



KERN HEALTH SYSTEMS POLICY AND PROCEDURES			
Policy Title	Pharmaceutical Patient Safety Issues	Policy #	13.24-P
Policy Owner	Pharmacy	Original Effective Date	04/18/2024
Revision Effective Date	04/18/2024	Approval Date	04/18/2024
Line of Business	<input checked="" type="checkbox"/> Medi-Cal <input type="checkbox"/> Medicare		

I. PURPOSE

Kern Health Systems (KHS) will monitor the appropriate use of pharmaceuticals of its members in terms of safety standards. Best practice standards not only involve the right medication is provided for the appropriate condition, but other quality and safety standards are applied as well.

II. POLICY

These procedures will include Drug Utilization Review (DUR) activities such as identifying cases of potential inappropriate concurrent use of opioids, antipsychotics, mood stabilizers, benzodiazepines, and other centrally acting agents as outlined by H.R. 6, The SUPPORT Act.¹

The monitoring will also encompass some medications that are considered to be avoided or used with caution in the elderly, as identified the American Geriatrics Society (AGS) Beers Criteria (AGS Beers Criteria®).²

KHS will also ensure quality health practices with pharmaceuticals by notifying Members and Providers of recalled medications.³

These monitoring processes will conform to the requirements outlined in the following statutory, regulatory, and contractual sources:

- A. DHCS Contract
- B. APL 22-012, Appendix A
- C. NCQA HP Accreditation UM Standards

III. DEFINITIONS

TERMS	DEFINITIONS
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AGS Beers Criteria® ⁴	A list published by Dr. Mark Beers and colleagues in 1991 describing a consensus of medications considered to be inappropriate for long-term care facility residents. The "Beers list" is intended for use by clinicians in outpatient as well as inpatient settings (but not hospice or palliative care) to improve the care of patients 65 years of age and older. The list includes medications that should generally be avoided in all elderly, used with caution, or avoided in certain elderly. There is also a list of potentially harmful drug-drug interactions in seniors as well as a list of medications that may need to be avoided or have their dosage reduced based on renal function.
Class II recall ⁵	Removal of a distributed product where the use of or exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious, adverse health consequences is remote.
Class I recall ⁶	Removal of a distributed product due to reasonable probability that use of or exposure to the product will cause serious, adverse health consequences, or death.
Market withdrawal ⁷	Removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA.

IV. PROCEDURES

A. Monitoring of Potential Inappropriate Controlled Substances as Defined by the SUPPORT Act

KHS will monitor potentially inappropriate use of controlled substances as outlined in H.R.6, commonly referred to as the SUPPORT Act. Instances of inappropriate concurrent use of opioids and antipsychotics, mood stabilizers, benzodiazepines, and other centrally acting agents will be reviewed monthly. Antipsychotics provided to members under the age of 18 years will also be part of the retrospective review. Additionally, inappropriate concurrent use of opioids and Medication-assisted treatment (MAT) drugs in the course to treat opioid use disorder (OUD) will be monitored. Instances of high dose of opioids, or potentially dangerous combination of opioids and the aforementioned drug classes without a corresponding prescription for some opioid reversal agent such as naloxone will also be tracked.

Providers of members identified in these reviews will be notified of the potential inappropriate therapies. The providers can then review and determine the appropriate next steps in therapy.

B. Identifying Members Receiving Medications Flagged by the AGS Beers Criteria

KHS through monthly DUR retrospective review will identify members receiving drugs that should generally be avoided due to AGS Beers Criteria®. According to the National Center for Health Statistics, United States (NCHSUS), more than 88% of older people use at least one prescription and more than 66% use three or more in any given month. The AGS Beers Criteria®⁸ are an important clinical, educational, and quality assurance tool for clinicians across disciplines and healthcare system as a whole. Though not exhaustive, five lists include:

1. Avoided by most older adults (outside hospice and palliative care)
2. Avoided by older adults with specific health conditions.
3. Used with caution because of harmful side effects; or
4. Avoided in combination with other treatments because of the risk for harmful “drug-drug” interactions; or
5. Dosed differently or avoided among older adults with reduced kidney function, which impacts how the body processes medicine.

