

Sunset Public Hearing Questions for
State TennCare Pharmacy Advisory Committee
 Created by Section 71-5-2401, *Tennessee Code Annotated*
 (Sunset Termination June 2021)

Enabling Statute, Purpose, and Rules and Regulations

1. Provide a brief introduction to the committee, including information about its purpose, statutory duties, staff, and administrative attachment.

The purpose of the TennCare Pharmacy Advisory Committee is to make recommendations regarding a preferred drug list (PDL), the safety and efficacy of drugs and prior authorization criteria and step therapy.

2. Has the committee promulgated rules and regulations? If yes, please cite the reference.

Yes, Section 71-5-2401-04, Tennessee Code Annotated. There have been no significant rule changes since the last sunset hearing.

Commission Organization

3. Provide a list of current members of the committee. For each member, please indicate who appointed the member, statutory member representation, the beginning and end of the member's term, and whether the member is serving a consecutive term.

Name	Organization	Appointment	Committee Title	Term	Consecutive Term
Victor Wu, MD	TennCare - Chief Medical	TennCare	Officer Ex Officio Member	N/A	N/A
Renee Williams-Clark, PharmD	TennCare – Chief Pharmacy	TennCare	Officer Ex Officio Member	N/A	N/A
Representative Bryan Terry	House of Representatives - Chair of the Health Committee	House of Representatives	Officer Ex Officio Member	N/A	N/A
Senator Rusty Crowe	Senate - Chair of the Health and Welfare Committee	Senate	Officer Ex Officio Member	N/A	N/A

Edward Capparelli, MD	Tennessee Medical Association	Speaker of the Senate	Chair/General Internist	1/1/2019 – 1/1/2022	Yes
Rodney Poling, MD	Tennessee Geriatrics Society	Governor	Vice-Chair/Physician	8/1/2017 – 7/31/2020	Yes
Karen Rhea, MD, FAPA, FAAP	Tennessee Psychiatric Association	Governor	Psychiatrist	8/1/2017 – 7/31/2020	Yes
Christopher Schwerdt, PharmD	Tennessee Pharmacist Association	Speaker of the House of Representatives	Long-term Care Pharmacist	6/18/2019 – 7/31/2022	Yes
Eleanor Twigg, PharmD	Tennessee Chain Drug Council	Governor	Retail Chain Pharmacist	8/1/2019 – 7/31/2021	Yes
Shana Bush, PharmD	Managed Care Organization-UHC	Governor	Pharmacy Director	8/1/2017 – 7/31/2020	Yes
James A. Johns, MD	Tennessee Chapter of the American Academy of Pediatrics	Governor	Pediatrician	8/1/2017 – 7/31/2020	Yes
Joel Phares, MD	American College of Cardiology	Governor	Cardiologist	9/6/2018 – 7/31/2021	Yes
Sherry Page, DNP, CPNP, PMHS, RN-C	Tennessee Nurses Association	Governor	Nurse Practitioner	8/1/2019 – 7/31/2022	No
Danielle Sims	Knoxville Area Project Access/Knoxville Academy of Medicine Foundation	Governor	Patient Health Advocate	8/1/2018 – 7/31/2021	No
Brent Dunlap, PharmD.	Tennessee Pharmacist Association	Speaker of the Senate	Independent Pharmacist	8/1/2017 - 7/31/2020	No

VACANT	Tennessee Academy of Family Physicians	Governor	Family Physician	-	-
VACANT	Tennessee Chapter of the American College of Physicians	Speaker of the House of Representatives	Internist	-	-

4. Are there any vacancies on the committee? If so, please indicate how long the position has been vacant and explain steps that have been taken to fill any vacancies.

Yes, the following positions are vacant:

- One Governor appointment (Family Practitioner) has been vacant since November 2019. TennCare has been actively working with the Tennessee Academy of Family Physicians to obtain nominees to present to the governor. Nominees are expected by June 29, 2020. Once received, we will submit to the Governor for consideration.
- One Speaker of the House of Representatives (General Internist) has been vacant since March 20, 2013. To fill this position, we have gathered recommendations from the Tennessee Chapter of the American College of Physicians (ACP) and submitted for consideration on 9/28/19. Nominations were resubmitted on 6/26/2020.

