

POLICY AND PROCEDURE

POLICY NAME: Conflict of Interest and Confidentiality Statement for Pharmacy and Therapeutics Committee Membership	POLICY ID: CC.PHAR.17
BUSINESS UNIT: Corporate	FUNCTIONAL AREA: Quality Improvement
EFFECTIVE DATE: 01/17	PRODUCT(S): Commercial, Marketplace (On Exchange and Off Exchange), Medicaid, Medicare
REVIEWED/REVISED DATE: 05/18, 05/19, 05/20, 12/20, 5/21, 11/21, 05/22, 11/22, 02/23, 05/23, 05/24, 6/24, 5/25	
REGULATOR MOST RECENT APPROVAL DATE(S):	

PURPOSE:

The purpose of this policy is to provide evidence that all members and guests of the Centene Pharmacy and Therapeutics committee are clear of conflicts of interest, and do not appear on the U.S. Department of Health and Human Services Office of Inspector General (OIG) Exclusion List or the U.S. Government's System for Award Management (SAM). All members and guests of the Pharmacy and Therapeutic committee will maintain and ensure the confidentiality of Centene proprietary information and comply with all requirements as outlined on the Confidentiality Statement and Centene Pharmacy Confidentiality Policy.

SCOPE:

This policy applies to the Centene Pharmacy and Therapeutics Committees (P&T). Where Marketplace is indicated as Product applicable to this policy, this includes both On Exchange and Off Exchange plans.

DEFINITIONS:

NCQA – National Committee for Quality Assurance

POLICY:

It is the policy of Centene to ensure all Pharmacy and Therapeutics Committee membership is free of conflict and agrees to the confidentiality of information presented during meetings.

PROCEDURE:

- 1) The Confidentiality Statement and Conflict of Interest form are collected annually and kept on file per the following steps:
 - a. Annually, mid-August, the Director of Operations Shared Services or designee will reach out to the Health Plans to confirm membership by obtaining a list/roster of P&T Committee members. The plans will have 30 days to provide the required documentation, including contact information for each member.
 - b. A link to the Confidentiality Statement and Conflict of Interest form will be distributed via email to confirmed members by October 1st.
 - i. To centralize the process, the distribution and collections of forms will be performed by a shared services team. All forms will be stored on the Centene Pharmacy SharePoint site. When requested, completed forms can be shared with the plan.
 - ii. The form must be completed between October 1st and the fourth business day of January to ensure continued participation in the P&T Committee. If a member or guest fails to complete the form by the deadline, they will be ineligible to participate in P&T meetings for the remainder of the year. The only exception would be for documented leave.
 - c. The Director of Operations Shared Services or designee collects and reviews the form and files it for Compliance.
 - d. All forms collected are retained no longer than the period of time sufficient to meet all legal and regulatory retention requirements and business needs, as outlined in the Records Management policy and the Records Retention Schedule.
- 2) Office of Inspector General (OIG) Exclusion List and System for Award Management (SAM)
 - a. Any P&T Committee member or guest found to be on the OIG List of Excluded Individuals/Entities or registered with SAM will be removed from the Committee.
 - b. The basis for OIG exclusion includes conviction for federally funded health care program-related fraud and patient abuse, licensing board actions and default on Health Education Assistance loans.
 - c. OIG exclusion prohibits the ability to receive payment from any Federal health care program for items or services furnished, ordered or prescribed. Federal programs include Health Insurance Marketplace, Medicare and Medicaid, among others.
 - d. SAM registration is used to do business with the federal government, for bidding on and getting paid for federal contracts, or to receive federal funds.

- e. Centene Compliance performs, at minimum, a monthly screening of all Centene employees against the OIG List of Excluded Individuals/Entities and SAM (CC.COMP.36)
- f. The Director of Operations Shared Services or designee reviews external (non-Centene employee) voting and non-voting members of the P&T Committee monthly to ensure that none appear on the OIG List of Excluded Individuals/Entities or SAM.