Providers will be notified of members who are receiving medications that follow under one of these categories for the opportunity to eliminate, optimize, or alter the member’s therapy to improve their safety and quality outcome.

C. Pharmaceutical Recall Procedures

1. Drugs are recalled and withdrawn from the market by the Food and Drug Administration (FDA). A drug recall is the most effective way to protect the public from a defective or potentially harmful product. A recall is a voluntary action taken by a company at any time to remove a defective drug product from the market⁹

KHS will identify and notify members and prescribers affected by a Class II recall or voluntary drug withdrawals from the market for safety reasons within 30 calendar days of the FDA notification.

KHS will have an expedited process for prompt identification and notification of members and prescribing practitioners affected by a Class I recall.

KHS will also post a link to the FDA website’s recall page so members, their caregivers, and providers may reference the full FDA recall notice in detail.

2. After January 1, 2022, the outpatient drug benefit is no longer managed by the health plan. Medi-Cal Rx (MCRx) began operating and managing the benefit. At that time only those drugs known as Physician Administered Drugs (PADs) are managed and the responsibility of KHS. APL 22-012, Appendix provides guidance on this separation of managing the pharmaceutical benefit. In the Appendix concerning recalls the directive from the Department of Health Care Services (DHCS) states:

“NCQA recognizes that these drugs are often dispensed through clinics, practitioner offices, hospitals and other facilities, and that plans may have no ability to identify individual batch or lot recalls for drugs covered under the medical benefit unless the drug was removed from the market in its entirety. NCQA reviews procedures for notification when a PAD is completely removed from the market.

NCQA reviews communication to members and prescribing practitioners for PAD that were completely removed from the market, if applicable.”¹⁰

V. ATTACHMENTS

Attachment A: SUPPORT Act Letter MAT
Attachment B: SUPPORT Act Letter Naloxone
Attachment C: SUPPORT Act Letter Opioid Combination
Attachment D: Act Letter Under 18
Attachment E: Recall Letter Member
Attachment F: Recall Letter Provider
Attachment G: Recall Log

VI. REFERENCES

Reference Type	Specific Reference
DHCS Contract (Specify Section)	1. H.R. 6 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act. Compliance with this act is required by DHCS contract.
Other	The American Geriatric Society Beers Criteria®
Regulatory	Required by NCQA, UM 11C.
Other	Pharmacist Letter
Regulatory	NCQA UM 11C
Regulatory	6. NCQA UM 11C
Regulatory	7. NCQA UM 11C
Other	8. The American Geriatric Society Beers Criteria®
Regulatory	9. FDA Recall website page
All Plan Letter(s) (APL)	10. APL 22-012, Appendix

VII. REVISION HISTORY

Action	Date	Brief Description of Updates	Author
Revised	1/25/2024	Compliance updated signatories per Chief Medical Officer request.	Compliance
Created	1/2024	Pharmaceutical Patient Safety Issues. New policy developed by Director of Pharmacy.	B.W. Pharmacy

VIII. APPROVALS

Committees Board (if applicable)	Date Reviewed	Date Approved
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Choose an item.		
Choose an item.		

Regulatory Agencies (if applicable)	Date Reviewed	Date Approved
Department of Health Care Services (DHCS)	11/8/2023, P&P	1/18/2024
Department of Health Care Services (DHCS)	12/1/2023, Attach. E	12/28/2023
Choose an item.		



