KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES					
SUBJECT: Drug Utilization and Non-Formulary Treatment Request				POLICY #: 13.01-P	
DEPARTMENT: Pharmacy					
Effective Date: 08/1997	Review/Revised Date: 05/20/2020	DMHC		PAC	
		DHCS		QI/UM COMMITTEE	
		BOD		FINANCE COMMITTEE	

_____ Date _____
Douglas A. Hayward
Chief Executive Officer

_____ Date _____
Chief Medical Officer

_____ Date _____
Director of Pharmacy

POLICY:
All non-formulary medications or formulas require prior authorization. All medically necessary outpatient prescription drugs, except for those specifically excluded from the Medi-Cal contract, shall be available to KHS Medi-Cal members.[1] This determination will be made through the non-formulary treatment request process as outlined in this policy and procedure.

The non-formulary treatment request process will conform to the requirements outlined in the following statutory, regulatory, and contractual sources:

- Code of Federal Regulations Title 42 §§431.211; 431.213; and 431.214
- California Health and Safety Code §§ 1367.01[2]; 1367.21; 1367.22; 1367.24
- California Welfare and Institutions Code §14185
- CCR Title 28 §1300.67.24
- CCR Title 22 §§ 51003; 51014.1; 51014.2; 53854; 53894
- DHS Contract Exhibit A - Attachment 5 (3)(F); Exhibit A –Attachment 10 (7)(F)
- DHS MMCD Letters 04006 (November 1, 2004) and 05005 (April 11, 2005), and 08-013 (December 16, 2008).

This document shall be disclosed to the public upon request.[3]

DEFINITIONS:

Chronic and Seriously Debilitating[4]	Diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.
Life Threatening[5]	Diseases or conditions (1) where the likelihood of death is high unless the course of the disease is interrupted and/or (2) with potentially fatal outcomes where the endpoint of clinical intervention is survival.

PROCEDURES:

1.0 SUBMISSION OF A NON-FORMULARY DRUG REQUEST

Non-Formulary drug requests can be made by KHS providers electronically via the secure KHS portal or on a *61-211 Form* if one does not have access to the KHS Provider Portal. (See Attachment A). Form should be mailed/faxed to the following location:

KHS Pharmacy Department
2900 Buck Owens Boulevard
Bakersfield, CA 93308
661-664-5191

KHS only requests information reasonably necessary to make a decision regarding the request.[6] Documentation must be complete and include:

A. Patient name.
B. CIN number.
C. Diagnosis with brief history.
D. Reason for request/justification including formulary medication failures.
E. Drug name, strength, directions, and National Drug Code.
F. Prescriber's name.

2.0 REVIEW OF TAR

Incoming requests are date and time stamped. TAR review includes the actions outlined in the following table.

Action	Timeline	Comments
Review by Pharmacist or MD		Evaluation for medical necessity denials signed by licensed pharmacist or MD[7]
Decision (approve or deny)	Within 24 hours of receipt[8].	

Medications and supplies are evaluated on the basis of appropriateness, efficacy, safety,

pharmacokinetics and cost effectiveness.

3.0 PRACTITIONER/PROVIDER AND MEMBER NOTIFICATION

Results of the TAR review are communicated by Pharmacy staff to the practitioner/provider and member as outlined in the following table. Notification to providers is provided via portal or facsimile if possible. The notification confirmation is attached to the request. If notice by electronic portal or facsimile is not possible, verbal notice is provided via phone within 24 hours of receipt. In such cases, written notice follows as outlined in the table below.

Result of Review	Practitioner/Provider Notice	Member Notice
Approved	Approved form[9] (within 24 hours of receipt). [10]	
Denied	Denied form (within 24 hours of receipt).[11]	*Notice of Action Documents* (within 2 business days of the decision). [12] Documents include all of the following: ❖ *Notice of Action – Denial* (Attachments B- D) *Your Rights Under Medi-Cal Managed Care* & *Form to File a State Hearing*. Medi-Cal members only.

