EXHIBIT N

DEPARTMENT OF HUMAN SERVICES, MEDICAL SERVICES

SUBJECT: Pharmacy 3-12

DESCRIPTION: Section 251.301 of the Pharmacy Manual is updated to remove information regarding the use of a voice response system to obtain prior authorization for non-MedWatch drugs. The section is also updated to remove the exception information regarding the following drugs: Carbamazepine, Primidone, Valproic acid, and Warfarin. These drugs will now be included in the MedWatch list.

PUBLIC COMMENT: No public hearing was held. The public comment period expired on July 10, 2012. No public comments were submitted to the agency. The proposed effective date is October 1, 2012.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT:

Economic Impact Statement:

1. **The type or types of small businesses that will be directly affected by the proposed rule, bear the cost of the rule, or directly benefit from the proposed rule.** Physicians.

2. **A description of how small businesses will be adversely affected.** Although there is no direct financial impact associated with this promulgation, additional administrative time may be required to complete MedWatch documentation. These same requirements are currently required of physicians for all other brand name drugs.

3. **A reasonable determination of the dollar amounts the proposed rule will cost small businesses in terms of fees, administrative penalties, reporting, recordkeeping, equipment, construction labor, professional services, revenue loss, or other costs associated with compliance.** No direct financial impact associated with compliance.

4. **A reasonable determination of the dollar amounts of the costs to the agency of implementing the proposed rule, as well as the financial benefit to the agency of implementing the rule.** Arkansas Medicaid could experience a potential savings of approximately $300,000 (based on SFY 2011 claims) on brand name drugs that were authorized through the Voice Response System (VRS) that will now require submission through MedWatch. The actual dollar savings resulting from this change cannot be easily determined. Savings would be dependent on the number of brand name prescriptions that may not be approved through MedWatch.

5. **Whether and to what extent alternative means exist for accomplishing the objectives of the proposed rule that might be less burdensome to small businesses and why such alternatives are not being proposed.** Not applicable.

6. **A comparison of the proposed rule with federal and state counterparts.** Not applicable.

LEGAL AUTHORIZATION: Arkansas Code § 20-76-201 authorizes the Department of Human Services to administer programs for the indigent and to "make rules and regulations" pertaining to the administration of those programs. Arkansas Code § 20-77-107 specifically authorizes the department to "establish and maintain an indigent medical care program."

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE

DEPARTMENT/AGENCY Department of Human Services
DIVISION Division of Medical Services
DIVISION DIRECTOR Andrew Allison, PhD
CONTACT PERSON Brett Hays
ADDRESS P.O Box 1437, Slot S295, Little Rock, AR 72203
PHONE NO. 682-8859 **FAX NO.** 682-2480 **E-MAIL** brett.hays@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Marilyn Strickland
PRESENTER E-MAIL marilyn.strickland@arkansas.gov

INSTRUCTIONS

A. **Please make copies of this form for future use.**
B. **Please answer each question completely using layman terms. You may use additional sheets, if necessary.**
C. **If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.**
D. **Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:**

Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
Room 315, State Capitol
Little Rock, AR 72201

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1. What is the short title of this rule?

   Pharmacy 3-12

2. What is the subject of the proposed rule?

   Addition of drugs to the MedWatch list and elimination of the requirement to access the Voice Response System in order to obtain prior authorization for non-MedWatch drugs.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes ___ No __X__.
   If yes, please provide the federal rule, regulation, and/or statute citation.

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes___ No__X__.

   If yes, what is the effective date of the emergency rule?

   When does the emergency rule expire?

   Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes___ No _____

5. Is this a new rule? Yes___ No __X__ If yes, please provide a brief summary explaining the regulation.

   Does this repeal an existing rule? Yes____ No__X__ If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does.

   Is this an amendment to an existing rule? Yes__X__ No ___If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give Arkansas Code citation.

   Arkansas Statute 20-76-201

7. What is the purpose of this proposed rule? Why is it necessary?

   Brand name medication requests through the voice response system established in previous policy will no longer be granted. All brand name medically necessary prior authorization requests for brand name medications with a generic upper limit will be reviewed using the FDA MedWatch form.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b).

   https://www.medicaid.state.ar.us/InternetSolution/general/comment/comment.aspx

9. Will a public hearing be held on this proposed rule? Yes_____ No __X__.
   If yes, please complete the following:
   Date:_____
   Time:_____
   Place:_____

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)

    July 10, 2012

11. What is the proposed effective date of this proposed rule? (Must provide a date.)

    October 1, 2012

12. Do you expect this rule to be controversial? Yes_____ No __X__ If yes, please explain.

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules? Please provide their position (for or against) if known.

