



ADVERSE REACTION TRACKING

USER MANUAL

Version 4.0

GMRA*4.0*26

GMRA*4.0*37

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Revision History

Revision Date	Page or Chapter	Description	Project Manager	Author
February 2007	Pages 1-4	Updated descriptions of recent patches	Al Ebert	JoAnn Green
August 2006	Page 52	Added note regarding dates, per GMRA*4*35	Al Ebert	Tim Dawson, VMP
May 2006	Throughout	Various edits, including fixing DOBs to comply with Patient privacy SOP 192-352	Al Ebert	JoAnn Green
February 2006	Appendix 3	FAQ re Data Standardization	Al Ebert	JoAnn Green
February 2006	Pages 1-4	Descriptions of recent patches	Al Ebert	JoAnn Green
September 2005	Appendix 2	Patch 26 Release Notes	Al Ebert	JoAnn Green
April-July 2005	Pgs 5, 140	Updates for GMRA*4.0*23 and data standardization.	Al Ebert	JoAnn Green
December 2004	Throughout manual.	Edits based on SQA review, including removal of Marked on Chart prompts.	Al Ebert	JoAnn Green
November 2004	Pages 4-5 and 129	Added description of NKA deletion	Al Ebert	JoAnn Green
October/November 2004	Throughout manual.	Patient name and SSN and provider name updates to comply with Patient privacy SOP.	Al Ebert	JoAnn Green
October 2004	Appendix 1	CPRS GUI 25 Release Notes for ART added and updated.	Al Ebert	JoAnn Green
January 2004	Page 24	Patch 17 (GMRA*4*17) Free Text Allergy Clean Up Utility info added.	Al Ebert	JoAnn Green

Preface

Assumptions about the Reader

This guide is written with the assumption that readers have experience with the following:

- VistA computing environment
- Kernel Installation and Distribution System [KIDS]
- VA FileMan data structures and terminology

Reference Materials

To learn more about ART and current standardization activities, consult the following:

- VUID Planning Requirements Document from Enterprise Reference Terminology (ERT): <http://tspr.vista.med.va.gov/warboard/ProjectDocs/ERT/VUID%20Server%20plan.doc>
- Standards and Terminology (Data Standardization) Project Website: http://vaww.infoshare.va.gov/Data_Standardization/default.aspx
- [STS Terminology Model Guidance Document](#)
- The NTRT Program website. This website allows users to submit new terms to be included in the national standard. The website also features a user guide that provides instructions for submitting a new term: <http://vista.med.va.gov/ntrt/>
- The VistA documentation library has more detailed information about all aspects of VistA: <http://www.va.gov/vdl/>

ART Documentation

- ART Installation Guide GMRA_4_IG.PDF
- ART Technical Manual GMRA_4_TM.PDF
- ART Patch 26 Release Notes GMRA_4_26_RN.PDF

ART documentation is available on the VHA Software Document Library (VDL): <http://www.va.gov/vdl/application.asp?appid=57>

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Introduction

Updates to the Adverse Reaction Tracking (ART) system

ART has been modified in order to standardize the data stored in the allergy package. Standardized data is necessary for inclusion in the Health Data Repository (HDR).

The data standardization program is the cornerstone of the Veterans Health Administration's (VHA) plan to share health information across the entire VHA system. Data standardization establishes a consistent way of defining data. This will enable all sites in the VA health system to speak the same language and will ensure that data not only crosses from system to system, but retains the same meaning. For example, an allergy to penicillin entered in the Tuscaloosa VAMC will be automatically included in order checks and decision support at every other VAMC and will also be computable within the Department of Defense if the patient seeks treatment at one of their facilities. The ability to access complete and accurate health information for a Veteran at any site is not only critical in ensuring patient safety, but supports informed clinical decision-making, personalized patient care, and improved population health.

Two new cross-references and a new Application Programmer Interface (API) were created that will allow changes to existing reactant terms to propagate through existing allergy entries in the PATIENT ALLERGIES file (120.8).

The GMR ALLERGIES file (120.82) and the SIGNS/SYMPTOMS file (120.83) have been standardized. As a result of standardization, sites will no longer be allowed to add or edit entries in either of these files. In addition, users will no longer be able to add "free text" signs /symptoms.

Remote Data Interoperability (RDI)

The Remote Data Interoperability (RDI) project will provide a method of comparing clinical data about a patient received from all VA Medical Centers as well as clinical data from military facilities where active dual consumers are treated. Active dual consumers may be military personnel treated at a VHA facility or VA patients treated at a military facility. The medication orders and allergies will be compared across all sites to determine if any orders are contraindicated, based on clinical data originating at any other site. More about RDI training can be found at:

<http://vaww.vistau.med.va.gov/vistau/rdi/>

GMRA*4*26 - Remote Data Interoperability (RDI) update

GMRA*4.0*26 provides the Remote Data Interoperability (RDI) project the ability to use remote allergy data when determining drug-allergy order checks.

The remote data will come from the Health Data Repository (HDR) and that data will be used to determine if an order check should be given on the local system for the drug being ordered.

GMRA*4*26 accompanies OR*3.0*232, which is the Order Entry/Results Reporting portion of the Remote Data Interoperability project. This project's aim is to include DoD and VA-wide data in the data set used to perform order checking on new patient orders.

Order Checks for Allergies to Drugs

Drug Allergy Order Check Upon Placing a Medication Order

At the time a provider enters either an Outpatient or Inpatient medication order is entered into the Computerized Patient Record System (CPRS), CPRS will provide the details of the order to ART. If known, CPRS will also provide the standardized VUID (VHA Unique Identifiers) of the drug from the VA Product file (#50.68). ART will check the patient's active allergies to attempt to determine if potential allergy-drug interactions exist. ART will retrieve active allergies from HDR-Hx and HDR-IMS via a CPRS API call to CDS and include those in the drug allergy-drug order checks. ART queries the National Drug File Pharmacy application for the drug ingredients and the drug classes associated with the product, and compares the ingredient and drug class information against the information on file for the patient. The first check is on the ingredients; if no match is found, the next check is for drug classes. ART provides any potential interactions to CPRS, and CPRS notifies the ordering provider if potential interactions exist at the time the order is entered and before the order is signed.

ART converts VUIDs to IENs if necessary

If RDI sends a drug ingredient or drug class VUID to ART, ART calls an API to convert drug ingredient VUIDs to IENs and drug class VUIDs to drug class codes in order to accomplish order checking.

Display of Potential Drug Allergy Interactions

At the time the order is entered, CPRS will display, in a pop-up window, any potential drug allergy interactions.

Outpatient Pharmacy and Allergies

Outpatient Pharmacy calls a CPRS API to retrieve the patient's allergy information from all sites where the patient has been seen in order to perform allergy/adverse reaction checking.

Inpatient Medication Drug Allergy Order Checks for Backdoor Orders (and remote data).

When a new order is entered, a pending order is finished, or an order is copied or renewed in the Inpatient Order Entry [PSJ OE] option, or the Non-Verified/ Pending Orders [PSJU VBW] option, or the Order Entry [PSJU NE] option, or the Order Entry (IV) [PSJI ORDER] option, a call is made to the ART order checking API, which returns any drug allergy information to Inpatient Medications, including the site where the allergy was entered. If interactions exist, this information is displayed to the finishing pharmacist to be acted upon. This display includes the name of the site where the drug order and/or allergy interaction originated.

RDI allergy calls are made for entry of Non-VA med and also when a RAD order that is marked for contrast media is entered.

GMRA*4*37 - Add Remote Data to Contrast Media Order Checks

Patch GMRA*4*37 expands RDI functionality to include remotely entered allergy data when determining if there is a contrast media allergy when ordering radiological procedures.

When a radiological request is entered that uses contrast, either from within the radiology package or within CPRS, an order check will be displayed if there is contrast media allergy data on file either locally or remotely.

Patch OR*3*267 includes updates to enhance the order check display and should be installed at the same time as patch GMRA*4*37. However, these patches can be installed independently of each other without any adverse effect.

OR*3*267 - Remote Contrast Media Order Checking

This purpose of this patch is to implement changes related to CONTRAST MEDIA order checking. The specific changes occur in the OE/RR EXPERT SYSTEM in order to allow the display of the designation for the facility on the order checks when an allergy is found to be against a remotely recorded allergy.

Other Recent ART Patches

GMRA*4*36 - Eliminate Originator Delete

Previously, if a user edited an existing allergy in VISTA that had the ORIGINATOR SIGN OFF (15) field in the PATIENT ALLERGIES (120.8) file set to “no,” the user would be given the option to delete the entry.

With the Health Data Repository (HDR) now in place for allergies, deletions of data that are already part of the HDR cannot be allowed. As a result, any existing allergy that hasn't been “signed off” will be marked entered in error if the user chooses to “delete” the entry.

In a previously released patch, a post-installation routine identified allergy entries that should have been auto-verified but weren't, due to a logic issue. Those entries were then auto-verified as they should have been. When those entries were auto-verified, the ORIGINATOR SIGN OFF (15) field in the PATIENT ALLERGIES (120.8) file should have been set to yes.

A post-install routine, GMRAY36, has been added to this patch to identify and fix any auto-verified allergies that have the ORIGINATOR SIGN OFF (15) field set to “no.”

The post-install will also review existing allergy entries to make sure that the ALLERGY TYPE (3.1) field in the PATIENT ALLERGIES (120.8) file is consistent with its corresponding entry in the GMR ALLERGIES (120.82) file. Prior to this patch, any changes to the ALLERGY TYPE (1) field in GMR ALLERGIES (120.82) file made by the standardization team would not have updated existing patient allergies. The ALLERGY TYPE (1) field in the GMR ALLERGIES (120.82) file has also been updated to include a new style cross-reference that will now update

existing patient allergies, should the value change. The new style cross-reference will be added during the post-install.

The post-install will also make sure that the name of the reactant that is stored in the PATIENT ALLERGIES (120.8) file matches the name of the reactant from the GMR ALLERGIES (120.82) file. Prior to standardization, it was possible for a site to change the name of a locally entered allergy without that change updating existing allergies. The post install will check existing allergies associated with the GMR ALLERGIES (120.82) file and make sure the reactant field matches the name of the allergy.

The post-install will also identify any patient allergies that are associated with an entry from the GMR ALLERGIES (120.82) file that is inactive and convert it to a free text entry.

Finally, the post-install will check for patient allergies that are associated with the DRUG (50) file. While the DRUG (50) file may no longer be selected from, there are pre-standardization entries that may be pointing to locally created entries in the DRUG (50) file that did not have ingredient and/or drug class information. In cases where the entry doesn't have appropriate drug information, the allergy will be converted to a free text entry.

A mail message will be sent to the installer indicating the total number of entries that were converted to free text. When patch GMRA*4*29 is installed, most of the entries that were converted to free text will be automatically updated to a standardized term. As a result, you do not need to take any action on the newly created free text entries at this time.

This patch updates the GMR ALLERGIES (120.82) file so that the DRUG INGREDIENTS (4) multiple will only allow primary ingredients to be selected. The DRUG INGREDIENTS (2) multiple in the PATIENT ALLERGIES (120.8) file has had this restriction for quite some time. This update will get them in synch. As the GMR ALLERGIES (120.82) file is standardized, this change has effectively been in place since standardization but this will assure compliance.

This patch also fixes the problem where a user may have been asked the “have the ID BANDS been marked” question more than once when entering or verifying allergies in the roll-and-scroll environment.

During internal testing, it was noted that in the roll-and-scroll package, when the user is asked “does the patient have any known allergies or adverse reactions,” an entry is created in the ADVERSE REACTION ASSESSMENT (120.86) file before the question is asked. If the user hits return or enters an “^,” the entry is then deleted from the file. This causes unnecessary traffic to the HDR. The entry is now created after the question is answered by the user.

GMRA*4*35 - Possible Problem With List By Location Unassessed

When a user ran the report List by Location of Undocumented Allergies [GMRA PRINT-PATIENTS NOT ASKED] option, the listing showed a patient that had allergies, were autoverified, and should not have shown up on the list

Resolution:

A notation message was added to the code to further help the user in how to run the report: “Please note! This report will show patients as not having received an assessment if the assessment was entered after the end date of the range. For this reason, it is recommended to end the range with today. This can be done with an entry of 'T' (for Today) at the 'Enter END Date (time optional): T/' prompt.”

Remedy Ticket: HD67868 - ALX-0204-70164 Possible problem with List by Location
Unassessed Allergies

GMRA*4*34 - Update to HL7 messages

In patch GMRA*4*23, routines were distributed to send HL7 messages containing allergy data to the Health Data Repository (HDR). This patch adds a check for HL7 control characters that are embedded in text type data elements in the HL7 message and converts these control characters to the correct HL7 Escape Sequence.

****NOTE**** You must suspend the VDEF Request Queue before installing this patch and then re-enable it after installation of the patch. The steps for doing that are outlined in the installation instructions.

GMRA*4*31 - Check for compiled cross-references in file 120.8

In preparation for the installation of the data standardization related patches, sites needed to check to see if file 120.8 compiled cross-references.

Patch GMRA*4*23, which installed the necessary data dictionary updates in support of the allergies data standardization, added some new cross-references to file 120.8.

In some cases, sites may have compiled the cross-references on file 120.8. If that is the case, then the cross-references that will be added by patch GMRA*4*23 won't be executed as a result of the compilation of the existing cross-references.

In general, the only sites that will have this problem are integrated sites. In some cases, during the integration of the site's database, the cross-references for file 120.8 may have been compiled. In order to ensure that file 120.8 does not have compiled cross-references this informational patch was provided to give directions on how to identify and fix this issue if it existed on a local system.

GMRA*4*30 - Prevent Deceased Patients From Appearing On Report

This patch addresses Remedy ticket HD67463, where deceased patients are appearing on the Patient Not Asked Report [GMRA PRINT-PATIENTS NOT ASKED].

The sites use this report to identify patients who have not had an allergy/adverse reaction assessment. The sites then follow up with the patients on the list to get the allergy information. By preventing deceased patients from appearing on this list, the sites will not be attempting to contact the family of a deceased individual for this assessment.

GMRA*4*29 - Automated clean up of free text allergies

This patch will find all active free text allergies and will update the entry in one of three ways.

1. If the free text term is found in the conversion matrix, then the term will be updated to the associated term from the matrix. The conversion matrix is loaded into the ^XTMP global when the patch is installed and is used to determine if there is an update that can be done.
2. If the free text term is not found in the matrix or if the term to update to would cause a duplicate term, then the free text term is updated to include the phrase (FREE TEXT) after the term. This will now serve as a visual cue that the term is a free text term and will not be considered during order checking.

3. Finally, if the matrix indicates that the term is an erroneous term, then the allergy will be marked as entered in error.

When the post-install has reviewed all active free text allergy terms, a mailman message will be sent indicating the outcome of the conversion. The report will include the number of entries that were updated and will also report any entries that couldn't be updated and why that entry couldn't be updated.

Upon completion of the update, the allergy free text utility can be used to review the remaining free text entries for manual updating.

For more information about patch 29, see the VistaU CPRS Monthly Teleconference February 2007 presentation:

http://vaww.vistau.med.va.gov/vistau/cprs/files/Calls/CPRS_2007-02AllergyFreeTextClean-up_GMRA-FC_013107.ppt

GMRA*4*27 - Allergy Order Check Does Not Fire For Contrast Media

PSI-05-054 documents a patient safety issue due to allergy bulletin not being fired if the contrast media has a VA DRUG CLASS of DX109. Ticket is HD99674.

This patch corrects the problem.

GMRA*4.0*25 - Blank Sign/Symptom Problem

Patient Safety Issue - PSI-05-049 identifies a problem where an allergy may be stored without the corresponding drug classes or drug ingredients. As a result, order checking may not occur as expected.

In version 25 of the GUI, a change was made to the way allergies are entered. When the list of signs/symptoms are displayed on the form the site's top ten entries are listed first and then there's a space and a dashed line and another space. It's possible for the user to accidentally select the dashed line or the space as a sign/symptom. When this happens the system fails when attempting to store the allergy data.

With this update, the allergy package will no longer attempt to store non-existent signs/symptoms.

This patch also contains a post-installation routine that will attempt to identify any allergies that may not have been saved correctly. Upon completion of the post-install, a report will be generated listing any patients and their associated allergies that need to be reviewed. In general, the best course of action is to mark the existing allergy as entered in error and then re-enter the allergy information to make sure all required data is accounted for.

GMRA*4*24 Update HDR trigger code

The logic used to determine when messages should be sent to the HDR is updated in this patch. If the patient is a test patient or if a patient merge is occurring at the site, the allergy data will no longer be sent to the HDR.

GMRA*4.0*23 - HDR/DS Changes

This patch introduces the changes necessary to standardize the data stored in the allergy package. Standardized data is necessary for inclusion in the Health Data Repository (HDR).

In addition, this patch introduces two new cross-references and a new Application Programmer Interface (API) that will allow changes to existing reactant terms to propagate through existing allergy entries in the PATIENT ALLERGIES file (120.8).

The GMR ALLERGIES file (120.82) and the SIGNS/SYMPTOMS file (120.83) are being standardized. As a result of standardization, sites will no longer be allowed to add or edit entries in either of these files. In addition, users will no longer be able to add "free text" signs /symptoms.

The data standardization team has reviewed existing local entries at the sites and has added those terms to files 120.82 and 120.83 as appropriate. Requests for new terms will be made via the New Term Rapid Turnaround (NTRT) process. If approved, the new term will be sent to all sites for inclusion in file 120.82 or 120.83. For more information on this process, see these websites:

- Standards and Terminology Project Website:
http://vaww.infoshare.va.gov/Data_Standardization/Information%20for%20VISNsSites/Forms/AllItems.aspx
- NTRT Program website.
<http://vista.med.va.gov/ntrt/>

In addition to the updates to files 120.82 and 120.83, existing active entries in file 120.8 need to be updated to use standard reactants. In a previous allergy patch, a utility was distributed that identified free text entries. The utility also included options that allowed the user to fix these entries by either updating them or marking them as entered in error.

GMRA*4.0*21 - Removal of allergies as orders

Free-text allergies may no longer be entered through CPRS. At sites that have installed OR*3.0*195, OR*3.0*216, and GMRA*4.0*21, CPRS users can no longer enter allergies and adverse reactions as orders that are placed in the *ORDERS* file, and allergies do not appear on the Orders tab. Patch OR*3.0*216 includes a post-installation routine that changes the status of all active allergy orders to complete and, therefore, removes the allergy orders from the Orders tab.

In addition, users can no longer select OTHER ALLERGY/ADVERSE REACTION as a type of causative agent, nor can they select OTHER REACTION as a type of sign/symptom. Changes to the ART package have eliminated these items as choices. These changes mark a continuing effort to end free-text and unspecific entries.

CPRS GUI 24 introduced a dialog through which users can request that a causative agent be added to their site's *ALLERGIES* file. Users access this dialog via a warning that pops up when they attempt to enter a free-text causative agent. The warning dialog asks users to indicate—by clicking either its YES or NO button—if they want to send a causative-agent inclusion request. In CPRS GUI 24, the default button was YES. In this version, the default button is NO. Furthermore, when users click the system X button (located in the top right-hand corner of each screen) to exit any of the screens that comprise the inclusion-request dialog, CPRS now cancels the request action.

No Known Allergies (NKA): It is now possible to delete an assessment of NKA from within the ART package.

When you select a patient for entering/editing allergies and that patient doesn't have any active allergies on file, the “Does this patient have any known allergies or adverse reactions?” prompt is presented to you. If the patient has no assessment, there is no default answer. If the patient has been assessed as NKA, the default is NO. In the case where the default answer is NO (meaning, the patient is NKA), you may enter an @ sign to indicate that the assessment should be deleted and the patient should be returned to the 'not assessed' state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

GMRA*4*20 - ALLERGY DATA UPDATES

Patch 20 expands the utility to identify ingredient-based allergies as well as drug class-based allergies. The site can then take the same two actions on those lists as it can on free text.

This utility does NOT automatically match any entry to a “better” entry, nor does it suggest better entries. It's simply a tool for identifying allergies that may be problematic and allows you to take action on them.

Another patch, GMRA*4*29, will automatically update existing free-text entries to entries identified as being the best match for the free-text term. Once patch 29 runs, the sites will still have entries in their free-text list, because the automated cleanup cannot get all of them.

Sites currently have the ability to identify and fix free-text entries. The purpose of the automated cleanup is to do the majority of the work for the sites that haven't begun working on the cleanup. Those sites will still need to fix the remaining free-text entries, as well as review the ingredient and drug class-based allergies for possible repair.

A new mail group, GMRA REQUEST NEW REACTANT, was added with patch 17. Sites should populate this mail group with the people responsible for addressing requests to add new reactants. If users attempt to enter a reactant that is not found during the look-up process, they are asked if they would like to send an email requesting the addition of the new reactant. The request can then be reviewed for accuracy and new local entries can be added, if appropriate. Previously, users were asked if they wanted to add the new entry and it was immediately available in the patient's record. Under the new system, the mail message that's sent to the user now indicates in the text the name of the reactant that has not been added to the record.

Order Checking

Remedy tickets 67740, and 117610, as well as Patient Safety Issues PSI-03-050 and PSI-05-075, describe situations where order checks did not fire, due to the fact that only ingredient information was stored with the patient allergy. While this patch will not stop a user from selecting from the ingredient file while entering an allergy, it does give the site a tool to identify and fix entries that are associated with an ingredient file entry.

When reactants are selected from either the ingredient or drug class files, only that specific piece of information is stored with the patient's allergy. Order checking looks at both the ingredients and the drug classes when determining if an order check should be activated. Therefore, reactants should be selected from either the GMR ALLERGY file or one of the pharmacy drug-related files, to increase the likelihood of producing an order check. The order in which the files are searched when looking for reactants was altered in patch GMRA*4*23 so that the ingredient and drug class files are at the bottom. This change helps promote selection from files that include both

ingredients and drug classes as part of the definition of the reactant. The ingredient and drug class files are still available to choose from, as there are times when selection from one of these files is the best choice.

Progress Note Updates

The progress note that is sent when an allergy has been marked as entered in error has been updated to clarify that the reactant may have been entered in error or may have been found to no longer be an allergy or adverse reaction for the patient. Previously, when a patient's allergy was marked entered in error (in the roll-and-scroll environment), if the patient didn't have a location associated with them, you were asked for a location. If you didn't answer that question, a progress note wasn't filed. With the update, the location question isn't asked.

The progress note will include a statement similar to the following:

The adverse reaction to X was removed on --/--/--. This reaction was either an erroneous entry or was found to no longer be a true adverse reaction.

The message notes whether the entry being marked entered in error is an adverse reaction or an allergy, so the text will change depending on how the entry was entered.

Top Ten Sign/Symptom List Update

This patch also includes a post-installation routine that will review the site's "top 10" sign/symptom list to make sure it only has 10 entries. In a previously released patch, additional sign/symptoms may have been added at positions 11 or higher. The site is unable to delete or edit these entries and the user never sees these entries as possible choices when adding signs/symptoms. However, when NTRT updates are sent out, it is possible to get an email message telling you that an entry on the top 10 list is now inactive and that you must update the entry. As stated above, you have no way to do that and entries above number 10 shouldn't be part of the definition. This post-install will remove any entries numbered 11 or higher.

Invalid Pointers Check

The post-install also identifies any allergies with an invalid pointer in the GMR ALLERGY field of file 120.8. If invalid data is found the entry is converted to a "free text" entry and an email message with information related to that allergy is sent to the installer after the post-install finishes. The allergy clean-up utility can then be used to fix the entry.

The line "no active orders" was also added in the order checking segment of the utility, so you'll be aware that the check was made and the patient had no active orders.

CPRS Changes affecting ART

PATCH OR*3*233

Support for Allergy Synonyms – Allergy synonyms, if present, are now included in the SIGNS/SYMPTOMS selection box. This is included in patch OR*3*233, which will be distributed with GMRA patch 23.

CPRS GUI 26

- **Marking Allergies as Entered in Error Now Controlled by Parameter** - In CPRS v25, any user could enter new allergies, mark a patient as NKA (no known allergies), and mark allergies entered in error from the cover sheet and the detailed display window. In v.26, the

Entered in Error option requires the new parameter OR ALLERGY ENTERED IN ERROR to be enabled for the user. The other options remain open to all users as before.

- **Free-Text Signs and Symptoms No Longer Allowed** – To support of data standardization efforts, developers removed the ability to enter free-text signs/symptoms. Users must now select items from the list of available signs/symptoms.
- **Inconsistent Sending of Bulletin for Marked on Chart** – CPRS always sent the “Marked on Chart” bulletin if the user entered an allergy from the Orders tab. CPRS never sent the bulletin if the user entered the allergy from the Cover Sheet. This inconsistency has been corrected, and CPRS will never send the bulletin when the user enters a new allergy.
- The "Bulletin has been sent" message that CPRS displays after the user requests the addition of a new causative agent now includes the same warning included in the bulletin about that reactant not being added to the patient's record.

Use of ART within CPRS is primarily described in CPRS documentation, but some examples are provided in this manual.

Overview to ART

The objective of Allergy Reaction Tracking (ART) is to track and report patient allergy and adverse reaction data. This is accomplished through three interfaces:

1. ART menus and options within character-based VistA
2. Character-based CPRS
3. CPRS GUI

ART Package Components

The four major components of the ART package are:

1. Data Entry Options - Adverse Reaction Tracking has two options where a user can enter data.
 - a. Enter/Edit Patient Reaction Data - This option allows the clinical users (i.e., doctors, nurses, other clinicians and clerks) to enter data into ART.
 - b. Verify Patient Reaction Data - This option allows the verifiers designated by ART to verify the correctness of data entered by the clinical users into ART. This option does NOT perform evaluation of suspected Advanced Drug Reactions (ADR) as described in Section 5.a.(2).(d) of Directive 10- 92-070.
2. Reporting options - These options report the patient causative agent data to you via a print option. Also, this data is made available to other software applications via a data extract utility.
3. Enter/Edit Site Configurable Files - This menu allows the various site configurable files to be modified to allow ART to better meet the needs of an individual site.
4. Adverse Drug Reaction (ADR) options - These options support implementation of Directive 10-92-070. It allows for the evaluation of a suspected ADR by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist) other than the attending physician, as specified in Section 5.a.(2).(d) of Directive 10-92-070. This component also generates the reports needed by the FDA.

There are four major users of the software:

1. Clinical users - These are the doctors, nurses, other clinicians, and clerks entering the data into ART. They are required to enter data pertinent for a particular allergy/adverse reaction. If the allergy/adverse reaction was observed at the site, data pertaining to any possible legal action could be tracked. This data would then be made available to users of any service using the Reporting options, thus avoiding any errors in care. Two other data elements that are tracked are the date/time that the patient chart was marked and the date/time that the patient ID band was marked, indicating the patient's reaction to the particular causative agent. Automated mail bulletins are sent to the appropriate users when the date/time patient chart marked data field has not been recorded.
2. Verifiers - These are designated users by the site who verify the correctness of the data in ART. The verifiers are designated when the Information Resources Management Service (IRM) allocates the GMRA-ALLERGY VERIFY security key to a user and assigns the

ART Verifier Menu. The verifiers may be clinical pharmacists, dietitians, or other clinical personnel. Automated mail bulletins will be sent to the ART verifiers when an allergy/adverse reaction has been entered and signed (completed) by a user. Verification may be important in observed instances of adverse drug reactions where a Quality Assurance (QA) investigation may be conducted. In general, it is a good principle to have someone verify all of the data entered into ART.

3. Pharmacy and Therapeutics (P&T) Committee users - These users are the members of the hospital's P&T Committee and are assigned the P&T Committee Menu option. They will use the information in ART to review ADRs in the hospital, classify them as significant reactions, and determine whether they are related to particular drugs, and depending on the severity of the ADR, may report it further to the FDA. A printed copy of the form used to report to the Food and Drug Administration (FDA) can be generated by ART. Automated mail bulletins will be sent to the P&T Committee users when an observed drug reaction is entered into the system.
4. Software developers - These users will use the data extract utility (GMRADPT routine) to gather ART data for display within their specific VistA application.

Package Management

This package does not impose any additional legal requirements on you, nor does it relieve you of any legal requirements. All users are reminded that many of the reports and mail bulletins generated by this package contain confidential patient information, which is protected by the Privacy Act. A basic knowledge of VistA is presumed for most users of the software. The Application Coordinator (ADPAC) should have more than a basic knowledge of VistA and the needs of a clinical environment.

Security keys

The software does contain two security keys. The GMRA ALLERGY VERIFY key is needed to verify allergy/adverse reactions. The GMRA SUPERVISOR key should be given only to those users who have the authority to override the software's security in order to edit data.

The software itself does not prompt for a user's electronic signature. However, it does contain a programming interface with the Progress Notes package in order to create, edit, and sign progress notes. The Progress Notes software does prompt you for an electronic signature.

GMRA UPDATE RESOURCE

ADI (Allergy Domain Implementation/Data Standardization) uses a resource device to control the updating of existing patient allergies. When changes are made to existing allergy definitions in file 120.82, all associated patient allergies in file 120.8 are updated to match the new definition of the entry from 120.82. The resource device controls the updating process. Because of the way the updates are implemented, the resource device needs to manage the updates one at a time. As a result, the resource slots field is set to **one** and should not be changed.

Mail bulletins

The software generates mail bulletins when certain events happen and sends a bulletin to a specified mail group. The mail groups are:

1. GMRA MARK CHART - A list of users who will need to be notified that the ID Band needs to be updated. The new message reads "The ID band for the following patient needs to indicate that the following Allergy/adverse reaction has been reported"
2. GMRA VERIFY DRUG ALLERGY - A list of all verifiers who will need to be sent drug reaction information.
3. GMRA VERIFY FOOD ALLERGY - A list of all verifiers who will need to be sent food reaction information.
4. GMRA VERIFY OTHER ALLERGY - A list of all verifiers who will need to be sent other types of reaction information (i.e., not drug or food).
5. GMRA P&T COMMITTEE FDA - A list of the members of the Pharmacy and Therapeutic (P&T) Committee.

6. GMRA REQUEST NEW REACTANT - When adding a new allergy entry, you are prompted for the reactant. If you cannot find a reactant to match your input, then you are given the option to send an email message requesting that the new reactant be added.

Contact the ADPAC or IRM support staff if you need to be a member of one of these mail groups.

Package Operation

Adverse Reaction Tracking (ART) can be used through CPRS – both the GUI and List manager interfaces, and through GMRA options in character-based VistA. This manual primarily describes the latter use, but also briefly describes the use in CPRS.

Within the character-based VistA, the ART software includes six menus to assist users in tracking and reporting allergy/adverse reaction data:

1. Adverse Reaction Tracking [GMRAMGR] - This is the top-level menu. It should be given to the package's ADPAC and/or IRM support person.
2. Adverse Reaction Tracking User Menu [GMRA USER MENU] - This menu can be assigned to clerks who will enter adverse reaction data.
3. Adverse Reaction Tracking Clinician Menu [GMRA CLINICIAN MENU] - This menu can be assigned to clinicians who will use the package.
4. Adverse Reaction Tracking Verifier Menu [GMRA VERIFIER MENU] - This menu should be assigned to users who will verify adverse reaction data.
5. P&T Committee Menu [GMRA P&T MENU] - This menu can be given to Pharmacy and Therapeutic Committee members.

The rest of this chapter describes the menus and options. Also, examples of each option are given.

Adverse Reaction Tracking [GMRAMGR]

This is the main menu that has all options of the Adverse Reaction Tracking System. This menu should only be given to the ART Applications Coordinator (ADPAC) and/or IRM support personnel.

- 1 Enter/Edit Site Configurable Files ... [GMRA SITE FILE MENU]
- 2 Adverse Reaction Tracking User Menu ... [GMRA USER MENU]
- 3 Adverse Reaction Tracking Clinician Menu ... [GMRA CLINICIAN MENU]
- 4 Adverse Reaction Tracking Verifier Menu ... [GMRA VERIFIER MENU]
- 5 P&T Committee Menu ... [GMRA P&T MENU]

Enter/Edit Site Configurable Files

This is a menu of the various options that the site can use to tailor ART to better meet its needs. This menu should be used by the ADPAC or IRM Support Staff only.

NOTE: The GMR ALLERGIES file (120.82) and the SIGNS/SYMPTOMS file (120.83) have been standardized. As a result of standardization, sites are longer allowed to add or edit entries in either of these files. In addition, users will no longer be able to add free-text signs/symptoms. The ability to add free-text reactants was removed by a previous allergy patch.

The data standardization team has reviewed existing local entries at the sites and has added those terms to files 120.82 and 120.83 as appropriate. Requests for new terms are made via the New Term Rapid Turnaround (NTRT) process. If approved, the new term will be sent to all sites for inclusion in file 120.82 or 120.83.

The options on this menu are still available, but will not allow entries; this was done to further emphasize the changes to the application.

1. Edit Allergy File
2. Enter/Edit Signs/Symptoms Data
3. Enter/Edit Site Parameters
4. Sign/Symptoms List
5. Allergies File List
6. Allergy clean up utility

Edit Allergy File
Enter/Edit Signs/Symptoms Data

The GMR ALLERGIES file (120.82) and the SIGNS/SYMPTOMS file (120.83) are standardized. As a result of standardization, sites are longer allowed to add or edit entries in either of these files. In addition, users will no longer be able to add "free text" signs/symptoms.

