



**PXRM*2*22
OR*3*357**

Clinical Reminders

TERATOGENIC MEDICATIONS ORDER CHECKS

Release Notes

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Product Development
Office of Information Technology
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Introduction

A teratogenic medication is one that can increase the risk of birth defects if taken at a particular time during pregnancy. In response to several requests, a CPRS Order Check was developed to remind providers when they prescribe a known or potential teratogen for a female patient of child-bearing potential. This reminder system is based on the FDA pregnancy categories (A, B, C, D, and X) and a set of additional criteria from First Data Bank that uses published literature and other available information. For lactating patients, the system also uses criteria to notify providers when a medication can cause serious side effects in a breastfeeding infant

This Teratogenic Medication Order Check project contains two patches, PXR*2.0*22 and OR*3.0*357.

PXR*2.0*22 releases two new National Reminder Order Checks for placing Teratogenic Medications. A pre-installation routine will identify any previously identified components and rename them correctly, and the patch installation will create or overwrite VA-named, national reminder components

This patch also addresses two bug fixes in the Reminder Order Check setup. To address these fixes, the Reminder Order Check System was divided into two files:

- File 801 Reminder Order Check Items Group
File 801 contains the grouping of Orderable Items. This file has also been modified to allow groups to include entries from the Drugs file, file #50, VA Generic file, file #50.6 and VA Drug Class file, file # 50.605.
- File 801.1 Reminder Order Check Rules.
File 801.1 contains the Reminder Order Check Rules.

These changes will allow sites to modify the Active and Testing Fields for National Rules.

OR*3.0 *357 contains changes to support the modifications to the Reminder Order Check System release. To support these changes. ORKCHK5 has been updated to support the new API format for PXR*2.0*22. While testing this patch, a bug was found in the Order Check System, it was possible for the medium severity reminder order check to not show in CPRS if the order check system could not connect to First DataBank. ORCHECK, has been updated to fix this problem.

Remedy Tickets fixed

- 502067 Timeout error in clinical reminder order checks
- 536991 National reminder order checks don't allow for proper active/testing flag management
- 599706 Usage setting not displaying for clinical reminder checks on reminder definition inquiries

- 603685 Reminder dialog elements set as disable and do not send, were getting changed to disable and send upon reminder exchange
- 606277 Error in loading reminder dialogs via reminder exchange; some IMM entries were not getting installed.
- 616620 Errors when \$P was being used in a Function Finding.

To support the two-file structures, the existing menu options have been renamed and two new options are released with this patch:

- Reminder Order Check Rule Inquiry
- Reminder Order Check Test.

The method for creating and editing Reminder Order Checks has been modified to use ScreenMan forms. See the Reminders Manager’s Manual for further instructions.

Pre-Installation Step:

- All existing reminder order checks will need to be rebuilt after installation of PXRМ*2*22. We recommend that you print a copy of any existing Reminder Orderable Item Groups (File #801) on your system, using FileMan or Reminder Order Checks Inquiry. This will be used to help you re-create order checks after the install. See [Appendix B](#) in the Installation Guide for an example of using the Reminder Order Checks Inquiry to do this.

Clinical Reminders PXRМ*2*22 Documentation

Documentation	Documentation File name
Installation Guide	PXRМ_2_22_IG.PDF PXRМ_2_22_IG.DOC
Clinical Reminders Manager’s Manual	PXRМ_2_22_MM.PDF PXRМ_2_22_MM.DOC
Release Notes	PXRМ_2_22_RN.PDF PXRМ_2_22_RN.DOC

Web Sites

Site	URL	Description
National Clinical Reminders site	http://vista.med.va.gov/reminders	Contains manuals, PowerPoint presentations, and other information about Clinical Reminders
National Clinical Reminders Committee	http://vaww.portal.va.gov/sites/ncrcpublic/default.aspx	This committee directs the development of new and revised national reminders
VistA Document Library	http://www.va.gov/vdl/	Contains manuals for Clinical Reminders and CPRS (OR).

