first denial for each patient was used. Outcomes were evaluated in the 90 days following the initial denial.

	Before		After	
	N=	%	N=	%
Denied Claim				
Opioid paid within 30 days after the denial	380	38.9%	519	32.0%
Opioid paid within 31-90 days after denial	112	11.5%	95	5.9%
Never had an opioid paid within 90 days of denial	486	49.7%	1,007	62.1%
PA not requested within 5 days before or 90 days after the denial	462	47.2%	976	60.2%
PA denied within 5 days before or 90 days after the denial	26	2.7%	58	3.6%
Never received opioid and had diagnosis of malignant neoplasm (ICD-10 Cx) or end of life diagnosis (Z515)	28	2.9%	46	2.8%
Prior opioid history in patients with a denied claim				
Opioid paid within 30 days before the denial	476	48.7%	740	45.7%
Opioid paid within 31-90 days before the denial	103	10.5%	195	12.0%
Never had an opioid paid within 90 days before the denial	399	40.8%	686	42.3%

Table 11 shows the number of emergency department visits and hospitalizations during the study period for identified patients with a paid or denied opioid claim. Overall, the total number of ED visits and hospitalizations was unchanged in the 6 months before and after the policy implementation. In the 6 months before the policy implementation, there were a total of 4933 ED visits in 2185 patients (on average 2.25 visits per patient for those with a ED visit). A similar number of visits occurred in the 6 months following the policy implementation (4149 visits in 1903 patients; average 2.18 ED visits per patient). Almost half of these visits appear to be unrelated to opioid use. The number of visits occurring in the 90 days following a denied claim increased from 5% to 15% of visits and there was a decrease in visits occurring following a paid opioid claim. Similar trends were observed for hospitalizations. This is not unexpected as the number of patients with denied opioid claims increased after implementation of the policy. Because of multiple confounding factors, it is difficult to draw firm conclusions about whether ED visits are correlated to denied opioid prescriptions. One limitation of this analysis is that patients could be included in both the before and after groups. Patients were included in both groups in order to capture data on patients with a history of chronic opioid use. While increases in ED visits were observed in patients with denied opioid claims, a proportional decrease was observed in patients with paid opioid claims. It is possible that the same patients were included in both the before and after group and have just been categorized differently based on a denied claim in the 6 months after the policy implementation.

Upon evaluation of primary diagnoses associated with ED visits, the most common diagnoses associated with ED visits were comparable in the 6 months before and after the implementation of days' supply limits. Common diagnoses for ED visits included abdominal and pelvic pain, pain in throat and chest, dorsalgia, other pain, and other joint disorder. These diagnoses, occurring both before and after the policy implementation, indicate that pain continues to be a complex condition to adequately control. In patients with an ED visit or hospitalization following a paid or denied opioid claim, visits associated with diagnoses of OUD, overdose, or any substance use disorder were infrequent (<0.3% of patients prescribed opioids) and few patients had medical claims indicating naloxone administration in a hospital or outpatient setting. However, this data is unlikely to capture naloxone administration which occurs outside the hospital setting and is administered by non-medical personnel (e.g., patient, family, friends, etc.) or by emergency medical services.

Table 11. ED visits and hospitalizations for patients with claims for opioids.

		Before		After	
All-cause ED visits	N=	4,933	%	4,149	%
Paid FFS opioid claim (short or long acting) within 90 days prior to the visit		2,345	47.5%	1,472	35.5%
Denied FFS opioid claim (short or long acting) within 90 days prior to the visit		252	5.1%	616	14.8%
No FFS opioid claim (paid or denied) within 90 days prior to the visit		2,336	47.4%	2,061	49.7%
All-cause hospitalizations (unique admissions)	N=	1,186	%	1,017	%
Paid FFS opioid claim (short or long acting) within 90 days prior to the hospitalization admission		278	23.4%	175	17.2%
Denied FFS opioid claim (short or long acting) within 90 days prior to the hospitalization admission		45	3.8%	73	7.2%
No FFS opioid claim (paid or denied) within 90 days prior to the hospitalization admission		863	72.8%	769	75.6%

Limitations:

Data presented in this report is based on Medicaid claims history and has several inherent limitations.