5. How many times did the committee meet in Fiscal Years 2018, 2019 and 2020? How many members were present at each meeting? Please note meetings where the committee did not have a quorum.

The committee met 12 times during SFY 2018, 2019, and 2020.

State Fiscal Year	Date	Members in Attendance
2018	August 24, 2017	10
2018	November 14, 2017	12
2018	February 13, 2018	10
2018	May 17, 2018	12
2019	August 21, 2018	11
2019	November 8, 2018	11
2019	February 14, 2019	12
2019	May 16, 2019	13
2020	August 15, 2019	13
2020	November 14, 2019	11

2020	February 13, 2020	11
2020	May 14, 2020	12

Financial Information

6. What were the committee's revenues and expenditures for Fiscal Years 2018, 2019 and 2020? Does the committee carry a reserve balance?

Expenditures include travel reimbursement, rental of meeting space and A/V equipment, and food and beverages. Starting CY 2020, meeting facility costs as well as audio visual costs, meals, production, and postage will be paid by the contractor. Expenditures are broken down below:

- FY 2018
 - o Travel Reimbursement: \$2541.21
 - o Meeting Space Rental and A/V Equipment: \$130.00
 - o Food and Beverages: \$1816.74
 - o Internal Agency Costs: \$659.69

- FY 2019
 - o Travel Reimbursement: \$3010.38
 - o Meeting Space Rental and A/V Equipment: \$90
 - o Food and Beverages: \$2219.62
 - o Internal Agency Costs: \$1346.03

- FY 2020
 - o Travel Reimbursement: \$2737.62
 - o Meeting Space Rental and A/V Equipment: 0
 - o Food and Beverages: \$1401.20
 - o Internal Agency Costs: \$954.38

The committee has no revenues or fund balance and does not have language that allows a fund balance.

7. What per diem or travel reimbursements do committee members receive? How much was paid to committee members in Fiscal Years 2018, 2019, and 2020?

Committee members receive travel reimbursements for mileage, food, and lodging. For fiscal years 2018, 2019, and 2020, committee members were reimbursed \$2541.21, \$3010.38, and \$2737.62, respectively.

8. Please provide a list of fees collected and indicate whether these fees were established through rule or through state law.

No fees were collected.

Sunshine Law, Public Meetings, and Conflict of Interest Policies

9. Is the committee subject to Sunshine law requirements (Section 8-44-101 et seq., *Tennessee Code Annotated*) for public notice of meetings, prompt and full recording of minutes, and public access to minutes? If so, what procedures does the committee have for informing the public of meetings and making minutes available to the public?

The committee is subject to Sunshine law requirements.

Proposed meeting dates and locations are available at least 30 days in advance of the meeting via the web. Currently, the meeting dates and location have been confirmed and posted through CY 2020. A proposed drug class review schedule is posted to the web and available for review up to 60 days prior to the meeting date. The meeting agenda is finalized and made available 14 days prior to the meeting date. Meeting minutes are transcribed and reviewed within 30 days after the corresponding meeting date occurrence and are submitted to the committee for approval at the next scheduled meeting. Upon approval, minutes are posted on the dedicated website on the first business day of the next full calendar month. All information is made publicly available via the web address below.

10. Does the committee allow for public comment at meetings? Is prior notice required for public comment to be heard? If public comment is not allowed, how does the committee obtain feedback from the public and those they regulate?

Yes, individuals can make a public presentation to the Committee regarding a drug or classes of drugs that are under consideration by the board. A request to make a verbal presentation shall be submitted in writing by fax or electronically no later than seventy-two (72) hours in advance of the scheduled meeting. The link to the form is posted on the dedicated website:

<https://www.optumrx.com/content/dam/openenrollment/pdfs/TennCare/pac-committee/PAC%20Requests%20for%20Public%20Testimony.pdf>

11. Does the committee have policies to address potential conflict of interest by commission members, employees, or other state employees who work with the committee?

The committee follows the conflict of interest laws of the State. Members are required to complete a yearly conflict of interest form. Form attached.

12. Does the committee have a website? If so, please provide the web address. What kind of public information is available on the website?

Committee information is available at a joint TennCare, OptumRx website: https://www.optumrx.com/oe_tennCare/pac-committee

Available information includes a list of committee members, a form to request drug class review or public testimony and procedure for doing so, meeting dates and location, agenda, minutes, drug class review packets.

