Policy: Interested Parties Meeting – 1st Revised



In accordance with the Open Public Meetings Act, this meeting notice was sent to individuals requesting notification of the Washington Medical Commission (WMC) meetings. This agenda is subject to change. The WMC will take public comment at the Policy: Interested Parties meeting. To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email <u>doh.information@doh.wa.gov</u>.

Virtual via Teams Webinar: Registration link can be found below. Commissioners and staff will attend virtually.

Physical location: 111 Israel Rd SE, TC2 Room 166, Tumwater, WA 98501

Thursday, March 27, 2025

Open Session

10:00 am Agenda To attend virtually, please register here: WMC Policy: Interested Parties The goal of this meeting is to provide an opportunity for anyone to comment on and suggest changes to the WMC's policies, guidance documents, procedures, and interpretive statements. The WMC encourages the public to provide comments on the items on this agenda. To participate, please use the Raise Hand function or add your comments to the chat. Be sure to identify yourself and your affiliation, if applicable. If you prefer to submit written comments, please email them to medical.policy@wmc.wa.gov by 5 p.m. on March 24, 2025. Organizers: Kyle Karinen, Executive Director & Micah Matthews, Deputy Executive Director Policy: Practitioners Exhibiting Disruptive Behavior (MD2021-01) 1 Review and discuss proposed revisions to the document as part of its scheduled Pages 3-6 four-year review process. **Procedure: Interactive and Transparent Development of Evidence-based** Policies and Guidelines (PRO2018-02) 2 Pages 7-9 Review and discuss proposed revisions to the document as part of its scheduled four-year review process. **Guidance Document: Medical Professionalism** Review and discuss proposed revisions to the document as part of its scheduled 3 Pages 10-14 four-year review process. **Proposed: Joint Guidance for Retail Intravenous Therapy Clinics** 4 Pages 15-19 Review and discussion of proposed document. **Open Forum** Interested parties are invited to share ideas for new policies or suggestions for reforming 5

also welcome; please see below for details.

existing ones. Each speaker will have a two-minute comment period. Written comments are

	Written Comments		
6	These comments are provided for informational purposes at this meeting and will be presented		
	at the next Policy Committee meeting for the Committee members' consideration.		
	6.1	Dr. Kay Funk	Page 20
	6.2	Dr. Chris Bundy, Washington Physicians Health Program	Pages 21-23

Euturo Topico for Disquesion				
Future Topics for DiscussionThe following items are next up for review. Feel free to provide comments regarding				
these items at medical.policy@wmc.wa.gov.				
2025				
1	Guidance Document: <u>A Collaborative Approach to Reducing Medical Error and Enhancing</u> Patient Safety (GUI2014-02)			
2026				
1	Guidance Document: Practitioner competence (GUI2018-02)			
2	Guidance Document: Overlapping and simultaneous surgeries (GUI2018-03)			
3	Guidance Document: Reentry to Practice guideline (GUI2019-01)			
4	Guidance Document: Reentry to Practice for suspended licenses guideline (GUI2019-02)			
5	Guidance Document: Informed Consent and Shared Decision-Making (GUI2022-01)			
6	Guidance Document: Ownership of Clinics by Physician Assistants MD2015-06			
7	Guidance Document: Medical marijuana authorization guidelines			
8	Policy: Discrimination in Healthcare (POL2022-01)			
9	Policy: Self-Treatment or Treatment of Immediate Family Members (POL2022-02)			
10	Policy: Terminating the Practitioner-Patient Relationship (POL2022-03)			





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Title:	Practitioners Exhibiting Disruptive Behavior
Policy Statement Number:	POL2025-XX
Document Number:	
References:	Chapter 18.130 RCW
Contact:	Washington Medical Commission
Phone:	(360) 236-2750
Email:	medical.policy@wmc.wa.gov
Effective Date:	TBD
Supersedes:	MD2021-01
Approved By:	,Chair

The Washington Medical Commission (Commission) considers disruptive behavior to be a threat to patient safety. If the Commission receives a complaint or report that a practitioner has engaged in disruptive behavior, the Commission may investigate a complaint and, if warranted, take disciplinary action against the practitioner to protect the public.

Disciplinary action may be based on the belief that the disruptive behavior constitutes unprofessional conduct under <u>RCW 18.130.180(4)</u> (negligence that creates an unreasonable risk of harm), RCW 18.130.180(1) (moral turpitude relating to the profession) or another subsection of RCW 18.130.180.

The Commission may also issue a statement of charges under <u>RCW 18.130.170(1)</u> if there is evidence that the practitioner is unable to practice with reasonable skill and safety due to a mental or physical condition. This statute does not require that the practitioner have a diagnosable mental condition under the DSM.¹

If the Commission is unsure whether the practitioner has a mental or physical condition that may impact his or her ability to practice with reasonable skill and safety, the Commission may choose to order the practitioner undergo a mental or physical examination under <u>RCW</u> <u>18.130.170(2)</u>. The results of such an examination may provide evidence to support a statement of charges under <u>RCW 18.130.170(1)</u>.

The Commission is aware that if a practitioner denies engaging in disruptive behavior, an evaluation under $\underline{\text{RCW 18.130.170(2)}}$ is particularly challenging, if not impossible, for the

evaluator. In most cases, the preferred option is to issue a statement of charges under RCW 18.130.180 on the theory that the disruptive behavior constituted unprofessional conduct.

The Commission may refer the practitioner to the Washington Physician Health Program at any point in the process, beginning with making a recommendation during the initial investigation up to imposing a requirement in a disciplinary order.