Enter/Edit Site Parameters

The Enter/Edit Site Parameters [GMRA SITE FILE] option allows site configuration for multiple divisions at the site. The software provides a generic site configuration entry called HOSPITAL. These parameters are stored in the GMR Allergy Site Parameters file (#120.84).

The site can configure the following:

1. The list of the ten most common signs/symptoms that you will see.
2. The autoverification of data. Autoverification is the process by which the software automatically changes the status of the data to verify when you who entered the data signs off (completes) on it. The site can determine which of the types of reactions are to be autoverified and which are to follow the normal verification procedure. There are three parameters used to autoverify data: Autoverify Food/Drug/Other, Autoverify Observed/Historical, and Autoverify Logical Operator. The verification of data is important. Minimally, all drug reactions will need verification. Depending on the site, food and other allergies may also need to be verified. Users who will verify the data must have the GMRA-ALLERGY VERIFY security key.
3. Whether the originator of the data should provide comments.
4. Whether the site documents the marking of a patient's ID band or chart to indicate the presence of an allergy/adverse reaction. There are three parameters with regards to this documentation: Mark ID Band Flag Method of Notification, Alert ID Band/Chart Mark, and Send Chart Mark Bulletin for New Admissions.
5. FDA reporting data. The site can choose to require you to enter FDA data at the time a reaction is entered. Also, the site may edit the reporter information that will appear on the FDA Adverse Reaction reports.
6. Whether to allow comments to be added to the reaction data that is entered in error. This allows you to indicate why the data is incorrect.

Example:

```
Select Enter/Edit Site Configurable Files Option: 3 Enter/Edit Site Parameters
Select GMR ALLERGY SITE PARAMETERS NAME: ??
HOSPITAL

    You may enter a new GMR ALLERGY SITE PARAMETERS, if you wish
    This field is the name of this set of parameters. The name of the base
    set that is sent out is "HOSPITAL". The code will work more efficiently
    if the name of the base set of parameters is not changed from "HOSPITAL"
.

Select GMR ALLERGY SITE PARAMETERS NAME: HOSPITAL
NAME: HOSPITAL// (No editing)
Select DIVISION: ?
    Answer with DIVISION
    Choose from:
    VAMC ONE
    VAMC TWO
    VAMC THREE
```

You may enter a new DIVISION, if you wish

Answer with INSTITUTION NAME, or STATUS, or STATION NUMBER, or
OFFICIAL VA NAME, or CURRENT LOCATION, or CODING SYSTEM/ID PAIR, or
NAME (CHANGED FROM), or CODING SYSTEM

Do you want the entire INSTITUTION List? **N** (No)

Select DIVISION: **VAMC ONE**

The following are the ten most common signs/symptoms:

- | | |
|--------------------------|--------------|
| 1. CHILLS | 6. DIARRHEA |
| 2. ITCHING,WATERING EYES | 7. HIVES |
| 3. HYPOTENSION | 8. DRY MOUTH |
| 4. DROWSINESS | 9. DRY NOSE |
| 5. NAUSEA,VOMITING | 10. RASH |

Enter the number of the sign/symptom that you would like to edit: ??

ENTER THE CORRECT NUMBER (1-10) OF THE SIGN/SYMPTOM TO BE EDITED

Enter the number of the sign/symptom that you would like to edit: **6**

REACTION: DIARRHEA// ??

One of the ten most commonly selected reactions.

Choose from:

AGITATION	NATIONAL SIGN/SYMPTOM
AGRANULOCYTOSIS	NATIONAL SIGN/SYMPTOM
ALOPECIA	NATIONAL SIGN/SYMPTOM
ANAPHYLAXIS	NATIONAL SIGN/SYMPTOM
ANEMIA	NATIONAL SIGN/SYMPTOM
ANOREXIA	NATIONAL SIGN/SYMPTOM
ANXIETY	NATIONAL SIGN/SYMPTOM
APNEA	NATIONAL SIGN/SYMPTOM
APPETITE,INCREASED	NATIONAL SIGN/SYMPTOM
ARRHYTHMIA	NATIONAL SIGN/SYMPTOM
ASTHENIA	NATIONAL SIGN/SYMPTOM
ASTHMA	NATIONAL SIGN/SYMPTOM
ATAXIA	NATIONAL SIGN/SYMPTOM
ATHETOSIS	NATIONAL SIGN/SYMPTOM
BRACHYCARDIA	NATIONAL SIGN/SYMPTOM
BREAST ENGORGEMENT	NATIONAL SIGN/SYMPTOM
BRONCHOSPASM	NATIONAL SIGN/SYMPTOM
CARDIAC ARREST	NATIONAL SIGN/SYMPTOM
CHEST PAIN	NATIONAL SIGN/SYMPTOM

REACTION: DIARRHEA// **AGITATION** NATIONAL SIGN/SYMPTOM

The following are the ten most common signs/symptoms:

- | | |
|--------------------------|--------------|
| 1. CHILLS | 6. AGITATION |
| 2. ITCHING,WATERING EYES | 7. HIVES |
| 3. HYPOTENSION | 8. DRY MOUTH |
| 4. DROWSINESS | 9. DRY NOSE |
| 5. NAUSEA,VOMITING | 10. RASH |

Enter the number of the sign/symptom that you would like to edit: **<Enter>**

AUTOVERIFY FOOD/DRUG/OTHER: NO AUTOVERIFY// ??

This field determines which types of allergies a site wants autoverified
at you sign off.

Choose from:

0	NO AUTOVERIFY
1	AUTOVERIFY DRUG ONLY
2	AUTOVERIFY FOOD ONLY
3	AUTOVERIFY DRUG/FOOD
4	AUTOVERIFY OTHER ONLY

```

5      AUTOVERIFY DRUG/OTHER
6      AUTOVERIFY FOOD/OTHER
7      AUTOVERIFY ALL
AUTOVERIFY FOOD/DRUG/OTHER: NO AUTOVERIFY// <Enter>
AUTOVERIFY OBSERVED/HISTORICAL: NO AUTOVERIFY// ??
    This field is configurable by the site to allow autoverification of
    observed or historical allergies.

Choose from:
0      NO AUTOVERIFY
1      AUTOVERIFY HISTORICAL ONLY
2      AUTOVERIFY OBSERVED ONLY
3      AUTOVERIFY BOTH
AUTOVERIFY OBSERVED/HISTORICAL: NO AUTOVERIFY//
AUTOVERIFY LOGICAL OPERATOR: OR// ??
    This field will determine how the Autoverify Food/Drug/Other and
    Autoverify Observed/Historical parameters relate to each other. OR means
    that the reaction will be autoverified if it meets the criteria of one of
    the two parameters, while AND means the reaction will be autoverified only
    if it meets the criteria of both parameters. If this field is left null,
    the OR condition will be used.

For example, if you want to verify only observed drug reactions, you would
set the Autoverify Food/Drug/Other parameter to AUTOVERIFY FOOD/OTHER
and the Autoverify Observed/Historical to AUTOVERIFY HISTORICAL ONLY, and the
Autoverify Logical Operator to OR. This means that a reaction that has
a type of Food/Other OR is Historical will be autoverified, thus leaving
observed drug reactions to be verified.

Another example would be if you wanted to verify all observed reactions
and all drug reactions whether observed or historical. The parameters
should be set accordingly: Autoverify Food/Drug/Other to AUTOVERIFY
FOOD/OTHER, Autoverify Observed/Historical to AUTOVERIFY HISTORICAL ONLY and
Autoverify Logical Operator to AND. In this case to be autoverified, a
reaction has to have a type of Food/Other AND it must be Historical, all
other reactions will need to be verified.

Choose from:
!      OR
&      AND
AUTOVERIFY LOGICAL OPERATOR: OR// <Enter>
REQUIRE ORIGINATOR COMMENTS: NO// ??
    This field indicates whether the originator will be required to enter
    comments for an OBSERVED reaction.

Choose from:
0      NO
1      YES
REQUIRE ORIGINATOR COMMENTS: NO// <Enter>
MARK ID BAND FLAG: YES// ??
    This field is an indicator to denote whether the site wants
    to document if the patient ID band should be marked for
    a certain allergy.
    The system will assume the site wants to document the marking of inpatient
    ID bands. If this field is answered NO, the site does not want to
    document the marking of inpatient ID bands.

Choose from:
0      NO
1      YES
MARK ID BAND FLAG: YES// <Enter>
METHOD OF NOTIFICATION: BULLETIN// ??
    This field tells ART if or how users should be notified for chart

```

or ID band markings. There are three methods. The first method is the use of BULLETINS, which is the current way ART works. The second method is the use of OE/RR Teams. If this method is used, then you will need to set up different teams for each ward and also assign printers to these teams. The third method is to turn off the function.

Choose from:

- 0 BULLETIN
- 1 OE/RR TEAMS
- 2 NO NOTIFICATION

METHOD OF NOTIFICATION: BULLETIN// <Enter>

ALERT ID BAND/CHART MARK: YES// ??

This field is to let the system know if you want to issue alerts if the fields have not been answered in the Enter/Edit Patient Reaction Data portion of the system. If the field is answered yes(1) or is null then, the system will continue to issue the alerts. If this field is no(0), then the system will not issue alerts for this record.

Choose from:

- 1 YES
- 0 NO

ALERT ID BAND/CHART MARK: YES// <Enter>

SEND CHART MARK BULLETIN FOR NEW ADMISSIONS: YES// ??

This is to indicate if the site wants to send chart mark bulletin for a new admission.

Choose from:

- 1 YES
- 0 NO

SEND CHART MARK BULLETIN FOR NEW ADMISSIONS: YES// <Enter>

FDA DATA REQUIRED: YES// ??

This field will indicate whether the entry of FDA Data should be required during the Enter/Edit Patient Reaction Data. If this field is answered "YES", then you must enter the FDA Data at the time of entering a reaction. If this field is left null or answered "NO", then the FDA Data entry will not be required during the Enter/Edit Patient Reaction Data option.

Choose from:

- y YES
- n NO

FDA DATA REQUIRED: YES// <Enter>

ENABLE COMMENTS FIELD FOR REACTIONS THAT ARE ENTERED IN ERROR: NO
// ??

Permit users to indicate why a reaction was Entered in Error.

Choose from:

- 1 YES
- 0 NO

ENABLE COMMENTS FIELD FOR REACTIONS THAT ARE ENTERED IN ERROR: NO
// <Enter>

REPORTER NAME:

ADDRESS:

CITY:

STATE:

ZIP:

PHONE:

OCCUPATION:

Do you want to edit Reporter Information shown above? No// <Enter> (No)

- 1 Edit Allergy File
- 2 Enter/Edit Signs/Symptoms Data
- 3 Enter/Edit Site Parameters

- 4 Sign/Symptoms List
- 5 Allergies File List
- 6 Free text allergy clean up utility

You have PENDING ALERTS

Enter "VA to jump to VIEW ALERTS option

Select Enter/Edit Site Configurable Files Option:

NOTE: These "Reporter" data fields contain the site's default values that will appear on the FDA adverse reaction reports. This information may be left blank. You will be prompted for the reporter information when creating an FDA report.

Sign/Symptoms List

This option lets you print a list of entries in the Sign/Symptoms file (#120.83). You may print all entries by accepting the default value (FIRST) at the "Name" prompt or may select a subset of entries. The listing includes the name of the sign/symptom, whether it is a nationally distributed entry or a locally created entry, and any of its synonyms. This option is meant to be a useful tool for ADPACs in maintaining the Sign/Symptoms file.

Example:

```
Select Enter/Edit Site Configurable Files Option: 4 Sign/Symptoms List
START WITH NAME: FIRST// <Enter>
DEVICE: (Enter a printer name for a hard copy or <Enter> to bring the
output to your screen)

SIGN/SYMPTOMS LIST                               JUN  8,2004  09:23    PAGE 1
NAME                                             Nat'l/Local  SYNONYM
-----
AGITATION                                     National
AGRANULOCYTOSIS                             National
ALOPECIA                                     National
ANAPHYLAXIS                                  National
ANEMIA                                        National
ANOREXIA                                     National
ANXIETY                                     National      ANX
APNEA                                        National
APPETITE, INCREASED                         National
ARRHYTHMIA                                  National
ASTHENIA                                     National
ASTHMA                                       National
ATAXIA                                       National
ATHETOSIS                                   National
BRACHYCARDIA                                National
BREAST ENGORGEMENT                          National
BRONCHOSPASM                                 National
CARDIAC ARREST                              National
CHEST PAIN                                  National
CHILLS                                       National
COMA                                         National
CONFUSION                                    National
CONGESTION, NASAL                           National
CONJUNCTIVAL CONGESTION                     National
CONSTIPATION                                National
COUGHING                                    National
DEAFNESS                                    National
DELERIUM                                    National
DELUSION                                    National
DEPRESSION                                  National
DEPRESSION, MENTAL                          National
DEPRESSION, POSTICTAL                       National
...

```

Allergies File List

This option prints a captioned list of all entries in the GMR Allergies file (#120.82). The list is sorted alphabetically by NAME. You may list all entries by accepting the default answer (FIRST) to the "start with" prompt or may select a subset to print. The list contains the allergy name, type, whether it is a nationally distributed entry, synonyms, if any, VA Drug Class, if applicable, and drug ingredients, if applicable. This option is meant to be a helpful tool for maintaining the GMR Allergies file.

Example

```
Select Enter/Edit Site Configurable Files Option: 5 Allergies File List
START WITH NAME: FIRST// <ret>
DEVICE: (Enter a printer name for a hard copy or <ret> to bring the output to
your screen)

GMR ALLERGIES LIST                                MAY  4,2006  11:08    PAGE 1
-----
NAME: ADHESIVE TAPE                                ALLERGY TYPE: OTHER
  NATIONAL ALLERGY: NATIONAL ALLERGY

NAME: ALCOHOL                                       ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
  DRUG INGREDIENT: ALCOHOL

NAME: ANIMAL HAIR                                   ALLERGY TYPE: OTHER
  NATIONAL ALLERGY: NATIONAL ALLERGY

NAME: ANISE OIL                                     ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
  DRUG INGREDIENT: ANISE OIL

NAME: ANTIRABIES SERUM                             ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
  VA DRUG CLASSES: IM400
  DRUG INGREDIENT: ANTIRABIES SERUM

NAME: ASCORBIC ACID                                ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
  VA DRUG CLASSES: VT400
  DRUG INGREDIENT: ASCORBIC ACID

NAME: ASPARTAME                                    ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
  SYNONYM: NUTRA SWEET
  DRUG INGREDIENT: ASPARTAME

NAME: ASPIRIN                                       ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
  VA DRUG CLASSES: MS101
  DRUG INGREDIENT: ASPIRIN

NAME: AUROTHIOGLUCOSE (SESAME OIL)                ALLERGY TYPE: DRUG, FOOD
  NATIONAL ALLERGY: NATIONAL ALLERGY
  SYNONYM: SOLGANAL
  VA DRUG CLASSES: MS160...
```

Allergy Clean Up Utility

This option was distributed with Patch GMRA*4.0*17 to help sites identify and fix allergy entries that have free-text reactants. NOTE: The name of the option has been changed from Free Text Allergy Clean Up Utility to Allergy Clean Up Utility.

After installing this patch, free-text entries were no longer allowed from within the ART package. A subsequent patch (OR*3*216) to CPRS prevented free-text entries from within CPRS as well.

Lower-case entries are also no longer allowed. Previously, lower-case entries could be added to the GMR ALLERGIES file (120.82). A patch 17 post-installation routine identified any local entries and updated the entries to upper case. Synonyms were also be checked and converted to upper case, if required.

Patch GMRA*4*20 expanded the utility to identify ingredient-based allergies as well as drug class-based allergies. The site can then take the same two actions on those lists as it can on free text.

This utility does NOT automatically match any entry to a “better” entry, nor does it suggest better entries. It’s simply a tool for identifying allergies that may be problematic and allows you to take action on them.

GMRA*4*29

GMRA*4*29 automatically updates existing free-text entries to entries identified as being the best match for the free-text term. Once patch 29 runs, the sites will still have entries in their free-text list, because the automated cleanup cannot get all of them.

There were items like antihypertensives, beta-adrenergic agonists, cephalosporins, inhaled corticosteroids, oral contraceptives, topical steroids that didn’t have an appropriate mapping and will be left as free text. These will need to be cleaned up by the sites.

If a medication was taken off of the market before the NDF was created then it will be left as free text and has not been added to the NDF such as cholera vaccine injection

For more information about patch 29, see the VistaU CPRS Monthly Teleconference February 2007 presentation:

http://vaww.vistau.med.va.gov/vistau/cprs/files/Calls/CPRS_2007-02AllergyFreeTextClean-up_GMRA-FC_013107.ppt

When you select free-text reactants, a list of currently existing free-text entries is displayed in alphabetical order. This list may take a few minutes to generate, as all existing entries need to be evaluated to determine which are “free text.” The list shows the name of the reactant. After the install of patch 29, the “FREE TEXT” will be appended to the reactant name, and the number of entries for that reactant. In most cases, they will be unique, but there will be some that have many entries (such as an entry for NO KNOWN ALLERGIES).

When entering the utility, any users who are currently working in the utility are listed. If users are listed as working with the utility, you will not be allowed to update the list. You can only update the list when nobody else is working in the utility.

Once the list is displayed, you can do two things:

1. Mark the entry as entered in error
2. Update the record so that it points to a reactant selected from GMR Allergy file or one of the National Drug Files.

Tip:

Please Keep GMRA UPDATE Resource device slot set at 1. If this has been changed, updates to the Allergies files could occur out of order. If this has been changed, please contact Allergy development and the NTRT team to assess the implications at your site

Select OPTION NAME: **GMRA SITE FILE MENU** Enter/Edit Site Configurable Files menu

- 1 Edit Allergy File
- 2 Enter/Edit Signs/Symptoms Data
- 3 Enter/Edit Site Parameters
- 4 Sign/Symptoms List
- 5 Allergies File List
- 6 Allergy clean up utility

Select Enter/Edit Site Configurable Files Option: 6
Select one of the following:

- 1 Free Text
- 2 Ingredient
- 3 Drug Class

Select the list you wish to work with: 1 Free Text
Allergy clean up utility

Building list of free text allergies...this may take a

NOTE: When you start the utility, you may see 3 different things: 1) If the list has never been built, you'll see the message below (building list...), 2) If the list has been previously built and nobody is using the utility, you'll see a message indicating the last time the list was built and you will be asked if you'd like to rebuild the list, 3) If the list is currently being built, you'll get a message indicating that you must wait. Most times a user will see the message in number 2.

Allergy Tracking Update Oct 27, 2003@08:17:58

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Allergy Tracking Free Text Entries

	Reactant	# Active Entries
1	CEFAZOLIN SOD 1GM INJ	1
2	Diabetes Mellitus Type II	1
4	Penicillin	1
5	WATERMELON	3

Select one or more entries

AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant
Select Item(s): Quit// ??

AE - Local site addition and modification functions are no longer available.

Use EE to mark all entries within the selected group as entered in error. You may select multiple groups if you like.

Use DD to get a detailed display. It's highly recommended that you use the detailed display menu to make all changes.

Use UR to update the reactant. Extreme caution should be used when doing mass updates. It would be better to do the updates from within the detailed display menu.

Press enter to continue:

Detailed Display

The detailed display window shows the patient name and the list of currently active allergies, separated by a tilde (~). This way, you can quickly look and see if the patient already has an active allergy that is the same as the free-text entry. In this case, you would mark it as entered in error.

The “free text detailed display” action lets you see a FileMan inquiry-style listing of the free text entry for selected patient(s). You'll now be able to see the comments, reactions, and other associated information for the free text entry that you're fixing.

When doing a group update or selecting multiple patients for updating from the detailed display listing, the reactant you select for the first patient in the list will become the default for the remaining patients. The exception to that would be if you decide to not accept the default while updating one of the patients. In that case, the last chosen reactant will become the default for the next patient. The default only holds while working with a particular group. Once you select a new reactant group or a new group of patients, you must re-select the reactant. This should cut down on the amount of time needed in selecting the reactant for each patient.

1. Select the Free text allergy clean up utility [GMRA FREE TEXT UTILITY] from the GMRA SITE FILE MENU.
2. Select the number of a reactant first, and then select DD to see details about the reactant. (Alternatively, you can select the action, DD, and then select the number of the reactant.)

NOTE: For detailed display, you can only select one group at a time.

GMRA SITE FILE MENU Enter/Edit Site Configurable Files menu

- 1 Edit Allergy File
- 2 Enter/Edit Signs/Symptoms Data
- 3 Enter/Edit Site Parameters
- 4 Sign/Symptoms List
- 5 Allergies File List
- 6 Allergy clean up utility

Select Enter/Edit Site Configurable Files Option: **6** Allergy clean up Utility

Select one of the following:

- 1 Free Text
- 2 Ingredient
- 3 Drug Class

Select the list you wish to work with: **1** Free Text

Building list of free text allergies...this may take a few minutes

Allergy Tracking Update Oct 24, 2003@15:09:28 Page: 1 of 1

Allergy Tracking Free Text Entries

	Reactant	# Active Entries
1	COCA COLA SYRUP 8OZ	1
2	Diabetes Mellitus Type II	1
3	NO ALLERGIES	1
4	NO KNOWN ALLERGIES	1
5	Penicillin	1
6	PIZZA	1
7	POLLEN ANTIGEN MIX	1

+ Select one or more entries

AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant

Select Item(s): Next Screen// **3**

Allergy Tracking Update Oct 24, 2003@15:09:28 Page: 1 of 1

Allergy Tracking Free Text Entries

	Reactant	# Active Entries
1	COCA COLA SYRUP 8OZ	1
2	Diabetes Mellitus Type II	1
3	NO ALLERGIES	1
4	NO KNOWN ALLERGIES	1
5	Penicillin	1
6	PIZZA	1
7	POLLEN ANTIGEN MIX	1

+ Select one or more entries

AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant

Select Item(s): Next Screen// **DD** Detailed Display

Patient listing for reactant CEFAZOLIN SOD 1GM INJ

Patient Name	Last 4
1 ARTPATIENT,ONE	0111

Allergies: PENICILLIN VK ORAL SOLUTION~AMIKACIN~PEANUT OIL~CORTISONE~NUTS~DUST~
STRAWBERRIES~CHICKEN~CHOCOLATE~PHENOL~HAYFEBROL SF~ASA~BILE SALTS~
BILBERRY EXTRACT~POLLEN~POLLEN ALLERGENIC EXTRACT~
ANTIHEMOPHILIC FACTOR,HUMAN~CEFAZOLIN SOD 1GM INJ~SHELL FISH~
RANITIDINE

Select a patient

EE Entered in Error PR Add/Edit Patient Reaction
UR Update to new reactant DD Free Text Detailed Display
AE Add/Edit Allergy File
Select Item(s): Quit// DD Free Text Detailed Display
Select Entries from list: 1

PATIENT: ARTPATIENT,ONE REACTANT: CEFAZOLIN SOD 1GM INJ
GMR ALLERGY: OTHER ALLERGY/ADVERSE REACTION
ORIGINATION DATE/TIME: OCT 02, 2003@14:02
ORIGINATOR: ARTPROVIDER,ONE OBSERVED/HISTORICAL: HISTORICAL
ORIGINATOR SIGN OFF: YES NATURE OF REACTION: UNKNOWN
VERIFIED: NO ALLERGY TYPE: DRUG

Press return to continue or '^' to stop: <Enter>

Mark Entered in Error

You can mark an entire group as entered in error from this opening screen. Upon marking the reaction as entered in error, a check is made to see if there are still active reactions for the patient. If there are not any, then you are prompted to enter an updated assessment for the patient.

1. Select the Allergy clean up utility [GMRA FREE TEXT UTILITY] from the GMRA SITE FILE MENU.
2. Select the number of the reactant(s) you wish to mark as entered in error. (Alternatively, you can select the action, Mark Entered in Error, and then select the number of the reactant(s).)

```
Select Enter/Edit Site Configurable Files Option: 6 Allergy clean up
utility
  Select one of the following:
      1      Free Text
      2      Ingredient
      3      Drug Class

Select the list you wish to work with: 1 Free Text
The free text list was last built on Oct 17, 2006
Do you want to rebuild the list? NO// y
Building list of free text allergies...this may take a few minutes

Allergy Tracking Update Oct 25, 2006@11:18:04 Page: 1 of 4
Allergy Tracking Free Text Entries
```

Reactant	# Active Entries
1 COCA COLA SYRUP 8OZ	1
2 COLD AIR	1
3 Diabetes Mellitus Type II	1
4 DOG HAIR	1
5 DONUTS	1
6 DOUGH	1
7 DR P'S SNAKE OIL ELIXIR	1
8 DRUGS	1
9 EIEIO	1
10 ENCAINIDE 25MG	1

```
Select one or more entries

AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant
Select Item(s): Quit// 5
```

3. Type EE for Mark entered in error, and then answer Yes to confirm that you want to mark ALL allergies as entered in error.

```
Select Item(s): Next Screen// EE Mark entered in error

You are about to mark ALL allergies with the selected reactant
as entered in error.

ARE YOU SURE? NO// Yes
```

Update to New Reactant

You may select and update groups of entries from the opening menu; however, it is recommended that you use the detailed display option to review entries in a group before doing a mass update. **Changes cannot be undone!** When the entry is updated, a comment is stored in the PATIENT ALLERGY file indicating who made the change, date/time of change, and a comment that indicates what the previous value was and what the new value is. In addition, the new reactant is compared against current orders and order checking information is returned, if appropriate. When a new reactant is selected, checks are made for duplicate entries and previously entered-in-error information.

NOTE: Due to the way the order checking software works, you may get “false positives.” In other words, if the patient currently has an allergy order check for some other order not related to this new reactant, you may still see the order check.

Finally, the drug ingredient/drug class information is updated, if appropriate.

1. Select the Allergy clean up utility [GMRA FREE TEXT UTILITY] from the GMRA SITE FILE MENU.
2. Select a reactant number and then select the action DD.

```
Select the list you wish to work with: 1 Free Text

Building list of free text allergies...this may take a few minutes

Allergy Tracking Update Oct 27, 2003@08:35:56 Page: 1 of 1
Allergy Tracking Free Text Entries
```

Reactant	# Active Entries
1 CEFAZOLIN SOD 1GM INJ	1
2 Diabetes Mellitus Type II	1
3 NO ALLERGIES	1
4 NO KNOWN ALLERGIES	1
5 Penicillin	1
6 WATERMELON	3

```
Select one or more entries
AE Add/Edit Allergy File EE Mark entered in error
DD Detailed Display UR Update to new reactant
Select Item(s): Quit// 6
```

```

Allergy Tracking Update      Oct 27, 2003@08:36:38      Page: 1 of 1
Allergy Tracking Free Text Entries
  Reactant                                # Active Entries
1  CEFAZOLIN SOD 1GM INJ                  1
2  Diabetes Mellitus Type II              1
3  NO ALLERGIES                           1
4  NO KNOWN ALLERGIES                     1
5  Penicillin                             1
6  WATERMELON                             3
+      Select one or more entries
AE Add/Edit Allergy File  EE Mark entered in error
DD Detailed Display      UR Update to new reactant
Select Item(s): Quit// dd Detailed Display

Reactant Detailed Display      Oct 27, 2003@08:25:50      Page: 1 of 1
Patient listing for reactant WATERMELON
  Patient Name                            Last 4
1  ARTPATIENT,ONE                          0111
Allergies: WATERMELON
2  ARTPATIENT,TWO                          0222
Allergies: WATERMELON
3  ARTPATIENT,THREE                        0333
Allergies: ASPIRIN~WATERMELON
+      Select one or more entries
EE Entered in Error          PR Add/Edit Patient Reaction
UR Update to new reactant    DD Free Text Detailed Display
AE Add/Edit Allergy File
Select Item(s): Quit// 1

```

3. Select an item # in the Detailed Display, then select UR for Update to New Reactant.

```

Reactant Detailed Display      Oct 27, 2003@08:40:29      Page: 1 of 1
Patient listing for reactant WATERMELON
  Patient Name                            Last 4
1  ARTPATIENT,ONE                          0111
Allergies: WATERMELON
2  ARTPATIENT,TWO                          0222
Allergies: WATERMELON
3  ARTPATIENT,THREE                        XXXX
Allergies: ASPIRIN~WATERMELON

Select a patient >>>
EE Entered in Error          PR Add/Edit Patient Reaction
UR Update to new reactant    DD Free Text Detailed Display
AE Add/Edit Allergy File
Select Item(s): Quit// ur Update to new reactant

You are about to update the selected patient's
WATERMELON allergy to a new reactant.

ARE YOU SURE? NO// YES
For patient ARTPATIENT,ONE

Enter Causative Agent: ONION

Checking GMR ALLERGIES (#120.82) file for matches...

Now checking INGREDIENT (#50.416) file for matches...

```


EXTRACT

...OK? Yes//<ENTER> (Yes)

You selected ONION EXTRACT
Is this correct? Y// <ENTER> ES
Performing order checking...No problems found
Press enter to continue: <ENTER>

Reactant Detailed Display Oct 27, 2003@08:44:13 Page: 1 of 1

Patient listing for reactant WATERMELON

	Patient Name	Last 4
1	ARTPATIENT, ONE	0111

Allergies: WATERMELON

2	ARTPATIENT, TWO	0222
---	-----------------	------

Allergies: ASPIRIN~WATERMELON

Select a patient

>>>

EE Entered in Error

PR Add/Edit Patient Reaction

UR Update to new reactant

DD Free Text Detailed Display

AE Add/Edit Allergy File

Select Item(s): Quit//

Add/Edit Patient Reaction

The addition of local reactants and sign/symptoms is no longer allowed. Requests for new terms/concepts should be made through the New Term Rapid Turn-around (NTRT) process.

Reactant Detailed Display	Sep 19, 2003@13:05:28	Page:	1 of 1
Patient listing for reactant DIABETES MELLITUS TYPE II			
Patient Name		Last 4	
1	ARTPATIENT,ONE	0111	
Allergies: AMOXICILLIN~ASPIRIN~MILK~ERYTHROMYCIN~CHROMA-PAK INJECTION~ Diabetes Mellitus Type II~PENICILLINS			
Select a patient			
EE	Entered in Error	PR	Add/Edit Patient Reaction
UR	Update to new reactant	DD	Free Text Detailed Display
AE	Add/Edit Allergy File		
Select Item(s): Quit// PR Add/Edit Patient Reaction			
<p>In support of national standardization of the contents of this file, local site addition and modification functions are no longer available. If you wish to request a new term or modify an existing term, please refer to the New Term Rapid Turnaround (NTRT) web site located at http://vista.med.va.gov/ntrt/. If you have any questions regarding this new term request process, please contact the ERT NTRT Coordinator via e-mail at VHA OI SDD HDS NTRT.</p>			
Press enter to continue: <Enter>			

Add/Edit Allergy File

The addition of local reactants and sign/symptoms is no longer allowed. Requests for new terms/concepts should be made through the New Term Rapid Turn-around (NTRT) process.

Signing off on Allergies

Before patch 17, the allergy tracking package allowed users to leave entries in a “not signed off” state. Although not complete, the allergy became part of the patient’s record, even though you were told that it would not be. Depending on how the entry was made, an alert might not be sent indicating that the entry needed to be signed off. Ultimately, an unfinished entry might never be finished, but still appear in the patient’s record.

A change has been made so that no new entry can be left in a “not signed off” state. Upon entering a new allergy, if you enter an “^” at any point during the data gathering process, the entry will be deleted. Upon completing the new entry, you will be asked if the entry is okay. If you enter no, then you’ll be given the opportunity to edit or delete the entry. The entry must then be deleted or accepted before exiting this process. As a result, no new entries will be allowed to be in an unsigned state.

NOTE: Sites should run the “Patient Allergies Not Signed Off” option to identify all existing entries that have not yet been completed. Each entry should be reviewed and marked as entered-in-error or completed by entering the required information. Once these entries are cleaned up, then no unsigned entries should appear in the patient’s chart. You are not required to update these entries as data may not be available, but you should review them and take action if possible. The post-installation routine will also list any allergies that are observed, have been signed off, but are missing either an observed date or a sign/symptom. These entries should also be reviewed and updated if possible.

```
GMRA CLINICIAN MENU      Adverse Reaction Tracking Clinician Menu

  1      Enter/Edit Patient Reaction Data
  2      FDA Enter/Edit Menu ...
  3      Reports Menu ...
  4      Edit Chart and ID Band
  5      Online Reference Card

Select Adverse Reaction Tracking Clinician Menu Option: 3  Reports Menu

  1      Active Listing of Patient Reactions
  2      Print Patient Reaction Data
  3      Print an FDA Report for a Patient
  4      List by Location of Unmarked ID Bands/Charts
  5      Patient Allergies Not Signed Off
  6      List by Location of Undocumented Allergies
  7      List by Location Not Verified Reactions
  8      List by Location and Date All Signed Reactions
  9      List FDA Data by Report Date

You have PENDING ALERTS
      Enter "VA to jump to VIEW ALERTS option

Select Reports Menu Option: 5  Patient Allergies Not Signed Off

DEVICE: HOME//      ANYWHERE
```

```
ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 9/30/03 12:12:09 pm

ORIGINATOR          PATIENT          ALLERGY          ORINATION DATE/TIME
-----

NO DATA FOR THIS REPORT
Enter RETURN to continue or '^' to exit:
```

NOTE: With GMRA*4.0*21, it is now possible to delete an assessment of NKA from within the ART package.