    Medical associations, interested providers, and advocacy organizations. Their positions for or against is not known at this time.

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Department of Human Services
DIVISION Division of Medical Services
PERSON COMPLETING THIS STATEMENT Tom Show
TELEPHONE NO. 683-2483 **FAX NO.** 682-2480 **EMAIL:** tom.show@arkansas.gov

To comply with Act 1104 of 1995, please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE – Pharmacy 3-12

1. Does this proposed, amended, or repealed rule have a financial impact?
   Yes X No ____.

2. Does this proposed, amended, or repealed rule affect small businesses?
   Yes X No ____.

   If yes, please attach a copy of the economic impact statement required to be filed with the Arkansas Economic Development Commission under Arkansas Code § 25-15-301 et seq.

3. If you believe that the development of a financial impact statement is so speculative as to be cost prohibited, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please give the incremental cost for implementing the rule. Please indicate if the cost provided is the cost of the program.

Current Fiscal Year	**Next Fiscal Year**
General Revenue_____	General Revenue_____
Federal Funds_____	Federal Funds_____
Cash Funds_____	Cash Funds_____
Special Revenue_____	Special Revenue_____
Other (Identify)_____	Other (Identify)_____
Total_____	Total_____

5. What is the total estimated cost by fiscal year to any party subject to the proposed, amended, or repealed rule? Identify the party subject to the proposed rule and explain how they are affected.

   Current Fiscal Year **Next Fiscal Year**

6. What is the total estimated cost by fiscal year to the agency to implement this rule? Is this the cost of the program or grant? Please explain.

   Current Fiscal Year **Next Fiscal Year**

   Arkansas Medicaid could experience a potential savings of approximately $300,000 (based on SFY 2011 claims) on brand name drugs that were authorized through the Voice Response System (VRS) that will now require submission through MedWatch. The actual dollar savings resulting from this change cannot be easily determined. Savings would be dependent on the number of brand name prescriptions that may not be approved through MedWatch.

ECONOMIC IMPACT STATEMENT
(As Required under Arkansas Code § 25-15-301)

Department: Arkansas Department of Human Services
Division: Medical Services
Person Completing this Statement: Randy Helms
Telephone Number: 501-682-1857 **Fax Number:** 501-682-3889
EMAIL: Randy.Helms@Arkansas.gov

Short Title of this Rule: Pharmacy-3-12

(1) The type or types of small businesses that will be directly affected by the proposed rule, bear the cost of the proposed rule, or directly benefit from the proposed rule.

Physicians

(2) A description of how small businesses will be adversely affected.

Although there is no direct financial impact associated with this promulgation, additional administrative time may be required to complete MedWatch documentation. These same requirements are currently required of physicians for all other brand name drugs.

(3) A reasonable determination of the dollar amounts the proposed rule will cost small businesses in terms of fees, administrative penalties, reporting, recordkeeping, equipment, construction labor, professional services, revenue loss, or other costs associated with compliance.

No direct financial impact associated with compliance.

(4) A reasonable determination of the dollar amounts of the costs to the agency of implementing the proposed rule, as well as the financial benefit to the agency of implementing the rule.

Arkansas Medicaid could experience a potential savings of approximately $300,000 (based on SFY 2011 claims) on brand name drugs that were authorized through the Voice Response System (VRS) that will now require submission through MedWatch. The actual dollar savings resulting from this change cannot be easily determined. Savings would be dependent on the number of brand name prescriptions that may not be approved through MedWatch.

(5) Whether and to what extent alternative means exist for accomplishing the objectives of the proposed rule that might be less burdensome to small businesses and why such alternatives are not being proposed.

Not Applicable

(6) A comparison of the proposed rule with federal and state counterparts.

Not Applicable

ECONOMIC IMPACT STATEMENT
(As Required under Arkansas Code § 25-15-301)

Department: Arkansas Department of Human Services
Division: Medical Services
Person Completing this Statement: Randy Helms
Telephone Number: 501-682-1857 **Fax Number:** 501-682-3889
EMAIL: Randy.Helms@Arkansas.gov

Short Title of this Rule: Pharmacy-3-12

(1) The type or types of small businesses that will be directly affected by the proposed rule, bear the cost of the proposed rule, or directly benefit from the proposed rule.