Background

Most physicians and physician assistants enter the field of medicine for altruistic reasons and have a strong interest in caring for and helping other human beings. The majority of practitioners carry out their duties with high levels of professionalism and recognize that quality care requires teamwork, communication and a collaborative work environment. However, several studies show that behavior that impedes teamwork and communication and interferes with patient care—often referred to as disruptive behavior—may be prevalent in somewhere between 1 and 5% of practitioners.²

Disruptive behavior has been defined as "an aberrant style of personal interaction with physicians, hospital personnel, patients, family members, or others that interferes with patient care or could reasonably be expected to interfere with the process of delivering good care."³ Disruptive behavior comprises a wide variety of behaviors including overt actions such as verbal outbursts and physical threats, as well as passive activities such as failing to respond to repeated calls, not performing assigned tasks or quietly exhibiting uncooperative attitudes during routine activities.⁴ A list of examples of disruptive behavior can be found in appendix A.

Disruptive behavior interferes with the ability to work with other members of the health care team, disrupts the effectiveness of team communication, and has been shown to be a root cause in a high percentage of anesthesia-related sentinel events.⁵ The consequences of disruptive behavior include job dissatisfaction for physicians, nurses and other staff; voluntary turnover; increased stress; patient complaints; malpractice suits; medical errors; and compromised patient safety.

Disruptive behavior is not a diagnosis and should not be used to label a practitioner who has an occasional reaction out of character for that individual. The disruptive label should refer to a pattern of inappropriate behavior that is deep-seated, habitual, and pervasive.⁶

Disruptive behavior may be a sign of an illness or a condition that may affect clinical performance. Studies have shown that some physicians demonstrating disruptive behavior have subsequently been diagnosed with a range of psychiatric disorders and medical disorders

² Williams, B. W., and Williams M.V. The Disruptive Physician: A Conceptual Organization, *Journal of Medical Licensure and Discipline*. 2008; 94(3):13.

³ Lang, D., and others. *The Disabled Physician: Problem-Solving Strategies for the Medical Staff.* Chicago, Ill.: American Hospital Publishing, Inc., 1989. *See also* Neff, K., Understanding and Managing Physicians with Disruptive Behaviors, pp. 45 – 72 (2000).

⁴ The Joint Commission. Behaviors that undermine a culture of safety. *Joint Commission Sentinel Event Alert*. 2008; issue 40 (updated September 2016).

⁵ Id.

⁶ Reynolds, N., "Disruptive Physician Behavior: Use and Misuse of the Label, Journal of Medical Regulation, Vol. 98, No. 1, p. 9-10 (2012).

with significant psychiatric symptoms, most of which were treatable.⁷ Referral for evaluation of impairment can identify health conditions, distress and other psychosocial factors that may be contributing to the disruptive behavior. If this is the case, an effective treatment and monitoring plan may resolve the disruptive behavior.⁸ On the other hand, ruling-out impairment can provide reassurance in proceeding with progressive remediation. The Washington Physicians Health Program accepts referrals for disruptive behavior and will tailor its approach and recommendations based on the presence or absence of an impairing health condition.

When the practitioner exhibiting disruptive behavior is part of an organization where the behavior can be identified, the organization should take steps to address it early before the quality of care suffers, or complaints are lodged. The best outcome is frequently accomplished through a combination of organizational accountability, individual treatment, education, a systems approach and a strong aftercare program.⁹ The Joint Commission has developed a leadership standard that requires leaders to develop a code of conduct that defines behaviors that undermine a culture of safety, and to create and implement a process for managing such behaviors.¹⁰ Psychiatrist Norman Reynolds, MD, has developed a set of strategies to manage this behavior and provides advice on the construction of medical staff policies and a program of remediation.¹¹

While organizations may be the best place to address disruptive behavior, state medical boards may also play a role when the behavior is brought to their attention. The Federation of State Medical Boards recommends that legislatures amend the practice acts of state medical boards to include disruptive behavior as a grounds for disciplinary action, explaining that it is imperative that state medical boards have the power to investigate complaints of disruptive behavior and to take action to protect the public.¹²

The Commission has taken disciplinary action against several practitioners who exhibited disruptive behavior. In some cases, the basis for the action is that the conduct constitutes unprofessional conduct under RCW 18.130.180(4) because it is negligence that creates an unreasonable risk that a patient may be harmed. The Commission has also taken action under RCW 18.130.180(1) when it deemed that the conduct amounted to acts of moral turpitude relating to the profession.

In one case, the Commission took action against a physician engaging in disruptive behavior under RCW 18.130.170(1) on the theory that the practitioner had a mental condition that prevented him from practicing with reasonable skill and safety. The Washington State Court of

⁷ Williams and Williams, p. 14.

⁸ Reynolds, p. 19.

⁹ Williams and Williams, p. 17.

¹⁰ The Joint Commission, Leadership Standard Clarified to Address Behaviors that Undermine a Safety Culture. *See also* Reynolds at pp. 14-17 for an excellent discussion of strategies for managing disruptive behavior.

¹¹ Reynolds, pp 14-19.

¹² Federation of State Medical Boards. *Report of Special Committee on Professional Conduct and Ethics*. 2000. <u>https://www.fsmb.org/siteassets/advocacy/policies/report-of-the-special-committee-on-professional-conduct-and-ethics.pdf</u>

Appeals, in a published opinion issued in 2017, upheld the Commission order imposing discipline for disruptive behavior, favorably citing the Commission's prior policy on disruptive behavior, and rejecting the respondent's argument that a diagnosable mental condition was required to proceed under RCW 18.130.170(1).¹³



Interactive and Transparent Development of Evidence-based Policies

Introduction

The Washington Medical Commission (Commission) develops policies¹ to encourage the medical profession to improve the delivery of medical care and enhance patient safety.¹¹ The Commission wishes to better engage the public and the profession by creating an interactive, consistent, and transparent procedure to obtain input to develop evidence-based policies.¹¹¹ This document describes the procedure the Commission uses to develop evidence-based policies.