When you select a patient for entering/editing allergies and that patient doesn't have any active allergies on file, the “Does this patient have any known allergies or adverse reactions?” prompt is presented to you. If the patient has no assessment, there is no default answer. If the patient has been assessed as NKA, the default is NO.

In the case where the default answer is NO (meaning, the patient is NKA), you may enter an @ sign to indicate that the assessment should be deleted and the patient should be returned to the 'not assessed' state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

Adverse Reaction Tracking User Menu

This menu is assigned to all users of Adverse Reaction Tracking who are not clinicians, verifiers, or ADP coordinators. The options on this menu allow you to enter, edit, and display allergy/adverse reaction data.

1. Enter/Edit Patient Reaction Data
2. Active Listing of Patient Reactions
3. Edit Chart and ID Band
4. List by Location of Unmarked ID Bands/Charts
5. Patient Allergies Not Signed Off
6. List by Location of Undocumented Allergies
7. Print Patient Reaction Data
8. Online Reference Card

Enter/Edit Patient Reaction Data

This option allows users to enter and edit patient allergies/adverse reactions. You are prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's ID band is marked for this reaction.

Selecting a Patient:

You may select a patient by name (last name, first name), full Social Security Number (SSN), the last four digits of the SSN (e.g., 1234), the first letter of the last name and last four digits of the SSN (e.g., A1234), or ward location (e.g., 1 North).

Does the patient have any known allergies/adverse reactions?

If the selected patient does not have any allergies/adverse reactions stored in the ART database, you are asked the above question. A Yes response will allow you to make an entry. A No response will take you back to the patient prompt. If the ART database contains allergy/adverse reaction information about the patient, the software will not ask this question, but will instead display information about the existing reactions. The software will display the name of the causative agent, the type of causative agent (e.g., food), any signs/symptoms, its mechanism (e.g., Allergy or Pharmacologic), whether it was an observed reaction or historical, and whether or not it was verified.

Selecting a Causative Agent:

The lookup procedure that is performed when you enter a causative agent deserves a detailed explanation.

- 1) If the causative agent exists as an entry for the patient, then you have the opportunity to edit the data concerning that entry.
- 2) If your response is not part of that patient's entry or you do not want to edit an existing choice given in Step 1, then a lookup for the particular agent is done using six files of choices, which are searched in the following order:
 1. GMR Allergies (#120.82) - this file is distributed with the ART software and contains nationally distributed food and other type agents plus any entries added locally by the facility,
 2. National Drug (#50.6) - this file contains the names of available drug products including trade names and manufacturer, and
 3. National Drug File - Trade Names (#50.67)
 4. Drug (#50) - this file contains the names of drugs that can be used to fill a prescription.
 5. Drug Ingredients (#50.416) - this file contains the names of individual generic drugs which are components of various drug products,
 6. VA Drug Class (#50.605) - this file contains the names of the various drug classes used within the Department,

- 3) If your reactant is not found after Steps 1 and 2, then you are asked “Would you like to send an email requesting (the reactant) be added as a causative agent?” If you answer NO, you will return to the reactant lookup; if you answer yes, you see the message “You may now add any comments you may have to the message that is going to be sent with the request to add this reactant. You may want to add things like sign/symptoms, observed or historical, etc., that may be useful to the reviewer.

Enter RETURN to continue or '^' to exit: “ If enter is pressed, you are allowed to enter comments, and when the comments are saved, you see the message “Message sent - NOTE: This reactant was NOT added for this patient.”

Enter another Causative Agent? YES//” If the you answer YES, you return to the reactant lookup prompt; if you answer NO, you return to the patient lookup prompt. A mail message is generated to the user making the request and to the Mail Group GMRA REQUEST NEW REACTANT, containing the comment entered, the user name and contact information, patient, and the reactant.

NOTE: If a particular causative agent is commonly selected, but it comes from a lookup on one of the later files (i.e., 2b, 2c, 2d or 2e) and the facility wishes to minimize the response lookup time, then that causative agent can be added to the GMR Allergies file as a local entry. Since this is the first file that is looked up in Step 2, the response time will be reduced.

Observed vs. Historical Reaction:

An observed reaction is an event that actually happened to the patient during the patient’s stay/visit at the facility. A historical reaction is one that is reported, but not observed by the facility personnel. If the reaction is observed, you will be asked to enter the observation date. The time of day may be entered, but it is optional.

Observed Report:

For an observed reaction, you are asked for additional information. You may enter the name of the person who observed the reaction (the default response is the name of you entering the data), the severity of the reaction (i.e., mild, moderate or severe), and the date a medical doctor was notified. Also, you may edit the date and time of the observation. You will only see these prompts if you have the GMRA-ALLERGY VERIFY KEY.

Signs/Symptoms:

This file is no longer editable by the site and free text is no longer allowed.

Mechanism:

The mechanism is the type of reaction. The choices are Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions such as exposure to a large amount. Unknown is provided if you are not sure what mechanism to enter. You will only see these prompts if he/she has the GMRA-ALLERGY

NOTE: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

Comments:

The site can determine whether comments from the originator of the entry are required, by setting a software parameter. If that site parameter is set to YES, you are required to enter comments for allergies designated as observed. If the entry is being edited and any existing comments exist for this causative agent, the software will display those comments and their author (the originator of the entry, a verifier, or a person who marked the entry as entered in error). This is only true for OBSERVED type allergies. Comments entered for allergies designated as historical are optional.

FDA Data:

When the type of the causative agent is a drug, you may enter further information about the reaction, which will be used by the software to generate an FDA report. The questions for the FDA report are categorized in four sections. Users are encouraged to provide as much information about the reaction as possible. The site can determine if you will be required to enter FDA data by setting a software parameter. You will only see these prompts if you have the GMRA-ALLERGY VERIFY KEY.

Verification of Data:

Entries can be verified by a user or by the software. The latter is known as autoverification. The site can determine how the entries are verified by setting three software parameters. The combination of these three parameters allows the software to automatically verify none, some, or all entries. Conversely, sites may wish to have their users verify none, some, or all entries. If the entry must be verified by a user and the user has the verification key, GMRAALLERGY VERIFY, the software will allow the verification of the data during the enter/edit option. The user has an opportunity to review and edit the data before verifying the entry.

Generating Progress Notes:

The ART software has an interface to the TIU package. A progress note will be generated when you verify or enter an observed drug reaction, or mark an entry as entered in error. Also, you may print the note. You will only see these prompts if you have the GMRA-ALLERGY VERIFY KEY.

Signing Off on an Entry:

Signing off (i.e., is the data correct?) on an entry means the user who entered/edited the entry is satisfied with the data entered. It does not mean an electronic signature. Users who have the verification key will not be asked to sign off on an entry if they verify it.

Users who have the verification key will be asked to sign off on an entry if they do not verify it. Users who do not have the verification key will be asked to sign off on the entry.

```
Select Adverse Reaction Tracking User Menu Option: 1 Enter/Edit Patient
Reaction Data
Select PATIENT NAME: ARTPATIENT,ONE XX-XX-23 666110111 SC VETERAN
OBS/REACTANT                                VER.  MECH.  HIST  TYPE
```

```

-----
ASPIRIN                AUTO  ALLERGY HIST  DRUG
  Reactions: CHILLS, DRY MOUTH, CHEST PAIN
DILANTIN              YES  ALLERGY OBS  DRUG
(PHENYTOIN)
  Reactions: DROWSINESS
IBUPROFEN            NO   UNKNOWN OBS  DRUG
PENICILLIN           YES  UNKNOWN OBS  DRUG
  Reactions: HIVES, DROWSINESS
PHENOBARBITAL       YES  ALLERGY OBS  DRUG
  Reactions: DEPRESSION
TETRACYCLINE         YES  PHARM   OBS  DRUG
  Reactions: DROWSINESS
Enter Causative Agent: CHEESE
Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

CHEESE OK? Yes// (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction: O OBSERVED

Select date reaction was OBSERVED (Time Optional): t (DEC 06, 2004) DEC
06,
2004 (DEC 06, 2004)
  Are you adding 'DEC 06, 2004' as
    a new ADVERSE REACTION REPORTING? No// y (Yes)

No signs/symptoms have been specified. Please add some now.

The following are the top ten most common signs/symptoms:
 1. CHILLS                7. HIVES
 2. ITCHING,WATERING EYES 8. DRY MOUTH
 3. HYPOTENSION           9. DRY NOSE
 4. DROWSINESS            10. RASH
 5. NAUSEA,VOMITING       11. OTHER SIGN/SYMPTOM
 6. DIARRHEA

Enter from the list above : 10
Date(Time Optional) of appearance of Sign/Symptom(s): Dec 06, 2004// (DEC 06,
2004)

The following is the list of reported signs/symptoms for this reaction:

      Signs/Symptoms                Date Observed
-----
 1  RASH                            Dec 06, 2004

Select Action (A)DD, (D)ELETE OR <RET>:

COMMENTS:
 1>
Complete the observed reaction report? Yes// (Yes)
DATE/TIME OF EVENT: DEC 6,2004//
OBSERVER: CPRS PROVIDER, EIGHT BCC Chief Medical Officer
SEVERITY: m
 1  MILD
 2  MODERATE
Choose 1-2: 1 MILD
DATE MD NOTIFIED: Dec 6,2004// (DEC 06, 2004)
Enter another Causative Agent? YES// n NO

```

Dec 06, 2004@14:02:53

Causative Agent Data edited this Session:
ADVERSE REACTION

CHEESE

Obs/Hist: OBSERVED

Obs d/t: Dec 06, 2004

Signs/Symptoms: RASH (12/6/04) Is this correct? NO// **y** YES

Active Listing of Patient Reactions

This option will give a brief listing of the active (i.e., data that is signed off and not entered in error) allergy/adverse reaction data for a selected patient. You may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms, and when they were observed or if they were historical, and whether it was verified.

If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

Select PATIENT: ARTPATIENT,ONE XX-XX -23 666110111	YES	ACTIVE DUTY
Enrollment Priority:	Category: IN PROCESS	End Date:
DEVICE: HOME// ;;999 ANYWHERE		
ACTIVE ALLERGY/ADVERSE REACTION LISTING		
Run Date/Time: 6/25/04 11:56:58 am		
ARTPATIENT,ONE	666-11-0000	XXX XX,1942 (62)
ADVERSE REACTION	VERIFIED	OBS/ HIST

TYPE: DRUG		
=====		
ALLENT	YES	HIST
ALUMINUM ACETATE	YES	HIST
Reactions: CHILLS (Nov 25, 2002)		
AMOXICILLIN	NO	HIST
AMPICILLIN	NO	HIST
BILBERRY	YES	HIST
CANDESARTAN	YES	HIST
CARAMEL	YES	HIST
Reactions: HIVES (Jan 22, 1998), ITCHING,WATERING EYES (Jan 22, 1998)		
CORICIDIN TAB	YES	OBS
Reactions: CHILLS, HYPOTENSION, NAUSEA,VOMITING		
CORN STARCH	YES	HIST
CORRECTOL	YES	HIST
CORTICOTROPIN	YES	HIST
CORTICOTROPIN/ZINC HYDROXIDE	YES	HIST
EYE WASHES/LUBRICANTS	NO	OBS
Reactions: DROWSINESS		
FILGRASTIM	YES	HIST
HAYFEBROL SF	NO	HIST
Reactions: ITCHING,WATERING EYES		
LOMEFLOXACIN	YES	OBS
Reactions: ITCHING,WATERING EYES (Mar 10, 1999)		
OXYCODONE	YES	HIST
PENICILLINS	NO	HIST

PENTAMIDINE	YES	HIST
PENTAZOCINE	YES	HIST
PENTETIC ACID	YES	HIST
RANITIDINE	YES	OBS
Reactions: CHILLS (Nov 26, 2002@11:16)		
TACRINE	YES	HIST
TAPE	YES	HIST
TAVIST	NO	HIST
TAVIST	NO	HIST
WARFARIN	YES	HIST
WATER	NO	HIST
ZANTAC	YES	HIST
TYPE: DRUG, FOOD		
=====		
CHOCOLATE	YES	HIST
FLUPHENAZINE DECANOATE	NO	HIST
PEANUT OIL	NO	OBS
Reactions:		
	ITCHING, WATERING EYES (Oct 05, 2000@24:00),	
	ANXIETY (Oct 06, 2000@09:27)	
SHELL FISH	NO	HIST
TYPE: FOOD		
=====		
NUTS	YES	HIST
Reactions: HIVES (Jan 02, 1998)		
PEACHES	YES	HIST
STRAWBERRIES	YES	HIST
TYPE: OTHER		
=====		
DUST	YES	HIST
Enter RETURN to continue or '^' to exit:		

Edit Chart and ID Band

All questions have been removed that ask if the patient's chart has been marked – as well as any displays that indicate whether the chart has been marked. The entry of an allergy into CPRS *is* the marking of the chart.

List by Location of Unmarked ID Bands/Charts

This option will produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that you will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1). This applies to Inpatients only. When entering an allergy on an Outpatient, the option to indicate if the ID Band has been marked is not available or displayed.

The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., inpatients), and any date ranges entered by you. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, name of the causative agent, and whether the patient ID band, patient chart, or both were unmarked.

```
Select Adverse Reaction Tracking User Menu Option: 4 List by Location of
Unmarked ID Bands/Charts
    1 Current Inpatients
    2 Outpatients over Date/Time range
    3 New Admissions over Date/Time range
    4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4): 4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-90 (MAR 30, 2004)
Enter END Date (time optional): T// <Enter> (JUN 28, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ?

    You may deselect from the list by typing a '-' followed by location
    name. E.g. -3E would delete 3E from the list of locations already
    selected.
    You may enter the word ALL to select all appropriate locations.
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
    1N
    1S
    GMC DR. PETIT
    PHYSICAL EXAM

Select Location: 1N
Another Location: < Enter>

QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER

Requested Start Time: NOW// <Enter> (JUN 28 2004@13:42:26)
Request queued...
```

Jun 28,2004 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 1
 CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
 FROM Mar 30,2004 TO Jun 28,2004@24:00

PATIENT	SSN	ALLERGY	UNMARKED

WARD: 1A(1&2)			
ARTPATIENT,ONE	666-11-0111	DAVE DRUG	ID BAND/CHART
		DUST	ID BAND/CHART
		AMPICILLIN	ID BAND/CHART
		ASPIRIN	ID BAND/CHART
		CHOCOLATE	ID BAND/CHART
		MILK OF MAGNESIA	ID BAND/CHART
		AMOXICILLIN	ID BAND/CHART
		PENICILLIN	ID BAND/CHART
		MENTHOL	ID BAND/CHART
ARTPATIENT,TWO	666-11-0222	AMOXICILLIN	ID BAND/CHART
		DUST	ID BAND/CHART
		ZANTAC	ID BAND/CHART
ARTPATIENT,THREE	666-11-0333	CEPHALEXIN TABLETS,	ID BAND/CHART
Enter RETURN to continue or '^' to exit:			

Jun 28,2004 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 2
 CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
 FROM Mar 30,2004 TO Jun 28,2004@24:00

PATIENT	SSN	ALLERGY	UNMARKED

		CHEESE	ID BAND/CHART
		BARIUM SULFATE	ID BAND/CHART
		OPIOID ANALGESICS	ID BAND/CHART
		RADIOLOGICAL/CONTRAS	ID BAND/CHART
		FOLIC ACID	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART
		PENICILLIN	ID BAND/CHART

un 28,2004 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 3
 CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
 FROM Mar 30,2004 TO Jun 28,2004@24:00

PATIENT	SSN	ALLERGY	UNMARKED

		ACETANILIDE	ID BAND/CHART
		ANTIRABIES SERUM	ID BAND/CHART
ARTPATIENT,FOUR	666-11-0444	STRAWBERRIES	ID BAND/CHART
ARTPATIENT,FIVE	666-11-0555	CHOCOLATE	ID BAND/CHART
		BLUE CROSS AMPICILLI	ID BAND/CHART
		ACETAMINOPHEN TAB	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART

Enter RETURN to continue or '^' to exit:

Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients who have not been signed off (completed) by the user entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. You may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

```
Select Adverse Reaction Tracking User Menu Option: 5 Patient Allergies
Not Signed Off
Include deceased patients on report? NO//

DEVICE: HOME// < Enter> HYPER SPACE
                ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
                Run Date/Time: 6/28/04 9:18:26 am

ORIGINATOR          PATIENT          ALLERGY          ORIGINATION
DATE/TIME
-----
PROVIDER,ONE ARTPATIENT,ONE (0111) PENICILLIN FEB 18, 2003@10:59
PROVIDER,ONE ARTPATIENT,ONE (0111) FROG FEB 18, 2003@15:14
PROVIDER,ONE ARTPATIENT,ONE (0111) THORAZINE 10MG FEB 22, 2003@13:20
PROVIDER,ONE ARTPATIENT,TWO (0112) PENICILLIN JUN 22, 2003@11:44
PROVIDER,ONE ARTPATIENT,TWO (0112) PHENYTOIN JUN 22, 2003@11:48
PROVIDER,ONE ARTPATIENT,TWO (0112) DEMECARIUM JUN 22, 2003@12:00
PROVIDER,ONE ARTPATIENT,TWO (0112) ASPIRIN JUN 22, 2003@12:08
PROVIDER,ONE ARTPATIENT,TWO (0112) PHENOBARBITAL JUN 25, 2003@10:33
PROVIDER,ONE ARTPATIENT,TWO (0112) PHENOBARBITAL JUN 25, 2003@10:39
PROVIDER,ONE ARTPATIENT,TWO (0112) CODEINE JUN 30, 2003@08:55
PROVIDER,ONE ARTPATIENT,TWO (0112) THOR - PROM AUG 11, 2003@10:35
PROVIDER,ONE ARTPATIENT,TWO (0112) IMMUNE GLOBULIN AUG 18, 2003@10:02
PROVIDER,ONE ARTPATIENT,THREE (0113) CYCLOBENZAPRINE JUL 11, 2004@14:11
PROVIDER,ONE ARTPATIENT,THREE (0113) SULFABENZAMIDE/S JUL 11, 2004@14:14
PROVIDER,ONE ARTPATIENT,THREE (0114) DUCK JAN 06, 2004@11:13
Enter RETURN to continue or '^' to exit: ^
```

List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that you will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered by you. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of
Undocumented Allergies
    1 Current Inpatients
    2 Outpatients over Date/Time range
    3 New Admissions over Date/Time range
    4 All of the above
Enter the number(s) for those groups to be used in this report:(1-4): 4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.
```

NOTE: This report will show patients as not having received an assessment if the assessment was entered after the end date of the range. For this reason, it is recommended to end the range with today. This can be done with an entry of "T" (for Today) at the "Enter END Date (time optional): T/" prompt.

```
Enter START Date (time optional): T-180 (JAN 04, 2004)
Enter END Date (time optional): T// <Enter> (JUL 02, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ??

    You may deselect from the list by typing a '-' followed by location name.
    E.g. -3E would delete 3E from the list of locations already selected.
    You may enter the word ALL to select all appropriate locations.
    Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
Choose from:
    1 CARY'S CLINIC
    13A PSYCH
    1A(1&2)
    2B MED
    8E REHAB MED
    8W SUBSTANCE ABUSE
    CARDIOLOGY
    CT ROOM

Select Location: 1A
Another Location: 2B
Another Location: Cardiology
Another Location: < Enter>

QUEUE TO PRINT ON
```

DEVICE: **SELECT APPROPRIATE PRINTER**

Requested Start Time: NOW// < Enter> (JUL 2, 2004@10:24:00)
Request queued...

Jul 2,2004 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 1
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 4,2004 TO Jul 2,2004@24:00

PATIENT	SSN	PROVIDER

WARD: 1A(1&2)		
ARTPATIENT,ONE	666-00-0111	ARTPROVIDER,ONE
ARTPATIENT,TWO	666-00-1112P	
ARTPATIENT,TWO	666-00-1112	ARTPROVIDER,TWO
Room/Bed: B-2		
ARTPATIENT,THREE	666-12-4443	ARTPROVIDER,THREE
Room/Bed: 9-B		
ARTPATIENT,FOUR	666-00-1114	
ARTPATIENT,FIVE	666-00-1115	
Enter RETURN to continue or '^' to exit:		

Jul 2,2004 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 2
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 4,2004 TO Jul 2,2004@24:00

PATIENT	SSN	PROVIDER

WARD: 2B MED		
ARTPATIENT,SIX	666-00-1116	ARTPROVIDER,FOUR
ARTPATIENT,SEVEN	666-00-1117	
Enter RETURN to continue or '^' to exit:		

Jul 2,2004 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 3
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 4,2004 TO Jul 2,2004@24:00

PATIENT	SSN	PROVIDER

CLINIC: CARDIOLOGY		
ARTPATIENT,EIGHT	666-00-1118	ARTPROVIDER,FIVE
ARTPATIENT,NINE	666-00-1119	
ARTPATIENT,TEN	666-00-1110	
Enter RETURN to continue or '^' to exit:		

If you select a ward/clinic location where no patients meet the report's criteria (i.e., all patients were asked about allergies), then an appropriate message will appear (No Patients for this Ward).

Print Patient Reaction Data

NOTE: Remote (or HDR) allergy data does not appear in the Patient Reaction Data report, but it can be viewed in RDV and VistaWeb.

This option will allow you to produce a captioned data display of all of the patient's allergy/adverse reaction data. You can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

You can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). You then select the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run, and the patient's name, SSN, date of birth, and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select Adverse Reaction Tracking User Menu Option: 7 Print Patient Reaction
Data

Select PATIENT: ARTPATIENT,ONE XX-XX-69 666000111 SC VETERAN
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?: (1-2): 1

DEVICE: HOME// < Enter> HYPER SPACE

                                ALLERGY/ADVERSE REACTION REPORTS
                                Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE                666-00-0111                XX XX,1942 (XX)
-----

STATUS: ACTIVE
-----
TYPE: DRUG
=====

          AGENT: ALLENT
INGREDIENTS: PSEUDOEPHEDRINE                VA DRUG CLASSES: ANTIHISTAMINE/DECONGE
          BROMPHENIRAMINE

ORIGINATOR: CRPROVIDER,ONE                ORIGINATED: MAR 17, 2004@14:34
SIGN OFF: YES                            OBS/HIST: HISTORICAL

ID BAND MARKED:                            CHART MARKED: MAR 17, 2004@14:34:16

          MECHANISM: ALLERGY

ARTPATIENT,ONE                666-00-0111                XX XX,1942 (XX)
-----
```

```

VERIFIER: AUTOVERIFIED                                VERIFIED: MAR 17, 2004@14:34:17
.....
AGENT: ALUMINUM ACETATE
INGREDIENTS: ALUMINUM ACETATE                        VA DRUG CLASSES:

ORIGINATOR: ARTPROVIDER,ONE                          ORIGINATED: NOV 26, 2002@11:25
SIGN OFF: YES                                         OBS/HIST: HISTORICAL

ID BAND MARKED:                                       CHART MARKED:

SIGNS/SYMPTOMS: CHILLS (Nov 25, 2002)

MECHANISM: UNKNOWN

VERIFIER: AUTOVERIFIED                                VERIFIED: NOV 26, 2002@11:26:27
.....
AGENT: AMOXICILLIN
INGREDIENTS: AMOXICILLIN                            VA DRUG CLASSES: PENICILLINS,AMINO DER

ORIGINATOR: ARTPROVIDER,TWO                          ORIGINATED: JAN 21, 1998@10:20
SIGN OFF: YES                                         OBS/HIST: HISTORICAL

ID BAND MARKED:                                       CHART MARKED:

MECHANISM: UNKNOWN

.....
AGENT: AMPICILLIN
INGREDIENTS: AMPICILLIN                            VA DRUG CLASSES:

ORIGINATOR: ARTPROVIDER,ONE                          ORIGINATED: JAN 21, 1998@10:25
SIGN OFF: YES                                         OBS/HIST: HISTORICAL

ID BAND MARKED:                                       CHART MARKED:

MECHANISM: UNKNOWN

```

Adverse Reaction Tracking Clinician Menu

This menu is assigned to all clinicians of Adverse Reaction Tracking who are not verifiers or ADP coordinators. The options on this menu allow users to enter, edit, and display allergy data, enter Food and Drug Administration report data, run various reports of importance to the clinician, and edit the patient's chart and identification band.

This menu should only be given to the clinicians of ART. This option contains the following options:

1. Enter/Edit Patient Reaction Data
2. FDA Enter/Edit Menu ...
3. Reports Menu ...
4. Edit Chart and ID Band
5. Online Reference Card

Enter/Edit Patient Reaction Data

This option allows users to enter and edit patient allergies/adverse reactions. You are prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs/symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's chart is marked for this reaction.

See Page 40 for descriptions of the prompts for this option. Enter/Edit Patient Reaction Data

Example

```
Select Adverse Reaction Tracking Clinician Menu Option: 1 Enter/Edit Patient Reaction Data

Select PATIENT NAME: CPRSPATIENT,TWO          XX-XX-42      666324321      YES
ACTIVE DUTY
  Enrollment Priority:          Category: NOT ENROLLED  End Date: 07/06/2004

REACTANT                                VER.  MECH.  HIST  TYPE
-----                                -
ACE INHIBITORS                          NO    UNKNOWN HIST  DRUG
ALLENT                                  AUTO  ALLERGY HIST  DRUG
  (BROMPHENIRAMINE, PSEUDOEPHEDRINE)
ALUMINUM ACETATE                         AUTO  UNKNOWN HIST  DRUG
  Reactions: CHILLS
AMOXICILLIN                              YES   UNKNOWN HIST  DRUG
AMPICILLIN                               YES   UNKNOWN HIST  DRUG
BILBERRY                                  AUTO  UNKNOWN HIST  DRUG
  (BILBERRY EXTRACT)
CANDESARTAN                              AUTO  ALLERGY HIST  DRUG
CARAMEL                                  YES   ALLERGY HIST  DRUG
  Reactions: HIVES, ITCHING,WATERING EYES
CORICIDIN TAB                            AUTO  ALLERGY OBS  DRUG
  Reactions: CHILLS, HYPOTENSION, NAUSEA,VOMITING
CORN STARCH                              AUTO  ALLERGY HIST  DRUG
  (CORN OIL)
CORRECTOL                                AUTO  ALLERGY HIST  DRUG
CORTICOTROPIN                            AUTO  PHARM  HIST  DRUG

Press RETURN to continue or '^' to stop listing: ^

Enter Causative Agent: cheese

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...

  CHEESE  OK? Yes// <Enter> (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction: o OBSERVED
Select date reaction was OBSERVED (Time Optional): t (DEC 06, 2004) DEC 06, 2004
(DEC 06, 2004)
Are you adding 'DEC 06, 2004' as
a new ADVERSE REACTION REPORTING? No// y (Yes)
```

No signs/symptoms have been specified. Please add some now.

The following are the top ten most common signs/symptoms:

- | | |
|---------------------------|------------------------|
| 1. CHILLS | 7. HIVES |
| 2. ITCHING, WATERING EYES | 8. DRY MOUTH |
| 3. HYPOTENSION | 9. DRY NOSE |
| 4. DROWSINESS | 10. RASH |
| 5. NAUSEA, VOMITING | 11. OTHER SIGN/SYMPTOM |
| 6. DIARRHEA | |

Enter from the list above : 10

Date(Time Optional) of appearance of Sign/Symptom(s): Dec 06, 2004//<Enter> (DEC 06, 2004)

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms	Date Observed
1 RASH	Dec 06, 2004

Select Action (A)DD, (D)ELETE OR <RET>: <RET>

COMMENTS:

1>

Complete the observed reaction report? Yes// <RET> (Yes)

DATE/TIME OF EVENT: DEC 6, 2004//

OBSERVER: CPRSPROVIDER,EIGHT BCC Chief Medical Officer

SEVERITY: m

1 MILD

2 MODERATE

Choose 1-2: 1 MILD

DATE MD NOTIFIED: Dec 6, 2004// <Enter> (DEC 06, 2004)

Enter another Causative Agent? YES// n NO

Dec 06, 2004@14:02:53

Causative Agent Data edited this Session:

ADVERSE REACTION

CHEESE

Obs/Hist: OBSERVED

Obs d/t: Dec 06, 2004

Signs/Symptoms: RASH (12/6/04)

Is this correct? NO// y YES

Enter Hospital Location:

Opening Adverse React/Allergy record for review...

Browse Document Dec 06, 2004@14:02:53 Page: 1 of 1

Adverse React/Allergy

CPRSPATIENT,T 666-32-4321

Visit Date: 12/06/2004 14:02

DATE OF NOTE: DEC 06, 2004@14:02:50 ENTRY DATE: DEC 06, 2004@14:02:52

AUTHOR: CRPROVIDER,TWO

EXP COSIGNER:

URGENCY:

STATUS: UNSIGNED

This patient has had the following reactions

signed-off on Dec 06, 2004@14:02:50.

CHEESE

+ Next Screen - Prev Screen ?? More actions >>>		
Find	Sign/Cosign	Link ...
Print	Copy	Encounter Edit
Edit	Identify Signers	Interdiscipl'ry Note
Make Addendum	Delete	Quit

Select Action: Quit//<Enter>
Select PATIENT NAME: <Enter>

FDA Enter/Edit Menu (Clinician)

This menu should be given to users responsible for the FDA portion of Adverse Reaction Tracking as designated by the site. The options on this menu allow users to enter and edit the FDA data.

1. Enter/Edit FDA Report Data
2. Enter/Edit P&T Committee Data

Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, you may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), you may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date, and how the drug was given (SIG Code). You can also enter a word-processing type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), you may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (i.e., Health Professional), whether the 15-day report was completed and the type of the report (e.g., Initial).

The Initial Reporter (5) section allows you to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option: 1 Enter/Edit FDA Report Data

Select PATIENT NAME: ARTpatient,Two 04-25-31 666001112 SC VETERAN

Select CAUSATIVE AGENT: ASPIRIN 10-04-69 666001112 SC VETERAN
ASPIRIN
Select date reaction was OBSERVED (Time Optional): T-10 (JAN 13, 2004) JAN
13, 1996 (JAN 13, 2004)
Are you adding 'JAN 13, 2004as
a new ADVERSE REACTION REPORTING? Y (Yes)
Indicate which FDA Report Sections to be completed:
1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter
Choose number(s) of sections to be edited: (1-5): 1

The following is the list of reported signs/symptoms for this reaction:
Signs/Symptoms
-----
1 ANXIETY

Select Action (A)DD OR (D)ELETE: A
```

The following are the top ten most common signs/symptoms:

1. ANXIETY 7. HIVES
2. ITCHING, WATERING EYES 8. DRY MOUTH
3. HYPOTENSION 9. CHILLS
4. DROWSINESS 10. RASH
5. CHEST PAIN 11. OTHER SIGN/SYMPTOM
6. DIARRHEA

Enter from the list above : 7

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms

-
- 1 ANXIETY
 - 2 HIVES

Select Action (A)DD OR (D)ELETE: < Enter>

Patient died?: N NO

Reaction treated with RX drug?: N NO

Life Threatening illness?: N NO

Required hospitalization?: N NO

Prolonged Hospitalization?: N NO

Resulted in permanent disability?: N NO

Is this event a Congenital Anomaly?: N NO

Did this event require intervention to prevent impairment/damage?: N NO

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT

Select Action (A/D/E): ADD

View Tx/Test from: JAN 13, 2004// < Enter> (JAN 13, 2004)

To: JAN 13, 2004// < Enter> (JAN 13, 2004)

LAB TEST:

Collection DT Test Name Specimen Results Hi/Low

THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.

Select TEST: ??

Choose from:

1,25-DIHYDROXYVIT D3

1/2HR LTT

1/2Hr.GTT

1/2Hr.GTT (URINE)

11-DEOXYCORTISOL

17-HYDROXYCORTICOSTEROIDS

17-HYDROXYPROGESTERONE

17-KETOGENIC STEROIDS

17-KETOSTEROIDS, TOTAL

1HR LTT

1Hr.GTT

1Hr.GTT (URINE)

25 OH VITAMIN D

2HR LTT

2Hr.GTT

2Hr.GTT (URINE)

3HR LTT

3Hr.GTT

3Hr.GTT (URINE)

4Hr.GTT

4Hr.GTT (URINE)

^

Select TEST: **1/2Hr.GTT (URINE)**

Are you adding '1/2Hr.GTT (URINE)' as
a new RELEVANT TEST/LAB DATA (the 1ST for this ADVERSE REACTION
REPORTING)? **Y** (Yes)

RESULTS: ??

This field will contain the results for the particular test.

RESULTS: Enter results here.

COLLECTION D/T: **T-10** (JAN 13, 2004)

Select TEST:

This patient has the following Test selected:

TEST/TX RESULTS DRAW DATE/TIME

1) 1/2Hr.GTT (URINE) Enter results here. 01/13/96

Select Action (A/D/E):

Indicate which FDA Report Sections to be completed: < Enter>

1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter

Choose number(s) of sections to be edited: (1-5): < Enter>

Enter/Edit P&T Committee Data

This option will allow you to edit P&T data. It allows for the evaluation of a suspected Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician.

You can also track a report to see if it has been sent to the FDA or manufacturer.

