

## Promotion of ethical principles in provision of medication therapy management services

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**Disclosure statement:** We would like to disclose that Sarah Kelling has a clinical practice site with The Kroger Company. We declare no other conflicts of interest or financial interests that the authors or members of their immediate families have in any product or service discussed in the manuscript, including grants (pending or received), employment, gifts, stock holdings or options, honoraria, consultancies, expert testimony, patents, and royalties.

**Key words:** bioethics, medication therapy management, pharmacist

### Abstract

*As pharmacists move toward more patient-centered care through medication therapy management (MTM), important issues and conflicts may arise within the therapeutic relationship, requiring pharmacists to use ethical knowledge and skills toward conflict-resolution. The purpose of this paper is to explore practical strategies that pharmacists and other champions of MTM may utilize to support the ethical principles of autonomy, veracity, nonmaleficence, beneficence, and justice, along with an ethic of care during the provision of MTM services. With a deeper understanding of ethical principles and the Code of Ethics for Pharmacists, pharmacists may be more prepared to make difficult ethical decisions, and ultimately, guide better patient care.*

### Introduction

The role of the pharmacist continues to move towards providing direct patient care, such as through provision of medication therapy management (MTM).<sup>1</sup> While MTM encompasses a diverse array of services, the overarching goal is to optimize therapeutic outcomes for individual patients.<sup>2</sup> One component of MTM is the comprehensive medication review and ongoing patient monitoring with personal interaction between the pharmacist and patient. Limited information exists regarding the number of pharmacists providing comprehensive medication reviews and other MTM services; however, one company has reported a network of pharmacists exceeding 70,000.<sup>3</sup> As the number of pharmacists providing MTM services continues to grow, care should be taken to ensure that the development and implementation of MTM programs aligns with key ethical principles that form the foundation of The Code of Ethics for Pharmacists.<sup>4</sup> Codes of ethics are adopted by professions to guide ethical decision-making by recognizing what is “right” or “wrong”, “good” or “bad” with application of such understanding to practice. Limitations of professional codes of ethics include vague guidelines and conflicting principles. However, codes of ethics are essential for recognizing the values of the profession and lack of adherence to the guidelines may even have legal repercussions. The most cited and frequently used principles among ethicists and

healthcare providers, since they were first espoused by Tom L. Beauchamp and James F. Childress in *Principles of Biomedical Ethics* 1979, include autonomy, nonmaleficence, beneficence, and justice.<sup>5</sup> The Code of Ethics for Pharmacists not only focuses on these widely used principles, but also on the principle of veracity (honesty and truthfulness). The purpose of this paper is to explore practical strategies that pharmacists and other champions of MTM may utilize to support the ethical principles of autonomy, veracity, nonmaleficence, beneficence, and justice, along with an ethic of care.

### Ethical Principles

#### *Autonomy*

Autonomy translates as “self rule” in which the self is free from controlling interferences by others or from personal limitations that hinder the ability to make choices. The principle of autonomy requires respect for autonomy, which may require that one not infringe upon the freedoms of others to be self-determining, or may suggest that we promote the self-determination of others. The latter is more consistent with the Code of Ethics for Pharmacists, which states “A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health.”<sup>4</sup> Through the provision of MTM services, pharmacists should promote the principle of autonomy. In doing so, they encourage patients to make choices that align with their moral viewpoint and life plan. For example, the medication therapy review “is designed to improve patients’ knowledge of their medications, address problems or concerns that patients may have, and empower patients to self-manage

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their medications and their health conditions.”<sup>1</sup> This principle includes the obligation to resist or eliminate controlling influences (e.g. directive counseling) and promote autonomous decision-making by patients and guardians.<sup>6</sup> The latter involves recognizing the worth of the patient and including his or her goals. For example, patient beliefs and preferences should be taken into account when developing self-management goals related to health and well-being.

It is of utmost importance to avoid actual or perceived coercive measures when promoting MTM services. Patients should be made aware of any fees, including those related to the medication review, laboratory work, or immunizations, prior to agreeing to participate and receiving the service. Care should be taken to avoid implying false information. For example, it is inappropriate to suggest that the patient will have reduced health plan benefits if he chooses not to participate in a particular program, unless specific plan benefits exist.