Procedure

Step One: Determine the need for a policy

Any Commission member, member of the medical profession, organization, or member of the public may ask the Commission's Policy Committee to consider developing a policy in a particular area of medical practice. In general, the Policy Committee will consider developing a policy for an issue that has broad application to practitioners or the public, to respond to an emerging problem, and to fulfill its regulatory charge to protect the public. The Policy Committee may decide that a policy is not necessary, or that the subject is more appropriately addressed by adopting a rule, which has the force of law.

Step Two: Policy Committee

If the decision of the Policy Committee is to develop a policy, the Policy Committee Chair may assign members to a work group to analyze the research and evidence, and to draft the policy. The workgroup will include one or more Commission members and may include subject matter experts on staff. The workgroup may also include subject matter experts outside the Commission.

The Policy Committee also reviews existing policies to ensure that they remain useful and informative, and reflect the current state of medical practice and the current view of the Commission.

Step Three: Research and Obtain Evidence

If the Policy Committee decides to develop a policy or guideline, the next step is to research the topic and obtain evidence that will inform the Commission's decision-making. The research may include:

- Reviewing complaints or other patient experiences related to the topic of the proposed policy.
- Conducting a literature review of the latest journal articles and studies.
- Reviewing the positions of appropriate stakeholders.
- Reviewing the positions of other state medical boards and the Federation of State Medical Boards.

• Identifying and researching relevant legal issues, consulting with the Attorney General's Office as needed.

Step Four: Analysis and Drafting

The work group will analyze the research and evidence, relevant law, and draft the policy. For existing policies, the workgroup will review feedback submitted to the Commission via the Commission web site or otherwise. The workgroup will create a first draft of the proposed policy.

Step Five: Policy Committee Review

In a public meeting, the Policy Committee will review the draft policy and proposes revisions. The Policy Committee presents the draft to the full Commission. The Commission provides feedback and then may approve posting the draft policy for public dissemination, including posting the draft on the Commission web site.

Step Six: Solicit Feedback from Public and Profession

Upon approval by the Commission, staff posts the draft policy to the Commission web site and invites members of the public and the profession to post comments on the proposed draft policy. The Commission will notify the public and the profession of the proposed policy by:

- Sending out notice of the draft policy on social media;
- Sending out notice of the draft policy to the Commission listserv;
- Sending the draft policy to stakeholders and interested parties

The Commission accepts comments on the proposed policy for 28 days. The Commission will have discretion to remove comments that do not contribute to a constructive discussion of the relevant issues.

Step Seven: Policy Committee Review of Feedback

In a public meeting, the Policy Committee reviews the feedback and comments from the public and the profession. The Policy Committee considers the extent to which the comments represent the expectations of the profession and are consistent with the Commission's mission to promote patient safety and our vision of advancing the optimal level of medical care for the people of Washington. The draft policy is revised accordingly.

Step Eight: Secretary Review of Policy

The Commission staff sends the proposed policy to the Secretary of the Department of Health for review and comment. Following the Secretary's review, the Policy Committee reviews and discusses the comments from the Secretary in a public meeting. The Policy Committee brings its recommendations to the full Commission. The full Commission reviews the proposed policy in a public meeting and may revise the policy. If the Commission revises the policy, the Commission sends the proposed policy back to the Secretary for review. Once the Commission approves a policy, the policy is filed with the Washington State Code Reviser and it is published in the Washington State Register.

Step Nine: Final Review and Adoption

Once the Policy Committee is satisfied with the proposed policy, it refers the draft to the full Commission with a recommendation to adopt the policy. The full Commission, in a public meeting, discusses the policy

and decides whether to adopt the final version. When the policy is final, the Commission publicizes it through its web site, social media channels, listserv, and newsletter.

Emergency Exception

In case of an emergency in which the development of a policy is required in a short time period, one or more of these steps may be waived.

Date of Adoption:	May 19, 2017
Date of Revision:	August 20,2021

ⁱ <u>RCW 34.05.010(15)</u> defines "policy statement" as "a written description of the current approach of an agency, entitled a policy statement by the agency head or its designee, to implementation of a statute or other provision of law, of a court decision, or of an agency order, including where appropriate the agency's current practice, procedure, or method of action based upon that approach." A policy is advisory only. <u>RCW 34.05.230</u>. Examples of Commission policy statements are "Complainant Opportunity to be Heard Through and Impact Statement," and "Practitioners Exhibiting Disruptive Behavior."

ⁱⁱ This procedure does not apply to the development of procedures, which merely establish the proper steps the Commission and staff take to conduct Commission business. Examples include "Consent Agenda Procedure" and "Processing Completed Investigations More Efficiently."

ⁱⁱⁱ This process is largely based on the "consultation process" developed by the College of Physicians and Surgeons of Ontario. <u>http://www.cpso.on.ca/Footer-Pages/The-Consultation-Process-and-Posting-Guidelines</u>

Guidance Document

Medical Professionalism

Introduction

In 2002, the American Board of Internal Medicine Foundation, the American College of Physicians-American Society of Internal Medicine Foundation, and the European Federation of Internal Medicine developed a Charter on Medical Professionalism, and published it simultaneously in the Annals of Internal Medicine and The Lancet.¹ The Charter on Medical Professionalism is designed to reaffirm the medical profession's commitment to patients and to the health care system by setting forth fundamental and universal principles of medical professionalism.