```
Select FDA Enter/Edit Menu Option: 2 Enter/Edit P&T Committee Data
Select PATIENT NAME: ARTpatient,One 10-04-69 666110111 SC VETERAN

Select CAUSATIVE AGENT: PENICILLIN 10-04-69 666110111 SC VETERAN PENICILLIN
Select date reaction was OBSERVED (Time Optional): T (JAN 24, 2004) JAN
24, 2004 (JAN 24, 2004)
  Are you adding 'JAN 24, 2004as
  a new ADVERSE REACTION REPORTING? Y (Yes)

P&T Report Completion
Serious ADR?: ??
  This field determines if the reaction is considered serious.
  Choose from:
    y YES
    n NO
Serious ADR?: y YES
ADR related to new drug?: n NO
Unexpected ADR?: y YES
ADR related to therapeutic failure?: n NO
Dose related?: n NO
P&T ACTION FDA REPORT: ??
  This field indicates if the P&T committee determined whether to send
  the report to FDA.
  Choose from:
    y YES
    n NO
P&T ACTION FDA REPORT: n NO
P&T ACTION MFR REPORT: n NO

ADDENDUM:
  1>ADD COMMENTS HERE
  2>
EDIT Option: < Enter>

Select PATIENT NAME: < Enter>
```

Reports Menu (Clinician)

This menu is part of the Adverse Reaction Tracking Clinician Menu. It is the only print option that the clinician needs for ART.

1. Active Listing of Patient Reactions
2. Print Patient Reaction Data
3. Print an FDA report for a Patient
4. List by Location of Unmarked ID Bands/Charts
5. Patient Allergies Not Signed Off
6. List by Location of Undocumented Allergies
7. List by Location Not Verified Reactions
8. List by Location and Date all Sign Reaction
9. List FDA data by Report Date

Active Listing of Patient Reactions

NOTE: This report lists the local data only. HDR data will not be included on these reports. Use VistaWeb and RDV to see remote data.

This option gives a brief listing of the active (data that is signed off and not entered in error) allergy/adverse reaction data for a particular patient. This report may be sent to a printer for a hard copy printout or displayed to the terminal screen. You may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms, and when they were observed or if they were historical, and whether it was verified. If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

```
Select Reports Menu Option: 1 Active Listing of Patient Reactions
Select PATIENT: ARTpatient,One XXX-XX-69 666000111 ACTIVE DUTY
DEVICE: HOME// < Enter> HYPER SPACE
```

ACTIVE ALLERGY/ADVERSE REACTION LISTING
Run Date/Time: 7/6/04 1:51:13 pm

ARTPATIENT,ONE 666122222 XX XX,1942 (XX)

ADVERSE REACTION	VERIFIED	OBS/ HIST

TYPE: DRUG		
=====		
ACETAMINOPHEN Reactions: ANXIETY (Jun 06, 2001@10:21)	NO	OBS
ACETANILIDE Reactions: CHILLS	NO	HIST
ALOE VERA Reactions: ANXIETY (Mar 06, 1997)	YES	OBS
ASPIRIN Reactions: RASH (Oct 31, 2001)	NO	HIST
ASPIRIN/BUTALBITAL/CAFFEINE Reactions: NAUSEA,VOMITING (Oct 31, 2001)	NO	HIST
BARIUM SULFATE Reactions: HIVES	YES	OBS
BERROPLEX Reactions: DROWSINESS	NO	HIST
CEPHALEXIN TABLETS, 250MG Reactions: THROMBOCYTOPENIA	YES	OBS
DILANTIN Reactions: CHILLS	NO	OBS
ERYTHROMYCINS/MACROLIDES Reactions: ITCHING,WATERING EYES (Mar 06, 1997)	YES	OBS
GREEN SOAP Reactions: ANXIETY (May 19, 1997@14:25)	YES	OBS
GREEN SOAP TINCTURE Reactions: DRY MOUTH (May 19, 1997@14:23)	YES	OBS
HALENOL 500MG CAPSULES Reactions: ANXIETY (May 19, 1997@14:26)	YES	HIST
HAYFEBROL SF	NO	HIST

Reactions: CHILLS, ITCHING, WATERING EYES		
OPIOID ANALGESICS	NO	OBS
Reactions: ITCHING, WATERING EYES		
PENICILLIN	NO	OBS
Reactions: NAUSEA, VOMITING, DIARRHEA		
PENICILLINS, AMINO DERIVATIVES	YES	HIST
Reactions: DEPRESSION (Jan 01, 1980)		
RADIOLOGICAL/CONTRAST MEDIA	YES	OBS
Reactions: HIVES		
WARFARIN	YES	OBS
Reactions: HIVES (Mar 01, 1996)		
TYPE: DRUG, FOOD		
=====		
ANTIRABIES SERUM	NO	OBS
Reactions: CHILLS (Jun 08, 2004)		
BEER	NO	HIST
Reactions: HYPOTENSION		
SUNFLOWER OIL	NO	HIST
TYPE: FOOD		
=====		
CHEESE	YES	HIST
Reactions: NAUSEA, VOMITING, DIARRHEA		
FOLIC ACID	YES	HIST
Reactions: DRY NOSE		
STRAWBERRIES	YES	OBS
Reactions: RASH		
WATER	NO	HIST
Reactions: CHILLS		
Enter RETURN to continue or '^' to exit: ^		

Print Patient Reaction Data

This option allows you to get a captioned data display of all of the patient's allergy/adverse reaction data. You can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

You can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). You then select the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run, and the patient's name, SSN, date of birth, and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select PATIENT: ARTPATIENT, TWO      X-XX-31      666001112P      YES      MILITARY RETIREE
Enrollment Priority: GROUP 2      Category: IN PROCESS      End Date:

Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?: (1-2): 1

DEVICE: HOME// ;;999 ANYWHERE

                                ALLERGY/ADVERSE REACTION REPORTS
                                Run Date/Time: 7/6/04 1:54:59 pm
ARTPATIENT, TWO                666001112P                XX XX,1930 (XX)
-----

STATUS: ACTIVE
-----
TYPE: DRUG
=====

AGENT: ACETAMINOPHEN
INGREDIENTS: ALCOHOL                VA DRUG CLASSES: NON-OPIOID ANALGESICS
              ACETAMINOPHEN                PHARMACEUTICAL AIDS/R
              PHENYLALANINE

ORIGINATOR: ARTPROVIDER, ONE        ORIGINATED: JUN 06, 2001@10:21
SIGN OFF: YES                        OBS/HIST: OBSERVED

ID BAND MARKED:                    CHART MARKED:

SIGNS/SYMPTOMS: ANXIETY (Jun 06, 2001@10:21)
MECHANISM: UNKNOWN

.....
AGENT: ACETANILIDE
INGREDIENTS: ACETANILIDE                VA DRUG CLASSES: PHARMACEUTICAL AIDS/R

ORIGINATOR: ARTPROVIDER, ONE        ORIGINATED: AUG 26, 2003@14:44
SIGN OFF: YES                        OBS/HIST: HISTORICAL

ID BAND MARKED:                    CHART MARKED:

SIGNS/SYMPTOMS: CHILLS
```

MECHANISM: UNKNOWN

```
.....
AGENT: ALOE VERA
INGREDIENTS: ALOE VERA                VA DRUG CLASSES: DERMATOLOGICALS, TOPIC

ORIGINATOR: ARTPROVIDER, THREE        ORIGINATED: MAR 06, 1997@14:14
SIGN OFF: YES                          OBS/HIST: OBSERVED

ORIGINATOR
COMMENTS:
    Date: Mar 06, 1997@14:14          User: ARTNURSE, ONE
                                      Title: NURSE
    TESTING

ID BAND MARKED:                        CHART MARKED:

SIGNS/SYMPTOMS: ANXIETY (Mar 06, 1997)

MECHANISM: UNKNOWN

VERIFIER: AUTOVERIFIED                 VERIFIED: FEB 16, 2004@11:44:19

VERIFIER
COMMENTS:
    Date: Feb 16, 2004@11:44:19      User: ARTPROVIDER, ONE
                                      Title: PHYSICIAN
    Auto-verified by patch 19 post-install

.Enter RETURN to continue or '^' to exit: ^
```

Print an FDA Report for a Patient

This option allows you to print an individual FDA report for a patient.

This option will also produce a listing of all allergy/adverse reactions that are awaiting sign-off by the person entering the data into the system. The report should be queued to run on a printer with a 132-column width.

```

Select Reports Menu Option: 3 Print an FDA Report for a Patient
Select PATIENT NAME: ARTPATIENT,THREE 12-01-34 666124443 SC VETERAN
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
  AMPICILLIN
  CYCLOSPORINE
  GENTAMICIN
  PENICILLIN

Select CAUSATIVE AGENT: AMPI 12-01-34 111124443 SC VETERAN
  AMPICILLIN
Select date reaction was OBSERVED (Time Optional): 1/10/96 (JAN 10,
1996).1249
  ...OK? Yes// (Yes)
THIS REPORT SHOULD BE SENT TO A 132 COLUMN PRINTER.

QUEUE TO PRINT ON
DEVICE: PRINTER 132 (132 COLUMN)

Requested Start Time: NOW// < Enter> (JAN 25, 1996@10:36:17)
Request queued...
  
```

MEDWatch		Approved by FDA on 10/20/93	
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM		Triage unit sequence #	

Page 1 of 1			
=====			
A. Patient Information		C. Suspect Medication(s)	
1. Patient Identifier 2. DOB: XX/XX/34 3. Sex 4. Weight		1. Name	
T4443 AGE: XX yrs FEMALE 0.0		#1 : AMPICILLIN	
-----		-----	
B. Adverse Event or Product Problem		2. Dose, frequency & route used	
1. <input checked="" type="checkbox"/> Adverse Event <input type="checkbox"/> Product problem		#1: -----	
2. Outcomes attributed to adverse event		3. Therapy dates	
<input type="checkbox"/> death: <input type="checkbox"/> disability <input type="checkbox"/> life-threatening <input type="checkbox"/> congenital anomaly <input type="checkbox"/> Hospitalization <input type="checkbox"/> required intervention to initial or prolonged prevent impairment/damage <input checked="" type="checkbox"/> other		#1: -----	
3. Date of event		4. Diagnosis for use (indication)	
01/10/96		#1: -----	
4. Date of this report		5. Event abated after use	
01/30/96		stopped or dose reduced?	
5. Describe event or problem		#1: [N/A]	
RASH		6. Lot # (if known)	
-----		#1: -----	
6. Relevant test/laboratory data. including dates		7. Exp. date	
treatment)		#1: -----	
-----		8. Event reappeared after	
7. Other relevant History, including preexisting medical		reintroduction	
conditions		#1: []	
-----		9. (Not applicable to adverse drug event reports)	
D. Suspect Medical Devices		-----	
Note: Please use the actual MedWatch form if the event		10. Concomitant medical products/therapy dates (exclude	
involves a suspected device as well as a suspect drug		-----	
E. Reporter		-----	
-----		-----	

<p>=====</p> <p>Mail to: MedWatch 5600 Fishers Lane Rockville, MD XXXXX</p> <p>or FAX to: 1-800-FDA-0178</p> <p>Manufacturer,</p> <p>FDA Form 3500</p> <p>=====</p> <p>Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.</p>	<p>1. Name, address & phone #:</p> <p>-----</p> <p>2. Health professional? <input type="checkbox"/> 3. Occupation 4. Reported to Mfr. [] [NO]</p> <p>-----</p> <p>5. If you don't want your identity disclosed to the place an "X" in the box. <input type="checkbox"/></p>
--	--

List by Location of Unmarked ID Bands/Charts

This option will find all patients in the system who have not had their ID bands or charts marked. This option will also produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that you will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

```
Select Reports Menu Option: 4 List by Location of Unmarked ID Bands/Charts
  1 Current Inpatients
  2 Outpatients over Date/Time range
  3 New Admissions over Date/Time range
  4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4): 4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-90 (APR 07, 2004)
Enter END Date (time optional): T// < Enter> (JUL 06, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ?

  You may deselect from the list by typing the - followed by location
  name.
  E.g. -3E would delete 3E from the list of locations already
  selected.
Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
  1A
  1S
  GMC DR. PETIT
  PHYSICAL EXAM
Select Location: 1A
Another Location: < Enter>

QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER
Requested Start Time: NOW// < Enter> (JUL 6 2004@13:42:26)
Request queued...
```

```
Jul 6,2004          PATIENTS WITH UNMARKED ID BAND/CHART          PAGE 1
                   CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                   FROM Apr 7,2004          TO Jul 6,2004@24:00

PATIENT              SSN              ALLERGY              UNMARKED
-----
                WARD: 1A(1&2)
ARTPATIENT, ONE      666-00-0111          Da DRUG              ID BAND/CHART
                   DUST              ID BAND/CHART
                   AMPICILLIN          ID BAND/CHART
                   ASPIRIN            ID BAND/CHART
                   CHOCOLATE          ID BAND/CHART
                   MILK OF MAGNESIA    ID BAND/CHART
                   AMOXICILLIN        ID BAND/CHART
                   PENICILLIN          ID BAND/CHART
                   MENTHOL            ID BAND/CHART
ARTPATIENT, TWO      666-00-1112          AMOXICILLIN          ID BAND/CHART
                   DUST              ID BAND/CHART
```

ARTPATIENT, THREE	666-00-1113	ZANTAC	ID BAND/CHART
		CEPHALEXIN TABLETS,	ID BAND/CHART
		CHEESE	ID BAND/CHART
		BARIUM SULFATE	ID BAND/CHART
		OPIOID ANALGESICS	ID BAND/CHART
		RADIOLOGICAL/CONTRAS	ID BAND/CHART
		FOLIC ACID	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART
ARTPATIENT, FOUR	666-00-1114	STRAWBERRIES	ID BAND/CHART
ARTPATIENT, FIVE	666-00-1115	CHOCOLATE	ID BAND/CHART
		BLUE CROSS AMPICILLI	ID BAND/CHART
		ACETAMINOPHEN TAB	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART
		ASPIRIN/BUTALBITAL	ID BAND/CHART

Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients that have not been signed off (completed) by the user entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. You may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

```
Select Reports Menu Option: 5 Patient Allergies Not Signed Off
DEVICE: HOME// < Enter> HYPER SPACE
ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
Run Date/Time: 1/18/96 1:23:52 pm
ORIGINATOR          PATIENT                      ALLERGY          ORIGINATION DATE/TIME
-----
ARTPROVIDER,ONE    ARTPATIENT,ONE (0111)      PENICILLIN      FEB 18, 1993@10:59
ARTPROVIDER,ONE    ARTPATIENT,ONE (0111)      FROG            FEB 18, 1993@15:14
ARTPROVIDER,ONE    ARTPATIENT,TWO (0112)      THORAZINE 10MG  FEB 22, 1993@13:20
ARTPROVIDER,ONE    ARTPATIENT,THREE (0113)    PENICILLIN      JUN 22, 1993@11:44
ARTPROVIDER,ONE    ARTPATIENT,THREE (0113)    PHENYTOIN       JUN 22, 1993@11:48
ARTPROVIDER,ONE    ARTPATIENT,THREE (0113)    DEMECARIUM      JUN 22, 1993@12:00
ARTPROVIDER,ONE    ARTPATIENT,THREE (0113)    ASPIRIN         JUN 22, 1993@12:08
ARTPROVIDER,ONE    ARTPATIENT,FOUR (0114)    PHENOBARBITAL   JUN 25, 1993@10:33
ARTPROVIDER,ONE    ARTPATIENT,THREE (0113)    PHENOBARBITAL   JUN 25, 1993@10:39
ARTPROVIDER,ONE    ARTPATIENT,TWO (0112)      CODEINE         JUN 30, 1993@08:55
ARTPROVIDER,ONE    ARTPATIENT,FIVE (0115)     THOR - PROM     AUG 11, 1993@10:35
ARTPROVIDER,ONE    ARTPATIENT,FIVE (0115)     IMMUNE GLOBULIN AUG 18, 1993@10:02
ARTPROVIDER,ONE    ARTPATIENT,FIVE (0115)     CYCLOBENZAPRINE JUL 11, 1994@14:11
ARTPROVIDER,ONE    ARTPATIENT,FIVE (0115)     SULFABENZAMIDE/S JUL 11, 1994@14:14
Enter RETURN to continue or '^' to exit: ^
```


List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that you will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of Undocumented Allergies
  1 Current Inpatients
  2 Outpatients over Date/Time range
  3 New Admissions over Date/Time range
  4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4): 4
Enter date/time range in which patients were admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-180 (JAN 08, 2004)
Enter END Date (time optional): T// (JUL 06, 2004)
Select Location: 2B MED
Another Location: 1A(1&2)
Another Location:<Enter>
QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER
Requested Start Time: NOW// < Enter> (JAN 19, 1996@10:29:44)
Request queued...

Jul 6,2004          PATIENTS NOT ASKED ABOUT ALLERGIES          PAGE 1
                  CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                  FROM Jan 8,2004      TO Jul 6,2004@24:00

PATIENT          SSN          PROVIDER
-----
                WARD: 1A(1&2)
ARTPATIENT,FIVE          666-00-0115          ARTPROVIDER,ONE
ARTPATIENT,THREE          666-00-0113
ARTPATIENT,TWO           666-00-0112          ARTPROVIDER,TWO
Room/Bed: B-2
ARTPATIENT,FOUR          666-00-0114          ARTPROVIDER,FOUR
Room/Bed: 9-B
Enter RETURN to continue or '^' to exit:<Enter>

Jul 6,2004          PATIENTS NOT ASKED ABOUT ALLERGIES          PAGE 2
                  CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
                  FROM Jan 8,2004      TO Jul 6,2004@24:00

PATIENT          SSN          PROVIDER
-----
                WARD: 2B MED
ARTPATIENT,SIX           666-00-0116          ARTPROVIDER,FOUR
ARTPATIENT,SEVEN          666-00-0117          ARTPROVIDER,FOUR
Enter RETURN to continue or '^' to exit: <Enter>
```

List by Location Not Verified Reactions

This option prints a list of patient reactions that have not been verified. The data is sorted by hospital location, patient, and reaction. You can send the report to a printer for a hard copy or to the terminal screen. This report can be scheduled to automatically run at a regular interval (e.g., daily). Contact your ADPAC or IRM support person to schedule this report to automatically run. The option name to schedule this report to automatically run is GMRA TASK A/AR NV.

The header of this report contains the name of the report, the date it was run, and the hospital location. The body contains the patient's name and SSN, the causative agent, the name of the originator of the reaction, and the date/time of data origination. The Room-Bed is also displayed for each patient.

```
Select Reports Menu Option: 7 List by Location Not Verified Reactions

DEVICE: HOME// ANYWHERE
Report Date: Jul 06, 2004 Page: 1
List of Unverified Reactions by Ward Location
Ward Location: 13A PSYCH
-----
Orignation Date/Time      Originator      Reaction
-----
ARTPATIENT,ONE (666-00-0111)
Jul 16, 2003@11:49      ARTPROVIDER,ONE      RANITIDINE
ARTPATIENT,TWO (666-00-0112)
Jul 09, 1996@08:04      ARTPROVIDER,TWO      STRAWBERRIES
ARTPATIENT,THREE (666-00-0113)
Jul 09, 1996@08:04      ARTPROVIDER,TWO      DUST
ARTPATIENT,FOUR (666-00-0114)
Jul 09, 1996@08:04      ARTPROVIDER,TWO      FISH LIVER OIL
ARTPATIENT,FIVE (666-00-0115)
May 24, 1999@14:21      ARTPROVIDER,THREE      MILK
Jul 02, 1999@13:40      ARTPROVIDER,THREE      BERGAMOT
Aug 20, 1999@09:27      ARTPROVIDER,THREE      RANITIDINE
Enter RETURN to continue or '^' to exit:
```

List by Location and Date all Signed Reactions

This option prints a list of all patient reactions that have been signed off (completed) for a user supplied date range. The data is sorted by location and date range. This report can be sent to a printer for a hard copy printout or displayed on your terminal screen.

The header of the report contains the title, the date range selected by you, the date that the report was run, and the hospital location. The body of the report contains the patient's name and SSN, the causative agent's name and type, the name of the data's originator, and the date/time of data origination.

```
Select Reports Menu Option: List by Location and Date All Signed Reactions
Enter Start Date: t-180 (JAN 08, 2004)
Enter Ending Date: t (JUL 06, 2004)

DEVICE: HOME// ANYWHERE

One moment please...

Jul 06, 2004 Page: 1
List all Signed Patient Reactions for Ward Location 1A(1&2)
From Jan 08, 2004 to Jul 06, 2004@24:00
Date Originator Type Causative Agent
-----
Patient: ARTPATIENT,SIX (666-00-0116)
Jan 12, 2004@12:56 ARTPROVIDER,ONE D HAYFEBROL SF
Jun 11, 2004@15:25 ARTPROVIDER,TWO D DIRITHROMYCIN
Jun 08, 2004@12:15 ARTPROVIDER,THREE DF ANTIRABIES SERUM

Patient: ARTPATIENT,SEVEN (666-00-0117)
Feb 26, 2004@11:29 ARTPROVIDER,ONE D ZANTAC
May 04, 2004@10:52 ARTPROVIDER,ONE D FORMALDEHYDE
May 04, 2004@10:55 ARTPROVIDER,ONE D CONTACT LENS WETTING
SOLN
May 04, 2004@10:56 ARTPROVIDER,ONE D NICO 400
May 04, 2004@10:57 ARTPROVIDER,ONE DF CORN
May 04, 2004@11:00 ARTPROVIDER,ONE DF BCG VACCINE

Patient: ARTPATIENT,EIGHT (666-00-0118)
Feb 26, 2004@11:31 ARTPROVIDER,ONE D ZANTAC

Patient: ARTPATIENT,NINE (666-00-0119)
Feb 05, 2004@10:51 ARTPROVIDER,TWO F STRAWBERRIES
Enter RETURN to continue or '^' to exit:
```

List FDA Data by Report Date

This option displays a report of FDA data that tracks when a reaction was observed and when it was entered into the database. You must enter a date range. This report can be printed or sent to the terminal screen.

The header of the report contains the name of the report, the date range that you selected, and the date that the report was run. The body of the report contains the patient's name and SSN, the name of the causative agent, the patient's location, the observation date of the reaction, the date the reaction was actually reported, the difference (i.e., the number of days) between the observation date and when it was reported, and the name of the person who observed the reaction.

```
Select Reports Menu Option: 9 List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date: t-180 (JAN 08, 2004)
Enter Ending Date: t (JUL 06, 2004)

DEVICE: HOME// ANYWHERE

Report Date: Jul 06, 2004 Page: 1
Adverse Reaction Tracking Report
From: 1/8/04 To: 7/6/04
Patient Dates Related Reaction
-----
ARTPATIENT, ONE Obs DT: 1/27/04 DUST
(666-00-1111) Trk DT: 1/27/04
Loc: 1A(1&2) -----
Obs: ARTPROVIDER, ONE 0 Days Difference

ARTPATIENT, TWO Obs DT: 1/30/04 CHOCOLATE
(666-00-1112) Trk DT: 1/30/04
Loc: OUT PATIENT -----
Obs: ARTPROVIDER, ONE 0 Days Difference

ARTPATIENT, THREE Obs DT: 1/30/04 CHOCOLATE
(355-67-1996) Trk DT: 1/30/04
Loc: 8E REHAB MED -----
Obs: ARTPROVIDER, ONE 0 Days Difference

ARTPATIENT, FOUR Obs DT: 2/2/04 ZANTAC
(666-00-0114) Trk DT: 2/2/04
Loc: 1A(1&2) -----
Obs: ARTPROVIDER, ONE 0 Days Difference

Enter RETURN to continue or '^' to exit:
```

Edit Chart and ID Band

This option allows you to enter whether a patient's ID band or the chart has been marked. It should be used by the personnel charged with the responsibility of making sure that the patient's paper chart has been marked to indicate that an allergy/adverse reaction is present. You select a patient and the various causative agents associated with that patient are displayed. Any number of agents may be selected by you to indicate whether the patient chart has been marked.

Select Adverse Reaction Tracking Clinician Menu Option: **4** Edit Chart and ID Band

Select Patient: **ARTPATIENT, ONE** XX-XX-69 666122222 SC VETERAN

CHOOSE FROM:

ASPIRIN
COD LIVER OIL
DEMECARIUM
FROGS
PENBUTOLOL
PENICILLIN
PHENOBARBITAL
PHENYTOIN
PREDNISONE
THOR - PROM
TIMOLOL
TYLOXAPOL

Select CAUSATIVE AGENT: **ASPIRIN** XX-XX-69 666122222 SC VETERAN
ASPIRIN

Select another CAUSATIVE AGENT: **PENICILLIN** XX-XX-69 666122222
SC VETERAN PENICILLIN

Select another CAUSATIVE AGENT: **< Enter >**

This session you have CHOSEN:

PENICILLIN
ASPIRIN

Has the ID Band been marked for these CAUSATIVE AGENTS? **??**

ANSWER YES IF THE ID Band HAS BEEN MARKED, ELSE ANSWER NO

Have the Chart(s) been marked for these CAUSATIVE AGENTS? **Y** (Yes)

Adverse Reaction Tracking Verifier Menu

This menu should be given to the verifiers of the Adverse Reaction Tracking data. The options on this menu will allow you to edit/verify/print the data.

This menu should *only* be given to the verifiers of ART.

1. Enter/Edit Patient Reaction Data
2. Verify Patient Reaction Data
3. Reports Menu ...
4. Edit Chart and ID Band
5. FDA Enter/Edit Menu ...
- 6 Online Reference Card

Enter/Edit Patient Reaction Data

This option allows users to enter and edit patient allergies/adverse reactions. You are prompted to enter the name of the agent that caused the reaction, whether the reaction was observed during the patient's stay/visit at the facility, any signs or symptoms associated with the reaction, the date and time the sign/symptom occurred, the type of reaction (i.e., mechanism), any appropriate comments concerning the entry, and whether the patient's chart is marked for this reaction.

See Page 10 for descriptions of the prompts for this option.

Example

```
Select Adverse Reaction Tracking Verifier Menu Option: 1 Enter/Edit Patient Reaction
Data
Select PATIENT NAME: ARTPATIENT,ONE X-X-51 666111995 NO EMPLOYEE
Enrollment Priority: GROUP 7 Category: IN PROCESS End Date:

REACTANT VER. MECH. OBS/
----- ---- -
CHOCOLATE AUTO ALLERGY HIST DRUG
(CHOCOLATE FLAVORING) FOOD
Reactions: CHILLS, DROWSINESS, DRY MOUTH

Enter Causative Agent: straw

Checking existing PATIENT ALLERGIES (#120.8) file for matches...

Now checking GMR ALLERGIES (#120.82) file for matches...
BERRIES
STRAWBERRIES OK? Yes// <Enter> (Yes)

(O)bserved or (H)istorical Allergy/Adverse Reaction: o OBSERVED
Select date reaction was OBSERVED (Time Optional): t (DEC 06, 2004) DEC 06,
2004 (DEC 06, 2004)
Are you adding 'DEC 06, 2004' as
a new ADVERSE REACTION REPORTING? No// y (Yes)

No signs/symptoms have been specified. Please add some now.

The following are the top ten most common signs/symptoms:
1. CHILLS 7. HIVES
2. ITCHING,WATERING EYES 8. DRY MOUTH
3. HYPOTENSION 9. DRY NOSE
4. DROWSINESS 10. RASH
5. NAUSEA,VOMITING 11. OTHER SIGN/SYMP TOM
6. DIARRHEA
Enter from the list above : 10
Date(Time Optional) of appearance of Sign/Symptom(s): Dec 06, 2004//<Enter> (DEC 06,
2004)

The following is the list of reported signs/symptoms for this reaction:

Signs/Symptoms Date Observed
```

```

-----
1  RASH                               Dec 06, 2004

Select Action (A)DD, (D)ELETE OR <RET>: <Enter>

COMMENTS:
1>
Complete the observed reaction report? Yes// <Enter> (Yes)
DATE/TIME OF EVENT: DEC 6,2004// <Enter>
OBSERVER:  ARTPROVIDER,TEN      TA      PHYSICIAN
SEVERITY:  mi  MILD
DATE MD NOTIFIED: Dec 6,2004// <Enter> (DEC 06, 2004)
Enter another Causative Agent? YES// n NO

                               Dec 06, 2004@15:01:50
Causative Agent Data edited this Session:
ADVERSE REACTION
-----
STRAWBERRIES

                Obs/Hist: OBSERVED
                Obs d/t: Dec 06, 2004
                Signs/Symptoms: RASH (12/6/04)

Is this correct? NO// y YES

Opening Adverse React/Allergy record for review...

Browse Document                Dec 06, 2004@15:01:50                Page: 1 of 1
                               Adverse React/Allergy
CPRSPATIENTCANC666-11-1995    2B MED                Adm: 02/18/2003 Dis:

DATE OF NOTE: DEC 06, 2004@15:01:49  ENTRY DATE: DEC 06, 2004@15:01:50
AUTHOR: ARTPROVIDER,TEN                EXP COSIGNER:
URGENCY:                                STATUS: UNSIGNED

This patient has had the following reactions
signed-off on Dec 06, 2004@15:01:49.

STRAWBERRIES

+ Next Screen - Prev Screen ?? More actions >>>
Find                Sign/Cosign                Link ...
Print               Copy                Encounter Edit
Edit                Identify Signers        Interdiscipl'ry Note
Make Addendum       Delete                Quit
Select Action: Quit// s
Enter your Current Signature Code: xxxxxx SIGNATURE VERIFIED
Print this note? Yes// n (No)
Enter another Causative Agent? YES// n NO
This session you have CHOSEN:
STRAWBERRIES

Has the ID Band been marked for this CAUSATIVE AGENT? y (Yes)??

Select PATIENT NAME: < Enter>

```


Verify Patient Reaction Data

This option allows designated verifiers to verify the correctness of data entered by the clinical users. The verifier may select a single patient's data to verify or a list or range (e.g., 1,3,7 or 1-10) of patients to verify. The verifier may select to view/verify drug reactions only, non-drug reactions only, or drug and non-drug reactions. The reaction data is displayed and the verifier may edit the causative agent, type, ingredients, drug class, observed/historical response, signs/symptoms, and mechanism. The verifier may enter any appropriate comments.

If the verifier answers YES to the "change status of this allergy/adverse reaction to verified" prompt, the reaction will be marked as verified. If the verifier answers NO to that prompt, the reaction is marked as entered in error.

If no hospital location is associated with the patient, the verifier will be prompted to enter a location.

A progress note is created. The verifier may electronically sign, edit, or delete the progress note. The verifier may print the progress note, too.

```

Select Adverse Reaction Tracking Verifier Menu Option: 2 Verify Patient
Reaction Data
Would you like to verify a single patient's data? NO// YES

Select PATIENT NAME: CPRSPATIENT, FIVE          X-XX-44      666466680      YES
EMPLOYEE
Enrollment Priority: GROUP 2      Category: IN PROCESS      End Date:

                D Drug
                N Non-drug
                B Both
Select type of AGENT to verify:(D/N/B): DRUG

                PATIENT                                ALLERGY                                OBS/
                -----                                -----                                HIST ADR TYPE
1. CPRSPATIENT, FIVE (6680) 1A(1&2)  ANTIRABIES SERUM  OBS UNK DRUG
                FOOD
2. CPRSPATIENT, FIVE (6680) 1A(1&2)  ASPARTAME         OBS UNK DRUG
                FOOD
3. CPRSPATIENT, FIVE (6680) 1A(1&2)  ASPIRIN           HIST UNK DRUG
                FOOD

Select a number between 1-3: 1

                PATIENT: CPRSPATIENT, FIVE            CAUSATIVE AGENT: ANTIRABIES SERUM
                INGREDIENTS: ANTIRABIES SERUM          VA DRUG CLASSES: IMMUNE SERUMS

                ORIGINATOR: ARTPROVIDER, ONE          ORIGINATED: Jun 08, 2004@12:15
                SIGN OFF: YES                          OBS/HIST: OBSERVED
                                                        OBS D/T: Jun 08, 2004@12:15

                ORIGINATOR
                COMMENTS:
                Date: Jun 08, 2004@12:16:50          User: CPRSPROVIDER, TWO
                                                        Title:

                chills and sweating
    
```

```

ID BAND MARKED:                                CHART MARKED:
SIGNS/SYMPTOMS: CHILLS (Jun 08, 2004@12:15)
    MECHANISM: UNKNOWN
Is the reaction information correct? Yes// <Enter> (Yes)

CAUSATIVE AGENT: ANTIRABIES SERUM
    TYPE: DRUG, FOOD
    INGREDIENTS: ANTIRABIES SERUM
VA DRUG CLASSES: IM400 - IMMUNE SERUMS
    OBS/HIST: OBSERVED

SIGNS/SYMPTOMS: CHILLS (Jun 08, 2004@12:15)
    MECHANISM: UNKNOWN

Would you like to edit any of this data? N (No)

    ORIGINATOR
    COMMENTS:
        Date: Jun 08, 2004@12:16:50                User: CPRSPROVIDER,TWO
                                                    Title:
                chills and sweating

COMMENTS:
1>
    PATIENT: CPRSPATIENT,FIVE                CAUSATIVE AGENT: ANTIRABIES SERUM
    INGREDIENTS: ANTIRABIES SERUM            VA DRUG CLASSES: IMMUNE SERUMS

    ORIGINATOR: ARTPROVIDER,TWO                ORIGINATED: Jun 08, 2004@12:15
    SIGN OFF: YES                            OBS/HIST: OBSERVED
                                                    OBS D/T: Jun 08, 2004@12:15

    ORIGINATOR
    COMMENTS:
        Date: Jun 08, 2004@12:16:50                User: CPRSPROVIDER,TWO
                                                    Title:
                chills and sweating

Enter RETURN to continue or '^' to exit:

                                Dec 06, 2004@15:51:38
ID BAND MARKED:                                CHART MARKED:
SIGNS/SYMPTOMS: CHILLS (Jun 08, 2004@12:15)
    MECHANISM: UNKNOWN

Change status of this allergy/adverse reaction to verified? Y (Yes)
Opening Adverse React/Allergy record for review...