Acronyms

The OIT Master Glossary is available at:

http://vaww.oed.wss.va.gov/process/Library/master_glossary/masterglossary.htm

National Acronym Directory:

<http://vaww1.va.gov/Acronyms/>

Term	Definition
ASU	Authorization/Subscription Utility
CPRS	Computerized Patient Record System
ESM	Enterprise Systems Management (ESM)
FIM	Functional Independence Measure
GUI	Graphical User Interface
IAB	Initial Assessment & Briefing
MH	Mental Health
MHA3	Mental Health Assistant Version 3
MHV	My Healthy Vet
MST	Military Sexual Trauma
OIT	Office of Information and Technology
OIF/OEF	Operation Iraqi Freedom/Operation Enduring Freedom
OR	Order Entry namespace
PCS	Patient Care Services
PD	Product Development
PTSD	Post Traumatic Stress Syndrome
PXRM	Clinical Reminder Package namespace
RSD	Requirements Specification Document
TIU	Text Integration Utility
VA	Department of Veteran Affairs
VHA	Veterans Health Administration
VistA	Veterans Health Information System and Technology Architecture
WV	Women's Health package namespace
YS	Mental Health package namespace

Appendix A: Frequently Asked Questions (FAQ) about the Teratogenic Medications Order Check

Q: What is a “teratogenic” medication?

A: A teratogenic medication is one that can increase the risk of birth defects if taken at a particular time during pregnancy. A **known teratogen** is a medication that causes birth defects in humans. Examples include thalidomide (limb defects), isotretinoin (syndrome of defects including oral clefts), valproic acid (neural tube defects), and mycophenolate (facial clefts, anotia). A **potential teratogen** is a medication that causes malformations or other abnormal pregnancy outcomes in animal studies – these outcomes are more concerning if they occur at doses similar to human doses. Some medications increase the risk for pregnancy loss (miscarriage), growth abnormalities (e.g., growth restriction), or functional deficits (e.g., decreased fetal kidney function). These are also important adverse reproductive effects.

Q: What is the new Teratogenic Medication Order Check?

A: In response to several requests, a CPRS Order Check was developed to remind providers when they prescribe a known or potential teratogen for a female patient of child-bearing potential. This reminder system is based on the FDA pregnancy categories (A, B, C, D, and X) and a set of additional criteria from First Data Bank that uses published literature and other available information. For lactating patients, the system also uses criteria to notify providers when a medication can cause serious side effects in a breastfeeding infant

Q: What are the FDA pregnancy categories?

A: The FDA categories are a helpful system for distinguishing the relative teratogenic risk of a medicine based on studies in animals and experience in human pregnancy. As a health care provider, your awareness of these issues can help you better prescribe for and counsel your female patients of child-bearing potential. See the following [table](#) for category descriptions.

Q: How will the Teratogenic Medication Order Check work?

A: When a provider prescribes a medication with a pregnancy category D or X for a female patient between the ages of 18 and 50, the system will automatically provide an order check to ensure that you are aware of the reproductive risk associated with the medication. Certain additional medications with evidence of concern (e.g., some category C medications or FDA-unclassified medications) will also trigger an alert.

Q: What do you do if you get an Order Check?

A: (1) Consider whether this medication is most appropriate for the patient's condition or whether there are other appropriate options with less reproductive risk.
(2) Counsel the patient about the risks and benefits of treatment should pregnancy occur.
(3) Ask the patient about pregnancy planning and use of contraception. This risk/benefit discussion is an important one.
(4) For breastfeeding patients, consider whether there is an alternative medication with lower concentrations in breast milk or fewer risks for the infant and encourage the patient to discuss her medications with the infant's pediatrician. LactMed (<http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?LACT>) is an online resource from the NIH that provides available information about use of medications during lactation.

Q: Where can I get information about the pros/cons of continuing use of a teratogenic medication during pregnancy?