WASHINGTON

Medical

Commission

The Washington Medical Commission (WMC) largely adopts the Charter on Medical Professionalism (Charter), as guidance for Washington physicians and physician assistants in fulfilling their professional responsibilities to their patients and to the public.²

Charter on Medical Professionalism

Preamble

Professionalism is the basis of medicine's contract with society. Professionalism demands placing the best interests of patients above those of the practitioner³, setting and maintaining standards of competence and integrity, and providing scientifically accurate advice to society on matters of health. The principles and responsibilities of medical professionalism must be clearly understood by both the profession and the public. Public trust in practitioners depends on the integrity of both individual practitioners and the profession as a whole.

At present, the medical profession is confronted by an explosion of technology, evolving practice conditions, and heightened regulatory obligations. As a result, practitioners find it increasingly difficult to meet their responsibilities to patients and society. In these circumstances, reaffirming the fundamental and universal principles and values of medical professionalism, which remain ideals to be pursued by all practitioners, becomes all the more important.

The medical profession everywhere is embedded in diverse cultures and national traditions, but its members share the role of healer, which has roots extending back to Hippocrates. Indeed, the medical profession must contend with complicated political, legal, and market forces. Moreover, there are wide variations in medical delivery and practice through which any general principles may be expressed in both complex and subtle

¹ "Medical Professionalism in the New Millennium: A Practitioner Charter." Annals of Internal Medicine, 2002;136(3):243-246, *available at* <u>http://annals.org/aim/article/474090/medical-professionalism-new-millennium-practitioner-charter</u>

² This Guidance Document is not identical to the previous Charter on Medical Professionalism. The WMC has edited that previous document in order to conform to state laws and rules. For example, in many places in this document, the WMC has replaced the word "shall" with the word "should," so as not to create mandates outside of the rule-making process.

³ In this guidance document, the WMC uses the term "practitioner" to refer to both allopathic physicians and physician assistants. GUI202X-XX medical.policy@wmc.wa.gov | WMC.wa.gov Page 1 of 5

ways. Despite these differences, common themes emerge and form the basis of this Charter in the form of three fundamental principles, and as a set of definitive professional responsibilities.

Fundamental Principles

- 1. Principle of primacy of patient welfare. This principle is based on a dedication to serving the interest of the patient. Altruism contributes to the trust that is central to the practitioner-patient relationship. Market forces, societal pressures, and administrative exigencies must not compromise this principle.
- Principle of patient autonomy. Practitioners should respect patient autonomy. Practitioners should be honest with their patients and empower them to make informed decisions about their treatment. Patients' decisions about their care must be paramount, as long as those decisions are in keeping with ethical principles and do not lead to demands for inappropriate care.
- 3. Principle of social justice. The medical profession should promote justice in the health care system, including the fair distribution of health care resources. Practitioners should work actively to eliminate discrimination in health care, whether based on race, gender, gender identity, sexual orientation, socioeconomic status, ethnicity, religion, or any other social category.

A Set of Professional Responsibilities

Commitment to professional competence. Practitioners should be committed to lifelong learning and to maintaining the medical knowledge and clinical and team skills necessary to deliver quality care. More broadly, the profession as a whole must strive to see that all of its members are competent⁴ and must ensure that appropriate mechanisms are available for the profession to accomplish this goal.

Commitment to honesty with patients. Practitioners should ensure that patients are adequately and honestly informed before the patient has consented to treatment, and also after treatment has occurred. This expectation does not mean that patients should be involved in every minute decision about medical care; rather, they must be empowered to decide on their course of therapy. Practitioners should acknowledge that in health care, medical errors that injure patients do sometimes occur. Whenever patients are injured as a consequence of medical care, patients should be informed promptly because failure to do so seriously compromises patient and societal trust. Reporting and analyzing medical mistakes provide opportunities to develop and apply appropriate risk management strategies that should improve patient care, not only for patients who have been injured but also to prevent future harm moving forward.

Commitment to patient confidentiality. Earning the trust and confidence of patients requires that appropriate confidentiality safeguards be applied to prevent disclosure of patient information unless disclosure is legally necessary. This commitment extends to discussions with persons acting on a patient's behalf when obtaining a patient's own consent is not feasible. Fulfilling the commitment to confidentiality is more pressing now than

⁴ Professional competence refers to "the habitual and judicious use of communication, knowledge, technical skills, clinical reasoning, emotions, values, and reflection in daily practice for the benefit of the individual and community being served." Epstein RM, Hundert EM. Defining and assessing professional competence. *JAMA* 2002; 287(2):226-235), *available at https://jamanetwork.com/journals/jama/article-*

abstract/194554?casa_token=nY5Pp29vutgAAAAA:fUtkGd2lVdqoe1p1T61lgKV1MYyhQNxUHoO4aEOxeZL21IchaFYoxgdHGCnwjXoYNQJkhYTK9k6

ever given the increasing availability of genetic information and the widespread use of electronic information systems for compiling patient data. However, practitioners recognize that their commitment to patient confidentiality must occasionally yield to overriding legal requirements that protect public health and safety (for example, when patients endanger themselves or others).

Commitment to maintaining appropriate relations with patients. Given the inherent vulnerability and dependency of patients, certain relationships between practitioners and patients must be avoided. Practitioners should avoid exploiting patients for personal financial gain, or other private purpose. For example, state law prohibits practitioners from engaging in sexual or romantic relationships with current patients. This includes behaviors such as soliciting a date or kissing a patient in a romantic or sexual manner.⁵ State law also prohibits romantic or sexual relationships with former patients if the practitioner uses or exploits the trust, knowledge, influence or emotions derived from the professional relationship, or uses or exploits privileged information to meet the practitioner's personal or sexual needs.⁶ Practitioners should also abide by any ethical restrictions regarding romantic or sexual relationships with former patients that are applicable to their specialties.⁷

Commitment to improving quality of care. Practitioners should be dedicated to continuous improvement in the quality of health care. This commitment entails not only maintaining clinical competence but also working collaboratively with other professionals to reduce medical error, increase patient safety, minimize overuse of health care resources, and optimize the outcomes of care. Practitioners should actively participate in the development and application of better quality of care measures to assess routinely the performance of all individuals, institutions, and systems responsible for health care delivery. Practitioners, both individually and through their professional associations, should take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.

