NABP
National Association of Boards of Pharmacy

Report of the Task Force on

MEDICATION ASSISTED TREATMENT

NABP

Members Present:

Jeanne Waggener (TX), *chair;* Jim Bracewell (GA), Luke Daniel (AR), Debra Feinberg (NY), Robert Giacalone (OH), Mike Godek (MA), Fiona Karbowicz (OR), Samuel "Sam" Lanctin (NB), Karen Ryle (MA), Katy Wright (TN), William "Bill" Lee (VA).

Others Present:

Nicole "Nicki" Chopski, *Executive Committee liaison;* James Gasper, College of Psychiatric and Neurologic Pharmacists (CPNP); Jake Nichols, Professional Recovery Associates; Erica Schlesinger, Tennessee Department of Mental Health and Substance Abuse; Timothy D. Fensky, NABP president; *Guests;* Lemrey "Al" Carter, Melissa Madigan, Eileen Lewalski, Maureen Schanck, Cameron Orr, Andrea Busch, *NABP staff*.

Introduction:

The task force met virtually on November 17, 2020. This task force was established pursuant to Tim Fensky's presidential initiative, which is to promote pharmacist-provided medication-assisted treatment (MAT) for patients diagnosed with opioid use disorder (OUD).

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review current federal and state laws and regulations related to medication-assisted treatment.
2. Examine the language in the *Model State Pharmacy Act and Model Rules of the National Association of Boards (Model Act)* and, if necessary, recommend amendments that allow pharmacists to be key leaders in opioid safety and patient care.

Background and Discussion:

The task force began their discussion by having the guests share their experiences with the current trends they are witnessing in various parts of the country regarding opioid use disorder (OUD) treatment. While it was revealed that there has been great progress in addiction treatment, including OUD, guests lamented that more needs to be done as too many OUD patients fail to receive treatment of any kind. Also mentioned was the reported increase in OUD patients due to the coronavirus disease 2019 (COVID-19) pandemic, which has also made obtaining treatment even more difficult in many areas of the country. In addition, it was noted that the lack of available and/or willing providers further hampered OUD patients from receiving treatment.

Guests stated that some patients report feeling stigmatized because of their disorder. They commented that there are many health care professionals, including pharmacists, who believe

that abstinence is the best treatment for long-term recovery. It was also noted that there has been a shift to the use of methadone from the use of buprenorphine in some areas, as patients choose this option to avoid the stigma and judgment they feel at the pharmacy. One guest described hearing from patients who claimed that they had negative experiences with pharmacists, particularly those who refuse to stock buprenorphine because they believe the treatment is substituting one addiction for another. Members agreed that it is vital to educate pharmacists and other health care professionals about the success of MAT using such medications as methadone or buprenorphine, and their crucial role in treating patients suffering from OUD. Members also stated that it is vital that health care professionals make buprenorphine available as soon as a patient is willing to seek treatment.

One guest furthered the discussion by mentioning that the term "medication-assisted treatment" is somewhat of a misnomer in that medications alone, with no counseling component, can be effective in treating OUD, and that the current term utilized by the Substance Abuse and Mental Health Services Administration (SAMHSA) is "medications for opioid use disorder" (MOUD) rather than MAT. Members were provided SAMHSA's Treatment Improvement Protocol 63, *Medications for Opioid Use Disorder – For Healthcare and Addiction Professionals, Policymakers, Patients, and Families,* which described the term's distinction and treatment protocols. While there was extensive discussion regarding which term should be used to best further the NABP presidential initiative, the task force agreed that both terms should be referenced in the *Model Act.* Members were aware of the need to prevent confusion among legislators and federal officials who are more familiar with the term MAT, particularly in reference to the Mainstreaming Addiction Treatment Act of 2019 (MAT Act), a bill currently pending in Congress. Members eventually agreed that the barriers to treatment are more at issue than the term that is used, remarking that increasing access to treatment to improve patient outcomes and prevent death by overdose is the primary goal of this task force and NABP.

Regarding patient outcomes, guests and members engaged in a very robust discussion as to whether counseling was necessary for OUD patients. Guests noted that patients who have life stressors can benefit from counseling; however, there is no difference when finite outcomes are reviewed. Others disagreed with that assessment, stating that OUD is a chronic disease with most patients suffering from one or more comorbidities. After some conversation, all agreed that psychological counseling should not be an eligibility requirement of MAT for OUD patients seeking immediate treatment.

Further discussion ensued regarding whether pharmacies are an appropriate setting for patients who are going through withdrawal to seek treatment. In support of the concept, members discussed how accessible pharmacies are and the fact that pharmacists are well-educated on the disorder and can provide compassionate and effective counseling, resulting in positive

outcomes. After much in-depth discussion, the task force determined that the pharmacist's role should involve initiation of short-term MAT therapy, including counseling on the medication and the need for further care, thus providing a "bridge" to long-term treatment.