A: Deciding whether to continue a potential or known teratogen during pregnancy is complicated. Not treating or under-treating a pregnant woman's medical condition can be riskier to the fetus than the medication itself. It is helpful to read the pregnancy subsection of drug labeling, which provides information about the reproductive risks of medications. Current labeling can be found at Drugs@FDA or at www.DailyMed.nlm.nih.gov. Reprotox is an online resource that summarizes available information about the reproductive risks of medications. Reprotox may be available online through your facility's library and will be available through the VACO library in the near future. The Organization of Teratology Information Services has fact sheets available online about medications and their risks during pregnancy (<http://www.otispregnancy.org/otis-fact-sheets-s13037#1>). Your local pharmacist and women's health providers can provide more information.

Q: How can I help my patients avoid unintended pregnancy?

A: About 50% of pregnancies in the United States are unplanned. During patient encounters, ask women of child-bearing potential (age 15 to 50) about their plans for pregnancy and need for contraception.

The most effective reversible contraceptives are the IUDs (Mirena or Paragard) and subdermal implants (Nexplanon, previously Implanon). These contraceptives are available through the VA prosthetics department and can be inserted by a local trained women's health provider. Oral contraceptive pills and emergency contraception are on the VA formulary, and condoms are available through the VA. Female Veterans using contraceptives other than IUDs and implants should be advised to keep a supply of emergency contraception on hand in case of unprotected intercourse or contraceptive failure.

Q: When will the Order Check be available?

A: The Order Check will come as a VistA Clinical Reminders patch, PXRМ*2*22. At the time of this message, release is anticipated during the fourth quarter of calendar year 2012.

Q: How often will this Order Check appear?

A: Clinicians will be notified every time any category D or X medications or certain other medications with evidence for concern (e.g., some category C medications or FDA-unclassified

medications) are ordered for a female patient of child-bearing potential who is without documentation of medical inability to become pregnant.

Q: Will the Order Check display even if the patient has no chance of becoming pregnant, such as post-hysterectomy?

A: No. The Order Check is designed to recognize several exclusion criteria that can be generally described as “medical inability to conceive.” For example, patients for whom the appropriate ICD-9^a code for hysterectomy is recorded will not trigger an alert. Other ICD-9^a exclusion criteria include menopausal state and IUD use.

Q: Can clinicians add information to the electronic health record that should exclude a patient from this Order Check?

A: Yes, each site can define additional situations or “Health Factors” when the Order Check does not apply. The local application support team can add these Health Factors to the Reminder Term called “VA-TERATOGENIC MEDICATIONS ORDER CHECK EXCLUSIONS (TERM).” The support team can also suggest to the Women’s Health Program Office that a Health Factor be added as part of a subsequent national update.

Points of Contact for further information about the Teratogenic Medications Order Check:

- Your facility’s pharmacy informaticist (ADPAC)
- Your facility’s clinical reminders manager (often one of the Clinical Application Coordinators)
- Rob Silverman at Pharmacy Benefits Management (Robert.Silverman@va.gov)
- Dr. Laurie Zephyrin, Director Reproductive Health, Women Veterans Health Strategic Healthcare Group, (Laurie.Zephyrin@va.gov)

^a At the time of this message, the transition from ICD-9 to ICD-10 has not yet taken place

FDA Pregnancy categories

Table 1. FDA Pregnancy categories (language summarized from 21CFR201.57)	
Category	Definition
A	Adequate and well-controlled (AWC) studies in pregnant women have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of a risk in later trimesters).
B	Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no AWC studies in pregnant women, OR animal studies demonstrate a risk and AWC studies in pregnant women have not during the first trimester (and there is no evidence of risk in later trimesters).
C	Animal reproduction studies have shown an adverse effect on the fetus, there are no AWC studies in humans, AND the benefits from the use of the drug in pregnant women may be acceptable despite its potential risks. OR animal studies have not been conducted and there are no AWC studies in humans.
D	There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, BUT the potential benefits from the use of the drug in pregnant women may be acceptable despite its potential risks (for example, if the drug is needed in a life-threatening situation or serious disease for which safer drugs cannot be used or are ineffective).
X	Studies in animals or humans have demonstrated fetal abnormalities OR there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, AND the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available).