13. Please provide information on any marketing and/or advertising efforts implemented in the last two fiscal years.

No marketing or advertising efforts have been implemented.

Reports, Major Accomplishments, and Proposed Legislative Changes

14. What actions has the committee taken to address the opioid crisis in Tennessee?

During the Q4 2019 meeting, the committee reviewed the clinical criteria of all medications on the TennCare PDL that are used for the treatment of opioid dependence (i.e. Agents for Opioid Use Disorder and Buprenorphine and Buprenorphine/Naloxone medications) to ensure clinical appropriateness. The committee's recommendations resulted in criteria changes for the following medications: Buprenorphine, Buprenorphine/naloxone film, Buprenorphine/naloxone tabs, Lucemyra, Suboxone Film, Zubsolv. Because of the committee's review, members who are taking opioids or benzodiazepines have a pathway to access buprenorphine-containing products as long as the patient has a clinically valid reason for the concomitant use and the provider gives a taper plan. Additionally, the committee voted to relax the criteria for Lucemyra by no longer requiring the member to try and fail both buprenorphine and methadone prior to Lucemyra use. These criteria changes will significantly impact the opioid crisis because more TennCare members will qualify for opioid dependence treatment.

Furthermore, TennCare rolled out additional formulary initiatives based on previously adopted PAC recommendations to model opioid coverage decisions after the CDC Chronic Opioid Guidelines. These initiatives included expanded coverage of OTC analgesic medications, removal of the Narcan prior authorization criteria, and the implementation of the 60 MME per day for acute patients based on current trends.

15. How has the committee addressed the finding reported by the Comptroller of the Treasury in the 2018 Sunset Audit Report?

No findings were addressed by the Comptroller of the Treasury in the 2018 Sunset Audit Report. The report did provide an observation regarding the attendance of PAC members.

Since the observation, there has been a marked increase in attendance. For FY 2018 – 2020, all members for all filled positions, except one, have attended at least half of the meetings in each applicable year. Membership per year is broken out below:

- FY 2018 Membership Attendance Rate
 - o All Members – 73%
 - o Non- Ex Officio Members – 85%

- FY 2019 Membership Attendance Rate
 - o All Members – 72%
 - o Non-Ex Officio Members – 82%

- FY 2020 Membership Attendance Rate
 - o All Members – 76%
 - o Non-Ex Officio Members – 87%

16. What were the committee’s major accomplishments during Fiscal Years 2018, 2019 and 2020?

During this review period, the committee had many accomplishments including the following:

- Evaluated criteria for drugs utilized to treat opioid dependence in response to the Tennessee Opioid Crisis.
- Reviewed recommendations submitted by the TennCare Pharmacy Drug Utilization Review (DUR) Committee
- Fast tracked the reviews of drug classes with newly released guidelines or those that are considered high impact for TennCare
- Completed the review of the Antibiotic/Antiviral/Anti-infective/Antifungal drug classes which included 28 distinct drug class reviews.
- Maintained a 99% recommendation approval rate via TennCare for FY 2018-2020.

Breakdown below:

- o FY 2018
 - Drug classes reviewed: 41 (13%)
 - New Medications/New Indications Reviewed: 34
 - Recommendations Approved via TennCare: 99%

- o FY 2019
 - Drug classes reviewed: 48 (16%)
 - New Medications/New Indications Reviewed: 49
 - Recommendations Approved via TennCare: 99%

- o FY 2020
 - Drug classes reviewed: 40 (13%)
 - New Medications/New Indications Reviewed: 50

- Recommendations Approved via TennCare: 99%

17. Please describe recommendations made by the committee that have been implemented or implemented with modifications during Fiscal Years 2018, 2019, and 2020. Please indicate which recommendations were modified when implemented.

