POLICY AND PROCEDURE

POLICY NAME: Pharmaceutical Management	**POLICY ID:** CC.PHAR.07
BUSINESS UNIT: Corporate	**FUNCTIONAL AREA:** Utilization Management
EFFECTIVE DATE: 02/2003	**PRODUCT(S):** Medicaid
REVIEWED/REVISED DATE: 10/04, 11/06, 04/07, 02/08, 02/09, 02/10, 02/11, 02/12, 02/13, 02/14, 08/14, 08/15, 08/16, 11/16, 11/17, 11/18, 02/19, 05/19, 02/20, 05/20, 05/21, 08/21, 05/22, 08/22, 05/23, 11/23, 05/24, 05/25, 08/25	
REGULATOR MOST RECENT APPROVAL DATE(S):	

PURPOSE:
To ensure that Pharmacy Services, to whom pharmaceutical management has been delegated, develop and annually review and update policies and procedures for pharmaceutical management, using sound clinical evidence and provide these policies to Centene health plans.

SCOPE:
Centene Pharmacy Services, Health Plan Pharmacy Departments.

DEFINITIONS: N/A

POLICY:
All policies and procedures utilized by Centene health plans, which relate to pharmaceutical management (including drugs covered under the medical benefit), consider guidance recommended by the Clinical Pharmacy Advisory Committee (CPAC) and adopted by the Centene Pharmacy and Therapeutics Committee. Pharmacy decisions are made using input from National Pharmacy Standards Organizations including, but not limited to, the Academy of Managed Care Pharmacy, Center for Drug Evaluation and Research, Food and Drug Administration, Facts and Comparisons, Clinical Pharmacology, and the governing bodies of medical specialties. Current medical and pharmaceutical literature is researched for relevant clinical studies and nationally recognized clinical guidelines (e.g. JNC, ATP, NHLBI, NIH, NCEP, AAP, Institute for Clinical and Economic Review, peer reviewed journals etc.) are utilized. Centene health plans adjust these policies and procedures to comply with state regulations as needed, reporting these changes to the Director of Operations Shared Services. Policies and procedures are reviewed and approved by the Corporate Pharmacy and Therapeutics (P&T) committee. The members of this committee include community practitioners, medical specialists, and pharmacists.

When pharmaceutical management is delegated to Centene Pharmacy Services, Centene health plans maintain responsibility for ensuring the functions are being performed according to the expectations outlined in this policy. In the event that the responsibility for pharmacy management has been retained by the State or other external entity, this policy does not apply.

Centene and its subsidiaries does not discriminate on the basis of race, color, national origin, sex, age or disability, nor exclude from participation in, deny the benefits of, or otherwise subject to discrimination under any applicable Company health program or activity.

PROCEDURE:
I. Pharmaceutical management policies include the following:
- A. The criteria used to adopt pharmaceutical management procedures. In particular, criteria used when constructing the preferred drug list, including those covered under the medical benefit, or preferred status, show how decisions are made regarding:
  1. Classes of pharmaceuticals
     - a. Classes preferred or covered at any level
     - b. Any exception processes available to members for obtaining non-covered pharmaceuticals
     - c. Considerations regarding limiting access to drugs in certain classes
     - d. *Prior Authorization Criteria*
     - e. Generic substitution, therapeutic interchange, step therapy or other management methods to which the practitioner's prescribing decisions are subject
  2. Within each class of pharmaceuticals
     - a. The pharmaceuticals preferred or covered at any level
     - b. The criteria for prior authorization of any pharmaceutical

c. Any exceptions process available to members
d. Substitutions made automatically or with physician permission
e. Evidence showing how preferred-status pharmaceuticals can produce similar or better results for a majority of the population as compared to other pharmaceuticals in the same class
f. Other requirements, restrictions, limitations, or incentives that apply to the use of certain pharmaceuticals

B. A process that uses clinical evidence from appropriate external organizations.
This evidence includes relevant findings of the Food and Drug Administration, Centers for Drug Evaluation and Research, drug manufacturer dossiers, the Academy of Managed Care Pharmacy, and others. In addition, clinical review using peer-reviewed journals, medical specialty guidelines, and authoritative compendia is performed for determination of pharmaceutical coverage positioning.

C. A system for point-of-service (POS) communications to identify drug-drug interactions. The pharmacy claims processing systems use a Medispan database or Concurrent Drug Utilization Review (CDUR) program to identify drug interactions. Electronic alerts are sent to dispensing pharmacies via standard POS messaging when potential drug interactions are detected. POS rejects, which can be overridden by the dispensing pharmacy, or passive alerts, which are informational warning messages that do not require an override code, are used to avoid interference with prescribed drug therapy.