Notice of Action letters together with the indicated enclosures contain all of the required elements for both provider and member notice of delay, denial, or modification including the following[13]:

A. The action taken.
B. A clear and concise explanation of the reason for the decision (including clinical reasons for decisions regarding medical necessity).
C. A description of the criteria/guidelines used.
D. A citation of the specific regulations or plan authorization procedures supporting the action[14].
E. Information on how to file a grievance with KHS including the Plan's name address and phone number.
F. Information regarding a Medi-Cal member's right to a State Fair Hearing including:
    1. The method by which a hearing may be obtained.
    2. That the member may either be self- represented or represented by an authorized third party such as legal counsel, relative, friend, or any other person.
    3. The time limit for requesting a fair hearing.
    4. The toll free number for obtaining information on legal service organizations for representation.
G. Nondiscrimination Notice.
H. Language Assistance Taglines.

I. Information regarding the member's right to an Independent Medical Review with DMHC.
J. DMHC required language regarding grievances[15].
K. Name and telephone number of the pharmacy department.

4.0 DOCUMENTATION

Letters regarding authorization requests, including those sent by KHS to both members and providers, are retained as outlined in *KHS Policy and Procedure #10.51 – Records Retention.*[16]

5.0 ALLOWED SUPPLIES OF MEDICATION

Members may receive up to a 30 day supply of medication. Women may receive up to 365 day supply of hormonal contraceptives.

5.1 Emergency Supplies[17]

During weekends, holidays and non-business hours a pharmacy may choose to dispense enough medication (72 hours supply maximum) as an emergency supply to the member until the next working day, at the dispensing pharmacist's discretion according to pharmacy policy and procedures as defined by Title 22 section 51056[18]. If the medication is not on the Plan Formulary, a request must be submitted for payment processing stating the emergency and relevant clinical information about the member's condition and why they were considered immediately necessary and medication dispensed. A mere statement that an emergency existed is not sufficient. It must be comprehensive enough to support a finding that an emergency existed.[19] TAR approval is not needed for reimbursement before dispensing of 72 hour emergency supply of non-formulary drugs.

6.0 CONTINUITY OF CARE[20]

Medi-Cal members are allowed continued coverage of a non-formulary single source drug which is part of a prescribed therapy previously approved for coverage by the plan for a medical condition of the member and the provider continues to prescribe the drug for the medical condition provided that drug is appropriately prescribed and is considered safe and effective for treating the member's medical condition. Nothing in this section shall preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate[21z] If previously approved by plan immediately prior to the date of enrollment, coverage may be continued until the prescribed therapy is no longer prescribed by a contracting practitioner[22]. Approval is contingent upon documentation that the patient had authorization from the previous plan of the medication at the time of enrollment no more than fifteen (15) days beyond the estimated day supply for the last documented pharmacy fill date.[23]

KHS does not require a new member to repeat step therapy when the member is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. For purposes of this section, "step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

Medi-Cal members are allowed continued coverage of a drug which is removed from the KHS formulary if the drug is part of a prescribed therapy in effect immediately prior to the date of removal until the prescribed therapy is no longer prescribed by a contracting practitioner.

7.0 BRAND NAME MEDICATIONS WHEN EQUIVALENT GENERIC BRAND IS AVAILABLE

If a medication is available or becomes available in an AB rated generic brand, the brand name version will become non-Formulary for KHS.

Unless it is determined to be medically necessary for the patient to continue using the brand name, if a generic brand becomes available during a patient's treatment, the patient will be expected to switch to the generic brand and must fail the generic brand prior to KHS granting authorization for the brand name.

Providers with patients having untoward effects from a generic brand must submit a completed FDA *MedWatch* form to KHS as part of the request for authorization to allow a brand name version instead of a generic brand. (See Attachment F).

Biosimilars and drugs considered as Follow Ons will be treated in the same fashion as if they were a traditional generic of the innovator drug. Per FDA rules, they are not automatically substitutable, but from clinical perspectives they are viewed as a generic version.

8.0 OFF-LABEL USE FOR LIFE THREATENING OR CHRONIC AND SERIOUS CONDITIONS[24]

8.1 Medi-Cal Product

Section does not apply to the Medi-Cal product.[25]

8.2 Peer Reviewed Professional Society Endorsed Supporting Documentation If a physician or other provider wishes to prescribe a non-formulary or restricted FDA approved medication for an off-label use for a life threatening or chronic and debilitating condition, he/she may submit a referral or TAR to the Plan for the same. In the referral, the provider must demonstrate the medication is recognized for the treatment of that condition in one of the following sources:

A. American Hospital Formulary Service's Drug Information.

B. One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:
   (1) The Elsevier Gold Standard's Clinical Pharmacology.
   (2) The National Comprehensive Cancer Network Drug and Biologics Compendium.
   (3) The Thomson Micromedex DrugDex.

C. Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

The provider is responsible for submitting the required documentation to KHS[26].

9.0 SAMPLE MEDICATIONS[27]

Providers are discouraged from providing samples; however, if samples are given to the member, the entire course of therapy must be covered by the samples. Medications provided as samples do not establish a continuity precedent or satisfy step therapy criteria and, therefore, do not obligate coverage by KHS. If providing samples, Providers shall follow the outlined steps in *KHS Policy and Procedure #2.24-P Pharmacy Guidelines*.

10.0 TRIAL PERIOD[28]

Barring any medically adverse responses from the member, the trial period of a medication shall be determined per the recommended dosing titration guidelines presented to the FDA.

11.0 MONITORING[29]

The Compliance Department will conduct bi-annual audits to monitor compliance of the contracted emergency departments to provide a sufficient quantity of drugs to Medi-Cal members under emergency circumstances to last until the member can reasonably to be expected to have a prescription filled prior to leaving the emergency department. Issues discovered by this monitoring will be brought to the attention of the contracted emergency department and a Corrective Action Plan (CAP) will be required.

ATTACHMENTS:

- Attachment A - Treatment Authorization Request (TAR) Form (61-211)
- Attachment B - Notice of Action – Denial letter, Deny – Criteria Not Met
- Attachment C - Notice of Action – Denial letter, Deny – Incorrect Form
- Attachment D - Notice of Action – Denial letter, Deny – Member Not Eligible
- Attachment E - Your Rights Under Medi-Cal Managed Care, How to File a State Hearing, Independent Medical Review, Nondiscrimination and Language Assistance Taglines
- Attachment F - MedWatch form

REFERENCE:

[1]**Revision 2020-02: Revision 2017-07:** Policy revised to comply with CMS Final Rule on prior authorization process. Attachments updated. **Revision 2017-03:** Policy reviewed and updated by Director of Pharmacy. New Section 8.2 provides guidelines for prescribing medication for an off-label use for a life threatening or chronic and debilitating condition. **Revision 2014-10:** Formatting changes to policy, no material changes. Notice of Action letters **(**NOAs) revised as a result of the DHCS 2013 Medical Audit ending in 2014- CAF-9. "Your Right's Forms" updated to ensure continued compliance. Translation changes made to comply with MMCD APL 05005. **Revision 2014-04:** Language included in Section 1.0 to add time statement on authorization request. Revised to remove references to Health Families product. **Revision 2013-07:** Reviewed by Director of Pharmacy. Routine revision, updated Section 1.0 regarding submission of treatment authorization request. **Revision 2009-10:** Revision requested by Director of Pharmacy. **Revision 2009-02:** Revised to comply with MMCD Policy Letter 08-013. Notice of Action letters updated with language assistance services notice. **Revision 2007-05:** Revised per DHS/DMHC Medical Audit comment 5/13/2007. **Revision 2007-04** Created Notice of Action Letters for Healthy Families product line per DHS/DMHC Medical Review Audit (YE 10/31/06). **Revision 2005-07:** Reviewed against MMCD Letters 04006 and 05005. New NOAs. **Revision 2005-04:** Continuity of care processes reviewed and revised. Reviewed against DHS Contract 03-76165 (Effective May 1, 2004). **Revision 2004-05:** Revised per DMHC/DHS Medical Audit YE Oct03; finding 1.2. (Addition of member notice of modifications). New single letter for deferral, modification, or denial. **Revision 2002-03**: Revised per DHS comment 01/30/02. **Revision 2002-01:** DHS CAP Verification Visit Report (Med Rev YE 08/00). **Revision 2001-02**: changes made for 2000 Legislation submission – DMHC and DHS/DMHC Medical Review Audit (YE 08/31/00).