- **Diagnostic accuracy:** Diagnoses based on claims history may be inaccurate or incomplete. Because diagnoses are not associated with prescriptions, it is difficult to determine the intended indication for the drug, particularly when therapy is used off-label.
- **Provider specialty:** Information on provider specialty may be inaccurate, out-of-date, or incomplete for some providers. Prescribers with multiple specialties or designations may not be identified.
- **Days' Supply Estimates:** Estimates of days' supply attempts to estimate the duration a patient has been prescribed opioids, but may not accurately correlate to actual medication adherence, and patients may not always be categorized appropriately. Days' Supply only captures claims paid by FFS and excludes any claims paid for by CCOs, by other insurances, or by the patient.
- **Definitions for new start patients:** Prior use of opioids was only evaluated in the 90 days prior to the IE. If patients have been paying cash for their opioid prescription, they may be inaccurately categorized as a new start patient because of the lack of paid claims.
- **Utilization, particularly medical and hospital visits may be partially impacted by the COVID pandemic in the time after the policy (10/1/19 to 3/31/20).** Medical visits were evaluated in the 90 days following a paid or denied opioid claim and for some patients, this period could have occurred when general medical offices were closed and stay-at-home orders were in place.
- **The retrospective nature of the study also does not control for potential unknown confounders which may influence results of the analysis.** Multiple prospective and retrospective initiatives were implemented during the same period and it is difficult to discern which initiatives had the greatest impact. Other potential confounders include changes in the population over time or changes in the general prescribing patterns of providers. For example, national and state programs to monitor overdose rates and increase access to counseling and medication assisted treatment for OUD may influence patterns of opioid prescribing. Similarly, ED visits and hospitalizations may be influenced by a variety of factors. Patients with more severe illness or breakthrough pain are more likely to have denied claims due to changes in therapy and are also likely to visit the ED more frequently.

References:

1. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. <https://www.congress.gov/bill/115th-congress/house-bill/6>. Accessed March 20, 2019.
2. Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements. A Rule by the Health and Human Services Department, and the Centers for Medicare & Medicaid Services. Federal Register: The Daily Journal of the United States Government. <https://www.federalregister.gov/documents/2020/12/31/2020-28567/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and>. Updated December 31, 2020. Accessed February 26, 2021.

Appendix 1: Drug Coding

Table A1. Included error codes for denied claims

<u>Error Code</u>	<u>Error Status Description</u>
6899	SHORT-ACTING OPIOID MAX 7-DAY SUPPLY EXCEEDED
6510	Pharmacy Opioid Limit - 2 Fills in 90 days
4165	DRUG QUANTITY PER DAY LIMIT EXCEEDED
4175	OPIATES DRUG QUANTITY PER DAY LIMIT EXCEEDED
3022	Non-Pref Drug. Prior Authorization Required.
3002	NDC REQUIRES PA
3000	UNITS EXCEED AUTHORIZED UNITS ON PA MASTER FILE
4025	AGE IS NOT ALLOWED FOR NDC
4026	DAY SUPPLY LIMIT EXCEEDED FOR COVERED NDC

Table A2. Excluded error codes for denied claims

<u>Error Code</u>	<u>Error Status Description</u>
2017	RECIPIENT SERVICES COVERED BY HMO PLAN
4999	THIS DRUG IS COVERED BY MEDICARE PART D
2002	RECIPIENT NOT ELIGIBLE FOR HEADER DATE OF SERVICE
2508	RECIPIENT COVERED BY PRIVATE INSURANCE (PHARMACY)
576	CLAIM HAS THIRD-PARTY PAYMENT
513	RECIPIENT NAME AND NUMBER DISAGREE
238	RECIPIENT NAME IS MISSING
2809	DOB IS INVALID
503	DATE DISPENSED AFTER BILLING DATE
5001	EXACT DUPLICATE
628	Other Coverage Reject Code Required for OCC 3

2507	RECIPIENT HAS MORE THAN ONE INSURANCE CARRIER
500	DATE PRESCRIBED AFTER BILLING DATE
221	DAYS SUPPLY MISSING
502	DATE DISPENSED EARLIER THAN DATE PRESCRIBED
643	INVALID OTHER COVERAGE CODE
205	PRESCRIBING PROVIDER ID MISSING

Table A3. ICD-10 codes associated with poisoning by or adverse effect of various agents. Codes for underdosing are excluded.