Pharmacists should assess medications for indication, efficacy, safety, and adherence during the MTM session.<sup>7</sup> As medication experts, pharmacists need to provide education to patients and caregivers in a manner that supports patient decision-making and informed consent. The information that is provided should be accurate, complete, and delivered in a way that each patient and/or caregiver can understand and act upon. More than 1 in 3 adults in the United States have basic or below basic health literacy.<sup>8</sup> Pharmacists should become familiar with signs of low health literacy and routinely incorporate plain language and the teach-back method when communicating with patients.<sup>9,10</sup> MTM includes the assessment of not just literacy and education levels, but also cultural issues and language barriers that may inhibit comprehensive care. Without taking the initiative to properly inform and educate, pharmacists are violating the principle of autonomy, and ultimately the dignity of each patient and caregiver.

The principle of autonomy does not rest with patients and caregivers alone. After assessing medications and discussing findings with the patient, the pharmacist must also communicate the information to other health care professionals so they too can make well-informed decisions and properly manage patient care. Consider sharing with patients at the beginning of the visit how information will be communicated with other members of the health care team and third-parties, including if professional judgment determines that the patient or others are at risk. If an established relationship between the MTM pharmacist and other health care professionals does not exist, it is important to ask patients how they would prefer to share non-urgent

information with other members of their health care team. Some patients may prefer that the pharmacist reach out directly to their primary care provider (PCP), whereas others may prefer to have a personal discussion with their PCP. Pharmacists can support the latter preference by using patient friendly language to describe specific recommendations in the medication-related action plan. Multiple copies of the medication list and recommendations can be provided and patients can be encouraged to share and discuss the documents with their PCP.

#### *Veracity*

Related to the principle of autonomy is the principle of veracity, or truthfulness. When informing and educating patients and caregivers, it is critical to provide truthful information even though such information may involve “bad news” or be perceived as harmful to the overall well-being of the patient. It is important to establish a therapeutic relationship with patients to understand how information should be delivered as each patient may have different expectations. In the Code of Ethics for Pharmacists, a pharmacist “has a duty to tell the truth and to act with conviction of conscience.”<sup>4</sup> Furthermore, in being trusted by others, there is a dialectical relationship surrounding trust and honesty, “Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.”<sup>4</sup>

Another aspect of veracity falls on the obligation of the pharmacist to represent his or her self accurately. That is, if a pharmacist lacks a particular skill or falsifies or misrepresents an ability or skill, he or she violates the principle of veracity. In the Code of Ethics for Pharmacists, there are two specific areas that speak to the principle of veracity. The first focuses on the guiding rule that a pharmacist maintains professional competency: “A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.”<sup>4</sup> In order to provide optimal care, pharmacists providing MTM services must remain current in their knowledge of medications, disease states, and clinical guidelines. Depending on the background and needs of the individual pharmacist, strategies to remain up-to-date may include seeking out continuing education that is beyond the minimum requirements set forth by the board of pharmacy or exploring opportunities to create a continuing professional development portfolio.<sup>11,12</sup> Some pharmacists may find that completing residency training, fellowship training, or

certifications may help to demonstrate competency to patients, other health care professionals, and payors.<sup>13</sup> Furthermore, the pharmacy site may wish to apply for accreditation, such as through the Center for Pharmacy Practice Accreditation.<sup>14</sup>

The second aspect of veracity focuses on the importance of collegial relationships, particularly when one may be limited in knowledge, skill, or resources: “When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient.”<sup>4</sup> This aligns with a core element of MTM, which includes referring patients to another health care professional when necessary.<sup>1</sup> Without being guided by the principle of veracity, the pharmacist may lose credibility and respect among patients, colleagues, and other healthcare professionals, and dishonest acts may lead to avoidable harms.