Browse Document                                Dec 06, 2004@15:51:38                Page: 1 of 1
                                Adverse React/Allergy
CPRSPATIENT,FIVE 666-46-6680 1A(1&2)                Adm: 10/15/2001 Dis:
DATE OF NOTE: DEC 06, 2004@15:51:37  ENTRY DATE: DEC 06, 2004@15:51:37
    AUTHOR: ARTPROVIDER,ONE                EXP COSIGNER:
    URGENCY:                                STATUS: UNSIGNED

```

This patient has had an allergy to ANTIRABIES SERUM
verified on Dec 06, 2004@15:51:37.

+ Next Screen - Prev Screen ?? More actions >>>		
Find	Sign/Cosign	Link ...
Print	Copy	Encounter Edit
Edit	Identify Signers	Interdiscipl'ry Note
Make Addendum	Delete	Quit
Select Action: Quit//		

NOTE: Users can enter/edit their own electronic signature code.

Reports Menu (Verifier)

This menu is part of the Adverse Reaction Tracking Verifier Menu. It is the only print menu that the verifier will need for ART.

1. Active Listing of Patient Reactions
2. Print Patient Reaction Data
3. Print an FDA report for a Patient
4. Print all FDA events within D/T range
5. Print Patient FDA Exception Data
6. Print all FDA Exceptions within a D/T range
7. List by Location of Unmarked ID Bands/Charts
8. Patient Allergies Not Signed Off
9. List by Location of Undocumented Allergies
10. List Autoverified Reaction Data
11. List by Location Not Verified Reactions
12. List by Location and Date all Sign Reactions
13. List FDA Data by Report Date

Active Listing of Patient Reactions

This option gives a brief listing of the active (data that is signed off and not entered in error) allergy/adverse reaction data for a particular patient. You may select a printer to get a hard copy printout, or display the report to the terminal screen.

The header of the display contains the report name, date and time it was run, patient's name, SSN, date of birth, and age. The body of the report divides the data by reaction type (e.g., Drug) and lists the causative agent, the signs/symptoms, and when they were observed or if they were historical, and whether it was verified.

If the patient has no known reactions, the body of the report will display that the patient has no known allergies. If the patient was never asked if he/she has any allergy/adverse reactions, the body of the report will display a message stating that there are no reactions on file.

Select PATIENT:	ARTPATIENT, TWO	X-XX-42	666000112	YES	ACTIVE DUTY
Enrollment Priority:		Category:	IN PROCESS	End Date:	
DEVICE: HOME// ; ;999 ANYWHERE					
ACTIVE ALLERGY/ADVERSE REACTION LISTING					
Run Date/Time: 6/25/04 11:56:58 am					
ARTPATIENT, TWO	666-00-0112		XX XX,1942 (XX)		
ADVERSE REACTION				VERIFIED	OBS/ HIST

TYPE: DRUG					
=====					
ALLENT				YES	HIST
ALUMINUM ACETATE				YES	HIST
Reactions: CHILLS (Nov 25, 2002)					
AMOXICILLIN				NO	HIST
AMPICILLIN				NO	HIST
BILBERRY				YES	HIST
CANDESARTAN				YES	HIST
CARAMEL				YES	HIST
Reactions: HIVES (Jan 22, 1998), ITCHING,WATERING EYES (Jan 22, 1998)					
CORICIDIN TAB				YES	OBS
Reactions: CHILLS, HYPOTENSION, NAUSEA,VOMITING					
CORN STARCH				YES	HIST
CORRECTOL				YES	HIST
CORTICOTROPIN				YES	HIST
CORTICOTROPIN/ZINC HYDROXIDE				YES	HIST
EYE WASHES/LUBRICANTS				NO	OBS
Reactions: DROWSINESS					
FILGRASTIM				YES	HIST
HAYFEBROL SF				NO	HIST
Reactions: ITCHING,WATERING EYES					
LOMEFLOXACIN				YES	OBS
Reactions: ITCHING,WATERING EYES (Mar 10, 1999)					
OXYCODONE				YES	HIST
PENICILLINS				NO	HIST
PENTAMIDINE				YES	HIST
PENTAZOCINE				YES	HIST
PENTETIC ACID				YES	HIST

RANITIDINE	YES	OBS
Reactions: CHILLS (Nov 26, 2002@11:16)		
TACRINE	YES	HIST
TAPE	YES	HIST
TAVIST	NO	HIST
TAVIST	NO	HIST
WARFARIN	YES	HIST
WATER	NO	HIST
ZANTAC	YES	HIST
TYPE: DRUG, FOOD		
=====		
CHOCOLATE	YES	HIST
FLUPHENAZINE DECANOATE	NO	HIST
PEANUT OIL	NO	OBS
Reactions:		
	ITCHING, WATERING EYES (Oct 05, 2000@24:00),	
	ANXIETY (Oct 06, 2000@09:27)	
SHELL FISH	NO	HIST
TYPE: FOOD		
=====		
NUTS	YES	HIST
Reactions: HIVES (Jan 02, 1998)		
PEACHES	YES	HIST
STRAWBERRIES	YES	HIST
TYPE: OTHER		
=====		
DUST	YES	HIST
Enter RETURN to continue or '^' to exit:		

Print Patient Reaction Data

This option allows you to get a captioned data display of all of the patient's allergy/adverse reaction data. You can send the report to a printer for a hard copy printout or have it displayed on the terminal screen.

You can select the types of reactions to include in the report. Any combination of types can be selected (i.e., FOOD and DRUG). You then select the status of the reaction entry. Any combination can be selected (i.e., ACTIVE and ENTERED IN ERROR).

The header of the report contains the title of the report, the date/time it was run, and the patient's name, SSN, date of birth, and age. The body contains the status of the reaction, its type, the name of the causative agent, any drug ingredients, any VA drug classes, the name of the person who entered the data, and the date and time it was entered. It also contains whether or not the data was signed off (completed), whether the reaction was observed or historical, whether the patient ID band or chart is marked, a list of the signs/symptoms, and additional comments made by the originator. A line of dots appears in the body of the report between the various reaction entries.

```
Select Adverse Reaction Tracking User Menu Option: 7 Print Patient Reaction
Data

Select PATIENT: ARTPATIENT,ONE XX-XX 666000111 SC VETERAN
Select 1:DRUG, 2:FOOD, 3:OTHER
Type of allergy: (1-3): 1
Select 1:ACTIVE, 2:ENTERED IN ERROR
Which would you like to see?: (1-2): 1

DEVICE: HOME// < Enter> HYPER SPACE

                                ALLERGY/ADVERSE REACTION REPORTS
                                Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE                666-00-0111                XX XX,1942 (XX)
-----

STATUS: ACTIVE
-----
TYPE: DRUG
=====

AGENT: ALLENT
INGREDIENTS: PSEUDOEPHEDRINE          VA DRUG CLASSES: ANTIHISTAMINE/DECONGE
              BROMPHENIRAMINE

ORIGINATOR: ARTPROVIDER,TWO          ORIGINATED: MAR 17, 2004@14:34
SIGN OFF: YES                        OBS/HIST: HISTORICAL

ID BAND MARKED:                    CHART MARKED: MAR 17, 2004@14:34:16

MECHANISM: ALLERGY

Enter RETURN to continue or '^' to exit:
```

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE 666-00-0111 XX XX,1942 (XX)

VERIFIER: AUTOVERIFIED VERIFIED: MAR 17, 2004@14:34:17

.....
AGENT: ALUMINUM ACETATE
INGREDIENTS: ALUMINUM ACETATE VA DRUG CLASSES:

ORIGINATOR: ARTPROVIDER,ONE ORIGINATED: NOV 26, 2002@11:25
SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED:

SIGNS/SYMPTOMS: CHILLS (Nov 25, 2002)

MECHANISM: UNKNOWN

VERIFIER: AUTOVERIFIED VERIFIED: NOV 26, 2002@11:26:27
Enter RETURN to continue or '^' to exit:

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE 666-00-0111 XX XX,1942 (XX)

.....
AGENT: AMOXICILLIN
INGREDIENTS: AMOXICILLIN VA DRUG CLASSES: PENICILLINS,AMINO DER

ORIGINATOR: ARTPROVIDER,TWO ORIGINATED: JAN 21, 1998@10:20
SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED:

MECHANISM: UNKNOWN

.....
AGENT: AMPICILLIN
INGREDIENTS: AMPICILLIN VA DRUG CLASSES:

Enter RETURN to continue or '^' to exit:

ALLERGY/ADVERSE REACTION REPORTS
Run Date/Time: 7/2/04 9:18:55 am
ARTPATIENT,ONE 666-00-0111 XX XX,1942 (XX)

ORIGINATOR: ARTPROVIDER,ONE ORIGINATED: JAN 21, 1998@10:25
SIGN OFF: YES OBS/HIST: HISTORICAL

ID BAND MARKED: CHART MARKED:

MECHANISM: UNKNOWN

Print an FDA Report for a Patient

This option allows you to print an individual FDA report for a patient. This option will produce a listing of all allergy/adverse reactions that are awaiting sign off by the person entering the data into the system. The report should be queued to run on a printer with a 132-column width.

```
Select Reports Menu Option: 3 Print an FDA Report for a Patient
Select PATIENT NAME: ARTPATIENT,TWO xx-xx-34 6660001112 SC VETERAN
Select CAUSATIVE AGENT: ??

CHOOSE FROM:
  AMPICILLIN
  CYCLOSPORINE
  GENTAMICIN
  PENICILLIN

Select CAUSATIVE AGENT: AMPI 12-01-34 111124443 SC VETERAN
  AMPICILLIN
Select date reaction was OBSERVED (Time Optional): 1/10/96 (JAN 10,
1996).1249
  ...OK? Yes// (Yes)
THIS REPORT SHOULD BE SENT TO A 132 COLUMN PRINTER.

QUEUE TO PRINT ON
DEVICE: PRINTER 132 (132 COLUMN)

Requested Start Time: NOW// < Enter> (JAN 25, 1996@10:36:17)
Request queued...
```

MEDwatch		Approved by FDA on 10/20/93	
THE FDA MEDICAL PRODUCTS REPORTING PROGRAM		Triage unit sequence #	
Page 1 of 1			
A. Patient Information		C. Suspect Medication(s)	
1. Patient Identifier 2. DOB: xx/xx/34 3. Sex 4. Weight T0112 AGE: xx yrs FEMALE 0.0		1. Name #1 : AMPICILLIN	
B. Adverse Event or Product Problem		2. Dose, frequency & route used 3. Therapy dates	
1. <input checked="" type="checkbox"/> Adverse Event <input type="checkbox"/> Product problem		#1: -----	
2. Outcomes attributed to adverse event <input type="checkbox"/> death <input type="checkbox"/> disability <input type="checkbox"/> life-threatening <input type="checkbox"/> congenital anomaly <input type="checkbox"/> Hospitalization <input type="checkbox"/> required intervention to initial or prolonged prevent impairment/damage <input checked="" type="checkbox"/> other		4. Diagnosis for use (indication) 5. Event abated after use stopped or dose reduced? #1: [N/A]	
3. Date of event 4. Date of this report 01/10/96 01/30/96		6. Lot # (if known) 7. Exp. date 8. Event reappeared after reintroduction #1: []	
5. Describe event or problem RASH		9. (Not applicable to adverse drug event reports)	
6. Relevant test/laboratory data. including dates treatment)		10. Concomitant medical products/therapy dates(exclude	
7. Other relevant History, including preexisting medical conditions		D. Suspect Medical Devices	
		Note: Please use the actual MedWatch form if the event involves a suspected device as well as a suspect drug	
		E. Reporter	
		1. Name, address & phone #:	

Mail to: MedWatch 5600 Fishers Lane Rockville, MD 20852-9787	or FAX to: 1-800-FDA-0178	----- 2. Health professional? <input type="checkbox"/> 3. Occupation <input type="checkbox"/> 4. Reported to Mfr. [] [NO] ----- 5. If you don't want your identity disclosed to the place an "X" in the box. <input type="checkbox"/>
Manufacturer, FDA Form 3500 =====		
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.		

Print all FDA Events within D/T Range

This report prints all the FDA reports over a given date range, entered by you. You may choose to print Complete FDA Adverse Event Reports or an abbreviated listing of reports. Complete reports should be queued to a printer that has 132-column width. An abbreviated listing may be sent to a printer or CRT. If an abbreviated listing is chosen and if the report has been sent to the FDA, the listing will display the date that the report was sent.

```
Select Reports Menu Option: 4 Print All FDA Events within D/T Range
Select Start Date/Time: T-30 (JUN 07, 2004)
Select End Date/Time: (6/7/2004 - 7/7/2004): T// <Enter> (JUL 07, 2004)
Do you want an Abbreviated report? Yes// <Enter> (Yes)

DEVICE: HOME//<Enter> ANYWHERE

Jul 07, 2004@07:38:46 Page: 1

PATIENT                FDA ABBREVIATED REPORT
                        SUSPECTED AGENT                D/T OF EVENT
-----
ARTPATIENT,ONE (666-00-0111)  ANTIRABIES SERUM                Jun 8,2004
ARTPATIENT,TWO (666-00-0112)  ANTIRABIES SERUM                Jun 8,2004@12:15
ARTPATIENT,THREE(666-00-0113)  SHRIMP                            Jun 15,2004
ARTPATIENT,FOUR (666-00-0114)  ZANAMIVIR                        Jun 21,2004
ARTPATIENT,FOUR (666-00-0114)  ACYCLOVIR                        Jun 21,2004
ARTPATIENT,FOUR (666-00-0114)  RANITIDINE                       Jun 21,2004
ARTPATIENT,FOUR (666-00-0114)  ZANAMIVIR                        Jun 21,2004@08:27
ARTPATIENT,FIVE (666-00-0115)  SHRIMP                            Jun 28,2004
ARTPATIENT,FIVE (666-00-0115)  FLOXURIDINE                      Jun 30,2004
ARTPATIENT,FIVE (666-00-0115)  FORMOTEROL                       Jun 30,2004
ARTPATIENT,FIVE (666-00-0115)  FORMALDEHYDE                    Jun 30,2004
Enter RETURN to continue or '^' to exit: <Enter>
```

Print Patient FDA Exception Data

This option allows you to print a list of all observed or drug allergies from a given date to the present for a patient that has been signed off (completed), but is missing sign/symptom data. You select a patient and the date from which to start the search.

The header of the report contains the name of the report and the date/time that it was run. The body contains the patient's name, SSN, the causative agent, the origination date/time of the entry and name of the originator.

```
Select Reports Menu Option: 5 Print Patient FDA Exception Data

Select PATIENT NAME: ARTPATIENT,ONE  ARTPATIENT,ONE          xx-xx-42
666000111      YES      ACTIVE DUTY
  Enrollment Priority:          Category: NOT ENROLLED  End Date: 07/06/2004

Enter the Date to start search (Time optional):  T-30// t-60  (MAY 08, 2004)

DEVICE: HOME// <Enter>      ANYWHERE

Jul 7,2004 07:42:26                               Page: 1
          FDA EXCEPTION REPORT (Starting at 5/8/04)
ORIGINATION D/T      CAUSATIVE AGENT      ORIGINATOR
-----
      Patient: ARTPATIENT,ONE (666-00-0111)
Jun 30,2004@10:31  FLOXURIDINE              ARTPROVIDER,ONE
Jun 30,2004@10:34  FORMOTEROL              ARTPROVIDER,ONE
Jun 30,2004@10:39  FORMALDEHYDE           ARTPROVIDER,ONE
Enter RETURN to continue or '^' to exit: <Enter>
```

Print all FDA Exceptions within a D/T Range

This option allows you to select a date range from which to print a list of all patients who had an Observed Drug Reaction that has not been reported to the FDA. The report can be sent to a printer or to your terminal screen. The header of the report contains the name of the report, the date range selected by you and the date/time that the report was run. The body of the report contains the patient's name and SSN, the causative agent, the name of the person who originated the data entry, and the origination date/time of the data.

```
Select Reports Menu Option: 6 Print All FDA Exceptions within a D/T Range
Select Start Date: T-90 (APR 08, 2004)
Select End Date: (4/8/2004 - 7/7/2004): T// <Enter> (JUL 07, 2004)

DEVICE: HOME// <Enter> ANYWHERE

Jul 7,2004 07:37:28 Page: 1
FDA EXCEPTION REPORT (4/8/04 to 7/7/04)
ORIGINATION D/T CAUSATIVE AGENT ORIGINATOR
-----
Patient: ARTPATIENT,ONE (666-00-0111)
Jun 8,2004@12:21 ANTIRABIES SERUM ARTPROVIDER,ONE
Patient: ARTPATIENT,TEN (666-00-0110)
Jun 8,2004@12:15 ANTIRABIES SERUM ARTPROVIDER,ONE
Patient: ARTPATIENT,TWO (666-00-0112)
Jun 30,2004@10:31 FLOXURIDINE ARTPROVIDER,ONE
Jun 30,2004@10:34 FORMOTEROL ARTPROVIDER,TWO
Jun 30,2004@10:39 FORMALDEHYDE ARTPROVIDER,THREE
Patient: ARTPATIENT,THREE (666-00-0113)
Jun 16,2004@08:27 SHRIMP ARTPROVIDER,ONE
Patient: ARTPATIENT,FOUR (666-00-0114)
Apr 30,2004@09:33 PENICILLIN ARTPROVIDER,ONE
Patient: ARTPATIENT,FIVE (666-00-0115)
May 20,2004@12:09 LEAD ACETATE PURIFIED POWDER ARTPROVIDER,FOUR
Jun 21,2004@08:23 ZANAMIVIR ARTPROVIDER,ONE
Jun 21,2004@08:38 ACYCLOVIR ARTPROVIDER,FOUR
Jun 21,2004@09:43 RANITIDINE ARTPROVIDER,TWO
Enter RETURN to continue or '^' to exit: <Enter>
```

List by Location of Unmarked ID Bands/Charts

This option will produce a list of all patients by ward/clinic who have not had their chart or ID bands marked. This report functions like the List of Patients Not Asked About Allergies option. It should be noted that you will be prompted to queue all reports except when choosing the Current Inpatients report by itself (i.e., #1).

The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., inpatients), and any date ranges entered by you. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, name of the causative agent, and whether the patient ID band, patient chart, or both were unmarked.

```
Select Reports Menu Option: 7 List by Location of Unmarked ID Bands/Charts
  1 Current Inpatients
  2 Outpatients over Date/Time range
  3 New Admissions over Date/Time range
  4 All of the above
Enter the number(s) for those groups to be used in this report: (1-4):4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): t-90 (APR 08, 2004)
Enter END Date (time optional): T// <Enter> (JUL 07, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL and the system will select all the appropriate hospital locations.

PATIENT	SSN	ALLERGY	UNMARKED
Jun 28,2004 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 1 CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS FROM Mar 30,2004 TO Jun 28,2004@24:00			

WARD: 1A(1&2)			
ARTPATIENT,ONE	666-00-0111	DAVE DRUG	ID BAND/CHART
		DUST	ID BAND/CHART
		AMPICILLIN	ID BAND/CHART
		ASPIRIN	ID BAND/CHART
		CHOCOLATE	ID BAND/CHART
		MILK OF MAGNESIA	ID BAND/CHART
		AMOXICILLIN	ID BAND/CHART
		PENICILLIN	ID BAND/CHART
		MENTHOL	ID BAND/CHART
ARTPATIENT,TWO	666-00-0112	AMOXICILLIN	ID BAND/CHART
		DUST	ID BAND/CHART
		ZANTAC	ID BAND/CHART
ARTPATIENT,THREE	666-00-0113	CEPHALEXIN TABLETS,	ID BAND/CHART
Enter RETURN to continue or '^' to exit:			
Jun 28,2004 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 2 CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS FROM Mar 30,2004 TO Jun 28,2004@24:00			

		CHEESE	ID BAND/CHART
		BARIUM SULFATE	ID BAND/CHART

PATIENT	SSN	ALLERGY	UNMARKED
Jun 28, 2004 PATIENTS WITH UNMARKED ID BAND/CHART PAGE 3 CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS FROM Mar 30, 2004 TO Jun 28, 2004@24:00			
ARTPATIENT, FOUR	666-00-0114	ACETANILIDE	ID BAND/CHART
ARTPATIENT, FIVE	666-00-0115	ANTIRABIES SERUM	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART
		CHOCOLATE	ID BAND/CHART
		BLUE CROSS AMPICILLI	ID BAND/CHART
		ACETAMINOPHEN TAB	ID BAND/CHART
		STRAWBERRIES	ID BAND/CHART
Enter RETURN to continue or '^' to exit:			

Patient Allergies Not Signed Off

This option prints allergy/adverse reactions for patients that have not been signed off (completed) by users entering data. Users who have the GMRA-ALLERGY VERIFY key will see all reactions that are not signed off. Users who do not have that key will see just the entries that they created. You may select a printer to get a hard copy printout or display the report to the terminal screen.

The header of the report contains the name of the report and the date and time that it was run. The body of the report lists the name of the person who entered the date, the patient's name followed by the last four digits of the SSN, the causative agent, and the date/time the entry was made.

```
Select Adverse Reaction Tracking User Menu Option: 5 Patient Allergies
Not Signed Off
Include deceased patients on report? NO// <Enter>

DEVICE: HOME// < Enter> HYPER SPACE
                ALLERGY/ADVERSE REACTIONS TO BE SIGNED OFF
                Run Date/Time: 6/28/04 9:18:26 am

ORIGINATOR          PATIENT          ALLERGY          ORIGINATION
DATE/TIME
-----
PROVIDER,ONE ARTPATIENT,ONE (0111) PENICILLIN FEB 18, 2003@10:59
PROVIDER,ONE ARTPATIENT,ONE (0111) FROG FEB 18, 2003@15:14
PROVIDER,ONE ARTPATIENT,ONE (0111) THORAZINE 10MG FEB 22, 2003@13:20
PROVIDER,ONE ARTPATIENT,TWO (0112) PENICILLIN JUN 22, 2003@11:44
PROVIDER,ONE ARTPATIENT,TWO (0112) PHENYTOIN JUN 22, 2003@11:48
PROVIDER,ONE ARTPATIENT,TWO (0112) DEMECARIUM JUN 22, 2003@12:00
PROVIDER,ONE ARTPATIENT,TWO (0112) ASPIRIN JUN 22, 2003@12:08
PROVIDER,ONE ARTPATIENT,TWO (0112) PHENOBARBITAL JUN 25, 2003@10:33
PROVIDER,ONE ARTPATIENT,TWO (0112) PHENOBARBITAL JUN 25, 2003@10:39
PROVIDER,ONE ARTPATIENT,TWO (0112) CODEINE JUN 30, 2003@08:55
PROVIDER,ONE ARTPATIENT,TWO (0112) THOR - PROM AUG 11, 2003@10:35
PROVIDER,ONE ARTPATIENT,TWO (0112) IMMUNE GLOBULIN AUG 18, 2003@10:02
PROVIDER,ONE ARTPATIENT,THREE (0113) CYCLOBENZAPRINE JUL 11, 2004@14:11
PROVIDER,ONE ARTPATIENT,THREE (0113) SULFABENZAMIDE/S JUL 11, 2004@14:14
PROVIDER,ONE ARTPATIENT,THREE (0114) DUCK JAN 06, 2004@11:13
Enter RETURN to continue or '^' to exit: ^
```


List by Location of Undocumented Allergies

This report is used to list all patients in the patient database who have never been asked if they have any known allergies. It should be noted that you will be prompted to queue all reports except stand-alone Current Inpatients' reports. The header of the report contains the date the report was run, title of the report, the list of the groups included (i.e., current inpatients), and any date ranges entered. The body of the report categorizes the patients by clinic or ward. It lists the patient's name, SSN, and provider. The room-bed will appear for current inpatients.

```
Select Adverse Reaction Tracking User Menu Option: 6 List by Location of
Undocumented Allergies
    1 Current Inpatients
    2 Outpatients over Date/Time range
    3 New Admissions over Date/Time range
    4 All of the above
Enter the number(s) for those groups to be used in this report:(1-4): 4
Enter date/time range in which patients were
admitted into the hospital or seen at an outpatient clinic.

Enter START Date (time optional): T-180 (JAN 04, 2004)
Enter END Date (time optional): T// <Enter> (JUL 02, 2004)
```

The location prompt allows you to select the ward or clinic that you want to print, or select all the wards/clinics by entering the word ALL, and the system will select all the appropriate hospital locations.

```
Select Location: ??

    You may deselect from the list by typing a '-' followed by location name.
    E.g. -3E would delete 3E from the list of locations already selected.
    You may enter the word ALL to select all appropriate locations.
    Answer with HOSPITAL LOCATION NAME, or ABBREVIATION
Choose from:
Choose from:
    1 DR'S CLINIC
    13A PSYCH
    1A(1&2)
    2B MED
    8E REHAB MED
    8W SUBSTANCE ABUSE
    CARDIOLOGY
    CT ROOM

Select Location: 1A
Another Location: 2B
Another Location: Cardiology
Another Location: < Enter>

QUEUE TO PRINT ON
DEVICE: SELECT APPROPRIATE PRINTER

Requested Start Time: NOW// < Enter> (JUL 2, 2004@10:24:00)
Request queued...
```

Jul 2,2004 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 1
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 4,2004 TO Jul 2,2004@24:00

PATIENT	SSN	PROVIDER

WARD: 1A(1&2)		
ARTPATIENT,ONE	666-00-0111	ARTPROVIDER,ONE
ARTPATIENT,TWO	666-00-1112P	
ARTPATIENT,TWO	666-00-1112	ARTPROVIDER,TWO
Room/Bed: B-2		
ARTPATIENT,THREE	666-12-4443	ARTPROVIDER,THREE
Room/Bed: 9-B		
ARTPATIENT,FOUR	666-00-1114	
ARTPATIENT,FIVE	666-00-1115	
Enter RETURN to continue or '^' to exit:		

Jul 2,2004 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 2
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 4,2004 TO Jul 2,2004@24:00

PATIENT	SSN	PROVIDER

WARD: 2B MED		
ARTPATIENT,SIX	666-00-1116	ARTPROVIDER,FOUR
ARTPATIENT,SEVEN	666-00-1117	
Enter RETURN to continue or '^' to exit:		

Jul 2,2004 PATIENTS NOT ASKED ABOUT ALLERGIES PAGE 3
CURRENT INPATIENTS / OUTPATIENTS / NEW ADMISSIONS
FROM Jan 4,2004 TO Jul 2,2004@24:00

PATIENT	SSN	PROVIDER

CLINIC: CARDIOLOGY		
ARTPATIENT,EIGHT	666-00-1118	ARTPROVIDER,FIVE
ARTPATIENT,NINE	666-00-1119	
ARTPATIENT,TEN	666-00-1110	
Enter RETURN to continue or '^' to exit:		

List Autoverified Reaction Data

This option lists autoverified reaction data by date/time range, location, and mechanism. It also displays previous sorting values that were used during this session. The first time that you run the report during this session, those previous values will be "not null." If you run the option again, the previous sorting values will display (e.g., *Previous Selection: Verification Date/Time from 1/1/96 to 1/31/96@24:00).

The header of this report contains the name of the report, the date it was run, and the date range entered. The body of the report contains the data sorted, first by ward location, then by mechanism, and finally by verification date. The report contains the patient's name, the last digits in the SSN, room-bed, the causative agent, the signs/symptoms, the name of the person who originated the entry and any comments entered by the originator.

```
Select Reports Menu Option: 10 List Autoverified Reaction Data
* Previous selection: VERIFICATION DATE/TIME from Feb 1,1996 to Feb
29,1996@24:00
START WITH VERIFICATION DATE/TIME: Feb 1,1996// <Enter> (FEB 01, 1996)
GO TO VERIFICATION DATE/TIME: Feb 29,1996// T (JUL 07, 2004)
* Previous selection: PATIENT:WARD LOCATION equals 1S
START WITH WARD LOCATION: 1S// 1A
GO TO WARD LOCATION: 1S// 2B
* Previous selection: MECHANISM equals A (ALLERGY)
START WITH NATURE OF REACTION: A// <Enter> ALLERGY
GO TO NATURE OF REACTION: A// <Enter> ALLERGY
DEVICE: <Enter> ANYWHERE Right Margin: 80// <Enter>
07/07/04 LIST OF AUTOVERIFIED ALLERGIES FROM 02/01/96 TO 07/07/04 Page: 1

PATIENT ROOM-BED REACTANT VER. DATE
-----
WARD LOCATION: 1A(1&2)
MECHANISM: ALLERGY
ARTPATIENT,ONE (0001) BEEF JAN 7,1999
ORIGIN.: ARTPROVIDER,ONE
SIGNS: NAUSEA,VOMITING
DIFFICULTY SWALLOWING
COMMENTS: Testing ART/TIU interface.
ARTPATIENT,TWO (0002) STRAWBERRIES MAY 7,2004
ORIGIN.: ARTPROVIDER,TWO
SIGNS: HIVES
COMMENTS:
```

List by Location Not Verified Reactions

This option prints a list of patient reactions that have not been verified. The data is sorted by hospital location, patient, and reaction. You can send the report to a printer for a hard copy or to the terminal screen. This report can be scheduled to automatically run at a regular interval (e.g., daily). Contact your ADPAC or IRM support person to schedule this report to automatically run. The option name to schedule this report to automatically run is GMRA TASK A/AR NV. The header of this report contains the name of the report, the date it was run, and the hospital location. The body contains the patient's name and SSN, the causative agent, the name of the originator of the reaction, and the date/time of data origination. The Room-Bed is also displayed for each patient.

```
Select Reports Menu Option: 11 List by Location Not Verified Reactions

DEVICE: HOME// <Enter> ANYWHERE

Report Date: Jul 07, 2004 Page: 1
List of Unverified Reactions by Ward Location
Ward Location: 13A PSYCH
-----
  Origination Date/Time      Originator      Reaction
-----
ARTPATIENT,ONE (666-00-0111)
  Jul 16, 2003@11:49      ARTPROVIDER,ONE      RANITIDINE
ARTPATIENT,TWO (666-00-0112)
  Jul 09, 1996@08:04      ARTPROVIDER,TWO      STRAWBERRIES
ARTPATIENT,THREE (666-00-0113)
  Jul 09, 1996@08:04      ARTPROVIDER,TWO      DUST
ARTPATIENT,FOUR (666-00-0114)
  Jul 09, 1996@08:04      ARTPROVIDER,TWO      FISH LIVER OIL
ARTPATIENT,FIVE (666-00-0115)
  May 24, 1999@14:21      ARTPROVIDER,THREE      MILK
  Jul 02, 1999@13:40      ARTPROVIDER,THREE      BERGAMOT
  Aug 20, 1999@09:27      ARTPROVIDER,THREE      RANITIDINE
Enter RETURN to continue or '^' to exit:
```

List by Location and Date all Signed Reactions

This option prints a list of all patient reactions that have been signed off (completed) for a user-supplied date range. The data is sorted by location and date range. This report can be sent to a printer for a hard copy printout or displayed on your terminal screen.

The header of the report contains the title, the date range selected, the date that the report was run, and the hospital location. The body of the report contains the patient's name and SSN, the causative agent's name and type, the name of the data's originator, and the date/time of data origination.

```
Select Reports Menu Option: List by Location and Date All Signed Reactions
Enter Start Date: t-180 (JAN 08, 2004)
Enter Ending Date: t (JUL 06, 2004)

DEVICE: HOME//<Enter> ANYWHERE

One moment please...

Jul 06, 2004 Page: 1
List all Signed Patient Reactions for Ward Location 1A(1&2)
From Jan 08, 2004 to Jul 06, 2004@24:00
Date Originator Type Causative Agent
-----
Patient: ARTPATIENT,SIX (666-00-0116)
Jan 12, 2004@12:56 ARTPROVIDER,ONE D HAYFEBROL SF
Jun 11, 2004@15:25 ARTPROVIDER,TWO D DIRITHROMYCIN
Jun 08, 2004@12:15 ARTPROVIDER,THREE DF ANTIRABIES SERUM

Patient: ARTPATIENT,SEVEN (666-00-0117)
Feb 26, 2004@11:29 ARTPROVIDER,ONE D ZANTAC
May 04, 2004@10:52 ARTPROVIDER,ONE D FORMALDEHYDE
May 04, 2004@10:55 ARTPROVIDER,ONE D CONTACT LENS WETTING
SOLN
May 04, 2004@10:56 ARTPROVIDER,ONE D NICO 400
May 04, 2004@10:57 ARTPROVIDER,ONE DF CORN
May 04, 2004@11:00 ARTPROVIDER,ONE DF BCG VACCINE

Patient: ARTPATIENT,EIGHT (666-00-0118)
Feb 26, 2004@11:31 ARTPROVIDER,ONE D ZANTAC

Patient: ARTPATIENT,NINE (666-00-0119)
Feb 05, 2004@10:51 ARTPROVIDER,TWO F STRAWBERRIES
Enter RETURN to continue or '^' to exit:
```

List FDA Data by Report Date

This option displays a report of FDA data that tracks when a reaction was observed and when it was entered into the database. You must enter a date range. This report can be printed or sent to the terminal screen.