DATE: January 25, 2024

«DHCS_FILE_PRESCRIBER_NAME» «DHCS_FILE_PRESCRIBER_NAME»
«DHCS_FILE_PRESCRIBER_ADDRESS»
«DHCS_FILE_PRESCRIBER_CITY» «DHCS_FILE_PRESCRIBER_ZIP»

Re: «RX_MEMEBR_NAME»
ID: «DHCS_FILE_PRESCRIBER_NAME»
CIN#: «DHCS_FILE_CIN»
DOB: «DOB»

Dear «DHCS_FILE_PRESCRIBER_NAME» «DHCS_FILE_PRESCRIBER_NAME»:

Kern Family Health Care performs Drug Utilization Review (DUR) as set out in our contract with Medi-Cal for one or more of your patients. Per 42 CFR 438.3(s), Section 1927(g) of the Social Security Act, and 42 CFR 456, Subpart K, and Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act, claims of opioids concurrently prescribed with drugs used with Medication Alternative Therapy (MAT) is discouraged. We are committed to keeping health care clinically safe for our members, and upon a Retrospective Drug Utilization review our records of paid claims show there is evidence of opioids and MAT drugs being used concurrently.

<u>Date</u>	<u>Medication</u>	<u>Prescriber</u>
«CARVEOUT_DOS»	«NDC_DESCRIPTION»	«DHCS_FILE_PRESCRIBER_NAME»
«DHCS_FILE_PRESCRIBER_NAME»		
«RX_DOS»	«RX_CLAIM_NDC_DESC»	«RX_CLAIM_PRESCRIBER_NAME»
«DHCS_FILE_PRESCRIBER_NAME»		
«DHCS_FILE_PRESCRIBER_NAME»	«DHCS_FILE_PRESCRIBER_NAME»	«DHCS_FILE_PRESCRIBER_NAME»
«DHCS_FILE_PRESCRIBER_NAME»	«DHCS_FILE_PRESCRIBER_NAME»	«DHCS_FILE_PRESCRIBER_NAME»
«DHCS_FILE_PRESCRIBER_NAME»	«DHCS_FILE_PRESCRIBER_NAME»	«DHCS_FILE_PRESCRIBER_NAME»
«DHCS_FILE_PRESCRIBER_NAME»	«DHCS_FILE_PRESCRIBER_NAME»	«DHCS_FILE_PRESCRIBER_NAME»

We are providing this information to support the quality of care you provide. Please review these medications to see if a modification is warranted, and to take appropriate action to optimize the drug regimen based on your professional judgment.

If you have any questions concerning this request, please contact the Pharmacy Department at 1-661-664-5101.

Sincerely,

Pharmacy Department

661-664-5000
661-664-5151

kernfamilyhealthcare.com
2900 Buck Owens Boulevard, Bakersfield, CA 93308-6316



DATE: January 25, 2024

«RX_CLAIM_PRESCRIBER_NAME» «RX_CLAIM_PRESCRIBER_TITLE»
«RX_CLAIM_PRESCRIBER_ADDRESS»
«RX_CLAIM_PRESCRIBER_CITY» «RX_CLAIM_PRESCRIBER_ZIP»

Re: «RX_MEMEBR_NAME»
ID: «RX_CLAIM_MEMBER_ID_»
CIN#: «DHCS_FILE_CIN»
DOB: «DOB»

Dear «RX_CLAIM_PRESCRIBER_NAME» «RX_CLAIM_PRESCRIBER_TITLE»:

Kern Family Health Care performs Drug Utilization Review (DUR) as set out in our contract with Medi-Cal for one or more of your patients. Per 42 CFR 438.3(s), Section 1927(g) of the Social Security Act, and 42 CFR 456, Subpart K, and Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act, claims of opioids concurrently prescribed with other centrally acting medications which can intensify side effects. Benzodiazepines and antipsychotics are specifically identified. Stimulants and muscle relaxants are other potential therapeutic combinations of concern. The SUPPORT Act outlines the use of naloxone to mitigate risk in those with high risk factors as mentioned. The Centers for Disease Control and Prevention in their guidelines recommend naloxone to be incorporated into the managing these therapies. We are committed to keeping health care clinically safe for our members, and upon a Retrospective Drug Utilization review our records of paid claims show there is a potential case of a high-risk regimen involving use of an opioid without an adjunct naloxone prescription.