Physicians

(2) A description of how small businesses will be adversely affected.

Although there is no direct financial impact associated with this promulgation, additional administrative time may be required to complete MedWatch documentation. These same requirements are currently required of physicians for all other brand name drugs.

(3) A reasonable determination of the dollar amounts the proposed rule will cost small businesses in terms of fees, administrative penalties, reporting, recordkeeping, equipment, construction labor, professional services, revenue loss, or other costs associated with compliance.

No direct financial impact associated with compliance.

(4) A reasonable determination of the dollar amounts of the costs to the agency of implementing the proposed rule, as well as the financial benefit to the agency of implementing the rule.

Arkansas Medicaid could experience a potential savings of approximately $300,000 (based on SFY 2011 claims) on brand name drugs that were authorized through the Voice Response System (VRS) that will now require submission through MedWatch. The actual dollar savings resulting from this change cannot be easily determined. Savings would be dependent on the number of brand name prescriptions that may not be approved through MedWatch.

(5) Whether and to what extent alternative means exist for accomplishing the objectives of the proposed rule that might be less burdensome to small businesses and why such alternatives are not being proposed.

Not Applicable

(6) A comparison of the proposed rule with federal and state counterparts.

Not Applicable

Summary for
Pharmacy 3-12

Section 251.301 of the Pharmacy manual is updated to remove information regarding the use of a Voice Response System to obtain prior authorization for non-MedWatch drugs. The section is also updated to remove the exception information regarding the following drugs: Carbamazepine, Primidone, Valproic acid and Warfarin. These drugs will now be included in the MedWatch list.

ARKANSAS DEPARTMENT OF HUMAN SERVICES

Division of Medical Services
Program Development & Quality Assurance
P.O. Box 1437, Slot S-295 · Little Rock, AR 72203-1437
501-682-8368 · Fax: 501-682-2480

TO: Arkansas Medicaid Health Care Providers – Pharmacy

DATE: October 1, 2012

SUBJECT: Provider Manual Update Transmittal PHARMACY-3-12

PROPOSED

REMOVE		INSERT	
Section	**Date**	**Section**	**Date**
251.301	9-1-04	251.301	10-1-12

Explanation of Updates

Section 251.301 is updated to remove information regarding the use of a Voice Response System to obtain prior authorization for non-MedWatch drugs. The section is also updated to remove the exception information regarding the following drugs: Carbamazepine, Primidone, Valproic acid and Warfarin. These drugs will now be included in the MedWatch list.

The paper version of this update transmittal includes revised pages that may be filed in your provider manual. See Section I for instructions on updating the paper version of the manual. For electronic versions, these changes have already been incorporated.

If you have questions regarding this transmittal, please contact the HP Enterprise Services Provider Assistance Center at 1-800-457-4454 (Toll-Free) within Arkansas or locally and Out-of-State at (501) 376-2211.

If you need this material in an alternative format, such as large print, please contact our Americans with Disabilities Act Coordinator at 501-683-4120 (Local); 1-800-482-5850, extension 3-4120 (Toll-Free) or to obtain access to these numbers through voice relay, 1-800-877-8973 (TTY Hearing Impaired).

Arkansas Medicaid provider manuals (including update transmittals), official notices and remittance advice (RA) messages are available for downloading from the Arkansas Medicaid website: www.medicaid.state.ar.us.

Thank you for your participation in the Arkansas Medicaid Program.

Andy Allison /rs

Andrew Allison, PhD
Director

TOC not required

251.301 Generic Upper Limit Override 10-1-12

The prescriber must determine whether the Medicaid recipient meets the required conditions to override a generic upper limit (GUL) cost of a drug. The prescriber must also complete the required MedWatch (see below) documentation to allow a prior authorization (PA) for a "Brand Medically Necessary" override of the GUL to reimburse at the brand name reimbursement rate.

MedWatch is the Food and Drug Administration (FDA) Safety Information and Adverse Event Reporting Program that allows healthcare professionals to report serious problems that they suspect are associated with certain drugs they prescribe.

The following criteria must be met to override the GUL when calculating the allowable amount of reimbursement:

A. For MedWatch drugs, the following conditions are required for approval of a Brand Medically Necessary override:

1. The prescriber shall establish that the recipient's condition meets the definition provided for the medical necessity of dispensing any brand name drug when a generic equivalent is available.