ICD-10 codes	Agent
T400X1x- T400X5x	opium
T401X1x- T401X4x	heroin
T402X1x- T402X5x	other opioids
T403X1x- T403X5x	methadone
T40411x- T40415x	fentanyl or fentanyl analogs
T40421x- T40425x	tramadol
T40491x- T40495x	other synthetic narcotics
T405X1x- T405X5x	cocaine
T40601x- T40605x	other and unspecified narcotics
T40691x- T40695x	other narcotics
T407X1x- T407X5x	cannabis (derivatives)
T408X1x- T408X4x	lysergide [LSD]
T40901x- T40905x	other and unspecified psychodysleptics [hallucinogens]
T40991x- T40995x	other psychodysleptics [hallucinogens]
T420X1x- T420X5x	hydantoin derivatives
T421X1x- T421X5x	iminostilbenes
T422X1x- T422X5x	succinimides and oxazolidinediones
T423X1x- T423X5x	barbiturates
T424X1x- T424X5x	benzodiazepines
T425X1x- T425X5x	mixed antiepileptics
T426X1x- T426X5x	other antiepileptic and sedative-hypnotic drugs
T427X1x- T427X5x	unspecified antiepileptic and sedative-hypnotic drugs
T428X1x- T428X5x	antiparkinsonism drugs and other central muscle-tone depressants
T43011x-T43015x	tricyclic antidepressants
T43021x-T43025x	tetracyclic antidepressants
T431X1x-T431X5x	monoamine-oxidase-inhibitor antidepressants
T43201x-T43205x	other and unspecified antidepressants

<i>T43211x-T43215x</i>	serotonin and norepinephrine reuptake inhibitors
<i>T43221x-T43225x</i>	selective serotonin reuptake inhibitors
<i>T43291x-T43295x</i>	other antidepressants
<i>T433X1x-T433X5x</i>	phenothiazine antipsychotics and neuroleptics
<i>T434X1x-T434X5x</i>	butyrophenone and thiothixene neuroleptics
<i>T43501x-T43505x</i>	other and unspecified antipsychotics and neuroleptics
<i>T43591x-T43595x</i>	other antipsychotics and neuroleptics
<i>T43601x-T43605x</i>	psychostimulants
<i>T43621x-T43625x</i>	amphetamines
<i>T43631x-T43635x</i>	methylphenidate
<i>T43641x-T43644x</i>	ecstasy
<i>T43691x- T43695x</i>	other psychostimulants
<i>T438X1x- T438X5x</i>	other psychotropic drugs
<i>T4391xx- T4395xx</i>	unspecified psychotropic drug
<i>T450X1x-T450X5x</i>	antiallergic and antiemetic drugs
<i>T481X1x-T481X5x</i>	skeletal muscle relaxants [neuromuscular blocking agents]
<i>T48201x-T48205x</i>	other and unspecified drugs acting on muscles
<i>T483X1x-T483X5x</i>	antitussives
<i>T485X1x-T485X5x</i>	other anti-common-cold drugs
<i>T50901x-T50905x</i>	unspecified drugs, medicaments and biological substances
<i>T50911x-T50915x</i>	multiple unspecified drugs, medicaments and biological substances
<i>T50991x-T50995x</i>	medicaments and biological substances

Table A3. Health Outcome Codes

ED Visits	Procedure Codes OR Revenue Center Codes	99281-99285, 99288 0450-0459 or 0981
Hospitalizations	Claim Type = I	
Medical claims for naloxone administration	CPT Code	J2310