The header of the report contains the name of the report, the date range that you selected, and the date that the report was run. The body of the report contains the patient's name and SSN, the name of the causative agent, the patient's location, the observation date of the reaction, the date the reaction was actually reported, the difference (i.e., the number of days) between the observation date and when it was reported, and the name of the person who observed the reaction.

```
Select Reports Menu Option: 9 List FDA Data by Report Date
Select a Tracking date range for this report.
Enter Start Date: t-180 (JAN 08, 2004)
Enter Ending Date: t (JUL 06, 2004)

DEVICE: HOME// ANYWHERE

Report Date: Jul 06, 2004 Page: 1
Adverse Reaction Tracking Report
From: 1/8/04 To: 7/6/04
Patient Dates Related Reaction
-----
ARTPATIENT, ONE Obs DT: 1/27/04 DUST
(666-00-1111) Trk DT: 1/27/04
Loc: 1A(1&2) -----
Obs: ARTPROVIDER, ONE 0 Days Difference

ARTPATIENT, TWO Obs DT: 1/30/04 CHOCOLATE
(666-00-1112) Trk DT: 1/30/04
Loc: OUT PATIENT -----
Obs: ARTPROVIDER, ONE 0 Days Difference

ARTPATIENT, THREE Obs DT: 1/30/04 CHOCOLATE
(355-67-1996) Trk DT: 1/30/04
Loc: 8E REHAB MED -----
Obs: ARTPROVIDER, ONE 0 Days Difference

ARTPATIENT, FOUR Obs DT: 2/2/04 ZANTAC
(666-00-0114) Trk DT: 2/2/04
Loc: 1A(1&2) -----
Obs: ARTPROVIDER, ONE 0 Days Difference

Enter RETURN to continue or '^' to exit:
```

Edit Chart and ID Band

This option allows you to designate that a patient's ID band or the chart has been marked. It should be used by the personnel charged with the responsibility of making sure that the patient's paper chart has been marked to indicate that an allergy/adverse reaction is present. You select a patient and the various causative agents associated with that patient are displayed. Any number of agents may be selected by you to indicate whether the patient chart has been marked.

```
Select Adverse Reaction Tracking Verifier Menu Option: 4 Edit Chart and ID Band
Select Patient: ARTPATIENT,TWO 10-04-69 6660000112 SC VETERAN

CHOOSE FROM:
  ASPIRIN
  COD LIVER OIL
  DEMECARIUM
  FROGS
  PENBUTOLOL
  PENICILLIN
  PHENOBARBITAL
  PHENYTOIN
  PREDNISONONE
  THOR - PROM
  TIMOLOL
  TYLOXAPOL

Select CAUSATIVE AGENT: ASPIRIN 10-04-69 6660000112 SC VETERAN
ASPIRIN

Select another CAUSATIVE AGENT: PENICILLIN 10-04-69 6660000112
SC VETERAN PENICILLIN
Select another CAUSATIVE AGENT: < Enter>
This session you have CHOSEN:
  PENICILLIN
  ASPIRIN
Has the ID Band been marked for this CAUSATIVE AGENT? Y (Yes)
```

FDA Enter/Edit Menu (Verifier)

This menu should be given to people responsible for the FDA portion of Adverse Reaction Tracking as designated by the site. The options on this menu will allow you to edit the FDA data.

1. Enter/Edit FDA Report Data
2. Enter/Edit P&T Committee Data

Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, you may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), you may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date, and how the drug was given (SIG Code). You can also enter a word-processing-type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), you may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (e.g., Health Professional), whether the 15-day report was completed, and the type of the report (i.e., Initial).

The Initial Reporter (5) section allows you to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option: 1  Enter/Edit FDA Report Data

Select PATIENT NAME: ARTPATIENT,ONE      x-xx-42      666000111      YES      ACTIVE DUTY
Enrollment Priority:                      Category: NOT ENROLLED  End Date: 07/06/2004

Select CAUSATIVE AGENT: FLOXURIDINE, PATIENT ARTPATIENT,ONE  xx-xx-42      666000111
YES      ACTIVE DUTY
Enrollment Priority:                      Category: NOT ENROLLED  End Date: 07/06/2004
FLOXURIDINE
Select date reaction was OBSERVED (Time Optional):  6/30/04  (JUN 30, 2004)
...OK? Yes// <Enter>  (Yes)

Indicate which FDA Report Sections to be completed:
1.  Reaction Information
2.  Suspect Drug(s) Information
3.  Concomitant Drugs and History
4.  Manufacturer Information
5.  Initial Reporter
Choose number(s) of sections to be edited:  (1-5): 1

The following is the list of reported signs/symptoms for this reaction:
      These reactions were entered by another user:
      Signs/Symptoms
-----
      RASH
```

Select Action (A)DD OR <RET>: **A**

The following are the top ten most common signs/symptoms:

- | | |
|--------------------------|------------------------|
| 1. CHILLS | 7. HIVES |
| 2. ITCHING,WATERING EYES | 8. DRY MOUTH |
| 3. HYPOTENSION | 9. DRY NOSE |
| 4. DROWSINESS | 10. RASH |
| 5. NAUSEA,VOMITING | 11. OTHER SIGN/SYMPTOM |
| 6. DIARRHEA | |

Enter from the list above : **7**

The following is the list of reported signs/symptoms for this reaction:

These reactions were entered by another user:
Signs/Symptoms

HIVES
RASH

Select Action (A)DD OR <RET>: **<Enter>**

Patient died?: **N** NO
Reaction treated with RX drug?: **N** NO
Life Threatening illness?: **N** NO
Required hospitalization?: **N** NO
Prolonged Hospitalization?: **N** NO
Resulted in permanent disability?: **N** NO
Is this event a Congenital Anomaly?: **N** NO
Did this event require intervention to prevent impairment/damage?: **N** NO

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT

Select Action (A/D/E): **ADD**

View Tx/Test from: JUN 30, 2004// **<Enter>** (JUN 30, 2004)

To: JUN 30, 2004//**T** (JUL 07, 2004)

LAB TEST:

Collection DT	Test Name	Specimen	Results	Hi/Low
---------------	-----------	----------	---------	--------

THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.

Select TEST: ??

You may enter a new RELEVANT TEST/LAB DATA, if you wish

Select TEST: ??

Choose from:

1,25-DIHYDROXYVIT D3
1/2HR LTT
1/2Hr.GTT
1/2Hr.GTT (URINE)
11-DEOXYCORTISOL
17-HYDROXYCORTICOSTEROIDS
17-HYDROXYPROGESTERONE
17-KETOGENIC STEROIDS
17-KETOSTEROIDS,TOTAL
1HR LTT
1Hr.GTT
1Hr.GTT (URINE)
25 OH VITAMIN D
2HR LTT
2Hr.GTT
2Hr.GTT (URINE)

```

3HR LTT
3Hr.GTT
3Hr.GTT (URINE)
4Hr.GTT
4Hr.GTT (URINE)
^
Select TEST: 1/2Hr.GTT (URINE)
  Are you adding '1/2Hr.GTT (URINE)' as a new TEST (the 1ST for this ADVERSE REA
CTION REPORTING)? No// Y (Yes)
  RESULTS: ??
    This field will contain the results for the particular test.

  RESULTS: Enter results here
  COLLECTION D/T: t (JUL 07, 2004)
Select TEST: <Enter>

This patient has the following Test selected:
TEST/TX                RESULTS                DRAW DATE/TIME
1) 1/2Hr.GTT (URINE)   Enter results here   07/07/04
Select Action (A/D/E): <Enter>

Indicate which FDA Report Sections to be completed:
1. Reaction Information
2. Suspect Drug(s) Information
3. Concomitant Drugs and History
4. Manufacturer Information
5. Initial Reporter
Choose number(s) of sections to be edited: (1-5): <Enter>

```

Enter/Edit P&T Committee Data

This option allows you to edit P&T data. It allows for the evaluation of a suspected Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician. You can also track a report to see if it has been sent to the FDA or manufacturer.

```
Select FDA Enter/Edit Menu Option: 2 Enter/Edit P&T Committee Data

Select PATIENT NAME: ARTPATIENT,ONE   xx-xx-42   666000111   YES   ACTIVE DUTY
Enrollment Priority:                   Category: NOT ENROLLED   End Date: 07/06/2004

Select CAUSATIVE AGENT: AMOXICILLIN,PATIENT  ARTPATIENT,ONE  x-xx-42  666000111
YES   ACTIVE DUTY
Enrollment Priority:                   Category: NOT ENROLLED   End Date: 07/06/2004
AMOXICILLIN

Select date reaction was OBSERVED (Time Optional):  JUNE 30, 2004  (JUN 30, 2004)
JUN 30, 2004  (JUN 30, 2004)
Are you adding 'JUN 30, 2004' as
a new ADVERSE REACTION REPORTING? No// Y (Yes)

P&T Report Completion
Serious ADR?: Y YES
ADR related to new drug? (Marketed within the last 2 yrs.): N NO
Unexpected ADR?: Y YES
ADR related to therapeutic failure?: N NO
Dose related?: N NO
P&T ACTION FDA REPORT: ??
This field indicates if the P&T committee determined whether to send
the report to FDA.

Choose from:
y   YES
n   NO
P&T ACTION FDA REPORT: N NO
P&T ACTION MFR REPORT: N NO

ADDENDUM:
1> <Enter>

Select PATIENT NAME: <Enter>
```

P&T Committee Menu

The Patient & Therapeutic (P&T) Committee menu should be given to the P&T Committee members of Adverse Reaction Tracking, as designated by the site. The options on this menu allow you to edit P&T data and print FDA data. It allows for the evaluation of a suspected ADR by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist) other than the attending physician, as specified in Section 5.a.(2).(d) of Directive 10-92-070.

1. Enter/Edit P&T Committee Data
2. Enter/Edit FDA Report Data
3. Reports Menu ...

Enter/Edit P&T Committee Data

This option allows you to edit P&T data. It allows for the evaluation of a suspected Advanced Drug Reaction (ADR) by a qualified individual (e.g., clinical pharmacist, clinical pharmacologist), other than the attending physician.

```
Select FDA Enter/Edit Menu Option: 2 Enter/Edit P&T Committee Data

Select PATIENT NAME: ARTPATIENT,ONE      x-xx-42      666000111      YES      ACTIVE DUTY
Enrollment Priority:                      Category: NOT ENROLLED End Date: 07/06/2004

Select CAUSATIVE AGENT: AMOXICILLIN,PATIENT ARTPATIENT,ONE      666000111      YES
ACTIVE DUTY
Enrollment Priority:                      Category: NOT ENROLLED End Date: 07/06/2004
AMOXICILLIN
Select date reaction was OBSERVED (Time Optional):  JUNE 30, 2004  (JUN 30, 2004)
JUN 30, 2004  (JUN 30, 2004)
Are you adding 'JUN 30, 2004' as
a new ADVERSE REACTION REPORTING? No// Y (Yes)

P&T Report Completion
Serious ADR?: Y YES
ADR related to new drug? (Marketed within the last 2 yrs.): N NO
Unexpected ADR?: Y YES
ADR related to therapeutic failure?: N NO
Dose related?: N NO
P&T ACTION FDA REPORT: ??
This field indicates if the P&T committee determined whether to send
the report to FDA.

Choose from:
y      YES
n      NO
P&T ACTION FDA REPORT: N NO
P&T ACTION MFR REPORT: N NO

ADDENDUM:
1> <Enter>

Select PATIENT NAME: <Enter>
```

Enter/Edit FDA Report Data

This option allows users to enter and edit FDA-related data concerning an adverse reaction.

There are five sections to the FDA Report. Fields for Reaction Information (1) are shown in the example. Sections 2-5 are discussed below.

For Suspect Drug(s) Information (2) of the data entry, you may enter/edit the name of a suspect agent for the observed reaction, the daily dose given, route of administration, how the drug was given (SIG Code), the start and stop dates that it was administered, the name of the manufacturer, lot number, number of previous doses given, the last fill date, the drug's expiration date, the National Drug Code number and the indication/reason for the drug's use.

In the Concomitant Drugs and History section (3), you may enter/edit information about the drugs that the patient was taking at the time of the reaction. This includes the name of the drug, the start/stop dates of administration, the last fill date, and how the drug was given (SIG Code). You can also enter a word-processing-type response to indicate any other related history for this drug.

In the Manufacturer Information section (4), you may enter/edit data concerning a manufacturer that should be notified, including the name of the manufacturer, address, the IND/NDA (Investigational New Drug/New Drug Application) number, the manufacturer's control number, the date the drug was received by the manufacturer, the source of the report (i.e., Health Professional), whether the 15 day report was completed and the type of the report (i.e., Initial).

The Initial Reporter (5) section allows you to enter/edit data concerning the person filling out the report, including name, address, phone number, whether the reporter is a health care provider, whether the name of the reporter should be disclosed to the manufacturer, and the reporter's occupational title.

```
Select FDA Enter/Edit Menu Option: 1  Enter/Edit FDA Report Data

Select PATIENT NAME:  ARTPATIENT,ONE      x-xx-42      666000111      YES      ACTIVE DUTY
  Enrollment Priority:                Category: NOT ENROLLED  End Date: 07/06/2004

Select CAUSATIVE AGENT:  FLOXURIDINE, PATIENT  ARTPATIENT,ONE      x-xx-42      666000111
YES      ACTIVE DUTY
  Enrollment Priority:                Category: NOT ENROLLED  End Date: 07/06/2004
  FLOXURIDINE

Select date reaction was OBSERVED (Time Optional):  6/30/04  (JUN 30, 2004)
  ...OK? Yes// <Enter>  (Yes)

Indicate which FDA Report Sections to be completed:
1.  Reaction Information
2.  Suspect Drug(s) Information
3.  Concomitant Drugs and History
4.  Manufacturer Information
5.  Initial Reporter
Choose number(s) of sections to be edited:  (1-5): 1

The following is the list of reported signs/symptoms for this reaction:
  These reactions were entered by another user:
  Signs/Symptoms
-----
  RASH
```

Select Action (A)DD OR <RET>: **A**

The following are the top ten most common signs/symptoms:

- | | |
|--------------------------|-------------------------|
| 1. CHILLS | 7. HIVES |
| 2. ITCHING,WATERING EYES | 8. DRY MOUTH |
| 3. HYPOTENSION | 9. DRY NOSE |
| 4. DROWSINESS | 10. RASH |
| 5. NAUSEA,VOMITING | 11. OTHER SIGN/SYMP TOM |
| 6. DIARRHEA | |

Enter from the list above : **7**

The following is the list of reported signs/symptoms for this reaction:

These reactions were entered by another user:
Signs/Symptoms

HIVES
RASH

Select Action (A)DD OR <RET>: **<Enter>**

Patient died?: **N** NO

Reaction treated with RX drug?: **N** NO

Life Threatening illness?: **N** NO

Required hospitalization?: **N** NO

Prolonged Hospitalization?: **N** NO

Resulted in permanent disability?: **N** NO

Is this event a Congenital Anomaly?: **N** NO

Did this event require intervention to prevent impairment/damage?: **N** NO

THIS PATIENT HAS NO LAB TEST ON FILE FOR THIS ADVERSE REACTION REPORT

Select Action (A/D/E): **ADD**

View Tx/Test from: JUN 30, 2004// **<Enter>** (JUN 30, 2004)

To: JUN 30, 2004//**T** (JUL 07, 2004)

LAB TEST:

Collection DT	Test Name	Specimen	Results	Hi/Low
---------------	-----------	----------	---------	--------

THERE IS NO LAB DATA FOR THIS PATIENT FOR THIS DATE RANGE.

Select TEST: **??**

You may enter a new RELEVANT TEST/LAB DATA, if you wish

Select TEST: **??**

Choose from:

1,25-DIHYDROXYVIT D3

1/2HR LTT

1/2Hr.GTT

1/2Hr.GTT (URINE)

11-DEOXYCORTISOL

17-HYDROXYCORTICOSTEROIDS

17-HYDROXYPROGESTERONE

17-KETOGENIC STEROIDS

17-KETOSTEROIDS,TOTAL

1HR LTT

1Hr.GTT

1Hr.GTT (URINE)

25 OH VITAMIN D

2HR LTT

2Hr.GTT


```

2Hr.GTT (URINE)
3HR LTT
3Hr.GTT
3Hr.GTT (URINE)
4Hr.GTT
4Hr.GTT (URINE)
^
Select TEST: 1/2Hr.GTT (URINE)
  Are you adding '1/2Hr.GTT (URINE)' as a new TEST (the 1ST for this ADVERSE REA
ACTION REPORTING)? No// Y
  (Yes)
  RESULTS: ??
    This field will contain the results for the particular test.

  RESULTS: Enter results here
  COLLECTION D/T: t (JUL 07, 2004)
Select TEST: <Enter>

This patient has the following Test selected:
TEST/TX                RESULTS                DRAW DATE/TIME
1)  1/2Hr.GTT (URINE)  Enter results here  07/07/04
Select Action (A/D/E): <Enter>

Indicate which FDA Report Sections to be completed:
1.  Reaction Information
2.  Suspect Drug(s) Information
3.  Concomitant Drugs and History
4.  Manufacturer Information
5.  Initial Reporter
Choose number(s) of sections to be edited: (1-5): <Enter>

```

Reports Menu (P&T)

This option is the menu of all reports that the Pharmacy and Therapeutics Committee can print. To view data for options 1 thru 12 below, please see the Reports Menu under the Verifier Menu (see Table of Contents for correct page numbers.) For options 13 thru 19, please continue on the following pages.

1. Print an FDA Report for a Patient
2. Print all FDA Events within D/T range
3. Print Patient FDA Exception Data
4. Print all FDA Exceptions within a D/T range
5. Patient Allergies Not Signed Off
6. Print Patient Reaction Data
7. Active Listing of Patient Reactions
8. List by Location of Undocumented Allergies
9. List Autoverified Reaction Data
10. List by Location Not Verified Reactions
11. List by Location and Date all Sign Reactions
12. List FDA Data by Report Date
13. List of Fatal Reaction Over a Date Range
14. Print Summary of Outcomes
15. Frequency Distribution of Causative Agents
16. Frequency Distribution of Drug Classes
17. Total Reported Reactions Over a Date Range
18. P&T Committee ADR Outcome Report
19. P&T Committee ADR Report

List of Fatal Reaction Over a Date Range

This option lists all fatal adverse drug reactions over a selected date range.

The header of the report contains the name of the report, the date range selected, and the date that the report was printed. The body of the report contains the name of the patient, the last four digits of the patient's SSN, the date of the reaction, the name of the related reaction, and the date the patient died.

```
Select Reports Menu Option: 13 List of Fatal Reaction over a Date Range
Select an Observed date range for this report.
Enter Start Date: T-365 (JAN 30, 1995)
Enter Ending Date: T (JAN 30, 1996)

DEVICE: HOME// <Enter> HOME

Report Date: Jan 30, 1996 Page: 1
                List of Fatal Reaction over a date range
                From: 1/30/95 To: 1/30/96

Patient          Dates          Related Reaction          Date Died
-----
ARTPATIENT,TWO (T0112) 2/8/95          TYLOXAPOL                  2/9/95

Enter RETURN to continue or '^' to exit: < Enter>
```

Print Summary of Outcomes

This option prints a summary report of patient outcomes for a selected date range.

The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the outcome and number of times a user answered with a “Yes, No or No Response” to the outcome question. A total is printed for each column of responses. The number of records processed is printed, also. The sum of each Yes, No, and No Response column equals the number of records processed (e.g., 3+38+249=290).

```
Select Reports Menu Option: 14 Print Summary of Outcomes
Select an Observed date range for this report.
Enter Start Date: T-365 (JUL 08, 2003)
Enter Ending Date: T (JUL 07, 2004)

DEVICE: HOME// <Enter> ANYWHERE

Report Date: Jul 07, 2004                               Page: 1
                                Summary of Outcomes
                                From: 7/8/03 To: 7/7/04
                                Yes           No           No Response
-----
Patients that Died:                | 2           | 50
Reactions treated with RX drugs:   | 2           | 50
Life Threatening illness:         | 2           | 50
Required ER/MD visit:              |             | 52
Required hospitalization:          | 2           | 50
Prolonged Hospitalization:         | 2           | 50
Resulted in permanent disability:  | 2           | 50
Patient recovered:                 |             | 52
Congenital Anomaly:                | 2           | 50
Required intervention:             | 2           | 50
-----
Totals: 0                          | 16          | 504

Total number of records processed 52
Enter RETURN to continue or '^' to exit: ^
```

Frequency Distribution of Causative Agents

This option prints a report of the frequency distribution of causative agents for a date range selected by you.

The header of the report contains the name of the report, the date range selected by you and the date that the report was run. The body of the report contains the name of the causative agent and the number of times it was reported within the date range.

```
Select Reports Menu Option: 15  Frequency Distribution of Causative Agents
Select an Observed date range for this report.
Enter Start Date: T-365  (JUL 08, 2003)
Enter Ending Date: T  (JUL 07, 2004)

DEVICE: HOME// <Enter> ANYWHERE
Report Date: Jul 07, 2004                                     Page: 1
                Frequency Distribution of Causative Agents
                From: 7/8/03 To: 7/7/04
Causative Agents                Number
-----
                CHOCOLATE : 6
                AMOXICILLIN : 3
                DUST : 3
                FILGRASTIM : 3
                PENICILLIN : 3
                ZANTAC : 3
                ACYCLOVIR : 2
                ANTIRABIES SERUM : 2
                BACAMPICILLIN : 2
                RANITIDINE : 2
                SHRIMP : 2
                STRAWBERRIES : 2
                ZANAMIVIR : 2
                AMPICILLIN : 1
                BENADRYL : 1
                BETA-LACTAM ANTIMICROBIALS : 1
Enter RETURN to continue or '^' to exit:
Report Date: Jul 07, 2004                                     Page: 2
                Frequency Distribution of Causative Agents
                From: 7/8/03 To: 7/7/04
Causative Agents                Number
-----
                CAFFEINE : 1
                CORICIDIN TAB : 1
                EYE WASHES/LUBRICANTS : 1
                FLOXURIDINE : 1
                FORMALDEHYDE : 1
                FORMOTEROL : 1
                GREEN BEAN : 1
                IODINE : 1
                LEAD ACETATE PURIFIED POWDER : 1
                MENADIONE : 1
                PARABEN : 1
                PEANUT OIL : 1
                POLLEN ALLERGENIC EXTRACT : 1
                SHILEY TRACH TUBE CFS : 1

                Total number of records processed 52
Enter RETURN to continue or '^' to exit:
```

Frequency Distribution of Drug Classes

This option prints a report of the frequency distribution of drug classes for a selected date range.

The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the drug classification name followed by its code in parentheses and the number of times it was reported during the selected date range.

```
Select Reports Menu Option: 16 Frequency Distribution of Drug Classes
Select an Observed date range for this report.
Enter Start Date: T-365 (JUL 08, 2003)
Enter Ending Date: T (JUL 07, 2004)

DEVICE: HOME// ANYWHERE

Report Date: Jul 07, 2004 Page: 1
Frequency Distribution of Drug Classes
From: 7/8/03 To: 7/7/04
Drug Class Number
-----
PENICILLINS,AMINO DERIVATIVES (AM052) : 6
      ANTIVIRALS (AM800) : 4
      HISTAMINE ANTAGONISTS (GA301) : 4
      BLOOD FORMATION PRODUCTS (BL400) : 3
PENICILLIN-G RELATED PENICILLI (AM051) : 3
      DERMATOLOGICALS, TOPICAL OTHER (DE900) : 2
      IMMUNE SERUMS (IM400) : 2
      ANTIVIRAL, TOPICAL (DE103) : 2
      BETA-LACTAM ANTIMICROBIALS (AM100) : 1
ANTINEOPLASTICS, ANTIMETABOLITE (AN300) : 1
      ANTISEPTICS/DISINFECTANTS (AS000) : 1
      IMMUNOLOGICAL AGENTS, OTHER (IM900) : 1
      EYE WASHES/LUBRICANTS (OP500) : 1
      PHARMACEUTICAL AIDS/REAGENTS (PH000) : 1
BRONCHODILATORS, SYMPATHOMIMETI (RE102) : 1
      SUPPLIES, OTHER (XA900) : 1
      ANTIHISTAMINES, ETHANOLAMINE (AH102) : 1
      MENADIOL (VT701) : 1

Total number of records processed 52
Enter RETURN to continue or '^' to exit:
```

Total Reported Reactions Over a Date Range

This option prints a report of the total number of reported reactions for a selected date range.

The header of the report contains the title of the report and when it was run. The body of report contains the total number of actions reported for the date range listed.

```
Select Reports Menu Option: 17 Total Reported Reactions Over a Date Range
Select an Observed date range for this report.
Enter Start Date: T-365 (JUL 08, 2003)
Enter Ending Date: T (JUL 07, 2004)
```

```
DEVICE: HOME// ANYWHERE
```

```
Report Date: Jul 07, 2004
```

```
Page: 1
```

```
Reported Reactions
```

```
-----
Total Number of Reported Reactions: 52
From: 7/8/03 To: 7/7/04
Enter RETURN to continue or '^' to exit:
```

P&T Committee ADR Outcome Report

This option displays a list of Adverse Drug Reactions (ADRs) over a date range and a summary of the listed outcomes for those ADRs. The header of this report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent, the signs and symptoms, whether the reaction required treatment (Req. Tx), whether the reaction required hospitalization (Req. Hosp), whether the reaction caused a permanent disability (Dis.), and did the patient die as a result of the reaction.