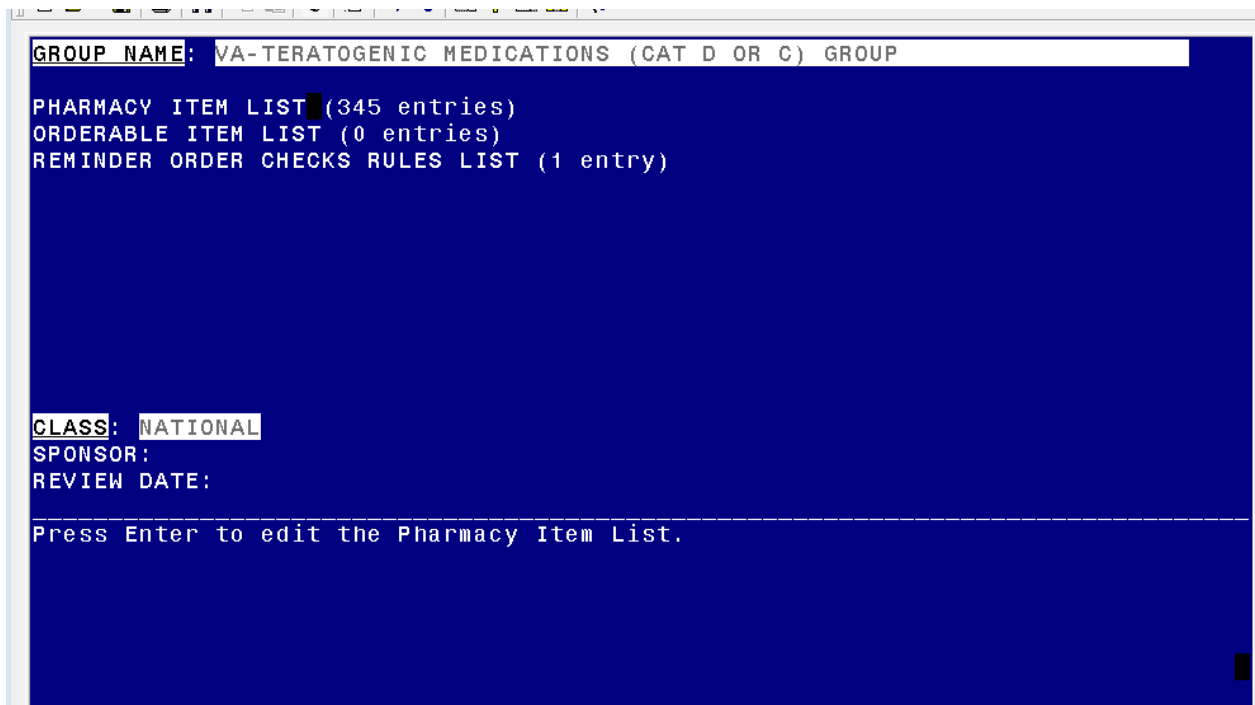
The FDA published a proposed rule in the May 29, 2008, Federal Register that proposes new labeling regulations for prescription drugs. These regulations, once implemented, will eliminate the pregnancy categories from drug labeling. When a final rule publishes, VHA will determine how to best update this order check process so that it will remain both current and useful to VA providers.

Appendix B: Creating an Order Check

ScreenMan Overview

The redesigned Reminder Order Check functionality uses ScreenMan. ScreenMan is VA FileMan's *screen-oriented* data entry tool. It is an alternative to the scrolling mode approach. With ScreenMan, data is entered in *forms*. Each form field occupies a fixed position on the screen (instead of scrolling off!). You can see many data fields at once, and use simple key combinations to edit data and move from field to field on a screen. You can also move from one screen to another like turning through the pages of a book. For a detailed explanation of using ScreenMan, please refer to the VA FileMan Getting Started manual.