Appendix 2. RetroDUR Program for High-Risk Opioid Patients

- Inclusion criteria
 - Patients currently enrolled in FFS; AND
 - Patients with a paid or denied claim for an opioid prescription within the past quarter; AND
 - At least one of the following:
 1. High dose: Patients with cumulative opioid dose >90 MME (for all opioid formulations) for >60 days (with <=7 day gap in therapy) in a 120 day lookback; OR
 2. SAO and LAO: Patients with paid claims in the Opioids, Short-acting PDL class AND claims in the Opioids, Long-acting PDL class for >60 days overlap with <=7 day gap in therapy in a 120 day lookback; OR
 3. Multiple opioids: Patients with paid claims for 2 or more GSNs in a given opioid PDL class (opioids, short-acting or long-acting) for >60 days overlap with <=7 day gap in therapy in a 120 day lookback; OR
 4. >110% covered days: Patients with sum of >110% of covered days for a specific opioid (based on HSN) in a 120 day lookback (filling an extra 12 days of opioids approximately); OR
 5. Opioid and Benzodiazepine: Patients with paid claims for opioids (opioids, short-acting OR opioids, long-acting PDL classes) AND paid claims in the Benzodiazepines PDL class for >60 days overlap with <=7 day gap in therapy in a 120 day lookback; OR
 6. Multiple denied claims: Patients with >=3 unique denied claims for an opioid in the past 120 days which may indicate cash-paying (PDL classes: opioids, short-acting or opioids, long-acting). Count only denied claims for unique prescription numbers for which there is not a paid pharmacy claim for the same prescription number. Count each prescription only once if there are multiple denials for the same prescription number; OR
 7. Overdose history: Patients with a history of opioid overdose in the past 2 years; OR
 8. Substance use disorder: Patients with a diagnosis of substance use disorder (excluding alcohol) in the past 2 years or patients prescribed medication assisted treatment (PDL class: substance use disorders, opioid and alcohol) within the past 6 months.
- Exclusion criteria
 - Patients with a malignant cancer diagnosis (ICD-10 codes beginning with C) or claim for palliative care (Z51.5) based on medical claims in the past year
 - Patients with a diagnosis of sickle cell disease in the past year (ICD-10 D57xxx)
 - Patients with currently active primary insurance or Medicare coverage (this population will bypass our edits)
 - Patients previously reviewed with this initiative in the last 6 months
 - Patients who have had a provider letter sent regarding concomitant use of opioid and sedating medications in the past 6 months
- Prioritize patients based on the number of inclusion criteria are met (#1-8 above). Higher priority patients will meet more inclusion criteria.

Concern: (drop-down choices)

- (A) Patient with > 90 Morphine Milligram Equivalents (MMEs) cumulative daily dose
- (B) Concurrent paid claims identified for short- and long-acting opioids
- (C) Concurrent paid claims identified for ≥ 2 unique opioids
- (D) Multiple paid claims identified for early opioid fills
- (E) ≥ 3 unique denied claims identified for opioid prescriptions
- (F) Paid claims identified for opioids and concurrent benzodiazepines or other sedative-hypnotic medications
- (G) No evidence of naloxone prescription on profile
- (H) History of overdose in the past year
- (I) Diagnosis, medical claims, or prescriptions indicating a substance use disorder

Rationale: (RPh will enter free-form text in box)

[1] Above 90 mg MME, the risk of overdose death increases 10 times.

[2] CDC recommends that clinicians discuss with patients known risks and realistic benefits of opioid therapy and mutual responsibilities for managing therapy.

[3] Naloxone is a pure opioid antagonist that reverses opioid overdose when administered properly. CDC recommends co-prescribing naloxone to patients at elevated risk of overdose who receive opioid analgesia.

[4] CDC recommends that clinicians offer or arrange evidence-based treatment (usually medication assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.

[5] When prescribing opioids for chronic pain, CDC recommends that clinicians use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

[6] If benefits do not outweigh harms of continued opioid therapy, CDC recommends clinicians optimize alternate therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. CDC guidance for opioid dose reduction may be found at: <https://www.hhs.gov/opioids/treatment/clinicians-guide-opioid-dosage-reduction/index.html>

[7] Denied claims may indicate the pharmacy is trying to fill the prescription early or your patient may be paying cash. Their current prior authorization (PA) for <drug name> expires on <XX/XX/XXXX>. The following information should be included with PA requests:

- A risk/benefit assessment including risk factors for overdose
- Objective documentation of improvement
- Documentation of a recent PDMP evaluation
- Documentation of a pain contract with the patient

[8] All opioids have a black box warning about the risks of profound sedation, respiratory depression, coma or death associated with concomitant use of opioids with benzodiazepines or other CNS depressants. Roughly 30% of opioid overdoses involve benzodiazepines.