3) Conflict of Interest (COI)

- a. All P&T Committee voting members, non-voting members, and non-voting guests who are present during the meetings must complete a form annually, pertaining to any financial or other relationship to a pharmaceutical manufacturer. If attendees have a substantial financial interest or other ties to a particular pharmaceutical manufacturer, members are excluded from voting, participating in the decision process or discussion for any of that company's products (see Conflict of Interest section of the form for examples of such relationships and activities). Members and non-voting guests that have a conflict of interest with a manufacturer are excluded from discussions for any of that company's products.
 - The P&T Committee annual Confidentiality Statement and Conflict of Interest form is completed in addition to the Centene Mandatory Annual Questionnaire, which is assigned to individuals at all levels of the company for disclosure of potential familial, financial, or personal conflicts of interest (CC.COMP.13 Conflict of Interest policy).
- b. The Pharmacy Services Business Compliance Consultant, an objective party who is not included in the normal P&T processes, will review the P&T agenda and Conflict of Interest statements prior to each quarterly meeting to discern any financial conflicts and inform the Director of Operations Shared Services or designee of any necessary recusals. The Director of Operations Shared Services or delegate will then work with the plans to ensure that voting members identified as having a conflict of interest with a manufacturer's product do not vote, and that non-voting members and guests having a conflict of interest are excluded from discussions of the product.
- c. Incomplete disclosure in the Conflict of Interest section of the form may result in disciplinary action, which may include termination of an individual's consulting agreement with Centene, termination from P&T Committee membership, or the institution of a bar against his/her attendance at any Centene P&T Committee meetings.
- d. Committee members will disclose outside relationships and activities, present questions related to whether an activity is a conflict of interest, and/or report new conflicts of interest that arise outside of the annual completion of the form to the Director of Operations Shared Services as soon as possible.
 - Potential conflicts of interest are documented by completion of a new Confidentiality Statement and Conflict of Interest form to replace the form on file.
 - Questionable activities are presented to the Director of Operations Shared Services and Compliance to determine whether the activity or relationship constitutes a conflict, and if so, the resulting consequences.
 - Committee members will disclose what they believe to be improper offers to the Committee Chair or the Director of Operations Shared Services.
- e. Meeting minutes will reflect any member(s) who abstains from voting and any member or guest who abstains from the discussion.
- f. The Committee Chair or Committee Secretary/Recorder will document separately the discussion of a conflict of interest and the determination that a conflict exists. This documentation will include the topic that the member/guest is required to abstain from voting or discussing.
- g. Under no circumstances will a representative or agent of a pharmaceutical manufacturer be a member of the P&T Committee or otherwise participate in a P&T Committee meeting.
- h. The identity of the voting and non-voting P&T Committee members and meeting attendees/non-voting guests are confidential and will not be disclosed to or accessed by any pharmaceutical manufacturer, its representative, or agent.
- i. Each P&T Committee member or guest will refrain from taking any action or participating in any activity that could potentially create an appearance of impropriety or conflict of interest with respect to the responsibilities and duties assigned to such P&T Committee member. Committee members are required to comply with Centene's Business Ethics and Code of Conduct.
 - To assist in determining what relationships are significant with regard to the perception of possible bias, the relationship should be considered according to the "Sunshine Rule." For example, if the relationship were examined in the "light of day" (made widely known), would it be perceived that bias exists? If so, the relationship should be disclosed.
 - It should be presumed that any form of payment from anyone with an interest in the placement or review of a product on the Centene preferred drug list and formularies might be considered as intended in whole or in part to attain business or preferential treatment, and creates a conflict of interest that must be disclosed. Such forms of payment could include contributions, bribes, gratuities, kickbacks, opportunities for professional development, or other illegitimate forms of payment that are

provided directly for the purpose of attaining business or preferential treatment, but could also include payments for items or services especially if such payments are inconsistent with fair market value. For example, the offer of an option to purchase stock at less than its fair market value or to provide services for a rate of payment in excess of fair market value would constitute an offer of an improper payment. The offer of such payment could be illegal and must be disclosed to the Committee Chair, even if the member or guest properly refuses to accept the payment.

- j. Members disqualified due to acceptance of unlawful forms of payment will be immediately removed from the P&T Committee. Disqualified members are subject to further action, including possible legal action, up to and including termination of employment.

- All company-confidential materials should be immediately returned to Centene.
- The P&T Committee Chair will report the action at the next scheduled National P&T Committee meeting and the update should be reflected in the minutes.

4) Confidentiality Statement

All P&T Committee voting members, non-voting members, and non-voting guests who are present during the meetings must complete a Confidentiality Statement annually.

- All P&T meeting attendees will maintain and ensure the confidentiality of Centene proprietary information and comply with all requirements as outlined in the Confidentiality Statement and Centene Pharmacy Confidentiality Policy.