The ScreenMan Screen



The screenshot shows a terminal window with a dark blue background and white text. At the top, a white box contains the text 'GROUP NAME: VA-TERATOGENIC MEDICATIONS (CAT D OR C) GROUP'. Below this, the following text is displayed: 'PHARMACY ITEM LIST (345 entries)', 'ORDERABLE ITEM LIST (0 entries)', and 'REMINDER ORDER CHECKS RULES LIST (1 entry)'. Further down, there are fields for 'CLASS: NATIONAL', 'SPONSOR:', and 'REVIEW DATE:'. At the bottom, a dashed line is followed by the instruction 'Press Enter to edit the Pharmacy Item List.'

ScreenMan Descriptions

The screenshot shows a ScreenMan window with the following text:

RULE NAME: DABIGATRAN AND RENAL FUNCTION-2
DISPLAY NAME: **DABIGATRAN AND RENAL FUNCTION**
STATUS: **PROD**
SEVERITY: **MEDIUM**

TERM: **Active Duty**

Reminder Term: Active Duty
Term Evaluation Status: **True**

ORDER CHECK TEXT: The dose of dabigatran should be reduced to 75mg PO BID wh
...

RULE DESCRIPTION:

CLASS: **LOCAL**
SPONSOR:
REVIEW DATE:

COMMAND: Press <PF1>H for help Insert

Annotations:

- Required fields are underlined**: Points to the underlined labels.
- Current field – reverse video**: Points to the bolded text "Active Duty".
- Initial Multiple field**: Points to the "TERM:" label.
- Pop-up subpage where you can edit the selected entry in the multiple.**: Points to the "Reminder Term" subpage.
- Command line: You can enter Exit, Save, Close, Next Page, and Refresh here.**: Points to the "COMMAND:" label.

Fields are usually composed of a *data element* and a *caption*. ScreenMan displays data elements in high intensity (boldface) and other text in regular intensity. Text that identifies a data element is called a *caption* and is usually followed by a colon (:). A caption and its associated data element are together called a *field*. Captions of *required* fields are underlined; to save any changes you make on the form, required fields *must* contain data.

How to Navigate Between Fields and Pages

There are a number of ways you can move the cursor from field to field on a form (i.e., navigate). This is to provide you with as much flexibility as possible so that you can work quickly and efficiently with forms.

You can use the keystrokes listed in the following table to move the cursor to various fields located on a ScreenMan form:

To	Press
Move to the next field (to right or below).	<Tab>
Move to the previous field (to left or above).	<PF4>
Move to the field above.	<ArrowUp>
Move to the field below.	<ArrowDown>
Move to the next field in the pre-defined edit sequence.	<Enter>
Edit a WORD-PROCESSING field.	At field, press <Enter>
Select a Subrecord in a Multiple.	At field, press <Enter>
Move to the next block on current page.	<PF1><PF4>
Jump to a specific field.	^ followed by Caption of field and <Enter>
Jump to the Command Line.	^<Enter>
Move to next page	<PF1><ArrowDown> or <PageDown>
Move to previous page	<PF1><ArrowUp> or <PageUp>
Move to a page you specify	<PF1>P

Saving and Exiting

To SAVE or EXIT the form, you need to reach ScreenMan's command line. It's reachable from any ScreenMan screen. To reach the command line, do any one of the following:

- Enter a caret ("^") at any field prompt.
- Press <Enter>, <Tab>, or <PF4> to move from field to field until you reach the command line.
- Press <ArrowDown> or <ArrowUp> to move the cursor from field to field downwards or upwards, until you reach the command line.

Then you can enter SAVE or EXIT at the command line (see below).

Word-Processing Fields

To edit or display a WORD-PROCESSING field, press the Enter/Return key at the WORD-PROCESSING field. This clears the screen and passes control to your Preferred Editor to edit the field. If you do not have a Preferred Editor, the Screen Editor is used. When you exit the editor, you return to the ScreenMan screen.