SFY	Date	Recommendation(s)
2018	August 24, 2017	All recommendations from the committee were accepted by TennCare.
2018	November 14, 2017	All recommendations from the committee were accepted by TennCare.
2018	February 13, 2018	All recommendations from the committee were accepted by TennCare.
2018	May 17, 2018	All recommendations from the committee were accepted by TennCare with the exception of the following: 1) Lyrica. TennCare accepted PAC's recommendation; however, the PA criteria will be modified to change the 3rd bullet point to "Provider must provide peer-reviewed medical literature documenting why the requested indication is the only appropriate choice versus immediate release pregabalin". As opposed to trial/failure of the immediate release pregabalin.
2019	August 21, 2018	All recommendations from the committee were accepted by TennCare.
2019	November 8, 2018	All recommendations from the committee were accepted by TennCare.
2019	February 14, 2019	All recommendations from the committee were accepted by TennCare.
2019	May 16, 2019	All recommendations from the committee were accepted by TennCare with the exception of the following: 1.) Xofluza. TennCare approved PAC's recommendation; however, the following was also added to the criteria: "Requires contraindication to both Relenza and Tamiflu that is not associated with requested agent; OR". 2.) Lobrena. TennCare did not accept the PAC's recommendation to remove the requirement to monitor serum cholesterol and triglycerides.
2019	August 15, 2019	All recommendations from the committee were accepted by TennCare.
2020	November 14, 2019	All recommendations from the committee were accepted by TennCare with the exception of the following: 1) TennCare partially accepted PAC recommendation to change the drug class name from Agents for Opiate

		<p>Detoxification to Agents for Opioid Use Disorder, however, TennCare did not accept adding clonidine to this drug class given its use to treat Opioid Use disorder is off label.</p> <p>2) TennCare partially accepted PAC recommendation for the Mood stabilizers, “it is recommended that at least 5 unique mood stabilizers be available.” TennCare did not accept specific agents to be listed in the recommendation.</p>
2020	February 13, 2020	<p>All recommendations from the committee were accepted by TennCare except for the following:</p> <p>1) Trikafta. TennCare partially accepted PAC recommendation to update the Trikafta prior authorization criteria with the removal of the 4th bullet point under the Initial criteria; however, TennCare did not accept removal of the 1st bullet with sub-bullets under the Renewal criteria:</p> <ul style="list-style-type: none"> a. Patient has disease response as indicated by at least 1 or more of the following: <ul style="list-style-type: none"> i. Decreased pulmonary exacerbations compared to pretreatment baseline ii. Improvement or stabilization of lung function compared to baseline iii. Decrease in decline of lung function (as evidenced per new FEV1 in the past 30 days) iv. Improvement in quality of life, weight gain, or growth;
2020	May 14, 2020	<p>All recommendations from the committee were accepted by TennCare except for the following:</p> <p>1.) Narcolepsy. TennCare did not accept PAC’s recommendation to remove the specialist requirement from the clinical criteria for the narcolepsy agents.</p> <p>2.) Eucrisa. TennCare partially accepted PAC’s recommendation with slight modification to the trial/failure agents required for a member under the age of 2 years old per KEPRO’s recommendation. The topical calcineurin inhibitors are not required to be tried and failed for members under the age of 2 years old.</p>

18. Please describe any items related to the committee that require legislative attention and your proposed legislative changes.

None at this time.

19. Should the committee be continued? To what extent and in what ways would the absence of the committee affect the public health, safety, or welfare of the citizens of Tennessee?

Yes, in the absence of the committee, public health, safety, and welfare of TennCare enrollees could be adversely affected. The committee makes evidence-based decisions that support the goal of providing optimal patient care while minimizing risks and costs to both the system and the patient. Being afforded evidence-based recommendations from varied practice types and specialties is helpful from both a patient safety and a healthcare professional engagement standpoint. The Committee's decisions also influence drug placement on the preferred drug list and prior authorization criteria, which ensures the availability of medications to TennCare enrollees.

Committee Representative

20. Please identify the appropriate agency representative or representatives possessing substantial knowledge and understanding of the responses provided to the sunset review questions.

Renee Williams-Clark, PharmD. – Chief Pharmacy Officer
Lora Underwood, PharmD. – Director of Clinical Pharmacy Services

21. Please identify the appropriate agency representative or representatives who will respond to the questions at the scheduled sunset hearing.

Renee Williams-Clark, PharmD. – Chief Pharmacy Officer
Lora Underwood, PharmD. – Director of Clinical Pharmacy Services

22. Please provide the office address, telephone number, and email address of the agency representative or representatives who will respond to the questions at the scheduled sunset hearing.

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