KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES			
Policy Title	Drug Recalls and Drug Shortages	**Policy #**	13.27-P
Policy Owner	Pharmacy	**Original Effective Date**	01/01/2026
Revision Effective Date		**Approval Date**	1/6/2026
Line of Business	☐ Medi-Cal ☒ Medicare ☐ Corporate		

I. PURPOSE

To provide oversight of Kern Health Systems' (KHS) Pharmacy Benefits Manager (PBM) to ensure removal of drug products that are in violation of laws administered by the Food and Drug Administration (FDA) and to ensure access to critically needed therapies during times of drug shortages.

II. POLICY

KHS will track and monitor all FDA Drug Recall and Shortage notifications with their PBM. KHS, along with its PBM, will also ensure access to critically needed therapies during times of drug shortages.

III. DEFINITIONS

TERMS	DEFINITIONS
BIA	Beneficiary Impact Analysis
Class I recall	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.
Class II recall	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.
CMS	Centers for Medicare and Medicaid Services
Drug Shortage	Those drug products that have been identified on the FDA Drug Shortage

	Webpage: http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm.
D-SNP/SNP	Dual Special Needs Plan or Special Needs Plan. Medicare Advantage coordinated care plans that serve the special needs of certain groups of individuals including institutionalized individuals (as defined by CMS), those entitled to Medical Assistance under a State Plan under Title XIX and individuals with severe or disabling chronic conditions, as defined by CMS.
FDA	Food and Drug Administration
HPMS	Health Plan Management System
Market Withdrawal	Removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration (FDA).
MPDBM	Medicare Prescription Drug Benefit Manual
NCPDP	National Council for Prescription Drug Programs
NDC	National Drug Code
PBM	Pharmacy Benefit Manager

IV. PROCEDURES

A. 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 Drugs are recalled and withdrawn from the market by the Food and Drug Administration (FDA).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 market.
2. Of note, drug recalls are not generally classified as Class I/II by the FDA until well after the initial recall notification, so the classification of the recall is not utilized to determine the actions to be taken.
3. On a weekly basis, the FDA publishes and posts the FDA Enforcement Report on the FDA Website: www.fda.gov
4. The FDA Enforcement Report will be monitored and claims data reviewed to identify Members and prescribers potentially affected by an FDA medication recall or a Market

Withdrawal.

5. In the event the FDA issues a Medication Recall, or a manufacturer withdraws a medication from the market,
    a. Potentially affected Members and prescribers will be identified through pharmacy utilization reports.
    b. KHS will use an expedited process for all notifications.
    c. Affected Members will be notified in writing as soon as they are identified of the FDA medication recall announcement or Market Withdrawal.
    d. Providers will be notified as soon as they are identified of the FDA announcement or Market Withdrawal.
    e. In instances where the recalled medication may cause serious adverse health consequences or death to Members, KHS or its PBM will block claims processing (e.g. for all lot recalls) for the affected drug as quickly as possible.
    f. Other actions that may be considered, especially for partial lot recalls, include a soft Point of Services (POS) message describing the situation, age edits or other edits, Prior Authorizations (PAs), etc. when it is appropriate to do so.
    g. KHS will work with its PBM to make determinations regarding drug substitutions, PAs, or benefit changes as appropriate.

B. Drug Shortage Procedures

1. Drug Shortages can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. Manufacturers provide the FDA most drug shortage information, and the agency works closely with them to prevent or reduce the impact of shortages.
2. In the event of a drug shortage, KHS and its PBM will work with its Members and providers to find appropriate therapeutic alternatives.
    a. The availability, or unavailability, of therapeutically equivalent drug products will be evaluated. Different scenarios to be addressed include:
        i. A single-source Formulary brand drug product is temporarily unavailable and no therapeutically equivalent products are available.
        ii. A multiple-source Formulary brand drug product is temporarily unavailable and only therapeutically equivalent generic products are available.
        iii. A multiple-source Formulary generic drug product is temporarily unavailable (all makers) and only therapeutically equivalent brand product is available.
        iv. A multiple-source Formulary drug product is temporarily unavailable, and no brand or generic therapeutically equivalent product is available.

b. In order to minimize unnecessary changes in therapy resulting from temporary shortages of multiple-source Formulary drug products, CMS expects access to therapeutically equivalent non-Formulary drug products, or therapeutically equivalent Formulary drug products that otherwise require prior authorization or step therapy, for those Members currently taking the drug product subject to a shortage be provided.

c. Under these circumstances, CMS does not consider access to therapeutically equivalent non-Formulary drug products, or therapeutically equivalent Formulary drug products that otherwise require prior authorization or step therapy, to be Formulary exceptions and, therefore, access to such drug products may be limited to the duration of the shortage.