Commitment to improving access to care. Medical professionalism demands that the objective of all health care systems is the availability of a reasonable and adequate standard of care that is accessible to all patients. Practitioners should individually and collectively strive to reduce barriers to equitable health care. Within each system, the practitioner should help eliminate barriers to access which are often based on education, laws, finances, geography, and social discrimination. A commitment to equity entails the promotion of public health and preventive medicine without concern for the self-interest of the practitioner or the profession.

Commitment to a just distribution of finite resources. While treating individual patients, practitioners should provide health care that is based on the standard of care which considers cost-effective management and limited resources. When medically necessary resources are scarce, such as during a pandemic, practitioners are encouraged to follow guidance from the Washington State Department of Health and local health departments to prioritize the needs of the public when there are not enough resources for all patients. Otherwise, practitioners should be committed to working with other practitioners, hospitals, and payers to develop and implement guidelines focused on the delivery of cost-effective care. While a practitioner, at times, may be tempted to "overtest" and "overtreat" to decrease their risk of medical malpractice claims, the

⁵ WAC 246-919-630, 246-918-410. See also RCW 18.130.180(24).

⁶ WAC 246-919-630(3). For additional guidance, see the WMC Guidance Document on "Sexual Misconduct and Abuse," GUI2017-03. ⁷ For example, the American Psychiatric Association takes the position that sexual activity with a current or former patient is unethical. American Psychiatric Association: The principles of medical ethics (with annotations especially applicable to psychiatry), section 2. Arlington, VA: American Psychiatric Association, 2013. <u>https://www.psychiatry.org/psychiatrists/practice/ethics</u>. Accessed May 7, 2019.

practitioner's professional responsibility involving appropriate resource allocation requires scrupulous avoidance of superfluous tests and procedures. Providing unnecessary services not only exposes patients to avoidable harm and expense but also diminishes the resources available for others.

Commitment to scientific knowledge. Much of medicine's contract with society is based on integrity and the appropriate use of scientific knowledge, technology, and evidence-based medicine. Practitioners should uphold scientific standards, to promote research, and to create new knowledge and ensure its appropriate use. The profession is responsible for the integrity of this knowledge, which is based on scientific evidence, practitioner experience, and effective communication.

Commitment to maintaining trust by managing conflicts of interest. Medical professionals and their organizations have many opportunities to compromise their professional responsibilities by pursuing private gain or personal advantage. Such compromises are especially threatening in the pursuit of personal or organizational interactions with for-profit industries, including pharmaceuticals, laboratory services, medical equipment, and insurance companies. Practitioners should recognize, disclose to the public, and deal with conflicts of interest that arise in the course of their professional duties and activities. Relationships between industry and opinion leaders should be disclosed, especially when the latter determines the criteria for conducting and reporting clinical trials, writing editorials or therapeutic guidelines, or serving as editors of scientific journals.

Commitment to professional responsibilities. As members of a profession, practitioners are expected to work collaboratively to maximize patient care, be respectful of one another, and participate in the processes of self-regulation, including remediation and discipline of members who have failed to meet professional standards. The profession should define and organize the educational and standard-setting process for current and future members. Practitioners have both individual and collective obligations to participate in these processes. These obligations include engaging in internal assessment, offering constructive feedback to peers, and accepting external scrutiny of all aspects of their professional performance.

Summary

The practice of medicine in the modern era faces unprecedented challenges in virtually all cultures within our society. These challenges center on disparities in our health care system, an inability to meet the legitimate needs of patients due to insufficient resources, the increasing dependence on market forces to transform health care systems, and the temptation for practitioners to forsake their traditional commitment to the primacy of patient interests for their own personal gain. To maintain the fidelity of medicine's social contract, the WMC believes that practitioners must reaffirm their active dedication to the principles of professionalism, which entails not only their personal commitment to the welfare of their patients but also collective efforts to improve our health care system for the welfare of society. The WMC adopts this Charter on Medical Professionalism to encourage such dedication among practitioners and the profession in general, and to assure the public that the WMC upholds ideals of professionalism in the State of Washington.

Number:	GUI2018-01	
Date of Adoption:	January 19, 2018	
Revised/Reaffirmed:	May 27, 2022	
GUI202X-XX	<pre>medical.policy@wmc.wa.gov WMC.wa.gov</pre>	Page 4 of 5

DRAFT

Joint Guidance for Retail Intravenous Therapy Clinics

WASHINGTON MEDICAL COMMISSION WASHINGTON BOARD OF OSTEOPATHIC MEDICINE AND SURGERY WASHINGTON BOARD OF NURSING WASHINGTON PHARMACY QUALITY ASSURANCE COMMISSION

Purpose

The Washington State Department of Health has received reports that IV therapy clinics in our state are operating in contravention of Washington law and established standards of care and creating a risk of harm to the residents of the state of Washington. The Washington Medical Commission, the Board of Osteopathic Medicine & Surgery, the Washington Board of Nursing, and the Washington Pharmacy Quality Assurance Commission, issue this Joint Guidance to advise practitioners on the requirements for the safe and legal operation of intravenous (IV) therapy clinics in the state of Washington.

This guidance is based upon the existing laws and regulations of Washington and sets forth the relevant scopes of practice and standards of care implicated by retail IV therapy businesses.¹ We offer no opinion or evaluation concerning the efficacy of IV therapy offered by retail IV therapy businesses. As with all matters concerning the regulation of medical, nursing and pharmacy practice, we encourage and expect every licensee to practice within the applicable standard of care, the legal scope of practice, and with reasonable skill and safety for patients.