Medications of concern are:

<u>Date</u>	<u>Medication</u>	<u>Prescriber</u>
«CARVEOUT_DOS»	«NDC_DESCRIPTION»	«DHCS_FILE_PRESCRIBER_NAME»
		«DHCS_FILE_PRESCRIBER_TITLE»
«RX_DOS»	«RX_CLAIM_NDC_DESC»	«RX_CLAIM_PRESCRIBER_NAME»
		«RX_CLAIM_PRESCRIBER_TITLE»
«Third_Date»	«Third_Drug»	«Third_Doctor» «Third_Title»
«Fourth_Date»	«Fourth_Drug»	«Fourth_Doctor» «Fourth_Title»
«Fifth_Date»	«Fifth_Drug_»	«Fifth_Doctor» «Fifth_Title»

We are providing this information to support the quality of care you provide. Please review these medications to see if a modification is warranted, and take appropriate action, such as prescribing naloxone, to optimize the drug regimen based on your professional judgment.

If you have any questions concerning this request, please contact the Pharmacy Department at 1-661-664-5101.

Sincerely,

Pharmacy Department

661-664-5000
661-664-5151

kernfamilyhealthcare.com
2900 Buck Owens Boulevard, Bakersfield, CA 93308-6316



DATE: January 25, 2024

«DHCS_FILE_PRESCRIBER_NAME» «DHCS_FILE_PRESCRIBER_NAME» Re: «RX_MEMEBR_NAME»
«DHCS_FILE_PRESCRIBER_ADDRESS» ID: «DHCS_FILE_PRESCRIBER_NAME»
«DHCS_FILE_PRESCRIBER_CITY» «DHCS_FILE_PRESCRIBER_ZIP» CIN#: «DHCS_FILE_CIN»
DOB: «DOB»

Dear «DHCS_FILE_PRESCRIBER_NAME» «DHCS_FILE_PRESCRIBER_NAME»:

Kern Family Health Care performs Drug Utilization Review (DUR) as set out in our contract with Medi-Cal for one or more of your patients. Per 42 CFR 438.3(s), Section 1927(g) of the Social Security Act, and 42 CFR 456, Subpart K, and Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act, claims of opioids concurrently prescribed with other centrally acting medications which can intensify side effects. Benzodiazepines and antipsychotics are specifically identified. Stimulants and muscle relaxants are other potential therapeutic combinations of concern. We are committed to keeping health care clinically safe for our members, and upon a Retrospective Drug Utilization review our records of paid claims show there is a potential case of excessive and perhaps unnecessary or duplicative prescriptions that in addition to adding to this member's pill burden, may contribute to the inability to adhere to the prescribed drug regimen. Sharing of treatment plan is paramount. Consolidation of the plans from the specialists should be undertaken.

Research has shown that as the number of medications used by the patient increases, the potential for adverse drug events increases. Medications of concern are:

Table with 3 columns: Date, Medication, Prescriber. Contains multiple rows of placeholder text for medication records.

We are providing this information to support the quality of care you provide. Please review these medications to see if a modification is warranted, and to take appropriate action to optimize the drug regimen based on your professional judgment.

If you have any questions concerning this request, please contact the Pharmacy Department at 1-661-664-5101.

Sincerely,

Pharmacy Department

661-664-5000
661-664-5151

kernfamilyhealthcare.com
2900 Buck Owens Boulevard, Bakersfield, CA 93308-6316



DATE: January 25, 2024

«Provider_Name» «DHCS_FILE_PRESCRIBER_TITLE»
«Provider_Address»
«Provider_City» «Provider_zip»

Re: «Member_Name»
ID: «Member_Id»
CIN: «Member_CIN»
DOB: «Memeber_DOB»

Dear «Provider_Name» «DHCS_FILE_PRESCRIBER_TITLE»:

Kern Family Health Care performs Drug Utilization Review (DUR) as set out in our contract with Medi-Cal for one or more of your patients. Per 42 CFR 438.3(s), Section 1927(g) of the Social Security Act, and 42 CFR 456, Subpart K, and Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act, claims of antipsychotics prescribed to members under 18 years are specifically identified. The Department of Health Care Services (DHCS) is also concerned about mood stabilizers and antidepressants used in members under the age of 18. We are committed to keep health care clinically safe for our members, and upon a Retrospective Drug Utilization review our records of paid claims show there is a potential case of excessive and perhaps unnecessary or duplicative prescriptions that in addition to adding to this member's pill burden, may contribute to the inability to adhere to the prescribed drug regimen. Sharing of treatment plan is paramount. Consolidation of the treatment plans from the specialists should be undertaken.

Research has shown that as the number of medications used by the patient increases, the potential for adverse drug events increases. Medications of concern are:

Date Filled

Medication

«DOS»	«NDC_Code_Description»
«Second_DOS»	«Second_Drug_name»
«Third_DOS»	«Third_Drug_Name»
«Fourth_DOS»	«Fourth_Drug_Name»
«Fifth_DOS»	«Fifth_Drug_Name»
«Sixth_DOS»	«Sixth_Drug_Name»
«Seventh_DOS»	«Seventh_Drug_Name»

We are providing this information to support the quality of care you provide. Please review these medications to see if a modification is warranted, and to take appropriate action to optimize the drug regimen based on your professional judgment.

If you have any questions concerning this request, please contact the Pharmacy Department at 1-661-664-5101.

Sincerely,

Pharmacy Department

 661-664-5000
 661-664-5151

kernfamilyhealthcare.com 
2900 Buck Owens Boulevard, Bakersfield, CA 93308-6316 



January 25, 2024

<Member Name>
<Mailing Address>

Subject: Notice of Drug Recall <Enter drug name>

Dear <Member Name>:

On <Date>, <Enter Pharmaceutical company name> has recalled <Enter Name of drug and Lot numbers>

Our records show that you have filled this drug within the last <Enter number of days, i.e., 120 days>. Please call your doctor's office immediately.

If you are not sure if your drug is part of this drug recall, you can call your pharmacy, <Enter member's pharmacy name> at <Enter pharmacy phone number> where you filled your prescription.


If you no longer take the drug listed above, please ignore this letter.

Sincerely,

Bruce Wearda, RPh
Director of Pharmacy
661-664-5000 (TTY 711)
Monday - Friday, 8 am – 5pm

Checked on: 12/01/2023, 5:04 pm

To create health literate documents aim for [Grade 6 or lower](#)

Flesch-Kincaid Grade: 5.60 

Flesch Reading Ease Score: 77.50 (Fairly Easy - Grade 6)



January 25, 2024

{Dr. Samantha Baker MD -sample}
{1002 John Way -sample}
{Los Angeles, CA 93215 -sample}

Subject: Notice of Drug Recall – Ondansetron{sample}

Dear Dr. Baker:

On 8/9/2023, the U.S. Food and Drug Administration (FDA) announced that Long Manufacturers has recalled all lots of {Ondansetron NDC # 23546-45-7891.} This recall affects all lot numbers of the following products:

Product Description	NDC

A complete copy of the FDA Med Watch may be viewed at <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>

Members identified as having a potential affected recall have been notified to call you and the dispensing pharmacy for further action.

Sincerely,

Martha Tasinga, M.D., MPH, MBA
Chief Medical Officer

Date Issued	Drug	Product Description	Reason	Company	NDC	Lot	Batch	Exp	Report Run	Member Notice sent	Provider Notice sent	Website updated	Type	Mbr Identified	Mbr impacted	DHCS Appendix	
	type name and hyperlink to FDA site																
ex. 3/31/2023	Camber	atovaquone oral susp	potential bacillus contamination	Camber Pharmaceuticals Inc	31722-0629-21	E220182		12/2023	4/15/2023	4/16/2023	4/17/2023	4/17/2023		1	Y	501	Y