In addition, members discussed at length how best to implement pharmacist-initiated MAT in light of current state and federal restrictions as many states do not allow pharmacists to obtain a state controlled substances (CS) license. Not only does this prevent pharmacists from independently prescribing CS, including buprenorphine, at the state level, it precludes pharmacists from obtaining a federal CS mid-level practitioner registration from the United States Drug Enforcement Administration (DEA), which is also needed to prescribe CS. Members acknowledged that, currently, many states allow pharmacists to prescribe MOUD through the use of collaborative practice agreements with practitioners who are licensed to prescribe CS at the state and federal levels. Members agreed, however, that access to treatment would be greatly expanded if pharmacists had independent authority at the state level to initiate MOUD for patients suffering from opioid withdrawal rather than having to enter into collaborative practice agreements.

Lastly, the federal Drug Addiction Treatment Act of 2000 (DATA 2000) limits the prescribing of MOUD, most notably buprenorphine, and requires certain health care practitioners to obtain DATA 2000 waivers, although pharmacists are excluded. The task force discussed the likelihood of pharmacists being added to the list of DATA 2000-waived practitioners, as well as the likelihood that the MAT Act, which would eliminate the DATA 2000 waiver requirement altogether, would be passed. The task force was informed that NABP is supportive of the MAT Act and is working to educate federal legislators and regulators about the importance of this Act in treating patients with OUD.

After careful review and deliberation, the task force recommended:

1. NABP amend the *Model Act* by adding a definition of MAT that includes a footnote to clarify that MOUD is a new term utilized by SAMHSA and adding an emergency-use prescribing and dispensing provision to Section 6. Pharmacy Care Services that allows a pharmacist to prescribe and dispense MAT for emergency-use to patients with OUD. When initiating MAT therapy, pharmacists must use professional judgment to assess clinical appropriateness of the request and the length of treatment needed until patient obtains treatment by an authorized practitioner.
2. NABP encourages state boards of pharmacy to promulgate regulations that allow pharmacists to obtain state CS licenses in order to prescribe CS at the state level and obtain a federal CS mid-level practitioner registration from DEA.

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

Title, Purpose, and Definitions

Section 104. Practice of Pharmacy.

The "Practice of Pharmacy" means, but is not limited to, the interpretation, evaluation, Dispensing, and/or implementation of Medical Orders, and the initiation and provision of Pharmacist Care Services. The Practice of Pharmacy also includes continually optimizing patient safety and quality of services through effective use of emerging technologies and competency-based training.

Section 104. Comment.

The definition of the "Practice of Pharmacy" is one of the most important, and perhaps one of the most discussed, clauses in the NABP *Model Act*. The definition is purposely expressed in broad terms to provide substantial latitude to the Board of Pharmacy in the adoption of implementing rules. Inclusion of or authorization for specific activities, such as the Administration of medications, is purposely not delineated in the definition in order to be empowering and not proscriptive. To assist states in the interpretation of the revised definition of the "Practice of Pharmacy," the *Model Act* includes the definition of "Pharmacist Care Services" and Model Rules for the Provision of Pharmacist Care Services for those states that need to include specific lists of activities or authorizations due to legislative and/or administrative policies and procedures.

The definition also acknowledges that pharmacy is a dynamic profession and a broad definition of the practice will permit the Board to make necessary changes from time to time to meet the changing practice. Such changes may be affected by new or amended rules, which would be promulgated pursuant to the requirements of the State Administrative Procedures Act, affording all interested parties an opportunity to review and comment on any proposed rules.

…

(d4) Medication-assisted treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a "whole-patient" approach to the treatment of substance use disorders. Medications used in MAT are approved by the Food and Drug Administration (FDA).[1]

[1] Substance Abuse and Mental Health Services Administration also refers to MAT as "Medications for Opioid Use Disorder" (MOUD), which are FDA-approved medications for the treatment of opioid use disorders and currently include methadone, naltrexone, and buprenorphine.

…

(e4) "Pharmacist Care Services" is the provision by a Pharmacist of patient care activities within this State or into this State, as defined by the Rules of the Board, with or without the Dispensing of Drugs or Devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process.[2]

…

(a5) "Pharmacy" means any place within this State where Drugs are Dispensed and Pharmacist Care Services is provided and any place outside of this State where Drugs are Dispensed and Pharmacist Care Services is provided to residents of this State.

…

(b5) "Primary Care" is the first level of contact of individuals, the family, and the community with the health care delivery system, bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process. (Areas of Primary Care where Pharmacists provide Pharmacist Care Services include, but are not limited to, the following: chronic disease management; smoking cessation; maternal and child health; immunizations; family planning; self-care consulting; Drug selection under protocol; treatment of common diseases and injuries; nutrition; and general health education and promotion.)

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Model Rules for the Practice of Pharmacy

Introductory Comment

The Board finds that in the interest of protecting the public health and welfare, in order to ensure optimum effect of Drug therapy, and to maximize the quality of Pharmacist Care Services, the following rules are essential.

[2] Objectives of Pharmacist Care Services include cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process, or prevention of a disease or symptomatology. Pharmacist Care Services should be provided by all Pharmacists within the Standard of Care to the extent of their abilities regardless of the practice setting.