   In the context of this policy, "Brand Medically Necessary" is defined as the necessity to prescribe and dispense a brand name medication when use of a generic product has resulted in adverse reaction(s) to the generic, allergic reaction(s) to the generic or therapeutic failure of the generic.

   a. Adverse reaction caused by a generic must meet one of the following criteria:

      1. Life threatening
      2. Hospitalization
      3. Disability
      4. Required intervention to prevent impairment or damage

   b. Allergic reaction is defined as when an allergen is present in a generic drug that is not present in a brand drug resulting in a hypersensitive reaction.

   c. Therapeutic failure is defined as, clinical failure due to the recipient's suboptimal plasma drug concentration for the generic drug when compared to published full pharmacokinetic profiles for the brand name drug.

2. The prescriber shall submit documentation to HP Enterprise Services using the FDA MedWatch form to support dispensing a brand name medication instead of the generic equivalent.

3. When a MedWatch drug is approved for a Brand Medically Necessary override, the HP Enterprise Services Pharmacy Help Desk will contact the pharmacy provider to inform them of the prior authorization number and the date range of the approved PA.

The PA is given for up to one year for MedWatch Drugs.

All prescriptions must be on file for review by auditors from the Division of Medical Services or their designated agents.

If the criteria stated above are met and the pharmacy claim is submitted with a code of "1" in the dispense as written (DAW) field, the prescription will be priced using the EAC price for the specific product dispensed rather than the generic upper limit price.

TOC not required

251.301 Generic Upper Limit Override ~~9-1-04~~10-1-12

The prescriber must determine whether the Medicaid recipient meets the required conditions to override a generic upper limit (GUL) cost of a drug. The prescriber must also complete the required MedWatch (see below) documentation to allow a prior authorization (PA) for a "Brand Medically Necessary" override of the GUL to reimburse at the brand name reimbursement rate~~average wholesale price (AWP)~~.

MedWatch is the Food and Drug Administration (FDA) Safety Information and Adverse Event Reporting Program that allows healthcare professionals to report serious problems that they suspect are associated with certain drugs they prescribe.

~~The prescriber must obtain the prior authorization (PA) for a "Brand Medically Necessary" override by accessing the Voice Response System (VRS) for non-MedWatch drugs (carbamazepine, primidone, valproic acid and warfarin). A PA number and date range of the approved PA will be issued to the prescriber at the time of the VRS transaction. The prescriber must include the PA number and date range on the recipient's written prescription.~~

The following criteria must be met to override the GUL~~generic upper limit cost restriction~~ when calculating the allowable amount of reimbursement:

A. For MedWatch drugs, the following conditions are required for approval of a Brand Medically Necessary override:

1. The prescriber shall establish that the recipient's condition meets the definition provided for the medical necessity of dispensing any brand name drug when a generic equivalent is available.

   In the context of this policy, "Brand Medically Necessary" is defined as the necessity to prescribe and dispense a brand-name medication when use of a generic product has resulted in adverse reaction(s) to the generic, allergic reaction(s) to the generic or therapeutic failure of the generic.

   a. Adverse reaction caused by a generic must meet one of the following criteria:

      1. Life ~~T~~threatening
      2. Hospitalization
      3. Disability
      4. Required intervention to prevent impairment or damage

   b. Allergic reaction is defined as when an allergen is present in a generic drug that is not present in a brand drug resulting in a hypersensitive reaction.

   c. Therapeutic failure is defined as, clinical failure due to the recipient's suboptimal plasma drug concentration for the generic drug when compared to published full pharmacokinetic profiles for the brand name drug.

2. The prescriber shall submit documentation to HP Enterprise Services using the FDA MedWatch form to support dispensing a brand-name medication instead of the generic equivalent~~, with the exception of the following drugs:~~

   ~~a. Carbamazepine~~

   ~~b. Primidone~~

   ~~c. Valproic acid~~

   ~~d. Warfarin~~

3. When a MedWatch drug is approved for a Brand Medically Necessary override, the HP Enterprise Services Pharmacy Help Desk will contact the pharmacy provider to inform them of the prior authorization number and the date range of the approved PA.

The PA is given for up to one year for MedWatch Drugs. ~~and up to six months for non-MedWatch drugs.~~

All prescriptions must be on file for review by auditors from the Division of Medical Services or their designated agents.

If the criteria stated above are met and the pharmacy claim is submitted with a code of "1" in the dispense as written (DAW) field, the prescription will be priced using the EAC price for the specific product dispensed rather than the generic upper limit price.