



COMPOUNDING PHARMACY
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Case Studies in Compounding Ethics

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Disclosures

- Employee, American Epilepsy Society
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- Ethics Committee Member, American Society of Association Executives

Learning Objectives

Participants will be able to apply ethical principles in the analysis of challenging ethical situations

Participants will be able to use an ethical decision-making framework to determine next steps

Participants will be able to critique elements of a case to develop an ethically supported solution

Why Ethics Matter



Trust and credibility



Ensuring mission-driven work



Framework for guidance



Organizational culture and leadership



Legal and regulatory compliance



Foster accountability



Ethical Culture Elements

Clear ethical standards and leadership

Accountability

Open and clear communication

Fair treatment

Ethical decision-making

Safe reporting mechanisms for unethical behavior

Consistency in application and enforcement of ethical policies

Alignment with organization mission, goals, and values

Fostering of ethical behavior among the team

Codes of Ethics

What is it?

A set of principles to guide an organization's decision-making and activities

What does it do?

Provide folks with guidelines for making ethical choices and ensuring accountability for those choices

Who does it apply to?

Employees

Volunteers

Board members

Key Elements of Codes of Ethics

Overarching statement for other policies that establish standards of integrity and accountability

Outlines the process/mechanism for implementing the culture and values within the organization

Can incorporate a values statement

Usually general in nature

(separate policies for conflict of interest, confidentiality, and other topics)

APC Compounder Code of Ethics

<https://a4pc.org/thecode>

The Pharmacy Compounding Professional's Code of Ethics

Responsibilities to One's Patients, Self, Colleagues, and Profession

As a pharmacy compounding professional, I will:

1. Uphold the triad relationship – patient, prescriber and pharmacist – as the foundation of pharmacy practice, acting in patients' best interest by collaborating with patients, their caregivers, and other healthcare professionals to manage a patient's treatment.
2. Comply with all applicable state and federal laws and regulations.
3. Practice the art and science of pharmacy compounding with competence and integrity, assuring patient safety and the quality of compounds, maintaining accurate records, and utilizing the proper compounding facilities, equipment, and materials in compounding for the benefit of patients.
4. Recognize the limits of my own expertise, practice only if I am fit and competent to do so and refer to colleagues on issues beyond my knowledge and skill.
5. Continually improve the quality of my work by keeping my knowledge and skills up to date via continuing education that enhances my practice.
6. Assist my healthcare colleagues, sharing information and ideas both to serve the best interests of the patient and to enhance our individual skills.
7. Provide care to my patients without discriminating on the basis of age, race, color, nationality, religion, gender, or disability.
8. In instances in which I may have a conscientious objection to providing a compounded medication, ensure that patients are promptly referred to an alternate pharmacy compounding professional who will provide the prescribed medication to the patient.
9. Assure the credibility of the pharmacy compounding profession by avoiding conflicts of interest and not engaging in business practices that are detrimental to the patient, my colleagues, or my profession.
10. Be an ambassador for pharmacy compounding, advancing my profession not only by demonstrating the highest ethical behavior but also by advocating for pharmacy compounding to patients, policymakers, news media, and others in my community.