[1] HSC 1367.24. CCR Title 22 §53854(d), CCR Title 28 1300.67.24

[2] Applicable to pharmacy per Title 28 §1300.67.24(a)(1)
[3] HSC §1367.01(b)
[4] HSC §1367.21(e)
[5] HSC §1367.21(d)
[6] HSC §1367.01(g)
[7] MMCD Policy Letter 08-013
[8] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to 1 business day. Although action must be taken on pain medications for the terminally ill within 72 hours, the Plan must follow the stricter Federal Medicaid 24 hours standard. HSC Section 1367.215. DHS Contract A-5 3(F). Change to comply with CMS Managed Care final Rule Prior Authorization Process (§438.3(s)(6))
[9] Must include specific service approved (HSC §1367.01(h)(4))
[10] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to 1 business day. Although action must be taken on pain medications for the terminally ill within 72 hours, the Plan must follow the stricter Federal Medicaid 24 hours standard. HSC Section 1367.215. HSC §1367.01(h)(3) requires notice to provider within 24 hours of the decision.
[11] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to 1 business day. Although action must be taken on pain medications for the terminally ill within 72 hours, the Plan must follow the stricter Federal Medicaid 24 hours standard. HSC Section 1367.215. HSC §1367.01(h)(3) requires notice to provider within 24 hours of the decision. Change to comply with CMS Managed Care final Rule Prior Authorization Process (§438.3(s)(6))
[12] HSC §1367.01(h)(3) has the shortest time period for member notice (2 b/days of decision).CCR Title 22 Section 53894(a) and (d)
[13] HSC §1367.01(h)(4) and (5) and 1367.24(b); CCR Title 22 §53894
[14] Required for member notice only. CCR Title 22 §53894(d)(3)
[15] Required for member notice only. HSC §1367.24(b)
[16] DHS Contract 03-76165 Exhibit A – Attachment 5 (2)(G)
[17] CCR Title 22 §53854(2)
[18] Title 22 51056
[19] Title 22 51056
[20] HSC 1367.22
[21] HSC § 1367.22
[22] W&I Code 14185(c)
[23] HSC §1367.22
[24] Health and Safety Code §1367.21
[25]Plan shall reserve the right to modify this.
[26] HSC 1367.21 (b)
[27] Section added upon request of the Director of Pharmacy (3/2/05). Language also included in *Policy 2.24 – Pharmaceutical Guidelines*
[28] Section added upon request of the Director of Pharmacy (3/2/05).
[29] DHS/DMHC Medical Review Audit (YE 10/31/06).

PRESCRIPTION DRUG PRIOR AUTHORIZATION OR STEP THERAPY EXCEPTION REQUEST FORM

Plan/Medical Group Name: _____ **Plan/Medical Group Phone#: (_____)**_____
Plan/Medical Group Fax#: (_____)_____ **Non-Urgent** ☐ **Exigent Circumstances** ☐

Instructions: Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization or step-therapy exception request. **Information contained in this form is Protected Health Information under HIPAA.**

Patient Information

First Name:	Last Name:	MI:	Phone Number:
Address:	City:	State:	Zip Code:

Date of Birth:	☐ Male ☐ Female	Circle unit of measure Height (in/cm): _____Weight (lb/kg):_____	Allergies:

Patient's Authorized Representative (if applicable):	Authorized Representative Phone Number:

Insurance Information

Primary Insurance Name:	Patient ID Number:
Secondary Insurance Name:	Patient ID Number:

Prescriber Information

First Name:	Last Name:	Specialty:

Address:	City:	State:	Zip Code:

Requestor (if different than prescriber):	Office Contact Person:
NPI Number (individual):	Phone Number:
DEA Number (if required):	Fax Number (in HIPAA compliant area):

Email Address:

Medication / Medical and Dispensing Information

Medication Name:

☐ New Therapy ☐ Renewal ☐ Step Therapy Exception Request
If Renewal: Date Therapy Initiated: Duration of Therapy (specific dates):

How did the patient receive the medication?
☐ Paid under Insurance Name:_____ Prior Auth Number (if known):_____
☐ Other (explain):

Dose/Strength:	Frequency:	Length of Therapy/#Refills:	Quantity:

Administration:
☐ Oral/SL ☐ Topical ☐ Injection ☐ IV ☐ Other:

Administration Location:	☐ Patient's Home	☐ Long Term Care
☐ Physician's Office	☐ Home Care Agency	☐ Other (explain):_____
☐ Ambulatory Infusion Center	☐ Outpatient Hospital Care	_____

PRESCRIPTION DRUG PRIOR AUTHORIZATION OR STEP THERAPY EXCEPTION REQUEST FORM

Patient Name:	ID#:

Instructions: Please fill out all applicable sections on both pages completely and legibly. Attach any additional documentation that is important for the review, e.g. chart notes or lab data, to support the prior authorization or step therapy exception request.