C. Delegated Oversight

1. KHS is responsible for ensuring that their delegates comply with all applicable state and federal laws and regulations, contract requirements, and other CMS guidelines and regulations. These requirements must be communicated by KHS to all delegated entities and subcontractors.

V. ATTACHMENTS

Attachment A:	Recall Member Letter English Standard
Attachment B:	Recall Member Letter English Large Font
Attachment C:	Recall Member Letter Spanish Standard
Attachment D:	Recall Member Letter Spanish Large Font
Attachment E:	Recall Provider Letter Standard
Attachment F:	Recall Log

VI. REFERENCES

Reference Type:	Specific Reference:
Regulatory	Medicare Prescription Drug Benefit Manual Chapter 5: Benefits and Beneficiary Protections Section 50.13
Regulatory	Medicare Prescription Drug Benefit Manual, Chapter 6: Part D Drugs and Formulary Requirements, Section 10.7
Regulatory	HPMS Memo Shortages of Formulary Drug Products During a Plan Year, July 21, 2009
Regulatory	21 CFR § 7.40-59
Regulatory	FDA, Product Recalls, Including Removals and Corrections Guidance for Industry, March 2020

Regulatory	FDA Website: www.fda.gov.

VII. REVISION HISTORY

Action	Date	Brief Description of Updates	Author
Effective	01/01/2026	New Policy created to comply with D-SNP	Pharmacy B.W.

VIII. APPROVALS

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

Regulatory Agencies (if applicable)	**Date Reviewed**	**Date Approved**
Choose an item.		

Kern Family Health Care
Medicare (D-SNP)

January 7, 2026

«Member_First_Name» «Member_Last_Name»
«Member_Address»
«Member_City» «Member_State» «Member_Zip_Code»

Cin#:
MEM#:
MBI#:

Subject: Notice of Drug Recall - «Drug_Name»

Dear «Member_First_Name» «Member_Last_Name»:

On «Date_of_Recall», «Drug_Company» has recalled the following lot(s) of «Drug_Name». The reason for the recall is due to «Reason_for_Recall».

Product	NDC*	Lot Number/Batch	Exp. Date
«Drug_Name»	«NDC»	«Lot_Batch»	«Exp_Date»
«Drug_Name»	«NDC»	«Lot_Batch»	«Exp_Date»

Our records show that you have filled this drug within the last 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, «Pharmacy_Name» at «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
1-866-661-3767

**National Drug Code*

Kern Family Health Care
Medicare (D-SNP)

January 7, 2026

«Member_First_Name» «Member_Last_Name»
«Member_Address»
«Member_City» «Member_State» «Member_Zip_Code»

Cin#:
MEM#:
MBI#:

Subject: Notice of Drug Recall - «Drug_Name»

Dear «Member_First_Name» «Member_Last_Name»:

On «Date_of_Recall», «Drug_Company» has recalled the following lot(s) of «Drug_Name». The reason for the recall is due to «Reason_for_Recall».

Product «Drug_Name»

NDC* «NDC»

Lot Number/Batch «Lot_Batch»

Exp. Date «Drug_Exp_Date»

Kern Family Health Care
Medicare (D-SNP)

Our records show that you have filled this drug within the last 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, «Pharmacy_Name» at «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
1-866-661-3767

**National Drug Code*

Kern Family Health Care
Medicare (D-SNP)

7 de January de 2026

«Member_First_Name» «Member_Last_Name»
«Member_Address»
«Member_City» «Member_State» «Member_Zip_Code»

Cin#:
MEM#:
MBI#:

Asunto: Aviso de Retirada de Medicamentos- «Drug_Name»

Estimado/a «Member_First_Name» «Member_Last_Name»:

En «Date_of_Recall», «Drug_Company» ha retirado el(los) siguiente(s) lote(s) de «Drug_Name». El motivo de la retirada es debido a «Reason_for_Recall».

Producto	NDC*	Número de lote	Fecha de Venc.
«Drug_Name»	«NDC»	«Recall_Information»	«Drug_Exp_Date»
«Drug_Name»	«NDC»	«Recall_Information»	«Drug_Exp_Date»

Nuestros expedientes indican que usted ha surtido este medicamento dentro de los últimos 120 días. Por favor, llame de inmediato al consultorio de su doctor. **Si no está seguro/a de si su medicamento forma parte de esta retirada de medicamentos, puede llamar a la farmacia, «Pharmacy_Name» al «Pharmacy_Phone_number», donde surtió su receta médica.**

Si ya no toma el medicamento mencionado, ignore esta carta.