For the purpose of this document, the term "practitioner" refers to allopathic physicians, osteopathic physicians, physician assistants, and nurse practitioners. These licensees have the legal authority to prescribe IV hydration therapy.

Introduction

Retail IV therapy is an "on demand" consumer driven business model where a bricks and mortar or mobile IV therapy clinic offers consumers a menu of pre-selected mixtures (cocktails) of additives to a basic IV saline drip. The IV therapy cocktails may include amino acids, vitamins, minerals, and some prescription drugs like Pepcid, Toradol, and Zofran. They are sometimes marketed with catchy names and are offered to patients for the treatment of conditions such as dehydration, migraines, hangovers, nausea, athletic recovery, appetite regulation, anti-aging, and inflammation support. Some basic health screening generally occurs prior to the selection and administration of the IV therapy cocktail. Generally, "wellness" IV therapy is self-paid by

¹ We acknowledge and appreciate the work done by other boards who have issued statements on this topic, in particular the West Virginia Boards of Medicine, Osteopathic Medicine, Pharmacy, and Registered Nurses; the Alabama Board of Medical Examiners; the South Carolina State Boards of Medical Examiners, Pharmacy, and Nursing; and the Mississippi State Board of Medical Licensure.

the person seeking treatment.

The Department has received reports that while a practitioner may be associated with the business, in many cases the practitioner is not on the premises; rather, in many instances, there is only a registered nurse is in the clinic. To obtain their IV supplies and additives, retail IV therapy business are using a prescribing practitioner's National Practitioner Identification number to acquire the IV supplies and additives. A practitioner will then issue "standing orders" directing the administration of IVs. The actual patient encounter, evaluation, diagnosis, formulation of the treatment plan, and administration of the IV may occur without input from the prescribing practitioner.

In many instances, the nurse may be the only licensed health care professional interacting with the patient or present at the facility. This business model is unacceptable and unlawful and have led to increasing concern about whether qualified individuals are administering these IVs based upon their statutorily defined scopes of practice and are complying with all the laws governing the practice medicine, nursing, and pharmacy.

While some IV therapy clinics are owned by practitioners, there is a national trend of business ownership by individuals who are not clinicians, or whose scope of practice does not include the authorization to establish a practitioner-patient relationship, evaluate a patient for IV therapy, and order the IV cocktail for the patient.

Legal Requirements and Best Practices

All practitioners should be aware of the legal requirements and best practices when offering IV therapy to patients in Washington, as follows:

- 1. The services provided in an IV therapy clinic—the diagnosis of the patient's condition and the recommendation of IV therapy--constitute the practice of medicine.²
- 2. IV therapy requires the insertion of a needle into a patient's vein for the intravenous administration of fluid into a patient's bloodstream, monitoring the patient during and at the conclusion of treatment, and removal of the IV catheter thereafter. This is a medical procedure that requires supervision by appropriately licensed health professionals.
- 3. A person who receives IV therapy is a patient, and an appropriate health care record for the patient must be created and maintained. The record should be available to the patient and other treating practitioners and should be maintained in a manner that fully complies with the medical record retention and confidentiality requirements of Washington law³ and the HIPAA Privacy and Security Rules.⁴

 ³ Chapter 70.02 RCW. See also <u>Washington Medical Commission Guidance Document: "Medical Records:</u> <u>Documentation, Access, Retention, Storage, Disposal, and Closing a Practice."</u> GUI2024-02. Adopted April 26, 2024.
⁴ See HIPAA Privacy Rule; HIPAA <u>Security Rule</u>.

² Under RCW 18.71.011, a person is practicing medicine when he or she "offers or undertakes to diagnose, cure, advise, or prescribe for any human disease...or other condition"...or "administers or prescribes drugs or medicinal preparations..." Likewise, under RCW 18.57.001(4) defines "osteopathic medicine and surgery" as "the use of any and all methods in the treatment of disease...and all other physical and mental conditions."

- 4. To provide IV therapy, a practitioner must first establish a practitioner-patient relationship with the patient. A practitioner-patient relationship is formed when the practitioner agrees to advise, diagnose, or treat a patient and the patient agrees that the practitioner will advise, diagnose or treat the patient.⁵ A practitioner-patient relationship may be established via telehealth, but not established through email, instant messaging, text messaging, or fax. Practitioners should be aware that the standard of care for telehealth care is the same as for in-person care.⁶
- 5. Practitioners may assess patients for IV therapy.⁷ The practitioner assessment requires the practitioner to personally evaluate the patient, take an appropriate history, diagnose the patient, and make treatment recommendations.
- 6. A practitioner should obtain and document informed consent in the medical record prior to the delivery of care.⁸
- 7. IV saline and any after-market additives are drugs that require a prescription or order to administer. IV therapy cannot be administered without a valid prescription or order.
- 8. Practitioners should only order IV therapy if they, as the assessing practitioner, determine it would be beneficial to the patient. The prescription or order must be part of a medically prescribed plan of care that includes a personal examination and a bona fide practitioner-patient relationship.
- 9. Practitioners should not issue "standing orders" for a retail IV therapy business, or its employees, to provide IV therapy to patients. A standing order does not create an independent practitioner-patient relationship between individual persons and the practitioner or the IV therapy business. IV therapy should not be administered based upon a standing order.⁹
- 10. The administering of IV therapy requires a professional license. A licensed person other than the physician (MD or DO), physician assistant, or nurse practitioner may administer IV therapy only if the administration of IVs is within that practitioner's scope of practice.
- 11. Registered nurses and licensed practical nurses may participate as part of the care

⁵ See <u>Washington Medical Commission Policy Statement: Terminating the Practitioner-Patient Relationship</u>, POL2022-03, adopted March 4, 2022.