1. Has the patient tried any other medications for this condition? ☐ **YES (if yes, complete below)** ☐ **NO**

Medication/Therapy (Specify Drug Name and Dosage)	**Duration of Therapy** (Specify Dates)	**Response/Reason for Failure/Allergy**

2. List Diagnoses:	**ICD-10:**

3. <u>Required clinical information</u> - Please provide all relevant clinical information to support a prior authorization or step therapy exception request review.

Please provide symptoms, lab results with dates and/or justification for initial or ongoing therapy or increased dose and if patient has any contraindications for the health plan/insurer preferred drug. Lab results with dates must be provided if needed to establish diagnosis, or evaluate response. Please provide any additional clinical information or comments pertinent to this request for coverage, including information related to exigent circumstances, or required under state and federal laws.

☐ Attachments

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan, insurer, Medical Group or its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature or Electronic I.D. Verification:_____ **Date**:_____

Confidentiality Notice: The documents accompanying this transmission contain confidential health information that is legally privileged. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or action taken in reliance on the contents of these documents is strictly prohibited. If you have received this information in error, please notify the sender immediately (via return FAX) and arrange for the return or destruction of these documents.

Plan/Insurer Use Only: Date/Time Request Received by Plan/Insurer:_____ Date/Time of Decision_____

Fax Number (_____)_____

☐ Approved ☐ Denied Comments/Information Requested: _____

Kern Family Health Care™

NOTICE OF ACTION
About Your Treatment Request - Deny

Today's date

Member name
Address
City, State, Zip

Treating Provider
Address
City, State, Zip

Identification Number: KHS ID

RE: [Service requested]

[Name of requesting provider] has asked Kern Family Health Care to approve [Service requested].This request is denied. This is because [Insert: 1. A clear and concise explanation of the reasons for the decision; 2. A description of the criteria or guidelines used, including a reference to the specific regulations or plan authorization procedures that support the action; and. 3. The clinical reasons for the decision regarding medical necessity]. Based on documentation provided, criteria was not met

You may ask for free copies of all information used to make this decision. This includes a copy of the actual benefit provision, guideline, protocol, or criteria that we based our decision on. To ask for this, please call Kern Family Health Care at (661) 632-1590 inside Bakersfield, or (800) 391-2000 outside of Bakersfield.

You may appeal this decision. The enclosed "Your Rights" information notice tells you how. It also tells you where you can get free help. This also means free legal help. You are encouraged to send in any information that could help your case. The "Your Rights" notice tells you the cut off dates to ask for an appeal.

The State Medi-Cal Managed Care "Ombudsman Office" can help you with any questions. You may call them at 1-888-452-8609. You may also get help from your doctor, or call us at (661) 632-1590 inside Bakersfield, or (800) 391-2000 outside of Bakersfield.

This notice does not affect any of your other Medi-Cal services.

Medical Directors Name

Enclosed: "Your Rights under Medi-Cal Managed Care"

Kern Family Health Care™

NOTICE OF ACTION
About Your Treatment Request - Deny

Today's date

Member name
Address
City, State, Zip

Treating Provider
Address
City, State, Zip

Identification Number: KHS ID

RE: [Service requested]

[Name of requesting provider] has asked Kern Family Health Care to approve [Service requested].This request is denied. This is because the request was not submitted on the State Mandated 61-211 from.

You may ask for free copies of all information used to make this decision. This includes a copy of the actual benefit provision, guideline, protocol, or criteria that we based our decision on. To ask for this, please call Kern Family Health Care at (661) 632-1590 inside Bakersfield, or (800) 391-2000 outside of Bakersfield.

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Kern Family Health Care™

NOTICE OF ACTION
About Your Treatment Request - Deny

Today's date

Member name
Address
City, State, Zip

Treating Provider
Address
City, State, Zip

Identification Number: KHS ID

RE: [Service requested]

[Name of requesting provider] has asked Kern Family Health Care to approve [Service requested].This request is denied. This is because no eligibility is recorded for the date of service.