REFERENCES:

1. CMS Chapter 6, Patient Protection and Affordable Care Act
2. HHS Notice of Benefit and Payment Parameters 45 CFR 156.122(a)(3)
3. Current NCQA Health Plan Standards and Guidelines
4. CC.LEGL.01 Records Management
5. Records Retention Schedule
6. CC.PHAR.13 Pharmacy and Therapeutics Committee
7. CC.PHAR.16 P&T Committee Member Documentation and Tracking
8. CC.COMP.13 Conflict of Interest
9. CC.COMP.36 Centene Screening for Exclusions from Federal and State Health Care Programs
10. Office of Inspector General <https://www.oig.hhs.gov/>
11. System for Award Management <https://www.sam.gov>

ATTACHMENTS:

- A. Confidentiality Statement
- B. Conflict of Interest Form

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New	Policy Developed.	11/16
Annual Review	Annual Review. Minor grammar changes.	11/17
Ad hoc	Added under Purpose, "All forms collected will be retained no longer than the period of time sufficient to meet all legal and regulatory retention requirements and business needs as outlined in the Records Management and Records Retention Schedule policies."; Added under i, "Non-voting members and non-voting guests that have a conflict of interest with a manufacturer will be excluded from discussions for any of that company's products."; Added under i2, "The Corporate Director of Pharmacy Operations will then work with the plans to ensure that voting members identified as having a conflict of interest with a manufacturer's product do not vote and	05/18

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
	that non-voting members and non-voting guests having a conflict of interest are excluded from discussions of the product.”; Updated references.	
Ad hoc	Changed Product Type from ALL to Commercial, Health Insurance Marketplace, Medicaid and Medicare. Add “guests” to the purpose and the first sentence of the procedure. Added the Policy statement. Clarified throughout the procedure guests are non-voting. Added the following to 1) a) If a member or guest fails to complete the forms by January 25 they will be ineligible to participate in P&T meetings for the remainder of the year. The only exception would be for documented medical leave. Under 3) removed “or attend” as some health plans are required to hold open P&T meetings which would allow a manufacturer to attend but not participate. In definitions, removed HHS, OIG and SAM because they are defined in the policy. Minor grammatical and formatting changes.	05/19
Ad hoc	Minor grammatical edits in section 5) a. Updated Conflict of Interest and Confidentiality Statement to include Drug Utilization Review Committee.	05/20
Ad hoc	Business Unit Adjustments	12/20
Annual Review	Annual Review. Added new Procedure step 1 regarding annual membership confirmation of health plan P&T Committee members by the Corporate Director, distribution of electronic forms to confirmed members, and a centralized process for the maintenance of all forms.	05/21
Ad hoc	Wellcare P&T Committee policy integrated into Centene policy. Moved “All forms collected are retained...as outlined in the Records Management policy and the Records Retention Schedule” from PURPOSE to PROCEDURE section. Changed “presenting during the meeting” to “present during the meeting” for all P&T members/guests who must complete a COI form. Added the P&T Committee annual COI form is completed in addition to the Centene Mandatory Annual Questionnaire. Added “gratuities, opportunities for professional development, and other illegitimate forms of payment” as additional COI examples. Removed “Quarterly, the Corporate Director of Pharmacy Operations or designee requests an updated roster of P&T Committee members from the regional pharmacy directors” from the OIG Exclusion List section, since this is actually done annually per section 1a. Added the following policies to REFERENCES section: CC.PHAR.13 Pharmacy and Therapeutics Committee, CC.PHAR.16 P&T Committee Member Documentation and Tracking, and CC.COMP.13 Conflict of Interest.	11/21
Annual Review	Annual Review- Changed Corporate Director of Pharmacy Operations to Director of Operations Shared Services. Changed Envolve Business Compliance Consultant to pharmacy department Business Compliance Consultant.	05/22
Ad hoc	Updated 1.b.ii from January 25 th to January 2, removed “medical” from the exception so it is just leave. Added that Centene Compliance performs a monthly review of Centene employees against OIG and SAM. The Director of Operations Shared Services will perform the monthly review for non-Centene employees (external members of P&T). Added to References: OIG website, SAM website, and policy CC.COMP.36.	11/22
Annual Review	Annual Review- Combined both forms (Conflict of Interest and Confidentiality Statement) into one form. Removed references to Health Plan P&T Committees.	5/23
Annual Review	Annual Review- Changed policy name in the header to say “Confidentiality Statement” instead of “Confidentiality Agreement”.	05/24
Ad hoc	Updated Confidentiality to statement to include the Centene Pharmacy Services Compliance officer. Updated Conflict of Interest to include date of birth for SAM and OIG checks.	06/24

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Annual Review	Annual Review – removed all reference to “CPTC” and replaced with “P&T” where applicable. Separated Conflict of Interest and Confidentiality Statement forms back into two separate attachments. Updated Individual Family Plans to Marketplace (On Exchange and Off Exchange) for PRODUCT(S). Added Where Marketplace is indicated as Product applicable to this policy, this includes both On Exchange and Off Exchange plans to SCOPE.	05/25

POLICY AND PROCEDURE APPROVAL

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