Section 6. Pharmacist Care Services. [3]

(a) Prospective Drug Utilization Review (DUR)[4]

A Pharmacist shall obtain and review the patient records and medical history for each Prescription Drug Order for:

(1) known allergies;
(2) rational therapy contraindications;
(3) reasonable dose, duration of use, and route of Administration, considering age, gender, and other patient factors;
(4) reasonable directions for use;
(5) potential or actual adverse Drug reactions;
(6) Drug-Drug interactions;
(7) Drug-food interactions;
(8) Drug-disease contraindications;
(9) therapeutic duplication;
(10) proper utilization (including over- or under-utilization), and optimum therapeutic outcomes; and
(11) abuse/misuse.

Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(b) Patient Counseling[5]

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:
   (i) the name and description of the Drug;
   (ii) the dosage form, dose, route of Administration, and duration of Drug therapy;
   (iii) intended use of the Drug and expected action;

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[3] Additional Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and medication eligibility and coverage; Administering Drugs, vaccines, or biologicals; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan /practice guidelines; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering lab tests; and performing lab tests as provided by State and Federal law.

[4] Pharmacists should be permitted to use computer software, if available, to accomplish this review.

[5] The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the Pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

(iv) special directions and precautions for preparation, Administration, and use by the patient;
(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(vi) techniques for self-monitoring Drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(3) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).

(4) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

(c) Medication Adherence Monitoring Services and Intervention Programs

Medication Adherence Monitoring Services and Intervention Programs designed to promote improved medication use behaviors, such as compliance and adherence, appropriate monitoring and self-reporting, increased patient knowledge, and improved therapy options, shall comply with established Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs. (See Appendix D for Guidelines for the Appropriate Use and Disclosure of Protected Health Information in Medication Adherence Monitoring Services and Patient Intervention Programs.)

(d) Collaborative Pharmacy Practice

(1) Collaborative Pharmacy Practice Agreement

A Pharmacist planning to engage in Collaborative Pharmacy Practice shall have on file at his or her place of practice the written Collaborative Pharmacy Practice Agreement. The initial existence and subsequent termination of any such agreement and any additional information the Board may require concerning the Collaborative Pharmacy Practice Agreement, including the agreement itself, shall be made available to the Board for review upon request. The Agreement may allow the Pharmacist, within the Pharmacist's Scope of Practice Pursuant to the Collaborative Pharmacy Practice Agreement, to conduct activities approved by the Practitioner, and as defined by law and by the Rules of the Board. The collaboration that the Practitioner agrees to conduct with the

Pharmacist must be within the scope of the Practitioner's current practice. Patients or caregivers shall be advised of such agreement.

(2) Contents

The Collaborative Pharmacy Practice Agreement shall include:

(i) identification of the Practitioner(s) and Pharmacist(s) who are parties to the Agreement;

(ii) the types of decisions that the Pharmacist is allowed to make;

(iii) a process for generating any necessary Medical Orders, including prescription orders, required to initiate allowed activities;

(iv) a method for the Practitioner to monitor compliance with the Agreement and clinical outcomes and to intercede where necessary;

(v) a description of the Continuous Quality Improvement Program used to evaluate effectiveness of patient care and ensure positive patient outcomes;

(vi) a provision that allows the Practitioner to override a Collaborative Practice decision made by the Pharmacist whenever he or she deems it necessary or appropriate;

(vii) a provision that allows either party to cancel the Agreement by written notification;

(viii) an effective date;

(ix) signatures of all collaborating Pharmacists and Practitioners who are party to the Agreement, as well as dates of signing; and

(x) a procedure for periodic review and renewal within a time frame that is clinically appropriate.

(3) Amendments to a Collaborative Pharmacy Practice Agreement must be documented, signed, and dated.

(4) Documentation of Pharmacist Activities

Documentation of allowed activities must be kept as part of the patient's permanent record and be readily available to other health care professionals who are providing care to that patient and who are authorized to receive it. Documentation of allowed activities shall be considered Protected Health Information.

(e) Emergency-Use Dispensing

Prescribing and Dispensing Drugs for emergency-use pursuant to a Pharmacist-issued Prescription[6] and appropriate patient counseling, including but not limited to:

(1) Opioid overdose reversal agents, such as naloxone;

(2) Epinephrine;

(3) Antidote kits; ~~and~~

(4) Short-acting beta agonist inhalers; and~~.~~

(5) Medication-assisted treatment for the purpose of initiating therapy for Opioid Use Disorder. The Pharmacist must:

(i) obtain a DEA registration and a state controlled substance licensure/registration, if required; and

[6] Pharmacist may prescribe pursuant to specific statewide protocols or standing orders.

(ii) use professional judgment to assess the clinical appropriateness of the patient's request and length of treatment until patient obtains treatment from an authorized practitioner. [7]

[7] It is contemplated that for long-term treatment, Pharmacists should be prescribing under a collaborative practice agreement rather than under an emergency use provision.