[9] Opioids are associated with increased risk of dependence, abuse, and misuse. Data indicate that overdose risk is increased in patients with a diagnosis of opioid or substance use disorder or in patients with a prior history of overdose.

Recommendation: (drop-down choices – option for multiple selections)

- Use extreme precaution when increasing opioid dose to ≥ 50 MME per day based on increased risk of overdose.
- Avoid daily opioid doses > 90 MME unless clinically justified.
- Evaluate benefits and harms of chronic opioid therapy every 3 months or more frequently.
- Optimize of multi-modal therapies to strategize with your patient to lower their daily opioid dose or to progress toward taper and discontinuation of opioids.
- Do not prescribe long-acting opioids for acute pain.
- Check the Oregon Prescription Drug Monitoring Program (www.orpdmp.com) at least every 3 months to verify appropriate opioid prescribing.
- Mobilize care coordination services to assess if prescriptions are being used according to physicians' directions.
- Co-prescribe naloxone to patients at elevated risk of overdose.
- Discuss the risk/benefit of opioids with your patient and submit prior authorization for the prescribed opioid if appropriate.
- Use extreme caution when prescribing opioids to patients on chronic benzodiazepine or sedative-hypnotic medications.
- Use extreme caution when prescribing opioids to patients with opioid use disorder or recent overdose.
- Discuss benefits of treatment for substance use disorder if appropriate. Medication assisted therapy for opioid use disorder is available without prior authorization.

Minimum standards for DUR programs

The Oregon Health Authority (OHA) and contracted managed care entities (MCEs) must follow these standards on and after **July 1, 2021**, for most Oregon Health Plan members. These standards are pursuant to 42 CFR § 456.703(h) and the SUPPORT Act.

Exempt populations: Individuals receiving hospice, palliative care, or cancer treatment; residents of long-term care facilities described in 42 USC 1396a(o)(3)(A)(ii); and individuals with sickle cell disease are exempt from these requirements. MCEs must ensure individuals in these categories continue to have appropriate access to opioid treatment.

1. Prospective “safety edit”¹ limitations and “claims review automated process”² for opioid fills above state-defined limitations for day supply and early refill

7-day supply limits for at least new starts of short acting opioids, and early refill thresholds to identify potential misuse or abuse.

- Thresholds must be equal to or more restrictive than general refill thresholds.
- Supply limits and early refill thresholds must be enforced by prior authorization (PA), quantity limits, or “soft edits” at point-of-sale.

Periodic claims review to look for concerning treatment (could include multiple prescribers, long courses of treatment, patients prescribed duplicate therapy, multiple early refills, or other indicators) and apply interventions *as deemed appropriate* (PA for further fills, patient or prescriber letters, “lock in,” continued monitoring, etc.).

2. Prospective safety edits and claims review automated process on quantity dispensed for initial and subsequent fills to minimize potential for inappropriate use and diversion

CCOs must apply prospective safety edits (such as PA review) to limit quantities of dispensed pills and to dose optimize when clinically appropriate to minimize the risk of inappropriate use and diversion. For example, dose optimization may be required for patients receiving long-acting opioids, and this requirement may be applied through prior authorization review.

Periodic claims review to look for concerning treatment (could include claims with quantities larger than typical FDA-labeled doses, quantities in excess of expected use for the probable indication, or quantities that are statistical outliers compared to similar

¹ CMS Guidance defines “safety edits” as prospective drug review, such as is defined in § 1927(g)(2)(A) of the Social Security Act

² CMS Guidance defines “claims review automated process” as retrospective drug use review, such as is defined in § 1927(g)(2)(B) of the Social Security Act

patients prescribed opioids) and apply interventions *as deemed appropriate*.

