



# Pharmacy Grand Rounds

200 First Street SW  
Rochester, Minnesota 55905  
<https://ce.mayo.edu/pharmacy-grandrounds-2024/series/pharmacy-grand-rounds-2024>

## Extending Compassion Through Expanded Access to Investigational Medicine

**Session Date:** 04/09/2024

**Session Time:** 11:00 – 11:45 AM (CST)

### Target Audience

This continuing education (CE) session was planned to meet the needs of professional staff who deal with the selection and monitoring of medication(s) as part of their patient care duties, including pharmacists, RNs, APRNs, PAs, MDs.

### Activity Overview

Expanded Access, also referred to as “Compassionate Use,” is a regulatory pathway through the U.S. Food and Drug Administration (FDA) to gain access to an investigational medicine for the treatment of patients with serious or life-threatening diseases when all other options are exhausted, and the patient is not eligible to enroll in a clinical trial. Drug approval is an extensive process not appropriate to address the emergent needs of a patient (ex: during the pandemic). Recent trends suggest an increase in the number of requests for expanded access, highlighting the need and interest of having early access to medicines. This presentation will review the various pathways through which a patient can access an investigational medicine and review literature assessing the risks and benefits of Expanded Access programs while comparing trends in expanded access requests within the Mayo Clinic Enterprise, as well as on a national and global level.

### Learning Objectives

At the conclusion of this knowledge-based CE session, participants should be able to:

1. Outline the various pathways through which patients can access an investigational drug.
2. Evaluate the trends in compassionate use of investigational drugs and analyze current challenges with FDA’s Expanded Access program.
3. Discuss best practices and illustrate the unique role of a pharmacist on an Investigational Drug Service team.

### Faculty Information

Trinkal Patel, PharmD  
PGY1 Pharmacy Resident  
Mayo Clinic Health System- Austin, MN

Trinkal Patel received a Doctor of Pharmacy degree from D’Youville School of Pharmacy and is a current PGY1 pharmacy resident at Mayo Clinic Health System – Albert Lea/Austin. Her practice interests include investigational drugs, oncology, and critical care.



## Approved Provider Statement



JOINT ACCREDITATION™  
INTERPROFESSIONAL CONTINUING EDUCATION

In support of improving patient care, this activity is planned and implemented by Mayo Clinic College of Medicine and Science. Mayo Clinic College of Medicine and Science is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

### Credit Statements

#### AMA

Mayo Clinic College of Medicine and Science designates this live activity for a maximum of 0.75 *AMA PRA Category 1 Credits*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

#### ACPE



**ACPE Universal Activity Number (UAN):** JA0000238-0000-24-004-L01-P

Mayo Clinic College of Medicine and Science designates this educational activity for a maximum of 0.75 ACPE Knowledge-based contact hours. Participants should claim only the credit commensurate with the extent of their participation in the activity

#### ANCC

Mayo Clinic College of Medicine and Science designates this activity for a maximum of 0.75 ANCC contact hours. Nurses should claim only the credit commensurate with the extent of their participation in the activity.

#### AAPA



Mayo Clinic College of Medicine and Science has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. This activity is designated for 0.75 AAPA Category 1 CME credits. PAs should only claim credit commensurate with the extent of their participation.

## Educational Format and CE Requirements

This CE session is available as a live presentation, including live webcast.

Participants must complete the following to record attendance and obtain CE credit:

1. Attend the entire session.
2. Text the session code to 507-200-3010 within 48 hours of the live presentation to record attendance.
  - a. This number is only used for receiving text messages related to tracking attendance
  - b. Employees are encouraged to create a contact in their mobile phone, as the same number is used to record attendance for every session
3. Complete the online evaluation for the respective session within 2 weeks of live presentation.

Pharmacist CE credit is electronically transferred to the National Association of Boards of Pharmacy CPE Monitor. To track CE, please go to [NABP CPE Monitor](#).

Non-pharmacist attendees can print out a record of attendance at [ce.mayo.edu](http://ce.mayo.edu) after completing the evaluation and claiming credit.

[Live Webcast](#) - access during presentation times

## Disclosure Summary

As a provider accredited by Joint Accreditation for Interprofessional Continuing Education, Mayo Clinic College of Medicine and Science must ensure balance, independence, objectivity and scientific rigor in its educational activities. All who are in a position to control the content are required to disclose all financial relationships with any ineligible company. Faculty will also identify any off-label and/or investigational use of pharmaceuticals or instruments discussed in their content for FDA compliance.

Listed below are individuals with control of the content of this program:

The faculty report the following relationships:

- Trinkal Patel, PharmD
  - Declares no financial relationship(s) pertinent to this session
  - Declares off-label use of medications will not be discussed during this presentation

Course Director and Planning Committee Members declare no relevant financial relationship(s) pertinent to this session. Members include:

- Jennifer Elmer, DNP, APRN, CCNS
- Andrew Herber, PA-C
- Sarah Jane Kotval, BSW, RSS Coordinator
- Scott Nei, PharmD, BCPS, BCCCP, FCCM, FMSHP
- Wayne Nicholson, MD, PharmD, BCPS
- Sara Thompson, PharmD, MEd, BCACP

All relevant financial relationships have been mitigated.

For additional disclosure information regarding Mayo Clinic School of Continuous Professional Development accreditation review committee members visit [ce.mayo.edu](http://ce.mayo.edu), About Us, Disclosures - or - <https://ce.mayo.edu/content/disclosures>

## System and Technical Requirements

For participants viewing the webcast, sessions are delivered via Mayo Clinic intranet web browser and Adobe® PDF. For participants viewing outside the Mayo Clinic firewall, a VPN connection is required for remote access. Recommended web browser includes Google Chrome. This session is planned and coordinated by **the Department of Pharmacy, Mayo Clinic**.