Multiples Linked to "Pop-Up" Subpages

A Multiple field can appear on a page and be linked to a regular or "pop-up" subpage. When you navigate to the Multiple field, select a Subrecord, and press the Enter/Return key, you are taken to the subpage, which contains the fields within the Multiple.

In the following illustration, the Multiple is the field with the caption "Select EMPLOYMENT HISTORY:". When you enter "FEB 1,1950" at this field, you are taken into a "pop-up" subpage, where you can edit the fields for that particular Subrecord:

Exiting a Subpage

While in a subpage, your only Command Line options are CLOSE and REFRESH. You cannot EXIT, Quit, or SAVE until you return to the parent page. You can return to the parent page by pressing <PF1>C or issuing the CLOSE command at the Command Line. From there, you can select another Subrecord to edit or navigate to another field.

Order Check Example

Purpose: Design an Order Check for dabigatran (Pradaxa®) to remind providers about dose reduction when creatinine clearance is less than 30 mL/min

This example uses serum creatinine values greater than 2 mg/dL to focus more on the order check than on the lab result

1. Create a reminder term that will identify patients with reduced renal clearance. (Patients with Cr > 2 mg/dL)

```
Select Reminder Term Management Option: TE Add/Edit Reminder Term
Select Reminder Term: ZZ CREATININE > 2 (TERM)
  Are you adding 'ZZ CREATININE > 2 (TERM)' as
    a new REMINDER TERM (the 1215TH)? No// Y (Yes)
    REMINDER TERM CLASS: L LOCAL
NAME: ZZ CREATININE > 2 (TERM) Replace
CLASS: LOCAL//
Reminder Term has no findings!
Select Finding: LT. CREATININE
Are you adding ' CREATININE' as a new FINDINGS (the 1ST for this
REMINDER TERM)? No// Y (Yes)
Editing Finding Number: 1
FINDING ITEM: CREATININE//
CONDITION: I v>2
```

2. Create a reminder order check rule that calls the reminder term created in step 1 when its status is TRUE. The rule also contains the text that will appear in the order check window.

- Each RULE exists as a part of the OI Group
- That allows you to set up multiple rules that apply to the same list of drugs

```
Select Reminder Managers Menu Option: ROC Reminder Order Check Menu
Select Reminder Order Check Menu Option: RE Add/Edit Reminder Order
Check Rule
Select Reminder Order Check Items Group by one of the following:
```

```
N: ORDER CHECK ITEMS GROUP NAME
C: VA DRUG CLASS
D: DRUG
G: VA GENERIC
O: ORDERABLE ITEM
R: ORDER CHECK RULE
Q: QUIT
```

Select Reminder Order Check Items Group by: (N/C/D/G/O/R/Q): N// **R**
ORDER CHECK RULE

Select REMINDER ORDER CHECK RULES RULE NAME: **DABIGATRAN AND RENAL FUNCTION**

Are you adding 'DABIGATRAN AND RENAL FUNCTION' as
a new REMINDER ORDER CHECK RULES (the 4TH)? No// **Y** (Yes)

RULE NAME: DABIGATRAN AND RENAL FUNCTION
DISPLAY NAME: **DABIGATRAN AND RENAL FUNCTION**
ACTIVE FLAG: **YES**
TESTING FLAG: **YES**
SEVERITY: **MEDIUM**
TERM: **<Enter>**

When you press Enter after Term:, a box pops up and prompts you for the Term name and Term Evaluation Status.

REMINDER TERM: ZZ **CREATININE > 2 (TERM)**
TERM EVALUATION STATUS: **TRUE**

Either a Term or a Definition must be defined; if you don't enter a Term, the prompt appears for DEFINITION.

DEFINITION **<Enter>**

REMINDER DEFINITION:
DEFINITION EVALUATION STATUS:
OUTPUT TEXT:

When you press Enter after Term:, a box pops up and prompts you for the Term name

ORDER CHECK TEXT:

Order Check Text and Rule Description are word-processing fields. When you press Enter, a word-processing screen opens up.