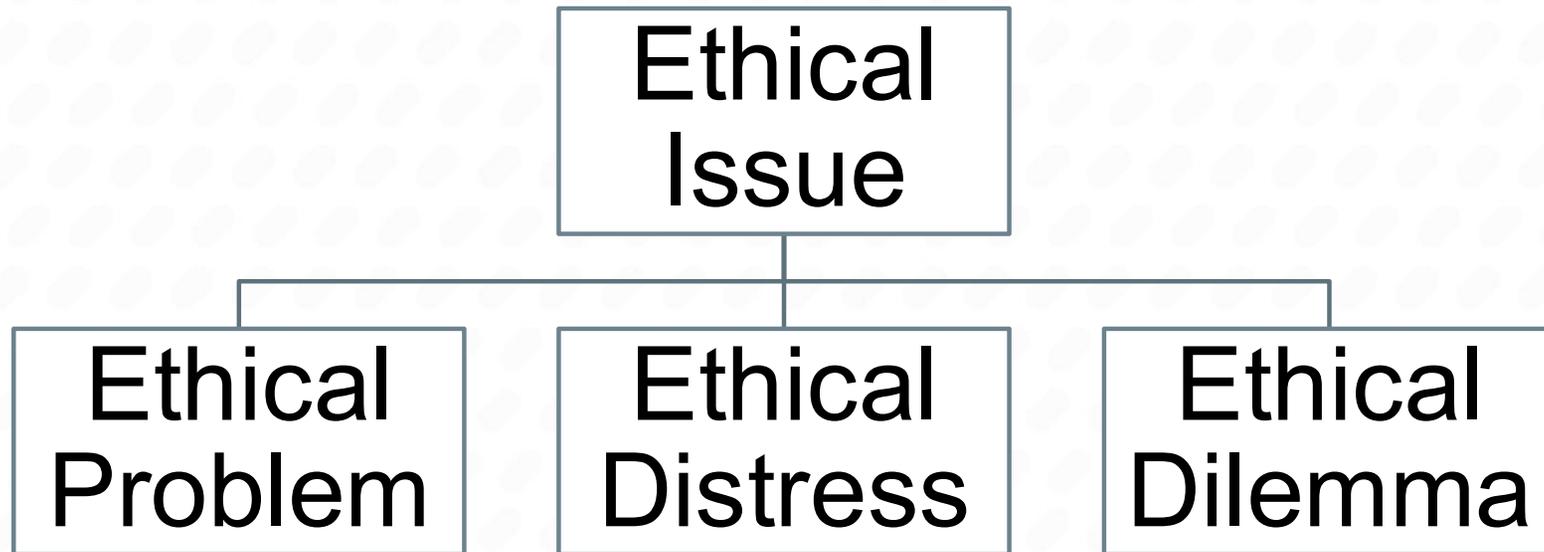
Components of Ethical Issues

Moral agent: someone who acts within the situation while trying to conform to a standard of behavior

Moral awareness: recognition that a situation raises ethical issues

Course of action: analysis of the situation and decision-making process

Desired outcome: intended result of the course of action



“This could be bad...”

“I think I know what to do but something is in my way.”

“So many options... what do I do?”

Ethical Distress

An employee notes that their peer is taking home pharmacy office supplies for their child's use in school.

Ethical Dilemma

A subject matter expert has offered to present a free lunch 'n learn for your team in exchange for their direct contact information.

What leads to ethical dilemmas?

Lack of explicit expectations

Lack of written standards or codes of conduct

Lack of association values statement

Lack of training or proper onboarding

Barriers to Ethical Behaviors

Cognitive biases

Cognitive dissonance

Organizational structures and norms

Situational pressures

Moral blindness

In-group biases

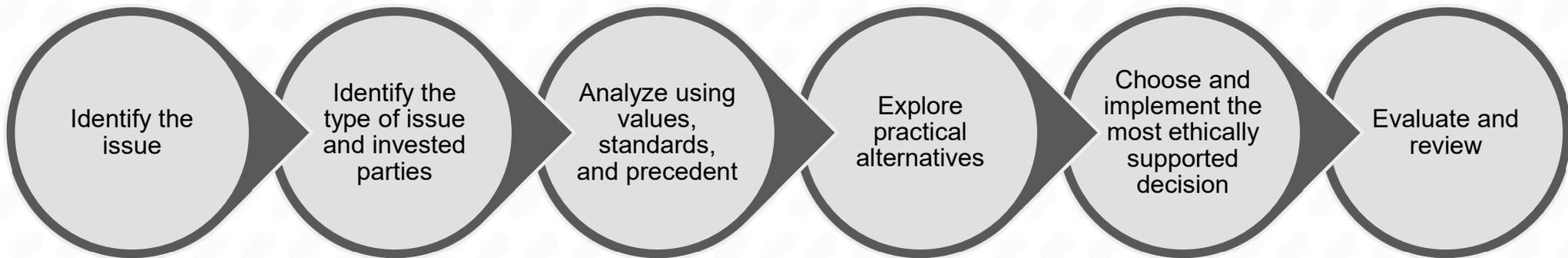
Ethical Decision-Making Models

6-Step Process	ETHIC Model	Four-Component Model
<ol style="list-style-type: none"> 1. Get the story straight; gather relevant information 2. Identify the type of ethical problem and invested parties 3. Use ethics theories or approaches to analyze the problem 4. Explore the practical alternatives 5. Complete the action 6. Evaluate the process and outcome 	<p>E: Examine relevant personal, societal, agency, client and professional values</p> <p>T: Think about applicable ethical standards, laws, and guidelines</p> <p>H: Hypothesize about possible courses of actions and consequences</p> <p>I: Identify who will benefit and who will be harmed</p> <p>C: Consult with colleagues, experts, or ethics bodies</p>	<p>Core elements:</p> <ul style="list-style-type: none"> • Moral sensitivity (recognizing the ethical issue) • Moral judgment (deciding what is right) • Moral motivation (prioritizing ethical values) • Moral character (acting ethically)

Which one is best?

Framework	Primary focus	Key strength	Key limitation	Best use
6-Step Process	Ethical principles and duties	Structured and defensible decisions	Time-intensive	Formal investigations
ETHIC Model	Practical action and consultation	Accessible and flexible	Less formal weighting	Training staff and leaders
Four-Component model	Moral behavior and capacity	Explains ethical failure	Not case-resolution focused	Assessing ethical climate

Applying an Ethical Decision-Making Model



Whistleblower or Weapon?

Two pharmacies specialize in nonsterile and sterile compounding, including hormone replacement therapy, dermatologic formulations, and veterinary compounds.

Both pharmacies operate in the same metropolitan area and serve overlapping prescribers and patient populations.

Pharmacy A recently experienced a decline in prescription volume after several local clinics shifted referrals to Pharmacy B, citing faster turnaround times and more responsive customer service.