D. Pharmacy Benefit Manager (PBM)-delegated identification and notification of drug recalls. It is Centene Pharmacy Services' responsibility to oversee the delegation of drug recalls to the PBM partner, where claims are paid on the PBM's platform. The PBM shall expedite the prompt identification and notification of members and prescribers affected by Class I Recalls, Class II Recalls, and voluntary Market Withdrawals for safety reasons. Communication to members and prescribers is not applicable if the recall or withdrawal is unrelated to safety issues.

E. Exception policies and procedures that describe the process for:
1. Making an exception request based on medical necessity
2. Obtaining medical necessity information from prescribing practitioners, including notifying prescribers for a request for additional information to support medical necessity.
3. Using appropriate pharmacists and practitioners to consider exception requests
4. Timely request handling
5. Communicating the reason for a denial and an explanation of the appeal process when an exception request is not approved.

II. The preferred drug list (PDL) and pharmaceutical management edits are posted on health plan websites. The health plan is also responsible for communicating information for all drugs covered under the medical and/or the pharmacy benefit. All communication of pharmacy information and pharmacy management procedures is done at least annually and upon updates, through the member and provider newsletter or other materials. Major changes in drug coverage and pharmaceutical management edits are communicated to providers and members by direct mail (e.g. fax, email, mail) as needed, including informing of the availability of information on the website. All pharmaceutical management edits and coverage limitations meet state-specific requirements and any variances are preapproved by the individual state Medicaid programs, where required.

The PDL or similar health plan material includes restrictions, preferences, and addresses:

A. How to use the pharmaceutical management procedures
B. An explanation of any limits or quotas
C. An explanation of how prescribing practitioners must provide information to support an exception request
D. The process for generic substitution, therapeutic interchange, and step-therapy protocols

III. In the event that Centene health plan staff is involved in the pharmaceutical prior authorization process, decisions are made by licensed health care professionals utilizing clinical judgment in consultation with the health plan Vice President, designated Medical Director and/or Plan Pharmacist, as appropriate. Centene Pharmacy Services may be delegated the responsibility for reviewing daily prior authorization and medical necessity requests for drugs not listed on the PDL. For drugs not designated as pharmacy benefits, procedures are outlined via Policy CC.UM.02. All

reviews are performed within 24 hours, upon receipt of all necessary and requested information. All denials or adverse determinations are made by a clinical pharmacist or physician, if required by state regulations.

IV. The health plan maintains accountability for services delegated to Centene Pharmacy Services and monitors performance of these services. Initial monitoring occurs through the approval of the delegate's applicable policies and procedures for the delegated portions of the program. Subsequent performance reviews are achieved through routine reporting and at least annual evaluation. Performance evaluation criteria include accreditation and state/federal requirements and health plan standards. The health plan also retains the right to reclaim the responsibility for performance of this function should standards not be maintained

REFERENCES:
- NCQA Standards and Guidelines
- CC.COMP.42_ACA 1557 Nondiscrimination in Health Programs Activities
- CC.PHARM.02 FDA Drug Alert and Recall Team (DART)

ATTACHMENTS:
- Attachment A: Iowa Addendum
- Attachment B: Arizona Addendum
- Attachment C: Oregon Addendum
- Attachment D: North Carolina Addendum
- Attachment E: Nebraska Addendum
- Attachment F: Texas Addendum

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad hoc	Insert applicable references to NCQA standard and elements. Updated E to reflect Class II recalls and associated exceptions. Added section IV regarding delegation of pharmacy management. Added policy approval section with appropriate signature lines.	05/07
Annual Review	Add "US Script, Inc." to the "SCOPE".	02/08
Ad hoc	Add "peer reviewed journals" to the list of "Current medical and pharmaceutical" under "POLICY".	02/08
Ad hoc	Remove the following from "POLICY": "In the absence of a PBM, the development of and adherence to the policies described within this policy will be the responsibility of the Corporate Pharmacy Department."	02/08
Ad hoc	Add the following to item "C" under "PROCEDURE" part "I": "US Script, as the delegated PBM, uses a Medispan database as the source of drug interactions. These are classified by severity."	02/08
Ad hoc	Add the following to item "D" under "PROCEDURE" part "I": "US Script, the delegated PBM, uses Medispan resources to send electronic alerts to dispensing pharmacies via standard point of service (POS) messaging when potential drug interactions are detected."	02/08
Ad hoc	Add "Class I or" to item "E" under "PROCEDURE" part "I".	02/08
Ad hoc	Move MHS-WI to the carve out section in "PROCEDURE" part "IV".	02/08
Annual Review	Adjust the POLICY to reflect the references used for development of clinical criteria and policies and procedures.	02/09
Ad hoc	Clarified the PROCEDURE to incorporate the PBM's role in POS messaging, identification, and notification to the Plan of members affected by drug recalls, and outline the PBM's responsibilities for the delegated task of reviewing a Prior Authorization requests and timeliness of same.	02/09
Annual Review	Revisions completed at this time were made align with NCQA standards and language.	02/10