==[WRAP]==[INSERT]=====< ORDER CHECK TEXT >===== [<PF1>H=Help]

The dose of dabigatran should be reduced to 75mg PO BID when the patient's creatinine clearance is estimated to be less than 30 mL/min.

```
<=====T=====T====T=====T=====T=====T=====T=====T=====T>====
```

RULE DESCRIPTION: <Enter>

```
RULE NAME: DABIGATRAN AND RENAL FUNCTION
DISPLAY NAME: DABIGATRAN AND RENAL FUNCTION
ACTIVE FLAG: YES
TESTING FLAG: YES
SEVERITY: MEDIUM

TERM: ZZ CREATININE > 2 (TERM)
TERM EVALUATION STATUS: TRUE

ORDER CHECK TEXT: The dose of dabigatran should be reduced to 75mg PO
BID wh ...

RULE DESCRIPTION:

CLASS: LOCAL
SPONSOR:
REVIEW DATE:

Exit      Save      Refresh

Enter a command or '^' followed by a caption to jump to a specific
field.

COMMAND:                                     Press <PF1>H for help      Insert
```

3. Create an Order Check Item Group

Similar ScreenMan actions and word-processing fields shown in the example above apply in this option.

```
Select Reminder Managers Menu Option: ROC  Reminder Order Check Menu
Select Reminder Order Check Menu Option: GE  Add/Edit
Reminder Order Check Items Group
Select reminder order check items group by: (N/C/D/G/O/R/Q): N//
<Enter>
```



```

ORDER CHECK ITEM GROUP NAME

Reminder Order Check Item Group: DABIGATRAN AND RENAL FUNCTION
  Are you adding 'DABIGATRAN RENAL FUNCTION' as
    a new REMINDER ORDER CHECK ITEMS GROUP (the 4TH)? No// Y (Yes)

--PHARMACY ITEM-----
. DR.DABIGATRAN ETEXILATE 150MG ORAL CAP
.
-----
Word-processing field

--REMINDER ORDER CHECK RULE-----
. DABIGATRAN AND RENAL FUNCTION
.
-----
Word-processing field

GROUP NAME: DABIGATRAN

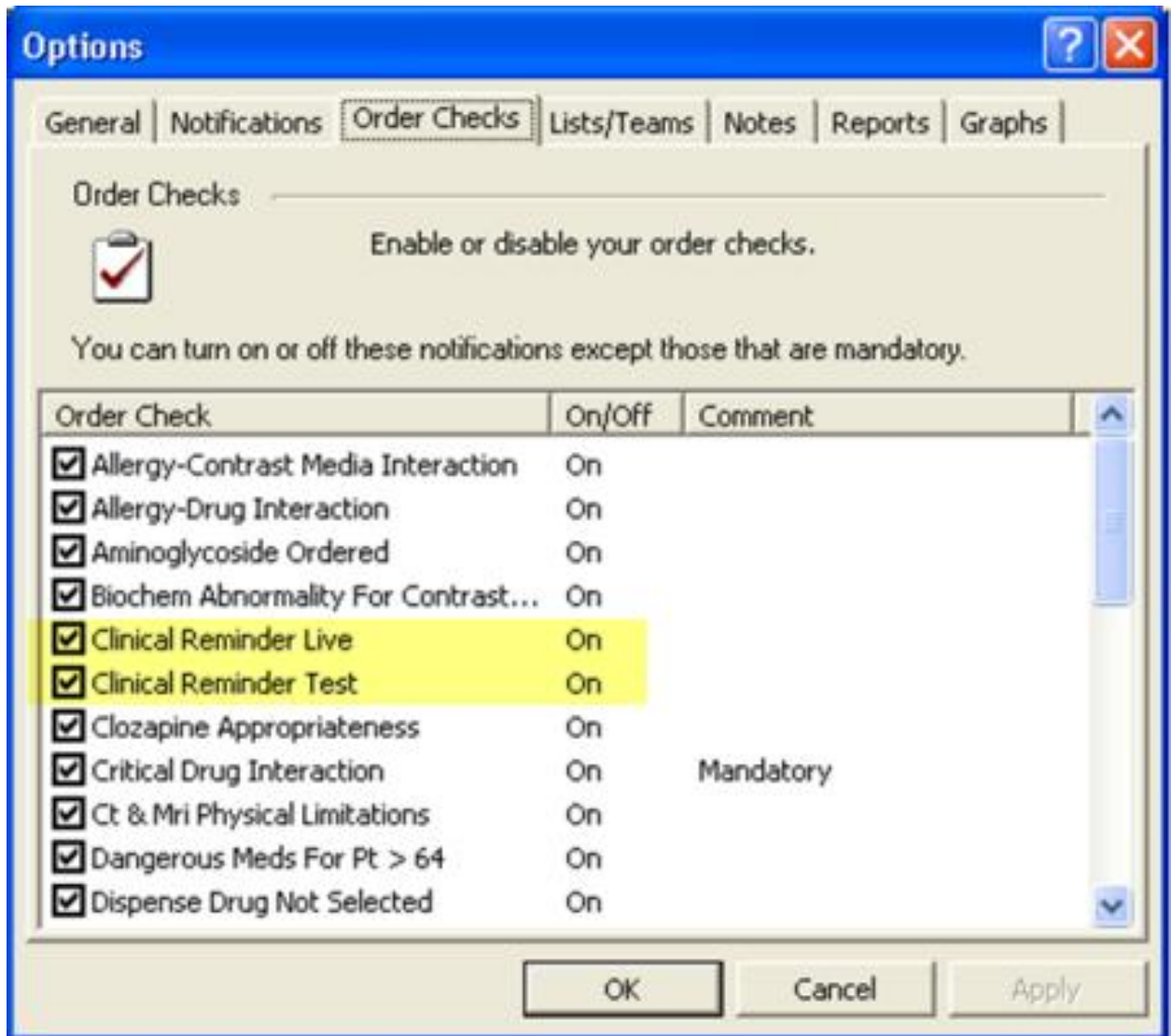
PHARMACY ITEM LIST (0 entry)
ORDERABLE ITEM LIST (0 entries)
REMINDER ORDER CHECKS RULES LIST (1 entry)

CLASS: LOCAL

Select reminder order check items group by: (N/C/D/G/O/R/Q): N// QUIT