#### *Nonmaleficence*

Nonmaleficence, or “Primum non nocere” is the obligation to avoid or not inflict harm on others whether intentionally or unintentionally.<sup>6</sup> Nonmaleficence expresses the limits of the principle of beneficence (discussed more thoroughly below), and reminds the pharmacist to consider the possible harms that may arise with any intervention. The presence of harm should be avoided or prevented, however this principle also guides the pharmacist to evaluate the levels and types of harms present. For example, if a pharmacist encounters a patient who is taking a harmful medication, the action that is guided by nonmaleficence is to stop the patient from taking the medication. Due to the patient-centered approach of MTM, the pharmacist’s observations and interpersonal patient care can lead to “early detection of medication-related problems and thus have the potential to reduce inappropriate medication use, emergency department visits, and hospitalizations.”<sup>1</sup>

Organizations frequently develop policies and procedures to decrease medication errors during the medication dispensing process.<sup>15,16</sup> Similarly, standardized policies and procedures for staff providing MTM services should be developed. This should include steps to minimize distractions, which can lead to unintentional patient harm. For example, a pharmacist who is interrupted while assessing a patient’s medications or documenting recommendations may miss important information. If the pharmacist is interacting with a patient and is interrupted by another patient or staff member, the covenantal relationship between the patient and pharmacist may be disrupted. This may result in the patient being less willing to share information, which may negatively impact patient care. Developing strategies to avoid this problem may be particularly relevant in programs where one

pharmacist is providing both dispensing and non-dispensing services concurrently. Having standardized policies and procedures for staff also encourages consistency of care and creates expectations, both within the profession and with stakeholders (i.e., patients, other health care professionals, and payors) regarding appropriate levels of cognitive services by pharmacists.

Comprehensive care should focus not only on disease management, but also health and wellness promotion. Pharmacists should be familiar with evidenced-based practices, such as U.S. Preventive Services Task Force (USPSTF) recommendations, related to indication for and frequency of screenings.<sup>17</sup> Pharmacists may wish to utilize an electronic search tool of USPSTF recommendations to systematically assess wellness needs of each individual patient.<sup>18,19</sup> Whenever possible, results from screenings should be shared with other members of the patient’s health care team to prevent duplication of testing. This may result in unnecessary health care expenditures, as well as the probability of false-positive results requiring additional, often more invasive, testing.

Additional considerations are warranted for programs that include potentially sensitive topics. This could include HIV and genomics testing, as well as the emerging obligations of pharmacists to warn and protect third-parties (e.g., sexual partners, department of health, or CDC), when there is a potential harm to individuals or populations.<sup>20,21</sup> Staff and pharmacists must understand legal obligations as well as present and future liabilities (e.g., access to genomic information). It is important to incorporate processes to ensure patient privacy, both during the visit and related to data storage. Furthermore, pharmacists should consider the possible psychological impact test results might have on patients and family members. Training in the area of cultural competence is important as patients and families that receive care may have a variety of beliefs.<sup>22</sup> It has been recognized that a lack of cultural competence can lead to poor health outcomes and health care disparities.<sup>23</sup> Be sure to develop protocols for referring patients to other health care professionals for confirmation of test results, treatment, and counseling services.

#### *Beneficence*

The primary aim of MTM is to optimize therapeutic outcomes for individual patients, which is an example of beneficence, the obligation to act for the benefit of others.<sup>1,2,6</sup> The principle of beneficence emphasizes the importance of weighing risks and benefits. As Gert, Culver, and Clouser (1997) state, “As properly used in the biomedical ethics literature this principle is cited simply to give “validation”

both to preventing or relieving harm and to doing good or conferring benefits.”<sup>24</sup> For example, a pharmacist providing a vaccine recognizes that there may be some harm involved when injecting a syringe (e.g., tenderness at the injection site), but that the overall benefits of being immunized from potentially harmful and/or transmittable diseases outweighs the discomfort of the injection. Thus, beneficence prompts the pharmacist to weigh and balance possible benefits against existing or possible risks.