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Annual Review	Clarified that Centene Corporation has currently delegated pharmacy benefit management to US Script for all Health Plans for which it provides a pharmacy benefit in section IV. of the PROCEDURE.	02/11
Annual Review	Reviewed 2012 NCQA standards and no substantive changes were made.	02/12
Annual Review	Reviewed 2013 NCQA standards and added or changed the following language accordingly. In element “F”, added language for requesting additional information supporting “medical necessity”. Added language to element II to expand the definition of the Preferred Drug List and how drug coverage changes are communicated to providers. In element “IV”, added URAC as a governing body for certifying quality performance measures.	02/13
Annual Review	No changes deemed necessary.	02/14
Annual Review	No changes deemed necessary.	08/14
Annual Review	Removed from Scope: “Corporate Pharmacy Department and US Script” and replaced with “Pharmacy Solutions Group”. Removed from initial paragraph: “incorporate the criteria instituted by the Corporate Pharmacy Department” and replaced with “shall consider guidance recommended by the pharmacy solutions group and adopted by the Centene Pharmacy and Therapeutics Committee”. Removed from I.E. “Corporate Pharmacy Department and US Script” and replaced with “Pharmacy Solutions Group”. In the first paragraph of item III, “Corporate Pharmacy Department” was replaced by “Pharmacy Solutions Group”. Deleted from item IV. “for all Health Plans for which it provides a pharmacy benefit” from first sentence.	08/15
Annual Review	Annual Review; changed reference to “NCQA Standards and Guidelines”.	08/16
Annual Review	Under section II, added “members” that changes are sent to as well as providers; changed US Script to Envolve Pharmacy Solutions	11/16
Annual Review	Added discrimination statement; Updated references.	11/17
Annual Review	Updated template. Annual review no changes.	11/18
Annual Review	Updated prior authorization review time from one business day to 24 hours in section III. NCQA Review: Updated section 1e to reflect the requirement that Class II recalls must have notification within 30 days.	02/19
	Minor edit to Procedure Section II, adding “pharmacy management procedures”. Added Addendum for Peach State Health Plan to Attachments section.	05/19
Annual Review	Updated to include drugs covered under the medical benefit and Clinical Pharmacy Advisory Committee (CPAC)	02/20
Ad hoc	Peach State Health Plan Addendum was retired by the plan and has been removed from Attachments. Minor grammatical update in Procedure F.5.	05/20
Annual Review	Added prescribing practitioners for receiving notification of FDA Class I-III Recalls. Update made to Procedure I.E.1.b. FDA Class I-III Recall notification section to mirror recently updated CC.PHAR.03 Drug Recall Notification policy: removed recalls that do not pose serious health hazards as an exception, and replaced it with recalled pharmaceuticals which are not covered by the pharmacy benefit.	05/21
Ad hoc	Added Addendums for Arizona and Iowa.	08/21
Annual Review	Revised Procedure E to reflect the new PBM-delegated process for Drug Recall Notifications. Added to the References section: CC.PHARM.02 FDA Drug Alert and Recall Team (DART). Changed Envolve Pharmacy Solutions to Centene Pharmacy Services. Removed Centene Corporate Pharmacy Solutions. Changed “Corporate Pharmacy Department” to Director of Operations Shared Services. Addendum for Arizona was removed.	05/22
Ad hoc	Added new Addendum for Arizona.	08/22
Annual Review	Removed Health Plan P&T Committee reference.	05/23

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
	Combined the two POS Drug Drug interaction notification bullets into one bullet. Added language to Procedure I. A. to mirror 2023 NCQA Standards. Addendums added for Oregon and North Carolina.	
Ad hoc	Addendum added for Nebraska.	11/23
Annual Review	Updated POS DUR alert section to add the CDUR process that is used by Express Scripts claims processing system. Added Institute for Clinical and Economic Review as a reference example to the Policy section. Added "informing of the availability of information on the website" to drug coverage and pharmaceutical management edits communicated to providers and members by direct mail. Addendum added for Texas.	05/24
Annual Review	No changes to the policy. Addendum updated for Arizona.	05/25
Ad hoc	Addendum for Arizona was updated.	08/25

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.