⁶ The newly enacted Uniform Telehealth Act provides, in part: "A health care practitioner may provide telehealth services to a patient located in this state if the services are consistent with the health care practitioner's scope of practice in this state, applicable professional practice standards in this state, and requirements and limitations of federal law and law of this state....A practitioner-patient relationship may be established through telehealth. A practitioner-patient relationship may not be established through email, instant messaging, text messaging, or fax. <u>RCW 18.134.030</u>.

⁷ Physician assistants may assess patients for IV therapy if it is within their education, training, and experience, and is consistent with their collaboration agreement. <u>RCW 18.71.A.030</u>, <u>WAC 246-918</u>. Nurse practitioners may assess patients for IV therapy if they are practicing within their education, training, and experience. <u>RCW 18.79.050</u>, <u>WAC 246-840-300</u>.

⁸ <u>Washington Medical Commission Guidance Document: Informed Consent and Shared Decision-Making</u>, GUI2022-01, adopted May 27, 2022.

⁹ See <u>Washington Board of Nursing Advisory Opinion NCAO 28.00: Standing Orders</u>, adopted November 12, 2021.

team at an IV hydration clinic.¹⁰

- 12. Registered nurses and licensed practical nurses may insert and remove IV catheters and monitor patients before, during and after IV therapy is administered. The on-site presence of a physician, physician assistant, or nurse practitioner is not required for a nurse to administer the prescribed or ordered IV hydration; however, the nurse must have the knowledge, skill, and competency necessary to carry out the administration procedures and monitor the patient in a safe manner. The nurse should perform a nursing evaluation and monitor the patient for such things as side effects, toxic effects, allergic reactions, unusual and unexpected effects, changes in a patient's condition that contraindicate continued administration of the pharmaceutical or treatment regimen, and effects that may rapidly endanger a client's life or well-being. A nurse should be prepared to make judgments and decisions concerning actions to take in the event such effects occur and should document all nursing acts performed by the nurse in carrying out the IV administration and noted during the monitoring of the patient during administration.
- 13. Registered nurses and licensed practical nurses may not:
 - a. Prescribe or order IV therapy.
 - b. Independently recommend or approve the patient's "selection" of a specific IV hydration cocktail.
 - c. Administer IV therapy without a valid prescription order for a prescribing practitioner who has established a practitioner-patient relationship with the patient and determined that a specific IV therapy would be beneficial to the patient.¹¹
- 14. The term "compounding" means "the act of combining two or more ingredients in the preparation of a prescription."¹² The FDA has cautioned that patients can be significantly harmed when drugs are compounded in a way that does not assure sterility and quality.¹³
- 15. IV therapy cocktails are compounded drugs. Adding vitamins, minerals, or prescription drugs to a bag of saline solution is compounding.
- 16. Drug compounding must follow specific safety and sterility guidelines, and may only be undertaken by licensed pharmacists and, in certain circumstances, legally qualified practitioners of medicine.¹⁴
- 17. Practitioners who order IV therapy and who do not receive compounded end-use cocktails from a licensed pharmacy may only compound IV therapy cocktails if they have the education, training, and experience to ensure the safety and sterility of the final

¹⁰ See Washington Board of Nursing Advisory Opinion, *Infusion Therapy Management*, NCAO 24.00, adopted September 11, 2020.

¹¹ Id.

¹² RCW 18.64.011(6).

¹³ FDA reminds compounders to use ingredients suitable for sterile compounding.

¹⁴ RCW 18.64.270; WAC 246-945-100. See also <u>Compounding and the FDA: Questions and Answers</u>; Federation of State Medical Boards <u>White Paper on Compounding of Medications by Physicians</u>.

product.

- 18. Practitioners who elect to engage in the compounding of IV therapy cocktails should personally compound the cocktails they order for their patients. Practitioners should not delegate the compounding of IV therapy cocktails to other members of the treatment team or other employees of the business.
- 19. Properly trained nurses may compound medication only for a specific patient and under the direction of an authorized health care practitioner with prescriptive authority.¹⁵
- 20. Treatment provided to a patient pursuant to a practitioner's order for IV therapy falls within the supervision and professional responsibility of the ordering practitioner. A physician who serves as a medical director for an IV hydration clinic is responsible for supervising all personnel in the clinic and is ultimately responsible for the safety of patients.¹⁶
- 21. Retail IV hydration clinics that are not owned by practitioners with prescriptive authority shall not exercise influence or control over the practitioner's independent exercise of medical judgment in the treatment of any patient.

If a licensed healthcare provider has questions concerning any of the guidelines set forth herein, the licensee should contact their licensing board for additional information. If a non-licensed retail IV therapy business owner has questions concerning these guidelines, the owner should contact any of the four Boards who are responsible for this Joint Advisory Opinion.

 ¹⁵ See Washington Board of Nursing Advisory Opinion, *Registered Nurse and Licensed Practical Nurse: Compounding and Reconstituting Medications,* NCAO 11.01, adopted November 12, 2021.
¹⁶ Washington Medical Commission Guidance Document: Medical Directors: Roles, Duties, and Responsibilities,
GUI2020-02, adopted August 21, 2020.

Kay Funk, MD

March 4, 2025

Washington Medical Commission Policy Committee PO Box 47866 Olympia, Washington 98504-7866 Medical.Commission@wmc.wa.gov

Honored Commissioners:

I am writing again to request clarification of the new policy regarding Washington Physician Health Program (WPHP) authority over medical students. I am again asserting that WPHP is not Americans with Disabilities Act (ADA) compliant, and does not have an adequate evidence base, especially for students.