```

4. **Connect the rule to the order check item group using the Add/Edit Reminder Order Check Items Group option.**
5. **In CPRS, turn off the Clinical Reminders Live Order Check.**



- Set the rule's testing flag to True.
- Set the group's Active Flag to True.
- Run the Reminder Order Check Test option to validate that the active rule shows for each patient.
- In CPRS, place a corresponding order for the order group for each test patient.
- Validate that only the active rule shows in the order check form.

Result

Order Checks

To cancel an order select the order by checking the checkbox and press the "Cancel Checked Order(s)" button.
If the order check description is cut short, hover over the text to view the complete description.

Cancel	Order/Order Check Text
<input type="checkbox"/>	DABIGATRAN CAP,ORAL 150MG TAKE 1 CAPSULE BY MOUTH TWICE A DAY Quantity: 60 Refills: 0 *UNSIGNED*

(1 of 4) Remote Order Checking not available - checks done on local data only
(2 of 4) Dabigatran and Renal Function
The dose of dabigatran should be reduced to 75mg PO BID when the patient's creatinine clearance is estimated to be less than 30 mL/min.

Cancel Checked Order(s)

Accept Order(s) **Return to Orders** Drug Interaction Monograph

Order Checking

(1 of 4) Remote Order Checking not available - checks done on local data only
(2 of 4) Dabigatran and Renal Function
The dose of dabigatran should be reduced to 75mg PO BID when the patient's creatinine clearance is estimated to be less than 30 mL/min.

Accept Order **Cancel Order** Drug Interaction Monograph