```
Select Reports Menu Option: 18 P&T Committee ADR Outcome Report
Select an Observed date range for this report.
Enter Start Date: T-365 (JUL 08, 2003)
Enter Ending Date: T (JUL 07, 2004)
```

DEVICE: HOME// <Enter> ANYWHERE

Report Date: Jul 07, 2004 Page: 1
P&T Committee ADR Outcome Report
From: 7/8/03 To: 7/7/04

Obsv. Date	Causative agent-Pat. ID	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death
7/16/03	BETA-LACTAM ANTIMICROB-C4573	HYPOTENSION ANAPHYLAXIS				
7/16/03	RANITIDINE-F8839	CHILLS				
7/30/03	PARABEN-F0388					
7/31/03	CHOCOLATE-W0167					
8/1/03	ACYCLOVIR-A2222	CHILLS				
8/1/03	BENADRYL-F0388	NAUSEA, VOMITING CHILLS				

Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004 Page: 2
P&T Committee ADR Outcome Report
From: 7/8/03 To: 7/7/04

Obsv. Date	Causative agent-Pat. ID	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death
8/19/03	CHOCOLATE-B5545	CHILLS				
8/21/03	DUST-J8910	CHILLS				
8/27/03	DUST-W1321	CHILLS				
8/27/03	SHILEY TRACH TUBE CFS-S4423	CHILLS				
8/28/03	CHOCOLATE-W1321	DRY NOSE				
8/28/03	GREEN BEAN-F8828	CHILLS				
8/28/03	STRAWBERRIES-A2222	CHILLS				

Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004

Page: 3

P&T Committee ADR Outcome Report
From: 7/8/03 To: 7/7/04

Obsv. Date	Causative agent-Pat. ID	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death
8/28/03	ZANTAC-A2222	ANXIETY				
8/28/03	ZANTAC-W1321	ANXIETY				
9/17/03	POLLEN ALLERGENIC EXTR-B8831	HYPOTENSION				
11/4/03	CAFFEINE-B8831	RASH				
1/19/04	EYE WASHES/LUBRICANTS-A4321	DROWSINESS				
1/27/04	DUST-N5423	CHILLS				
1/30/04	CHOCOLATE-B1996	CHILLS				

Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004

Page: 4

P&T Committee ADR Outcome Report
From: 7/8/03 To: 7/7/04

Obsv. Date	Causative agent-Pat. ID	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death
1/30/04	CHOCOLATE-Z3431	CHILLS				
2/2/04	PENICILLIN-L7727	ITCHING, WATERING EY				
2/2/04	ZANTAC-N5423	CHILLS				
2/12/04	AMOXICILLIN-Z4255	CHILLS DRY MOUTH				
2/18/04	FILGRASTIM-Z3333	CHILLS				
2/18/04	FILGRASTIM-Z3333	CHILLS ITCHING, WATERING EY				

Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004

Page: 5

P&T Committee ADR Outcome Report
From: 7/8/03 To: 7/7/04

Obsv. Date	Causative agent-Pat. ID	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death
2/19/04	AMOXICILLIN-Z4255	HYPOTENSION				
2/19/04	PENICILLIN-Z4255	CHILLS				
2/26/04	FILGRASTIM-Z6414	CHILLS FREE TEXT				
2/26/04	MENADIONE-Z8322	CHILLS				

		FREE TEXT				
2/27/04	BACAMPICILLIN-B8849	DIARRHEA				
2/27/04	BACAMPICILLIN-Z4255	DIARRHEA				

Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004 Page: 6
P&T Committee ADR Outcome Report
From: 7/8/03 To: 7/7/04

Obsv. Date	Causative agent-Pat. ID	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death
3/16/04	CHOCOLATE-A0150	DROWSINESS NAUSEA, VOMITING DIARRHEA				
3/16/04	PEANUT OIL-A0150	HYPOTENSION DIARRHEA DRY MOUTH				
3/17/04	CORICIDIN TAB-A4321	CHILLS HYPOTENSION				
4/2/04	AMPICILLIN-A8989	CHILLS				
4/5/04	STRAWBERRIES-A8989	CHILLS				

Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004 Page: 7
P&T Committee ADR Outcome Report
From: 7/8/03 To: 7/7/04

Obsv. Date	Causative agent-Pat. ID	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death
4/30/04	PENICILLIN-D6616	HIVES				
5/20/04	IODINE-B8847	DRY NOSE				
5/20/04	LEAD ACETATE PURIFIED -Z9558	HIVES				
6/8/04	ANTIRABIES SERUM-H2591	CHILLS				
6/8/04	ANTIRABIES SERUM-A0999	CHILLS				
6/15/04	SHRIMP-T8828	HIVES				
6/21/04	ACYCLOVIR-Z9558	HYPOTENSION				

Enter RETURN to continue or '^' to exit:

Report Date: Jul 07, 2004 Page: 8
P&T Committee ADR Outcome Report
From: 7/8/03 To: 7/7/04

Obsv. Date	Causative agent-Pat. ID	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death
6/21/04	RANITIDINE-Z9558	CHILLS				

6/21/04	ZANAMIVIR-Z9558	CHILLS				
6/21/04	ZANAMIVIR-Z9558	CHILLS HYPOTENSION				
6/28/04	SHRIMP-A4321	RASH				
6/30/04	AMOXICILLIN-A4321					
6/30/04	FLOXURIDINE-A4321	RASH HIVES				
Enter RETURN to continue or '^' to exit:						
Report Date: Jul 07, 2004			Page: 9			
P&T Committee ADR Outcome Report						
From: 7/8/03 To: 7/7/04						

Obsv. Date	Causative agent-Pat. ID	Sign/Symptoms	Req. Tx	Req. Hosp	Dis.	Death

6/30/04	FORMALDEHYDE-A4321	RASH				
6/30/04	FORMOTEROL-A4321	RASH				
Enter RETURN to continue or '^' to exit:						

P&T Committee ADR Report

This option displays a list of Adverse Drug Reactions (ADRs) over a date range. The Sign/Symptoms, Mechanism, Severity, and Comments are displayed for each ADR. This report should be queued to a printer that has a column width of 132 characters. The header of the report contains the name of the report, the date range selected, and the date the report was run. The body of the report contains the date the reaction was observed, the causative agent, the signs and symptoms, the mechanism of the adverse reaction (i.e., A=Allergy, P=Pharmacologic, and U=Unknown), and any comments entered. The comments are identified by category (i.e., Observer, Verifier or Entered in Error).

Select Reports Menu Option: **19** P&T Committee ADR Report

Select an Observed date range for this report.

Enter Start Date: **1/1/96** (JAN 01, 1996)

Enter Ending Date: **1/31/96** (JAN 31, 1996)

This report required a 132 column printer.

DEVICE: HOME// **QUEUE** TO PRINT ON

DEVICE: HOME// **SELECT APPROPRIATE PRINTER** COMPUTER ROOM

Requested Start Time: NOW// **< Enter >** (FEB 06, 1996@11:23:22)

Request queued...

Report Date: Feb 06, 1996 Page: 1

P&T Committee ADR Report

From: 1/1/96 To: 1/31/96

Obsv. Date	Causative agent	Sign/Symptoms	ADR Mech	ADR Svr.	Comments
1/1/96	PSUEDOEPHEDRINE	HIVES ITCHING, WATERING EY NAUSEA, VOMITING DIARRHEA ANXIETY CHILLS DROWSINESS DRY MOUTH HYPOTENSION	U		OBSERVER COMMENTS: THIS IS A TEST
1/8/96	SALT SUBSTITUTE	SWELLING (NON-SPECI NAUSEA, VOMITING	U	MOD.	OBSERVER COMMENTS: Patient's swelling was observed by the nurse.
1/8/96	FUZZEL	HIVES ITCHING, WATERING EY NAUSEA, VOMITING DIARRHEA ANXIETY	U		OBSERVER COMMENTS:
1/9/96	POLLEN	ITCHING, WATERING EY	U	MOD.	OBSERVER COMMENTS: the patient had a moderate reaction to some flowers.
1/10/96	ASPIRIN	NAUSEA, VOMITING DRY MOUTH	U		

Using ART in CPRS GUI

On the Cover Sheet

In the Allergies/Adverse Reactions pane on the Cover Sheet tab, CPRS displays a list of causative agents associated with patients' allergies or adverse reactions. If patients have causative agents listed in this pane, CPRS also displays the word *Allergies* in the Postings pane and the letter **A** (for allergies) on the Postings button. To view more information about allergies or adverse reactions associated with the causative agents listed in the Allergies/Adverse Reactions pane, simply click on the causative agent in which you are interested. CPRS then displays a comprehensive listing of the details associated with this causative agent.

You can obtain less comprehensive information about allergies and adverse reactions by clicking the word *Allergies* in the Postings pane. When you do this, CPRS displays information about the causative agents, severity, and signs/symptoms associated with patients' allergies and adverse reactions.

From the Cover Sheet tab, you can also:

- Enter new allergies
- Mark existing allergies or adverse reactions as having been entered in error
- Enter no-known-allergies (NKA) assessments

Entering Allergies from the Cover Sheet

You can enter a new allergy or adverse reaction from the Cover Sheet tab in either of two ways:

- Right-click anywhere within the Allergies/Adverse Reactions pane.
- Click to display more information about a causative agent listed in the Allergies/Adverse Reactions pane.

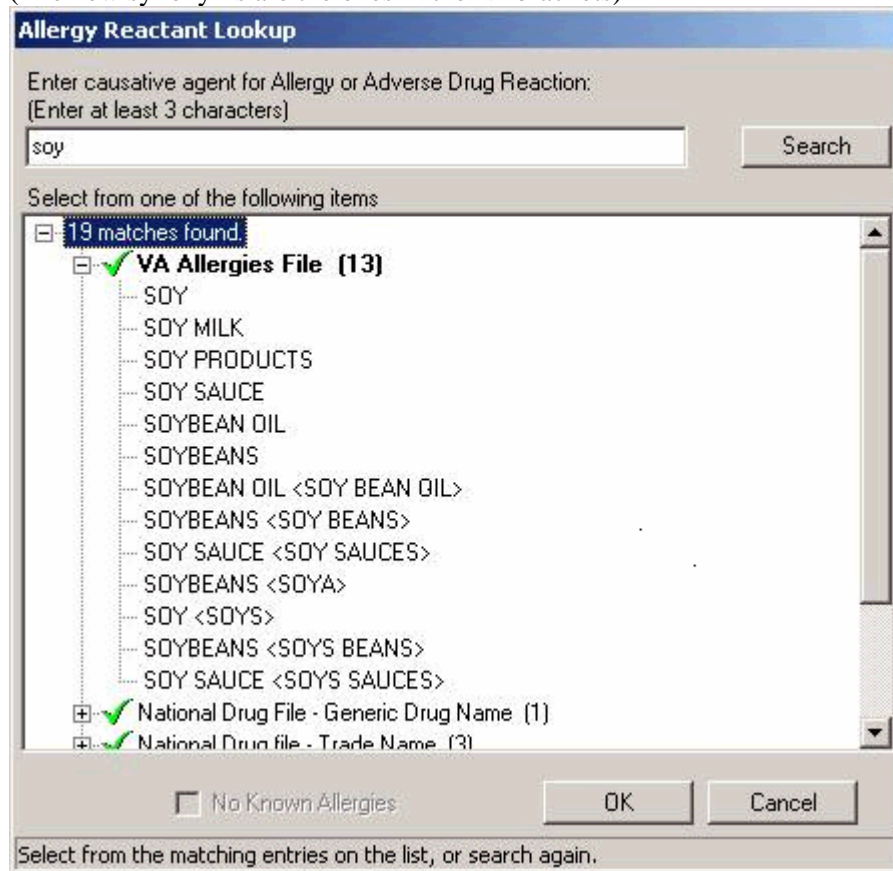
Method One

Follow these steps to enter new allergies using the first of the two methods mentioned above:

1. Move your mouse arrow to a location anywhere within the Allergies/Adverse Reactions pane.
2. Right-click to display a pop-up menu.
3. From this menu, select Enter new allergy. CPRS displays the Allergy Reactant Lookup dialog.

Note: Many new synonyms have been added to the ALLERGY REACTANT file #120.82, as part of data standardization. When you open the Allergy Reactant Lookup window and enter three characters for a causative agent, you might see a list of matches such as this:

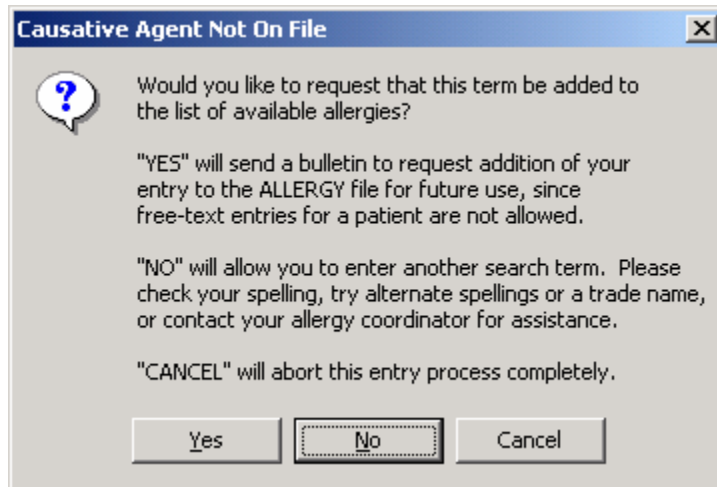
(The new synonyms are the ones in the <> brackets)



4. In the Enter causative agent for Allergy or Adverse Drug Reaction field, type the first three characters (minimum) of the causative agent's name.
5. Click Search. CPRS displays a list of possible matches. NOTE: in this example there are matches in the National Drug File – Generic Name, and also in the National Drug File – Trade name, and possibly even matches in the two files that can't be seen in the example, Drug Class and Drug Ingredient.

6. If the causative agent you typed does not match any of the agents currently available, CPRS displays the Causative Agent Not On File dialog, from which you can select one of the following three options:

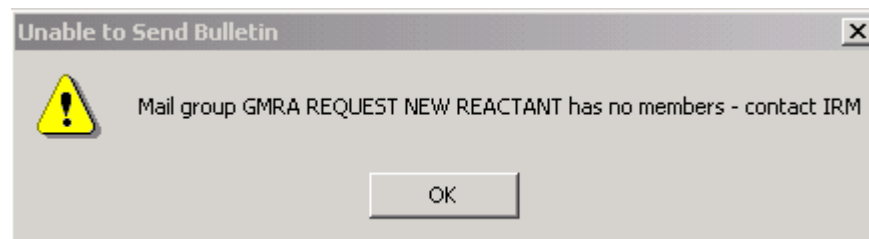
Note: The patient's chart will not be updated unless you choose a causative agent that is on file.



- a. **Yes:** Use this option to request that the causative agent be added to the ALLERGY REACTANT file. When you click Yes, CPRS displays the Enter Optional Comments dialog, which enables you to type additional comments (optional), such as the signs or symptoms that occurred as a result of contact with this causative agent, or whether you observed these symptoms firsthand. After you type your comments, click Continue. CPRS then sends to your site's mailgroup a message that includes the following items:
- The causative agent you attempted to enter
 - The name of the patient for whom you attempted to make this entry
 - Your name, title, and contact information
 - Your comments (if any)

Members of your mailgroup will review this message and, if appropriate, will request that the agent be entered using the NTRT system, so that it can add the causative agent to the ALLERGY REACTANT file for all sites.

Note: If your site's IRM staff has not yet added members to your site's GMRA Request New Reactant mail group, CPRS displays the following message:



- b. **No:** Clicking No enables you to try an alternate spelling or trade name for your causative agent, or to type another causative agent.
- c. **Cancel:** Use this option if you want to cancel your allergy entry.

7. If the causative agent you typed matches an agent that is currently available, select the agent. (Click + to expand a heading.)

Note: With CPRS GUI 24 or later, you may not add free-text causative agents. If you select an item under the “Add new free-text allergy” heading, CPRS displays the *Causative Agent Not On File* dialog. (See Step 6 above.)

8. Click OK. The Enter Allergy or Adverse Reaction dialog appears.

NOTE: Synonyms appear now in <> brackets.

Enter Allergy or Adverse Reaction

General

No Known Allergies

Active Allergies

Causative agent: ADHESIVE TAPE ...

Nature of Reaction: Allergy

Originator: CPRSPROVIDER,TWO

Origination Date: Jul 25,2005@15:40 ...

Observed Historical

Signs/Symptoms: RASH <CUTANEOUS

Selected Symptoms: CUTANEOUS ERUPTION

Comments

ID Band Marked

Date/Time Remove

OK Cancel

Note: You can view a patient’s current allergies or adverse reactions by clicking the Active Allergies button.

9. Using the Originator box, select an originator.
10. Use the Observed or Historical option button to indicate whether the entry is for an observed or historical allergy, respectively. (If you point your mouse at either of these option buttons, CPRS displays a hover hint that defines observed and historical.)

Note: CPRS does not allow you to select future dates for observed allergy/adverse reaction entries.

Note: When you select Observed for a drug reaction, CPRS generates a Progress Note. Once this note is signed by the user entering the allergy or by an administrative update user, the note will be viewable by all users.

11. Select the Nature of Reaction (Allergy, Pharmacological, or Unknown).

The Nature of Reaction can be Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent, regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions, such as exposure to a large amount. Unknown is provided if you are not sure what Nature of Reaction (mechanism) to enter.

Note: Allergies are a subset of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

12. If you are entering an observed allergy, use the Reaction Date/Time and Severity boxes to select a reaction date, time, and severity. (The Severity box is not visible for historical allergies. If the Severity box is visible, CPRS displays a ? button at its side. If you click this button, CPRS displays text explaining severity selections.)

13. Using the Signs/Symptoms box, select one or more signs or symptoms. The signs and symptoms you select appear in the Selected Symptoms pane.

14. To associate a date and time with a symptom (optional), click to select the symptom in the Selected Symptoms pane.

15. Click the Date/Time button located below the Selected Symptoms pane. CPRS displays the Select Date/Time dialog, from which you can select the date and time that the symptom first appeared.

Note: If you mistakenly enter a sign or symptom but have not yet accepted it by selecting OK, select the symptom in the Selected Symptoms pane and click the Remove button located beneath the pane.

16. Type comments for the allergy in the Comments box.

17. If you have marked the allergy or adverse reaction on the patient's identification (ID) band (or if you know that someone else has), select the ID Band Marked checkbox.

Note: CPRS activates the ID Band Marked checkbox only for inpatients and then only if your site's IRM staff has set a parameter indicating that your site wants to track this information. Depending on whether your IRM staff has set related parameters, if you do *not* select activated ID Band Marked checkbox, the system may send a bulletin notifying a mail group that the patient's allergy or adverse reaction is not marked on his or her ID band.

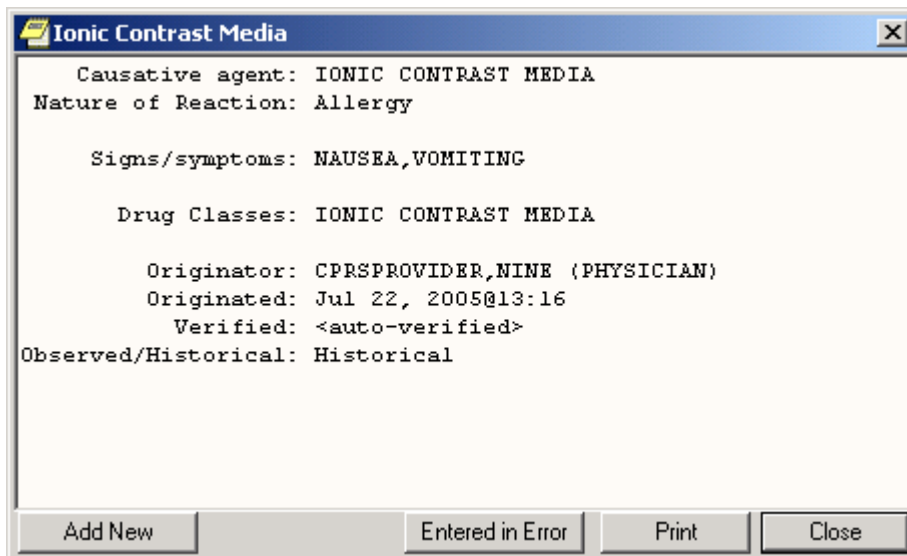
18. Click OK. CPRS displays the newly entered causative agent in the Allergies/Adverse Reactions pane. If you click on the causative agent, CPRS displays all of the information you just entered about the associated allergy or adverse reaction. CPRS also displays the letter **A** (for allergies) on the Postings button and the word *Allergies* in the Postings pane. If

you click the word *Allergies* in the Postings pane, CPRS displays selected information about all of the patient's active allergies and adverse reactions, including the allergy or adverse reaction you just entered.

Method Two

Follow these steps to enter a new allergy using the second of the two methods mentioned above:

1. Click to select a causative agent listed in the Allergies/Adverse Reactions pane. CPRS displays a dialog that includes details about the allergy or adverse reaction associated with the selected causative agent. The dialog also includes four buttons.

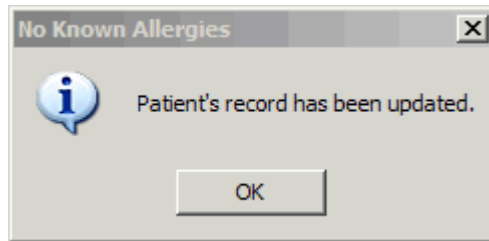


2. Click the Add New button. CPRS displays the Allergy Reactant Lookup dialog.
3. Follow steps 4 through 18 of the instructions for entering allergies using the first method. CPRS displays the newly entered causative agent in the Allergies/Adverse Reactions pane. If you click on the causative agent, CPRS displays all of the information you just entered about the associated allergy or adverse reaction. CPRS also displays the letter **A** (for allergies) on the Postings button and the word *Allergies* in the Postings pane. If you click the word *Allergies* in the Postings pane, CPRS displays selected information about all of the patient's allergies or adverse reactions, including the allergy or adverse reaction you just entered.

Entering No-Known-Allergies Assessments

You can enter no-known-allergies (NKA) assessments for patients who have no active allergies by taking the following steps:

1. Right-click within the Allergies/Adverse Reactions pane.
2. From this menu, select Mark patient as having No Known Allergies (NKA). CPRS displays the No Known Allergies dialog.



Note: CPRS activates The Mark patient as having No Known Allergies (NKA) menu selection only for patients who have no active allergies. When patients have active allergies, CPRS deactivates this selection.

3. Click **OK**.

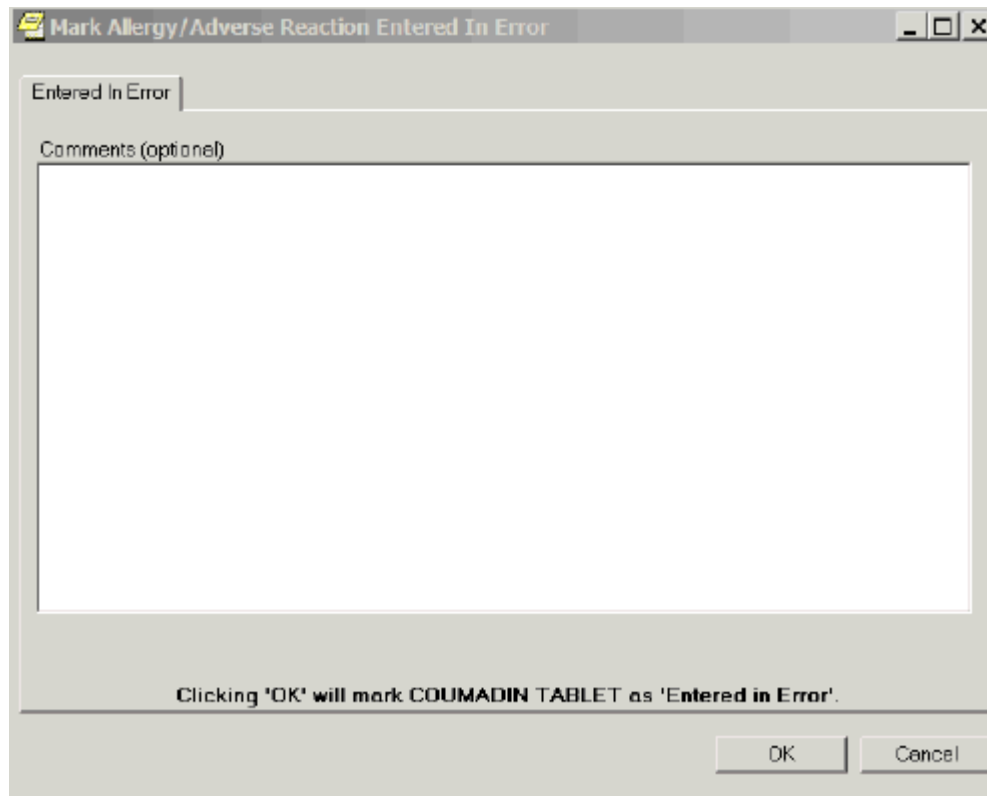
Marking Allergies as Entered in Error

CPRS offers two methods for marking allergies as having been entered in error. To mark an allergy as entered in error, the user must have the parameter OR ALLERGY ENTERED IN ERROR appropriately set.

Method One

Follow these steps to use the first method:

1. In the Allergies/Adverse Reactions pane, place your mouse pointer over an erroneously entered causative agent and right-click to display a menu.
2. From this menu, select Mark selected allergy as entered in error. CPRS displays the **Mark Allergy/Adverse Reaction Entered In Error** dialog.



3. If your site has enabled the *Comments* feature, you may (optionally) type comments in the Comments (optional) text box.

Note: If your site has not enabled the *Comments* feature, CPRS disables the dialog, which in this case is named Comments (disabled).

4. Click **OK**. CPRS displays an Are you Sure? dialog.

5. If you are sure the causative agent was entered in error, click **Yes**. CPRS removes the causative agent from the Allergies/Adverse Reactions pane and from the list of allergies it displays when you click *Allergies* in the Postings pane.

Note: CPRS also generates a Progress Note when an allergy is marked “Entered in Error”. When this note is signed by the user who marked the allergy as entered in error or by an administrative update user, the note will be viewable by all CPRS users.

Method Two

Take the following steps to use the second method:

1. Click a causative agent (or highlight using the Tab and arrow keys and press <Enter>) that appears in the Allergies/Adverse Reactions pane. CPRS displays a dialog that contains detailed information about the allergy or adverse reaction. This dialog includes four buttons.
2. Click the Entered in Error button. CPRS displays the Mark Allergy/Adverse Reaction Entered In Error dialog.
3. If your site has enabled the *Comments* feature, you may (optionally) type comments in the Comments (optional) dialog.
4. Click OK. CPRS displays an Are you Sure? dialog.
5. If you are sure the causative agent was entered in error, click **Yes**. CPRS removes the causative agent from the Allergies/Adverse Reactions pane and from the list of allergies it displays when you click *Allergies* in the Postings pane.

Note: CPRS also generates a Progress Note when an allergy is marked “Entered in Error”. When this note is signed by the user who marked the allergy as entered in error or by an administrative update user, the note will be viewable by all CPRS users.

Allergy Detail changes

When you look at the detail of an allergy, you may see updates based on the VETS push.

Sample of detail listed below:

```
Causative agent: PROPYL PARABEN
Nature of Reaction: Adverse Reaction

Signs/symptoms: ECG: EXTRASYSTOLE

                PAIN IN EYE
                MYOCARDIAL INFARCTION
                MUSCLE WEAKNESS
                AKATHISIA
                SERUM AMYLASE RAISED
                WEIGHT GAIN FINDING
                WEAKNESS PRESENT

Drug Classes: MULTIVITAMINS
Originator: CPRSTESTER,TWO (BAY PINES TEST LAB)
Originated: Jun 07, 2005@18:06
Obs dates/severity: JUN 07, 2005 SEVERE

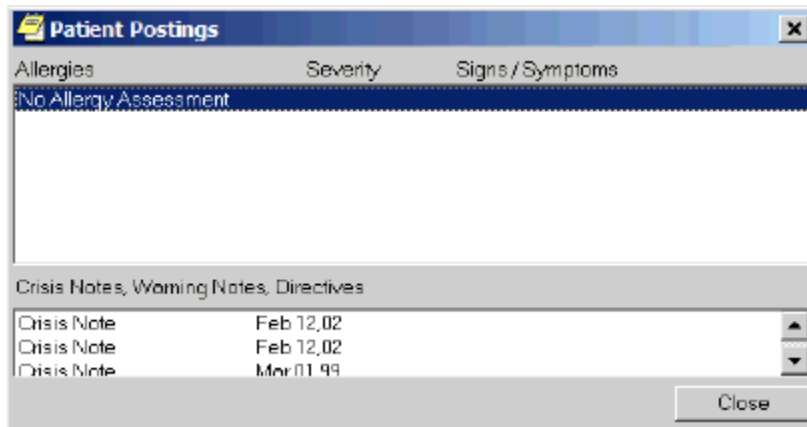
Verified: <auto-verified>
Observed/Historical: Observed
```

Reviewing and Creating Postings

Postings contain critical patient-related information that hospital staffs need to be aware of. The Postings button is visible on all tabs of the CPRS GUI window and is always located in the upper right corner of the window.

To view a posting using the Postings (CWAD) button, follow these steps:

1. Click the Postings button (available from any tab). CPRS displays the *Patient Postings* dialog.



2. From the *Patient Postings* dialog, click to select the particular posting in which you are interested.

To view the posting from the Cover Sheet, follow these steps:

3. On the Cover Sheet tab, click on a specific posting that appears in the Postings pane to display the details.
4. When finished, click Close.

Entering Allergies from the Orders Tab

Although allergies and adverse reactions are not orders and CPRS does not display them on the **Orders** tab, you can enter allergies and adverse reactions from the **Orders** tab. You can also enter allergies from the **Cover Sheet** tab. (See “Entering Allergies” in the Assessing, Entering, and Reviewing Allergies/Adverse Reactions” section of this manual.)

Entering New Allergies

To enter allergies or adverse reactions from the **Orders** tab, take the following steps:

1. Click the Orders tab.

2. Select Allergies from the Write Orders pane.
The Allergy Reactant Lookup dialog appears.

Note: Your site may have defined and configured other order menus to include allergy-entry dialogs. Regardless of the allergy-entry menu you select, if you haven't entered encounter information, the Location for Current Activities dialog appears before the Allergy Reactant Lookup dialog appears. You must complete the Location for Current Activities dialog before proceeding.

3. Type the causative agent in the search field. (You must enter the first three letters (minimum) of the agent's name.)

4. Click Search.

Matching agents appear in the Select from one of the following items pane. If the causative agent you typed does not match any of the agents currently available for your site, CPRS displays the Causative Agent Not On File dialog, from which you can select one of the following options:

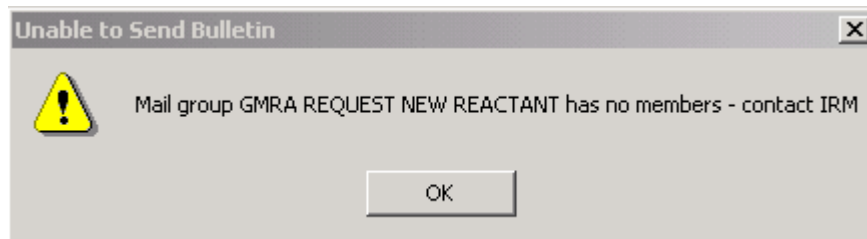
Note: The patient's chart will not be updated unless you choose a causative agent that is on file.

- a. **Yes:** Use this option to request that the causative agent be added for your site. When you click Yes, CPRS displays the Enter Optional Comments dialog, which enables you to type additional comments (optional), such as the signs or symptoms that occurred as a result of contact with this causative agent, or whether you observed these symptoms firsthand. After you type your comments, click **Continue**. CPRS then sends to members of your site's GMRA Request New Reactant mail group a message that includes the following items:

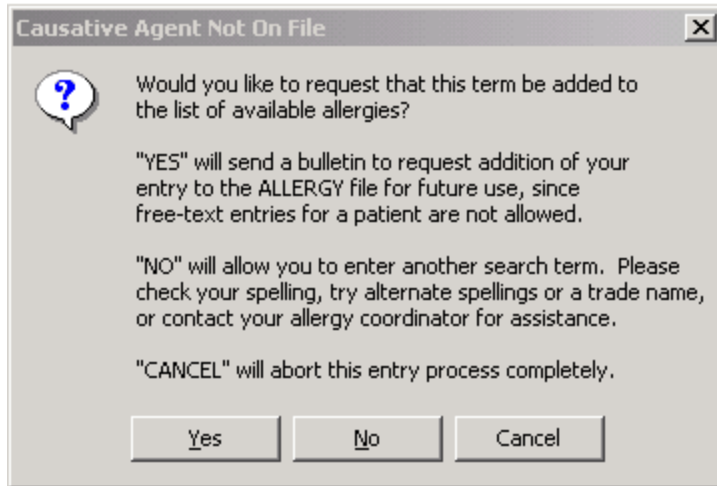
- The causative agent you attempted to enter
- The name of the patient for whom you attempted to make this entry
- Your name, title, and contact information
- Your comments

Members of your site's GMRA Request New Reactant mail group will review this message and, if appropriate, request (through NTRT) that the causative agent be added to the national ALLERGIES REACTANT file.

Note: If your site's IRM staff has not yet added members to your site's GMRA Request New Reactant mail group, CPRS displays the following message:



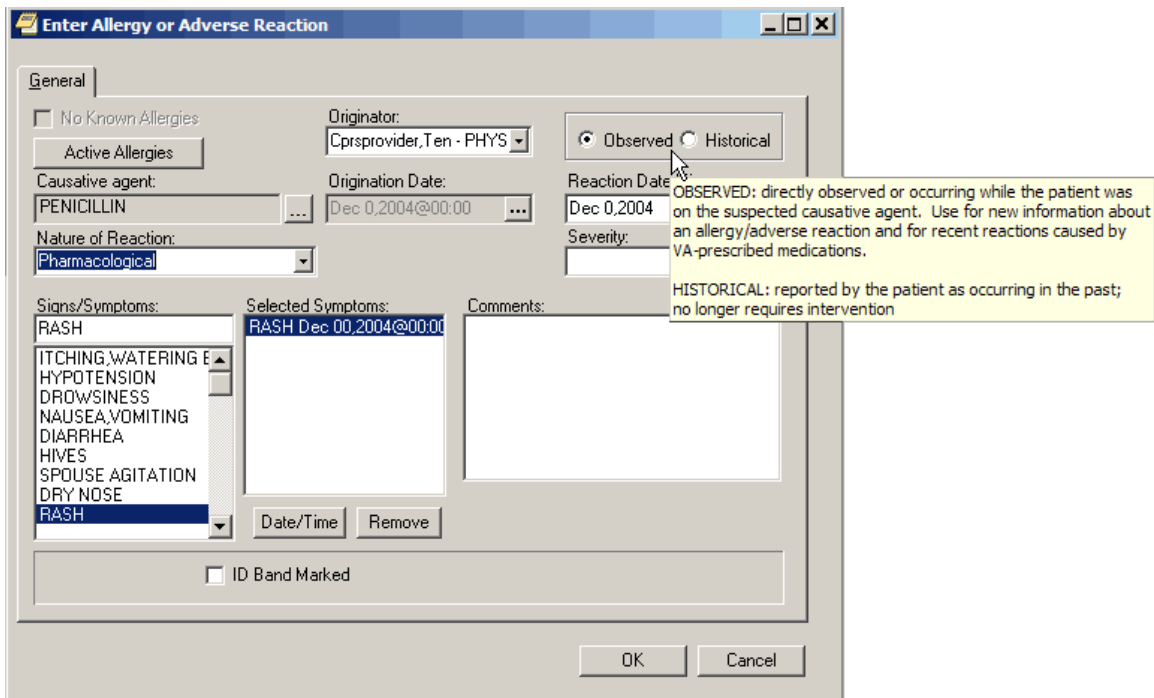
- b. **No:** Use this option if you want to try an alternate spelling or trade name for your causative agent, or if you want to type another causative agent.
- c. **Cancel:** Use this option if you want to cancel your allergy order.



- If the causative agent you typed matches an agent that is currently available for your site, select the agent. (Click + to expand a heading.)

Note: With CPRS GUI 24 or later, you may not add free-text causative agents. If you select an item under the "Add new free-text allergy" heading, CPRS displays the Causative Agent Not On File dialog. (See Step 4 above.)

- Click **OK**.
The Enter Allergy or Adverse Reaction dialog appears.



Note: You can view a patient's current allergies or adverse reactions by clicking the Active Allergies button.

- Using the Originator box, select an originator.

8. Use the Observed or Historical option button to indicate whether the entry is for an observed or historical allergy, respectively. (When you point your mouse at either of these buttons, CPRS displays a hover hint explaining the observed and historical options.)

Note: CPRS does not allow you to select future dates for observed allergy/adverse reaction entries.

Note: When you select Observed for a drug reaction, CPRS generates a Progress Note. Once this note is signed by the user entering the allergy or by an administrative update user, the note will be viewable by all users.

9. Select the Nature of Reaction (Allergy, Pharmacological, or Unknown).

The Nature of Reaction (also known as mechanism) can be Allergy, Pharmacologic, or Unknown. An allergic reaction occurs because the patient is sensitive to a causative agent, regardless of the amount the patient is exposed to. A pharmacologic (non-allergic) reaction occurs when the patient is sensitive to an agent under certain conditions, such as exposure to a large amount. Unknown is provided if you are not sure what mechanism to enter.

Note: Allergies are a subset of the world of adverse reactions. All allergies are adverse reactions, but not all adverse reactions are allergies.

10. If you are entering an observed allergy, use the Reaction Date/Time and Severity boxes to select a reaction date, time, and severity. (The Severity text box is not visible for historical allergies. When the Severity box is visible, CPRS displays a ? button next to it. If you click this button, CPRS displays text that provides information about available severity selections.)

Note: CPRS does not allow you to enter future dates for observed reactions.

11. Using the Signs/Symptoms box, select one or more signs or symptoms. The signs and symptoms you select appear in the Selected Symptoms pane.
12. To associate a date and time with a symptom (optional), click to select the symptom in the Selected Symptoms pane.
13. Click the Date/Time button located below the Selected Symptoms pane. CPRS displays the Select Date/Time dialog, from which you can select the date and time that the symptom first appeared.

Note: If you mistakenly entered a sign or symptom but have not yet accepted it by selecting OK, select the symptom in the **Selected Symptoms** pane and click the **Remove** button located beneath the pane.

14. Type comments for the allergy in the Comments box.
15. If you have marked the allergy or adverse reaction on the patient's identification (ID) band (or if you know someone else has), select the ID Band Marked checkbox.

Note: CPRS activates the ID Band Marked check box only for inpatients and then only if your site's IRM staff has set a parameter indicating your site wants to track this information. Depending on whether your IRM staff has set related parameters, if you do *not* select activated ID Band Marked checkbox, the system may send a bulletin notifying a mail group that the patient's allergy or adverse reaction is not marked on his or her ID band.

16. Click OK.

Although CPRS does not display allergy-related assessments on the Orders tab, you can also enter an assessment of no known allergies (NKA) from the Orders tab.

Entering No Known Allergies

To enter a no-known allergies assessment from the Orders tab, follow these steps:

1. Click the Orders tab.
2. Select Allergies from the Write Orders pane.
The Allergy Reactant Lookup dialog appears.

Note: Your site may have defined and configured other order menus to include allergy-entry dialogs. Regardless of the allergy-entry menu you select, if you haven't entered encounter information, the Location for Current Activities dialog appears before the Allergy Reactant Lookup dialog appears. You must complete the Location for Current Activities dialog before proceeding.

3. Select the No Known Allergies checkbox in the lower portion of the dialog box.
4. Click OK.

Note: You can also enter a no-known-allergies assessment from the Cover Sheet tab.

Glossary

Adverse Reaction	Any condition precipitated by a drug that requires patient treatment, admission or transfer; prompts a specialty consultation; or causes injury or death. Every allergy is an adverse reaction, but every adverse reaction is not an allergy.
Adverse Reaction Only	Something that is an adverse reaction but not an allergy.
Adverse Reaction Tracking	The software package that stores and reports the patient allergy or adverse reaction data.
Allergy	A state of hypersensitivity induced by exposure to a certain agent
Application	A system of computer programs and files that have been specifically developed to meet the requirements of a user or group of users. Examples of VistA applications are the MAS and Nursing modules
Application Coordinator	The person responsible for implementing a set of computer programs (application package) developed to support a specific functional area such as Nursing, MAS, etc.
ART See Adverse Reaction Tracking.	
Causative Agent	The name of the item that caused the patient to have a reaction (e.g., penicillin).
Data Standardization	The VA, in conjunction with DoD, is moving towards a unified Clinical Data Repository/Health Data Repository of computable patient data. Part of the Standards & Terminology Services, the data standardization effort is working to establish standard terminology, with clinical terms being mapped to national terminology.
Date/Time Chart Marked	In ART, this field indicates when the patient's chart has been marked to indicate this allergy or adverse reaction.
Date/Time ID Band Marked	In ART, this field indicates when the patient ID band or bracelet has been marked to indicate this allergy or adverse reaction
Date/Time MD Notified	A field in ART that indicates when the primary physician has been alerted about a patient allergy or adverse reaction.
Dechallenge	Discontinuation/removal of allergen.
GMR Allergies File	A file of allergies/adverse reactions that are used by ART. The file number is 120.82.
GMRA MARK CHART bulletin	Warning that is generated when Date/Time Chart Marked field is left blank. This warning indicates that someone has to record this allergy or adverse reaction in the patient's chart.
GMRA MARK CHART mail group	This is the group of people who are charged with the responsibility to see that all data entered into ART gets recorded in the patient's chart.
GMRA VERIFY ALLERGY bulletin	Warning that an allergy or adverse reaction has been signed off (completed) by the originator and that it is ready for the verification process.
GMRA-VERIFY ALLERGY security key	Should be given to all verifiers in ART. Allows a verifier access to the verification process
Historical	An allergy that has been stated by some source versus one that

Ingredient file	has actually been witnessed by some personnel at this facility. A file (#50.416) that contains generic drugs that are components of various drug products.
Likelihood	A measure of the probability that an allergy or adverse reaction was the cause of the patient problems indicated by the signs/symptoms. This field is calculated via an FDA algorithm
Local Drug File	The list of medications used at a particular VA facility. This file is also sent out by the VistA Pharmacy developers. The file number is 50.
Mechanism	In the context of ART, this is an indicator of whether the data for a patient is an adverse reaction only, or an allergy.
NTRT	New Term Rapid Turnaround. Requests for new terms will be made via the NTRT process. If approved, the new term will be sent to all sites for inclusion in file 120.82 or 120.83.
National Drug File	This file is a list of drug products available, which includes specific information for each product. Information included for the products are trade name, NDC number, manufacturer, VA Drug Class code, dosage form, route of administration, strength and units, ingredients, ingredient strength and units, package code, package size, package type, VA product name and VA generic name.
Observed	An allergy or adverse reaction that has actually been witnessed by some personnel at this facility.
Patient Allergies File	The file where the patient allergy/adverse reaction data is stored in ART. The file number of this file is 120.8.
Rechallenge	Reintroduction of allergen after dechallenge.
Remote Data Interoperability (RDI)	The Remote Data Interoperability (RDI) project provides a method of comparing clinical data about a patient received from all VA Medical Centers as well as clinical data from military facilities where active dual consumers are treated.
Severity	This is an index of how the allergy/adverse reaction affected the patient.
Sign/Symptom	Something that could be subjectively or objectively measured that indicates an allergy or adverse reaction.
Sign/Symptoms File	A list of signs/symptoms that can be selected for a patient allergy or adverse reaction. The file number is 120.83.
Standards & Terminology Services (STS)	The VA, in conjunction with DoD, is moving towards a unified Clinical Data Repository/Health Data Repository of computable patient data. The Standards & Terminology Services is working to establish standard terminology. Allergies and local clinical terms are being mapped to national terminology.
Top Ten Signs/Symptoms	A site-configurable set of indicators of an allergy or adverse reaction that is used to expedite data entry of these indicators.
Treatment	This is some lab test or drug intervention that was performed as a result of an allergy or adverse reaction.
True Allergy	Something that is an allergy, which implies that it is also an adverse reaction.
VA Drug Classification System file	A file (#50.605) that contains the VA Drug Classification codes and their descriptions. Each drug product in the

Verification	National Drug file is assigned a primary code, which is part of the information stored for each drug product in the National Drug file.
Verifier	The process of reviewing and approving the data entered by some clinical user. This process is done by a verifier. A person who has the GMRA-VERIFY ALLERGY security key. This person can perform verification of patient data in ART.
VUID	VHA User Identification

Appendix 1 – CPRS (GUI 25 & 26) Release Notes – ART

PATCH OR*3*233

Support for Allergy Synonyms –Allergy synonyms, if present, are now included in the SIGNS/SYMPTOMS selection box. This is included in patch OR*3*233, which will be distributed with GMRA patch 23.

GUI 26

- The “Bulletin has been sent” message that CPRS displays after the user requests the addition of a new causative agent now includes the same warning included in the bulletin about that reactant not being added to the patient's record.
- **Marking Allergies as Entered in Error Now Controlled by Parameter** - In CPRS v25, any user could enter new allergies, mark a patient as NKA (no known allergies), and mark allergies entered in error from the cover sheet and the detailed display window. In v.26, the Entered in Error option requires the new parameter OR ALLERGY ENTERED IN ERROR to be enabled for the user. The other options remain open to all users as before.
- **Free-Text Signs and Symptoms No Longer Allowed** – To support of data standardization efforts, developers removed the ability to enter free-text signs/symptoms. Users must now select items from the list of available signs/symptoms.
- **Inconsistent Sending of Bulletin for Marked on Chart** – CPRS always sent the “Marked on Chart” bulletin if the user entered an allergy from the Orders tab. CPRS never sent the bulletin if the user entered the allergy from the Cover Sheet. This inconsistency has been corrected, and CPRS will never send the bulletin when the user enters a new allergy.

GUI 25

The following functionality is available only to sites that have installed OR*3.0*195, OR*3.0*216, and GMRA*4.0*21. Sites that have not installed these patches will continue to receive the ART functionality that exists in CPRS GUI 24.

- **Allergies No Longer Entered as Orders (NOIS: SHR-0603-71103)** – At sites that have installed the patches listed above, users can no longer enter allergies and adverse reactions as orders that are placed in the *ORDERS* file. Patch OR*3.0*216 exports a modified order-dialog entry—*GMRAOR ALLERGY*—in the *ORDER DIALOG* file. This entry enables CPRS to interact directly with the Adverse Reaction Tracking (ART) package (i.e., CPRS adds new allergies and adverse reactions directly into the ART package as users submit them.)

With supporting patches OR*3.0*216 and GMRA*4.0*21, CPRS GUI 25 does not display allergy information on the **Orders** tab. It displays allergy information only on the **Cover Sheet** tab. Nevertheless, users can still enter allergy information from the **Orders** tab by selecting **Allergies** in the **Write Orders** pane. (i.e., users can still go to a familiar place to enter allergies.)

In addition, users can no longer select **OTHER ALLERGY/ADVERSE REACTION** as causative agent, nor can they select **OTHER REACTION** as a sign/symptom. Changes to the

ART package have eliminated these items as choices. These changes mark a continuing effort to end free-text and unspecific entries.

If ‘type of causative agent’ references the field ALLERGY TYPE, the GUI interface doesn’t allow the user to enter this information. It is determined internally by the selection made during the Reactant lookup process. “OTHER REACTION” is still selectable from the signs/symptoms list; free text entries of signs/symptoms are allowed.

Also, CPRS now requires users to enter information about the nature of the reaction that they are documenting (**Allergy, Pharmacological, or Unknown**).

Finally, CPRS GUI 24 introduced a dialog through which users can request that a causative agent be added to their site’s *ALLERGIES* file. Users access this dialog via a warning that pops up when they attempt to enter a free-text causative agent. The warning dialog asks users to indicate—by clicking either its **YES** or **NO** button—if they want to send a causative-agent inclusion request. In CPRS GUI 24, the default button was **YES**. In CPRS GUI 25, the default button is **NO**. Furthermore, when users click the system **X** button (located in the top right-hand corner of each screen) to exit any of the screens that comprise the inclusion-request dialog, CPRS now cancels the request action.

- **Allergy Changes on the Cover Sheet** - CPRS now enables users to perform several ART-related actions from the **Cover Sheet** tab—including the following:
 - **Enter new allergy**
 - **Mark selected allergy as entered in error**
 - **Mark patient as having “No Known Allergies” (NKA)**

When users right-click within the **Allergies/Adverse Reactions** pane, CPRS displays a menu offering the three selections listed in the previous paragraph (or a sub-set, depending on the current Allergy information recorded for the patient). When users left click to select one of the allergies listed within the **Allergies/Adverse Reactions** pane, CPRS opens a window that displays details about this allergy-as it always has. However, this window now includes two additional buttons: **Add New** and **Entered in Error**. As the names of these buttons suggest, clicking them enables users to add new allergies and designate the selected allergy as entered in error, respectively. When users mark allergy entries as entered in error, the ART package notifies (via MailMan bulletins) sites’ GMRA MARK CHART mail group.

Depending on how sites have configured their *GMR ALLERGIES SITE PARAMETERS* files, the ART package could also send bulletins to one or more of the following mail groups: GMRA VERIFY DRUG ALLERGY, GMRA VERIFY FOOD ALLERGY, and GMRA VERIFY OTHER ALLERGY. In addition, marking an allergy entry as entered in error triggers the Text Integration Utility (TIU) package to generate an Allergy/Adverse Reaction progress note that is sent to the originator to document the erroneous entry. Whether users enter new allergies via the **Cover Sheet** or **Orders** tab, CPRS displays an **Enter Allergy or Adverse Reaction** dialog, through which users enter adverse reactions and allergies directly into the ART package. This dialog includes several changes, including the following changes:

- CPRS no longer allows users to enter future origination dates or future dates for observed allergies; if users attempt to enter future dates for these items, CPRS prevents them from doing so when they click OK to submit their allergy entries

- A new button containing a question mark is associated with the Severity dialog; when users select this button, CPRS displays a text box defining severity selections
- CPRS displays a hover hint when users mouse over the Observed and Historical option buttons; a user group (as opposed to OI staff) specified the text of the hover-hint
- When the amount of text in the Comments dialog exceeds its viewing area, CPRS adds a scroll bar to the dialog
- Developers altered the tabbing sequence to more closely match users' expectations
- When an allergy is marked as "Entered in Error," Drug allergy, this action generates a Progress Note for the user who marked it as "entered in error" to sign. Once the user who marked the allergy as entered in error or an administrative user signs the note, all CPRS users can view the note to know that an allergy has been removed from the list.
- When an allergy is entered as an "Observed, Drug allergy," this action generates a Progress Note for the user who entered the Allergy/Adverse reaction to sign. Once the user who made the entry or an administrative user signs the note, all CPRS users can view the note.

The **Enter Allergy or Adverse Reaction** dialog also contains a new check box: **ID Band Marked**. If the patients are inpatients and the sites have set the MARK ID BAND parameter in the *GMR ALLERGY SITE PARAMETERS* file to **1 (YES)**, users can select this check box to indicate whether they have marked allergies and adverse reactions on the patient's identification (ID) bands. If users submit an allergy entry without selecting activated **ID Band Marked** check box, the ART package automatically notifies sites' GMRA MARK CHART mail group via a MailMan bulletin. *GMR ALLERGY SITE PARAMETER* file settings also determine to which verification mail groups (GMRA VERIFY DRUG ALLERGY, GMRA VERIFY FOOD ALLERGY, or GMRA VERIFY OTHER ALLERGY) the ART package sends MailMan bulletins when users enter specific combinations of allergy information.

Deleting an assessment of NKA

From within the ART package, it is now possible to delete an assessment of NKA.

When you select a patient for entering/editing allergies and that patient doesn't have any active allergies on file, the "Does this patient have any known allergies or adverse reactions?" prompt is presented to you. If the patient has no assessment, there is no default answer. If the patient has been assessed as NKA, the default is NO.

In the case where the default answer is NO (meaning, the patient is NKA), you may enter an @ sign to indicate that the assessment should be deleted and the patient should be returned to the 'not assessed' state. This would be used in those rare cases where an assessment is erroneously assigned to the wrong patient.

Examples:

1) Patient who is currently not assessed:

```
Select PATIENT NAME: ARTPATIENT,ONE          1-20-57      456334567
YES      MILITARY RETIREE          THIS IS A TEST
```

Does this patient have any known allergies or adverse reactions? :

2) Patient who has been assessed as NKA:

```
Select PATIENT NAME: ARTPATIENT,ONE      1-20-57      456334567
YES      MILITARY RETIREE      THIS IS A TEST
Does this patient have any known allergies or adverse reactions? :
No//
```

At this point, if I enter a ?, I see what my choices are:

```
Choose from:
1      Yes
0      No
```

You may also enter @ to delete a previous NKA assessment and return the patient to a 'not assessed' state. Use this if the NKA assessment was previously incorrectly entered.

Does this patient have any known allergies or adverse reactions? : No//

The information regarding the use of the @ will only show if the patient is currently NKA. If they are not, then it doesn't show.

3) Finally, here's what it looks like when you delete the assessment:

```
Select PATIENT NAME: ARTPATIENT,ONE      1-20-57      456334567      YES
MILITARY RETIREE      THIS IS A TEST
Does this patient have any known allergies or adverse reactions? :
No// @
Assessment deleted.
```

Appendix 2 – FAQ re Data Standardization

1. Can sites continue to enter local allergies after standardization is complete?

No. The files have been locked down and local additions for allergies are not permitted. The ability to enter free-text additions to the GMR Allergies file 120.82 was taken away from sites two years ago. Removing the ability to enter free-text additions to the Sign/Symptoms file 120.83 was included in the standardization process. Sites can request additions to the GMR Allergies file 120.82 and to the Sign/Symptoms file 120.83 through the New Term Rapid Turnaround (NTRT) process. Please see the [NTRT process](#) section of this document for more information.

2. What will happen if different sites have different attributes, such as drug ingredients, designated to the same inactive term for entries in GMR Allergies file 120.82? Will the attributes stay the same after standardization at each site?

The attributes will stay the same, including drug classes and drug ingredients, for inactive terms after standardization is complete.

3. What happens to local allergies in GMR Allergy file 120.82 that are currently on file when standardization occurs?

If a local allergy on file is in the standard, then the term will remain active, but all of the term attributes (e.g. synonyms, drug classes and drug ingredients) will be overwritten by the standardized file. This standardized term will be available for recording new allergies in the future.

If a local allergy on file is *not* in the standard, then the term will become inactive, and all term attributes (e.g. synonyms, drug classes and drug ingredients) will remain the same, and the data, if applicable, will be available for order checks. However, this term will not be available for selection when recording new allergies.

4. Is there a Sign/Symptom term called “other” in the new standard for file 120.83 Sign/Symptoms?

No. “Other” does not exist in the list of standardized terms for Sign/Symptoms file 120.83. If there is a term that is not available in the Sign/Symptoms list and it needs to be added, please enter an NTRT request. See the [NTRT process](#) section of this document for more information.

5. What does the allergy “contrast media” look like in the new standard for GMR Allergies file 120.82? Will the new standard also contain the many drug classes associated with this allergy?

The contrast media allergy is in the standard GMR Allergies file 120.82. In the standard, this allergy also includes the many drug classes that are associated with this entry. We encourage sites to review and ensure that the standard is comprehensive. Compare the

drug ingredients and drug classes that have been recorded in your site's file with what is in the standard.

If differences exist between what is in the standard and what is in your file, your site data will be overwritten. Submit an NTRT request if you believe that drug classes, drug ingredients, or synonyms should be included in the standards that are not included. Please see the [NTRT process](#) section of this document for more information.

6. Should a local allergy of “Bufferin” be changed to Aspirin in the GMR Allergies file 120.82?

No. Sites are not being asked to change local allergies in the GMR Allergies file 120.82.

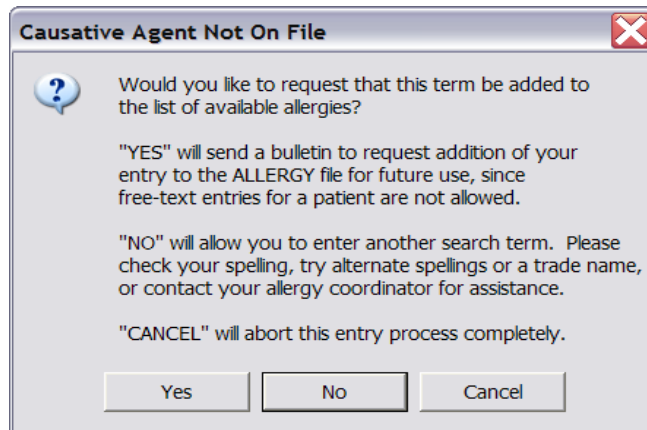
7. Will non-standard (inactivated) terms continue to be used for order checking? How?

Yes. Although inactivated terms are not available for new documentation, those that have been stored in patients' records will continue to be used for order checking. The internal entry numbers (IENs) of the inactivated terms have been preserved, and it is the IENs that are needed for order checking.

8. What is the workaround for a site, if the item that the patient is allergic to is not found in the standard GMR Allergies file 120.82 and the terms needs to be entered as an NTRT request? How does the end user document that a patient is allergic to an item that is not in the standard?

The ability to enter free-text allergies in GMR Allergies file 120.82 was taken away from sites two years ago. Please continue to use your site-developed processes to handle this documentation.

9. **Currently, there is a message or pop-up box telling an end user in CPRS that the allergy term they are searching for was not found, but that they can request that it be added (shown below). However, this message box is not available if a Sign/Symptom is not available. What is the desired work-around for a site to request that a Sign/Symptom term be added, since they will not have the instructions from this pop-up box?**



Sites may wish to handle these additions in the same manner as when requesting a new reactant, or they may wish to handle it differently. We recommend that sites communicate to the end users their desired work-around for handling these requests for additions of Sign/Symptoms.

End users are encouraged to update the patient record with the Sign/Symptom term when it becomes available in the standard. End users can enter free text Sign/Symptoms until CPRS GUI v26 is installed. However, these additions of free text Sign/Symptoms prior to CPRS GUI v26 release are highly discouraged.

10. What are sites being asked to do regarding the Top 10 List for Sign/Symptoms?

After standardization, the Top 10 List for Sign/Symptoms file #120.83 may have inactive terms. The GMRA REQUEST NEW REACTANT mail group will be notified of inactive Top 10 terms at your site after the VETS push has occurred. Sites are being asked to replace inactivated terms with standard terms as soon as possible, to prevent end users from viewing empty space in the GUI. If the inactivated terms are not replaced by active terms in the standard, the end user will need to click on the scrollbar for the Sign/Symptoms. This will cause the empty space to be auto-adjusted and the gap will no longer display in the GUI. CPRS GUI v26 will fix this so that there is no blank space.

It is possible to receive an email indicating that there are terms on the top ten list that need to be updated, but those terms do not appear when using the option to edit the terms. Some sites actually have more than 10 terms stored in the top 10 list but only the first 10 show to the user. If one of the additional terms is now inactivated, it will be included in the update message although you won't actually see it in the list.

If the e-mail update message contains terms that do not appear to be on your Top 10 list, you may ignore those terms. This problem will be fixed in a future patch.

To change inactive entries:

1. Use the Menu Option GMRA SITE FILE. The parameter is HOSPITAL.
2. Enter the number of the Sign/Symptoms that you need to change.

11. Why are sites getting e-mail messages about order checks to the GMRA mail group as the patch is being loaded and post routines are being run from this GMRA*4*23 patch?

Receipt of these messages is a result of the updates that are occurring to the Patient Allergy file 120.8 when GMR Allergies file 120.82 is standardized. Any time a file 120.82 entry has a change of drug classes or drug ingredients, and a patient has a previous allergy recorded to this entry, then the new drug classes or drug ingredients will be propagated to the Patient Allergy file 120.8. The purpose of the message is to inform the Allergy Clinical Application Coordinator of the possibility of a missed order check based on the updated allergy information. Order checks only occur when the order is placed, which means that updated allergy information is not compared against existing orders. During the update, the new allergy information is compared against the patient's active orders to determine if there are any possible drug-allergy conflicts based on the new information. There is a slight possibility of a false-positive report but each entry should be reviewed for a possible drug-allergy interaction.

12. What is the name of the mail group that will receive the e-mail notifications regarding order checks, as mentioned in the previous question?

The GMRA Request New Reactant mail group will receive these order check notifications through e-mail.

13. How can we record that a patient has No Known Allergies (NKA), when this term is not included in the standard for GMR Allergies file 120.82 and will be inactivated for future selection?

Enter no-known-allergies (NKA) assessments for patients who have no active allergies by taking the following steps in the CPRS GUI from the Coversheet:

1. Right-click within the Allergies/Adverse Reactions pane.
2. From this menu, select "Mark patient as having No Known Allergies (NKA)." CPRS displays the No Known Allergies dialog.
Note: CPRS will allow you to record a patient as having No Known Allergies (NKA) only for patients who have no active allergies. When patients have active allergies, CPRS deactivates this menu selection.
3. Click OK.

14. Can we continue to record allergies and No Known Allergies (NKA) from the Write Orders menu in the CPRS GUI?

Yes. You can continue to record new patient allergies or NKA from the Write Orders menu, or on other site-configured menus on the Orders tab in the CPRS

GUI.

15. How do we record that the patient has an “unknown reaction,” since this term is not included in the Sign/Symptoms file 120.83 for selection when recording a patient allergy reaction?

In CPRS GUI v25 you can still enter free-text Sign/Symptoms. This option has been disabled in List Manager. In the GUI, you must press <Enter> after you type the free-text Sign/Symptom. It is also possible to leave the Sign/Symptoms field blank, and make a note in the Comment field that the Sign/Symptom is unknown. Typing free-text Sign/Symptoms will not be possible with CPRS GUI v26. This FAQ will be updated when more information is available.

16. Will sites need to continue to update the Top 10 list of Sign/Symptoms when each NTRT push occurs?

Yes. If the new NTRT push inactivates entries on the Top 10 list of Sign/Symptoms, then an e-mail message will be sent to the “GMRA Request New Reactant” mail group. The message will list which terms have been inactivated and remind sites to use the menu option GMRA SITE FILE to correct these entries.

Details of what was contained in the NTRT push can be learned from the Automated Notification Report (ANR) message that will be sent, or from the NTRT Web site at <http://vista.med.va.gov/ntrt/> (under “NTRT Deployment Log”). The content list for a push will give you an idea about alternative terms that would be appropriate replacements for inactivated terms. If you are not currently receiving the ANR messages, please log a Remedy ticket to be added to the distribution of these messages.

If the e-mail update message contains terms that do not appear to be on your Top 10 list, you may ignore those terms. A problem has been identified where some sites have more than ten entries in their Top 10 list. This problem will be fixed in a future patch.

17. What is an example of a Top 10 List term that may need to be replaced due to an NTRT push?

The Enterprise Reference Terminologists are currently going through the standard for file 120.83 Sign/Symptoms and changing the primary terms to more user- or clinician-friendly terms. For example, in the most current update, some terms such as “Aptyalism,” “Face Goes Red,” and “Cutaneous Eruption” are being made inactive as primary terms, but are being added as synonyms to other primary terms. See question six in the NTRT section of this document for additional information.

In the Top 10 list, you may need to update the Top 10 list to display the updated active terms.

Example:

INACTIVATE as Primary term (Added as Synonym)	ACTIVATE as Primary term
Aptyalism	Dry Mouth
Face Goes Red	Flushing
Cutaneous Eruption	Rash

[To learn more about Data Standardization, please click this link.](#)

VA Enterprise Terminology Services (VETS) Push and Deployment Questions

1. How long will it take for a large integrated site to complete the cross-referencing of all the files after the initial VETS push or deployment has occurred, for the Allergy/Outpatient Pharmacy domain?

It is estimated to take three hours. This is approximately the amount of time it took a large integrated test site to complete this process.

2. What happens to an end user who is entering an allergy on a patient when the VETS push or deployment occurs?

There are not any effects visible to the end user who is entering in allergies while a VETS push or deployment is occurring.

3. Has this software been tested in production and the impact assessed for the use of Bar Coding Medication Administration (BCMA) and passing medications during the VETS push or deployment?

Yes. The three test sites reported that there were no reports of any adverse impacts to BCMA. Also, the software quality assurance testing included BCMA testing by the pharmacy team.

4. When will the VETS pushes or deployments occur?

The VETS pushes or deployments will be scheduled with the sites, most likely on a regular schedule to be determined. The deployments or pushes will be coordinated with the site, the HDR Implementation Manager, and the ERT team. The site will be notified prior to a VETS push.

5. Do sites need to have staff on site when the VETS push or deployment occurs?

No. Site staff do not need to be present when the VETS deployment or push occurs.

6. Is the VETS push or deployment equivalent to a patch load?

No, a push is not the same as a patch load. The VETS push or deployment is the final step in the standardization of the files after patches are loaded. These pushes or deployments will also continue as new terms are requested from the field. The pushes are HL7 messages that are sent through the interface engine to VistA.

7. Is the VETS push or deployment a site-initiated process?

No, it is not. However, the site will be contacted prior to the VETS push or deployment.

8. Is it true that sites are not to update or change the resource slots associated with the GMRA UPDATE Resource device?

Yes. The slot is set to one and needs to stay at one. It is very important that sites not change the number of slots for this resource device. If the resource device does not stay at one, then NTRT pushes may be processed inaccurately and may potentially corrupt Allergy files. If sites have changed this, they need to set it back to one. Then sites will need to work with the ERT team for a redeployment of the push. ERT is looking at ways to control the order in which updates are done in the future. However, in the meantime sites need to be aware of this potential issue and to monitor the GMRA UPDATE Resource device to ensure it stays set at one slot.

[To learn more about Enterprise Reference Terminology \(ERT\)/ Enterprise Terminology Services \(ETS\)/ or VA Enterprise Terminology Services, click this link.](#)

New Term Rapid Turnaround (NTRT) Process Questions

8. How fast will the NTRT request be granted? Are weekends taken into consideration?

At this time, NTRT requests will be deployed nationally every Thursday. The cutoff date for inclusion of a term in the Thursday deployment is COB the Friday before the scheduled deployment. Over the next 7 months, this timeframe may be adjusted. Any changes to the frequency of NTRT deployments will be communicated to sites and support personnel.

9. If there are a large number of New Term Rapid Turnaround (NTRT) requests at a site, is it necessary to enter each request separately?

If sites have a large number of NTRT requests that need to be submitted, your HDR Implementation Manager can help you get these entries to the ERT team without having to enter all of the requests into the NTRT website.

10. If there is a local term that is a synonym of a national standard term, then is an NTRT request needed for that local term?

No. The local term will not need to be added to the standard. If there is a compelling case for why it should be added, then that can be forwarded on as an NTRT request.

Consider the following example:

Local Term	New Standard Term	Add to standard?
Garbanzo beans	Chickpeas Synonym: Garbanzo beans	No. Synonyms are available for searching terms in CPRS.

11. If a new drug ingredient is needed, do we go through the NTRT process or will these still be handled through National Drug File (NDF) updates?

New drug ingredients will need to be added through the NDF process.

12. How has the issue related to Sulfa allergy documentation and order checking in VistA been resolved?

A generic Sulfa entry in the GMR Allergy file (120.82) has been deployed nationally. Standardization identified the need for consistent screening for Sulfa-containing drugs. The Data Standardization and Enterprise Reference

Terminology teams have worked with the National Drug File manager to determine which drugs need to be linked to the new generic sulfa entry in the GMR Allergy file 120.82. Order check screening for Sulfa allergies works consistently and completely on all VistA systems.

13. Concerns have been raised about user-friendly terms and equivalents in the Sign/Symptoms file 120.83 from some sites. What is being done to resolve these concerns?

A review of the Sign/Symptoms file 120.83 has been completed. This file was reviewed by a group comprised of clinicians from the field as well as terminologists and other key stakeholders.

Concerns have been raised from sites regarding clinical terms that are not user friendly. For example “cutaneous eruption” is the primary term in the standard and “Rash” is a synonym. Primary terms are stored in the patient record and on the patient arm band. Clinicians would like to see Rash become the primary term and cutaneous eruption the synonym. A complete review of the standard was conducted to identify other terms that may also benefit from a similar change.

Concerns have been raised that some terms in the standard are not equivalent and should not remain as synonyms to the primary term. For example, “Congestion of the Throat” is not the same as “Swelling of the Throat” and should be fixed in the standard. Other non-equivalent synonyms were identified and are associated with two separate terms when applicable.

14. How are sites being notified that NTRT additions are being made to the standardized files for Allergies?

An Automated Notification Report (ANR) is sent out through the National Help Desk by e-mail messages that alert sites about the changes that are being made to the Sign/Symptom file 120.83 and the GMR Allergies file 120.82. If you are not currently receiving these ANR messages and would like to in the future, please submit a Remedy ticket and you can be added to the distribution list for future information.

The information about the changes being made by NTRT can also be viewed on the NTRT Web site, under “NTRT Deployment Log.” Those interested can also join the NTRT listserv which provides the same information as the ANR messages, along with the potential for supplementary information. Join by going to <http://vista.med.va.gov/ntrt/> and clicking the link in the middle of the screen called "NTRT Notification Listserv."

15. Why didn't I receive an order check mail message when NTRT updates were made to the GMR Allergies file 120.82 for an entry that contained drug class and drug ingredient information?

The order check mail messages only fire for patients who meet the following conditions:

- Not deceased
- Not test patients
- File 120.82 entry not marked Entered in Error
- Matching allergy entry selected from File 120.82 is not a free text entry
- The patient has an active order that does not have an order check already logged against it that should have one based on the updated allergy information.

[To learn more about Enterprise Reference Terminology \(ERT\)/ Enterprise Terminology Services \(ETS\)/ or VA Enterprise Terminology Services please click this link.](#)

[To see a PowerPoint presentation on the NTRT process, please follow this link.](#)

Site Clean-up Questions

16. After allergy standardization, what is the impact to a site that has many free-text patient allergies that need to be cleaned up?

Sites will be able to continue cleaning up the free-text patient allergy entries after Allergy/Outpatient Pharmacy standardization is complete. The patches will not affect this clean-up effort. After standardization, there will be a more comprehensive list of allergies for your site to use for cleaning up free-text patient allergy entries.

New terms should not be added to GMR Allergies file 120.82 prior to standardization in order to map a free text patient allergy. The GMRA*4*23 patch locked down this file so sites can no longer add terms through the roll-and-scroll interface. Sites should clean up the patient allergy file 120.8 prior to standardization with what is currently available. Once standardization is complete, more terms will be available in the GMR Allergies file 120.82 to correct the remaining free text patient allergies.

An automated clean-up patch is being written to help sites in the free-text patient allergy clean-up effort. This patch will be released some time after the standardization patches. The content required for this patch is currently being

reviewed. Sites have been asked to clean up free-text entries that have a low number of occurrences. Free-text patient allergies that occur one or two times in the clean-up utility should be cleaned up first. Also, free-text patient allergies that have multiple allergies on one line (e.g. “Aspirin, Penicillin, chocolate”) should be cleaned up by recording each allergy separately for that patient.

The automated clean-up patch will help sites clean up free-text patient allergy entries, but not all data can be cleaned up in an automated fashion. Patient allergy data that has clinical relevance will be left as free text and will need to be cleaned up by the site.

17. What is the impact of Outpatient Pharmacy standardization to sites if they have not finished linking local drugs to the National Drug File (NDF)?

Sites can continue to clean-up the local drug file or file 50 mapping to the National Drug File (NDF) after standardization. The data in the local drug file needs to be mapped so that order checks work optimally.

Health Data Repository (HDR) Questions

18. What happens in the Health Data Repository (HDR) when one site has entered an allergy for Penicillin and another site has entered Penicillin as “entered in error”?

Allergies that are entered in error at one site will not overwrite the allergies recorded at another site. The HDR will err on the side of safety. The HDR will store both pieces of information: the patient allergy record and the “entered in error” record.

19. In regards to the question above, will one site be notified that another site has entered an allergy in error?

At this time, there is not a mechanism to do this. Site-to-site notification will not be done until a national process is put in place that determines when a site’s allergy record can be overruled. The clinician should get the information via Remote Data Views (RDV) and work with the patient to make sure the record is correct.

20. Where do we go for technical information about turning on the VDEF triggers? Is that something HDR Implementation Managers will help with?

Yes. The HDR Implementation Managers will be in contact with sites when it is time to turn on the VDEF triggers. They will communicate the necessary technical steps at that time.

21. In the CPRS GUI, the end user now sees that a light is blue on the HDR section of Remote Data Views (RDVs). Why is this there?

HDR data can now be seen in RDV. Vitals data has been standardized and it is being sent to the HDR. This blue text means that the patient has vital sign data stored in the HDR. With the release of CPRS GUI v. 26, end users will be able to view data from the HDR.

This may be confusing to some end users, because some patients will only have vital sign data available at the local site and the light will not be blue. VistaWeb is also impacted, but the new version of VistaWeb that should be available at the end of August will be able to retrieve the HDR data.

[To learn more about the HDR, please click this link.](#)

[To learn more about HDR Implementation, click this link.](#)