Pharmacists should encourage patients to take an active role in developing health and wellness goals. Example topics that may be addressed include medication adherence, disease self-management (e.g., blood glucose or blood pressure testing), healthy food choices, physical activity, and tobacco cessation. Pharmacists can assess vaccine needs and, if permissible under state law, provide necessary immunizations during MTM sessions. Working collaboratively, patient and pharmacists can develop goals that are specific, measurable, attainable, realistic, and timely (SMART).<sup>25</sup> These goals should be documented in the medication-related action plan if a comprehensive medication review is conducted. This will provide an opportunity for the patient, in collaboration with the pharmacist, to assess progress, identify successes, and modify the goals as needed. It may be beneficial to incorporate strategies, such as motivational interviewing, that emphasize the patient’s ability to make choices that align with their belief system.<sup>26</sup>

Consider developing a list of local community resources. These might include support groups, parks and fitness centers, weight loss organizations, the public health department, agencies associated with aging, and the local library. Some patients may bring up sensitive topics during the MTM session, particularly as they gain trust in their MTM pharmacist. Contact information for child protective services, domestic violence shelters, food banks, and homeless shelters may be useful. Finally, consider establishing policies to help patients who are at risk for or display warning signs of suicide.

#### *Justice*

The principle of justice is concerned with the fair distribution of benefits and burdens.<sup>6</sup> Concerns of justice often arise when resources are scarce or inequality is present. While there are various models of fair distribution to provide patients with resources or opportunities, the goal of these models is ultimately to protect vulnerable members of society and to minimize undue burdens, including the lack of available and accessible resources. For example, with recent drug shortages, patients and providers may not have access

to needed medications. In such tragic events, the principle of justice can guide pharmacists to not only determine how limited resources should be distributed to those who are in need, but also to develop new solutions when there are no longer any resources to distribute, (e.g., deriving compounded medications from available drugs).

Access to health services requires three steps: gaining entry into the health care system, accessing a location that provides the services, and finding a provider with whom the patient can communicate and trust.<sup>27</sup> Decision-makers should develop policies and procedures that increase equitable access to care across all three domains, while addressing possible barriers and finding solutions.

Patients may face a variety of challenges related to access of MTM services. Patients may not be aware of the existing programs that are available in their communities. Consider exploring if the patient population obtains health information from advertisements, community groups, news reports, social media, or other sources. Identifying how to harness these methods of communication may lead to increased awareness of available services, which may result in improved participation among community members.

Among patients with insurance coverage, inequities may exist related to accessing MTM services. For example, racial and ethnic minorities may be less likely to meet MTM eligibility criteria.<sup>28</sup> Out-of-pocket costs, particularly when there is a lack of insurance coverage for the MTM service, may be a barrier for some patients. Furthermore, MTM programs may not be available within communities where patients reside. If they are, patients may have difficulty accessing the location due to mobility or transportation barriers. Alternative strategies, such as telephonic, electronic, or home visits should be explored to determine if rates of participation improve. Additionally, pharmacists from diverse backgrounds should be encouraged to participate in the provision of MTM services. Literature suggests that patients who share a common race, ethnicity, and language with their health care professional may have improved access to care, improved communication and relationships with the health care professional, and may be more likely to receive and accept appropriate medical care.<sup>29</sup>

Finally, MTM program should consider formally evaluating clinical, economic, and humanistic outcomes (ECHO) for the services provided to patients.<sup>30</sup> Best practices should be disseminated so that effective strategies are integrated across programs. Stakeholders, including health insurance plans and patients, may look towards outcomes data to make decisions about the value of the services. Demonstrating

value may lead to expanded services, as well as increased patient inclusion criteria. Ultimately, these practices may result in improved patient and population health.

### Conclusion

A growing number of pharmacists are providing MTM services. Pharmacists and other champions of MTM should strive to incorporate strategies that lead to the promotion of the ethical principles of autonomy, veracity, nonmaleficence, beneficence, and justice, with the goal of improved patient and population health. With a deeper understanding of ethical principles and the Code of Ethics for Pharmacists, pharmacists may be more prepared to make difficult ethical decisions, and ultimately, guide better patient care.

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