Whistleblower or Weapon?

Pharmacy A's owner and lead pharmacist believes Pharmacy B is engaging in questionable practices, including aggressive marketing and offering discounted pricing that they suspect may violate state regulations.

During a management meeting, Pharmacy A's owner instructs the compliance manager to file formal complaints with the State Board of Pharmacy against Pharmacy B.

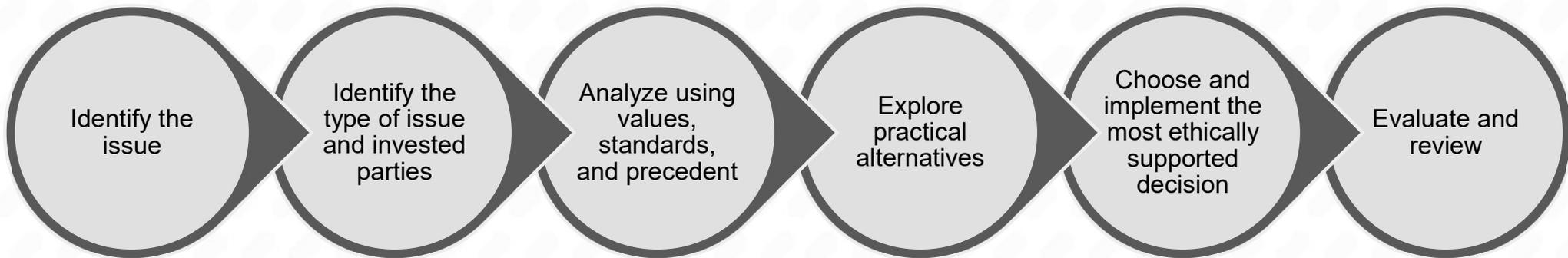
The complaints allege violations such as improper beyond-use dating, inadequate documentation, and potential sterility testing lapses.

Whistleblower or Weapon?

Pharmacy A's owner admits privately that there is no direct evidence of wrongdoing and that the complaints are intended to “trigger an investigation and slow them down.”

The compliance manager expresses discomfort, noting that complaints to the Board should be filed in good faith and based on credible concerns related to patient safety. The owner responds that “everyone does this,” and that the goal is to protect Pharmacy A's business and reputation.

Applying an Ethical Decision-Making Model



The Temptation to Compound

The Compounding Pharmacy specializes in personalized hormone therapy, pain management, and dermatologic formulations. The pharmacy has built a strong reputation for patient-centered care and physician collaboration.

Recently, several prescribers began requesting a compounded formulation containing a novel peptide that is gaining popularity in social media and wellness clinics.

The Temptation to Compound

The peptide is marketed by multiple vendors as “research-grade” and is not an FDA-approved drug substance nor listed on the FDA’s 503A bulks list. Some vendors provide certificates of analysis, but the product is labeled “for research use only” and not manufactured under FDA-regulated Good Manufacturing Practices (GMP) for human drug products.

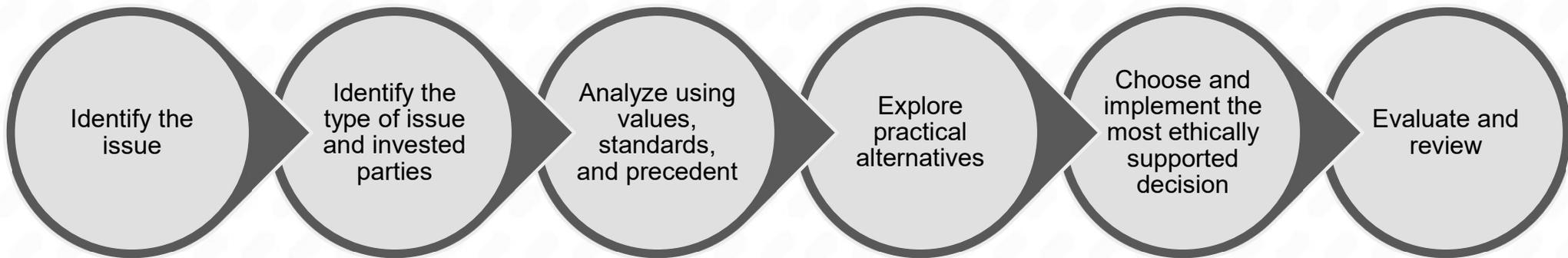
The Temptation to Compound

The pharmacy owner and lead pharmacist see a significant business opportunity and pressures the compounding team to source the peptide from a research supplier and begin compounding. They argue:

“Physicians are asking for it, patients want it, and other pharmacies are already doing it. We’ll lose market share if we don’t.”

The compliance manager warns that using non–FDA-approved or unauthorized bulk drug substances for human compounding may violate federal and state laws, FDA guidance, and USP standards. Dr. Alvarez responds that the risk is low and that enforcement is inconsistent.

Applying an Ethical Decision-Making Model



Key Points

- Focus on moral awareness
- Know your organization's policies
- Have a decision-making plan at the ready

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