3. Prospective safety edits and claims review automated process for therapeutically-duplicative initial and subsequent opioid prescription fills

CCOs must apply a point-of-sale alert (“soft edit” or “hard edit”) that requires pharmacist or prescriber review when the claims system detects clinically significant overlapping opioid treatment. Alert must be overridable so there is minimal interference with appropriate therapy, such as through NCPDP DUR/PPS codes or through MCE or PBM review and authorization.

Periodic claims review to look for concerning treatment (could include patients with concurrent prescriptions for more than one type of opioid [short and long-acting opioids or use of multiple molecular entities] or patients with concurrent opioid prescriptions from multiple providers) and apply interventions as deemed appropriate.

4. Prospective safety edits and claims review automated process for a state-defined maximum daily morphine equivalent for treatment of chronic pain

90 morphine equivalents daily (MED) for at least short acting opioids, applied at least to individual prescriptions and enforced by prior authorization, quantity limits, or “soft edits” at point-of-sale. Edits must apply to initial refills and refills, though method of enforcement may differ.

Periodic claims review to look for concerning treatment (could include high cumulative MED, rapid recent increase in MED, or other indicators) and apply interventions *as deemed appropriate* (patient or prescriber letters, “lock in,” continued monitoring, etc.).

5. Claims review automated process that monitors when a client is concurrently prescribed opioids and benzodiazepines or antipsychotics

MCEs must use the “push” list of mental health carve out drug claims to identify concerning concomitant opioid/benzo or opioid/antipsychotic treatment, and apply interventions *as deemed appropriate* (PA further fills, patient or prescriber letters, “lock in,” continued monitoring, etc.).

6. Prospective safety edits and claims review automated processes to identify when a patient is prescribed an opioid after a recent diagnosis of opioid use disorder (OUD) or a prescription used to treat OUD

MCEs must apply an automated point-of-sale edit or a manual opioid PA review process to assess appropriate opioid use for patients being treated for OUD or who have a known recent diagnosis of OUD. This process must not interfere with OUD treatment and must

not interfere with appropriate pain management for individuals with OUD.

Periodic claims review to look for concerning treatment (could include concomitant long-term opioid use in patients prescribed MAT, opioid prescriptions from multiple prescribers or in excess of state defined limits for patients with a diagnosis of OUD, multiple denied opioid prescriptions in patients with OUD) and apply interventions *as deemed appropriate*.

7. Edits or processes to identify when a patient may be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of an FDA-approved opioid antagonist/reversal agent (naloxone)

MCEs must apply either an automated point-of-sale pharmacy messaging edit or a regular retrospective review (at least quarterly) to identify members at high risk for opioid overdose who do not have a recent naloxone prescription. “High risk” must at least include patients receiving chronic high-dose opioid treatment and patients receiving high-risk concurrent treatment (such as concurrent long- and short-acting opioid, concurrent opioid a benzodiazepine, or concurrent buprenorphine for MAT and a controlled substance). Apply interventions to mitigate overdose risk, ensure access to naloxone, and increase care coordination between the member, pharmacy, and prescriber as clinically indicated.

8. Program to monitor and manage the appropriate use of antipsychotic medications by Medicaid children. [Handled by OHA, no additional CCO action required]

Handled by OHA as follows:

- **Non-foster care:** Periodic claims review with referral for specialist consultation when concerning treatment is identified (e.g., long-term antipsychotic use in patients < 10 years of age).
- **Foster care:** Yearly review of foster-care children prescribed mental health medications. If concerning treatment is identified, providers are referred for consultation with a specialist. Examples of concerning treatment may include patients <18 years of age prescribed antipsychotics, prescription of an antipsychotic without diabetic screening, prescription of three or more psychotropics, patients with no documented age-appropriate indication for therapy, or children prescribed a psychotropic not FDA-indicated for children.

9. Process that “identifies potential fraud or abuse of controlled substances” by Medicaid clients, enrolled prescribers, and enrolled dispensing pharmacies

Periodic claims review to look for potential fraud or abuse of controlled substances by clients, prescribers and pharmacies (could include clients filling prescriptions at multiple pharmacies, prescribers or pharmacies filling high volumes of controlled substances, or other indicators) and interventions *as deemed appropriate* (lock-in, PDMP assessment, peer-to-peer consultation, etc.)