I was surprised by Dr Bundy's reaction to my remarks. He correctly stated that I was censured by the Yakima City Council. The context was this: the City Manager, without consultation, fired the Chief of Police without cause. The patrolmen's union voted ~90% *No Confidence* in the City Manager. I spoke up for the concerns of the police regarding the new hiring process. That is not evidence that I am interfering with medical professionals seeking help from WPHP. Also, I was removed from the Yakima Health District Board when anti-vaxx elected officials gained a majority. Language comparing me to RFK is misleading. It's all in the newspapers if you wish to verify.

I am not harmed when Dr Bundy is angered by criticism of his program. But he and his program have been given authority over vulnerable medical professionals and, as demonstrated here, seem unconcerned about the collateral damage they cause.

As always, the route to resolution is through better quality outcome studies, according to standard evidence-based methodology.

To my reading, there are no RCW statutes showing legislative intent to place medical students under WPHP authority. In addition, medical schools receive federal funds, which require compliance with Title 2 of the ADA and reasonable accommodation of disability. Further, ADA duty of protection from discrimination cannot be delegated to a third party without adequate supervision and assurance of compliance. When medical schools allow this, they are violating ADA.

"If recipients of federal funds could evade liability by simply placing the burden on third-parties with which the recipient enters into a contract, then the statutes would lose much of their force." - Honorable Edmond E. Chang United States District Judge¹.

With Sincere Regards, Kay Funk, MD

¹ Access Living of Metro. Chi. v. City of Chicago. United States District Court, Northern District of Illinois. Sep 30, 2024. 1:18-CV-03399 (N.D. Ill. Sep. 30, 2024)

From:	Chris Bundy
То:	WMC Medical Policy
Cc:	Chris Bundy
Subject:	In Reply to Comments regarding WPHP
Date:	Thursday, March 20, 2025 9:11:20 PM
Attachments:	image001.png
	image002.png

External Email

Dear Members and Staff of the Washington Medical Commission Policy Committee,

I am writing in response to comments submitted on March 4, 2025 and included in the March 27, 2025 Interested Parties meeting packet. My purpose is to go on record with accurate information. I do not believe we should turn a deaf ear to our critics. However, I believe we have an ethical duty to stand against mis- and disinformation that may confuse or discourage members of our profession from seeking help when needed, potentially placing patient safety at risk.

The assertion that WPHP is not compliant with the Americans with Disabilities Act (ADA) is unsupported by any credible legal theory. It is not possible to determine from the provided comments which titles or provisions of the ADA WPHP might be violating nor any specific actions WPHP has taken (or failed to take) that might instantiate a violation.

WPHP has undertaken extensive legal review of its ADA compliance and related practices, has a meaningful and public ADA grievance process, and reports all ADA grievances and outcomes to the Department of Health in its Annual Report. Far from being unconcerned about such matters, WPHP has demonstrated a long history of advocating for individuals with disabilities and against discrimination. It is central to our mission.

WPHP is an independent, non-profit organization. We do not require statutory authorization to assist health professional students. That said, RCW 18.130.175 (6a) clearly indicates legislative intent to extend immunity protections to programs like WPHP when they serve students of health professions:

"The immunity from civil liability provided by this section shall be liberally construed to accomplish the purposes of this section, and applies to both license holders **and students and trainees when students and trainees of the applicable professions are served by the program**."

Surely, the legislature would not have authorized such protections if it intended to exclude students from participation in WPHP.

For over a decade, WPHP has had a contract with the University of Washington to serve medical, dental, and PA students as well as residents and fellows. We have a similar contract with the Elson S. Floyd College of Medicine at Washington State University. It is a testament to WPHP that the University of Washington and Washington State University trust WPHP to aid their students and trainees. Again, it is impossible from the provided comments to discern whether or how this relationship might run afoul of ADA. I suspect it

reflects a fundament misunderstanding of the process by which WPHP provides support to the students of these institutions.

All professional associations of the licensee groups served by WPHP, including the Washington State Medical Association, have assured WPHP that it is their will that WPHP extend its services to health professional students. All recognize that earlier intervention in the career span can prevent devastating consequences later on.

There have been a number of studies published in peer-reviewed journals that have established the effectiveness and superior outcomes achieved by the physician health program model. I have written numerous articles in the Washington Medical Commission newsletter over the years citing this evidence base. A summary of the peer-reviewed evidence can be found at the Federation of State Physician Health Programs website (https://www.fsphp.org/research-about-phps-and-health-professionals). The peer-reviewed evidence includes a seminal article, co-authored by Dr. Karen Domino, specifically citing WPHP outcomes and risk factors for return to use among PHP participants (Domino, Hankes. JAMA 2005). What is lacking is evidence of any better model of care.

WPHP is a transparent and data-driven organization that continues to be involved in research to advance the field at local and national levels. To that end, WPHP has contracted with a research scientist from the University of Washington to further our research mission, underscoring our commitment to scholarly work. In addition, WPHP's Annual Report to WMC and the DOH provides robust quality, performance, and satisfaction data that clearly demonstrate the ongoing, "real time," effectiveness of our program.

Thank you for your time and consideration of these comments. Please do not hesitate to contact me with any questions or concerns.

Sincerely,

Christopher Bundy, MD, MPH (he/him) Executive Medical Director | Washington Physicians Health Program Chief Medical Officer | Federation of State Physician Health Programs Clinical Associate Professor | University of Washington School of Medicine and Elson S. Floyd College of Medicine at Washington State University

Administrative Director and Executive Assistant: Nadine Rosete <u>nrosete@wphp.org</u> 206.905.2527

Schedule a meeting

1200 6th Avenue Suite 850 | Seattle, WA | 98101 Main: 206.583.0127 Toll Free: 800.552.7236 | Fax: 206.583.0418 | <u>wphp.org</u> **Follow us!**





WASHINGTON PHYSICIANS HEALTH PROGRAM

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