Atentamente,

Bruce Wearda, RPh
Director del Departamento de Farmacia
1-866-661-3767

**Número de Código nacional de medicamentos*

Kern Family Health Care
Medicare (D-SNP)

7 de January de 2026

«Member_First_Name» «Member_Last_Name»
«Member_Address»
«Member_City» «Member_State» «Member_Zip_Code»

Cin#:
MEM#:
MBI#:

Asunto: Aviso de Retirada de Medicamentos- «Drug_Name»

Estimado/a «Member_First_Name» «Member_Last_Name»:

En «Date_of_Recall», «Drug_Company» ha retirado el(los) siguiente(s) lote(s) de «Drug_Name». El motivo de la retirada es debido a «Reason_for_Recall».

Producto	NDC*	Número de lote	Fecha de Venc.
«Drug_Name»	«NDC»	«Recall_Information»	«Drug_Exp_Date»
«Drug_Name»	«NDC»	«Recall_Information»	«Drug_Exp_Date»

1-866-661-3767 / 661-716-5342
661-605-0160
kernfamilyhealthcare.com
2900 Buck Owens Boulevard, Bakersfield, CA 93308-6316

Kern Family Health Care
Medicare (D-SNP)

Nuestros expedientes indican que usted ha surtido este

medicamento dentro de los últimos 120 días. Por favor, llame de inmediato al consultorio de su doctor.

Si no está seguro/a de si su medicamento forma parte de esta retirada de medicamentos, puede llamar a la farmacia, «Pharmacy_Name» al «Pharmacy_Phone_number», donde surtió su receta médica.

Si ya no toma el medicamento mencionado, ignore esta carta.

Atentamente,

Bruce Wearda, RPh
Director del Departamento de Farmacia
1-866-661-3767

**Número de Código nacional de medicamentos*

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Medicare (D-SNP)

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

Kern Family Health Care
Medicare (D-SNP)

January 7, 2026

«Prescriber_First_Name» «Prescriber_Last_Name» «Title»
«Prescriber_Address»
«Prescriber_City», «Prescriber_State» «Prescriber_Zip_Code»

NPI#:

Subject: Notice of Drug Recall – «Drug_Name»

Dear Dr. «Prescriber_Last_Name»:

On «Date_of_Recall», the U.S. Food and Drug Administration (FDA) announced that «Drug_Company» has recalled the following lot(s) of «Drug_Name». The reason for the recall is due to <Reason for Recall>. This recall affects the following products:

Product	NDC	Lot Number/Batch	Exp. Date
«Drug_Name»	«NDC»	«Lot_Batch»	«Exp_Date»
«Drug_Name»	«NDC»	«Lot_Batch»	«Exp_Date»

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

1-866-661-3767 / 661-716-5342
661-605-0160
kernfamilyhealthcare.com
2900 Buck Owens Boulevard, Bakersfield, CA 93308-6316

Date Issued	Drug	Product Description	Reason	Company	NDC
5/21/2024	Buprenorphine Hydrochloride I	Buprenorphine Hydroc	Device & Drug Safety – Potential P	Hospira Inc.	00409-2012-32
5/21/2024	Buprenorphine Hydrochloride I	Buprenorphine Hydroc	Device & Drug Safety – Potential P	Hospira Inc.	00409-2012-03
5/21/2024	Labetalol Hydrochloride Injecti	Labetalol Hydrochlorid	Device & Drug Safety – Potential P	Hospira Inc.	00409-2339-34
5/21/2024	Labetalol Hydrochloride Injecti	Labetalol Hydrochlorid	Device & Drug Safety – Potential P	Hospira Inc.	00409-2339-24

Lot	Batch	Exp	Report Run	Date Mbr notice sent	Date Provider Notice sent	Recall Type	Mbr Identified	Mbr impacted	DHCS Exempt
HJ3965		9/2024	5/22/2024	N/A	N/A	Not indicated	0	0	Yes
HJ8546		10/2024	5/22/2024	N/A	N/A	Not indicated	0	0	Yes
HJ7566		5/2025	5/22/2024	N/A	N/A	Not indicated	0	0	Yes
HN8747		9/2025	5/22/2024	N/A	N/A	Not indicated	0	0	Yes
HN8749		9/2025	5/22/2024						