You may ask for free copies of all information used to make this decision. This includes a copy of the actual benefit provision, guideline, protocol, or criteria that we based our decision on. To ask for this, please call Kern Family Health Care at (661) 632-1590 inside Bakersfield, or (800) 391-2000 outside of Bakersfield.

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This notice does not affect any of your other Medi-Cal services.

Medical Directors Name

Enclosed: "Your Rights under Medi-Cal Managed Care"

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events and product problems

Page ____ of ____

Form Approved: OMB No. 0910-0291, Expires: 03/31/05
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence #

PLEASE TYPE OR USE BLACK INK

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event: or Date of Birth:	3. Sex	4. Weight
In confidence		☐ Female ☐ Male	____ lbs or ____ kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. ☐ Adverse Event and/or ☐ Product Problem *(e.g., defects/malfunctions)*

2. Outcomes Attributed to Adverse Event *(Check all that apply)*
- ☐ Death: _____ *(mo/day/yr)*
- ☐ Life-threatening
- ☐ Hospitalization - initial or prolonged
- ☐ Disability
- ☐ Congenital Anomaly
- ☐ Required Intervention to Prevent Permanent Impairment/Damage
- ☐ Other: _____

3. Date of Event *(mo/day/year)*

4. Date of This Report *(mo/day/year)*

5. Describe Event or Problem

6. Relevant Tests/Laboratory Data, Including Dates

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)*

C. SUSPECT MEDICATION(S)

1. Name *(Give labeled strength & manufacturer, if known)*
#1
#2

2. Dose, Frequency & Route Used
#1
#2

3. Therapy Dates *(if unknown, give duration)* from/to *(or best estimate)*
#1
#2

4. Diagnosis for Use *(Indication)*
#1
#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

6. Lot # *(if known)*
#1
#2

7. Exp. Date *(if known)*
#1
#2

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC# *(For product problems only)*
- -

10. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

D. SUSPECT MEDICAL DEVICE

1. Brand Name

2. Type of Device

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device
Catalog #	Expiration Date *(mo/day/yr)*	☐ Health Professional ☐ Lay User/Patient ☐ Other:
Serial #	Other #	

6. If Implanted, Give Date *(mo/day/yr)*

7. If Explanted, Give Date *(mo/day/yr)*

8. Is this a Single-use Device that was Reprocessed and Reused on a Patient?
☐ Yes ☐ No

9. If Yes to Item No. 8, Enter Name and Address of Reprocessor

10. Device Available for Evaluation? *(Do not send to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mo/day/yr)*

11. Concomitant Medical Products and Therapy Dates *(Exclude treatment of event)*

E. REPORTER *(See confidentiality section on back)*

1. Name and Address

Phone #

2. Health Professional?
☐ Yes ☐ No

3. Occupation

4. Also Reported to
☐ Manufacturer
☐ User Facility
☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

-or-

FAX to:
1-800-FDA-0178

FORM FDA 3500 (9/03) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

ADVICE ABOUT VOLUNTARY REPORTING

Report adverse experiences with:

- Medications *(drugs or biologics)*
- Medical devices *(including in-vitro diagnostics)*
- Special nutritional products *(dietary supplements, medical foods, infant formulas)*
- Cosmetics
- Medication errors

Report product problems - quality, performance or safety concerns such as:

- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening *(real risk of dying)*
- Hospitalization *(initial or prolonged)*
- Disability *(significant, persistent or permanent)*
- Congenital anomaly
- Required intervention to prevent permanent impairment or damage

Report even if:

- You're not certain the product caused the event
- You don't have all the details

How to report:

- Just fill in the sections that apply to your report
- Use section C for all products except medical devices
- Attach additional blank pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer *(or both)*

Confidentiality: The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. FDA will not disclose the reporter's identity in response to a request from the public, pursuant to the Freedom of Information Act. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

Important numbers:

- 1-800-FDA-0178 -- To FAX report
- 1-800-FDA-1088 -- To report by phone or for more information
- 1-800-822-7967 -- For a VAERS form for vaccines

To Report via the Internet:

http://www.fda.gov/medwatch/report.htm

The public reporting burden for this collection of information has been estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

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Rockville, MD 20857

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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