

PROFESSIONAL EXPECTATIONS REGARDING MEDICAL MISINFORMATION AND DISINFORMATION

Report of the FSMB Ethics and Professionalism Committee Adopted by the FSMB House of Delegates, April 2022

INTRODUCTION

Truthful and accurate information is central to the provision of quality medical care. It is instrumental for obtaining informed consent from patients and supports the trust that patients hold in the medical profession. Honesty, truthfulness and transparency are virtues that society expects of all health professionals, and they are traits that are indispensable to physicians carrying out their professional responsibilities and interacting with patients and the public. False information is harmful and dangerous to patients, and to the public trust in the medical profession, especially when licensed physicians disseminate misinformation or disinformation about a disease or illness, including its prevention, management or treatment.

Medical misinformation and disinformation have existed for centuries. However, their impact has been amplified in recent years by technology, e.g., social media, that has facilitated a growing distrust in traditional authorities, including the medical profession. This amplification has not been accompanied by any increase in accountability for those who disseminate the misinformation and disinformation. Prior to the COVID-19 pandemic, misinformation and disinformation regarding the safety and efficacy of vaccines prompted parents to refuse or delay their children receiving scheduled vaccinations, resulting in the reemergence in many parts of the United States of vaccine-preventable diseases like measles. Such misinformed decision-making causes needless harm, including deaths, and erodes the population-level immunity that is necessary to eradicate such infectious diseases.²

Inaccurate information spread by physicians can have pernicious influences on individuals with widespread negative impact,³ especially through the ubiquity of smartphones and other internetconnected devices on wrists, desktops and laptops reaching across thousands of miles to other

¹ Vaccine Hesitancy Represents Threat to Global Health, KAISER FAMILY FOUNDATION, (Feb 01, 2019), https://www.kff.org/news-summary/vaccine-hesitancy-represents-threat-to-global-health. ² Scott C. Ratzan et al., The Salzburg Statement on Vaccination Acceptance, 24 J. OF HEALTH COMMC'N, (May

³ Carl H. Coleman, Physicians Who Disseminate Medical Misinformation: Testing the Constitutional Limits on Professional Disciplinary Action, FIRST AM. L. REV. (forthcoming 2022), at 2, ("Of particular concern is medical misinformation disseminated by licensed physicians, whose professional credibility gives their voices disproportionate weight.").

individuals in an instant. Physicians' status and titles lend credence to their claims. The end result of physician-spread misinformation is often public confusion,⁴ further eroding trust in physicians and undermining confidence in the integrity of the medical profession—causing even greater harm to public health. Dissemination of misinformation by physicians leads to harmful consequences in "non-pandemic" circumstances and in a pandemic can raise the stakes and magnify the harms even further, by sowing confusion and reluctance among patients to follow considered and prevailing scientific guidance.⁵

Shortly after the declaration of the COVID-19 pandemic by the World Health Organization on March 11, 2020, the FSMB's Board of Directors adopted a statement in support of the value of face masks to limit the aerosolized transmission of the SARS-CoV2 virus. "Wearing a face covering is a harm-reduction strategy to help limit the spread of COVID-19," the statement said on October 6, 2020, "especially since physical distancing is not possible in health care settings. When seeing patients during in-person clinical encounters, physicians and physician assistants have a professional responsibility to wear a facial covering for their own protection, as well as that of their patients and society as a whole." The statement was prompted by reports from a number of state medical boards receiving complaints regarding physicians and physician assistants failing to wear face coverings during patient care or casting doubt with patients and the public about their effectiveness.⁶

In May of 2021, FSMB Chair Kenneth B. Simons, MD, tasked the FSMB's Ethics and Professionalism Committee with studying the issue of physician misinformation and disinformation in order to provide comprehensive guidance to state medical boards and practicing physicians to better protect patients and promote public health. On July 28, 2021, following a recommendation of the Committee, the FSMB's Board of Directors unanimously approved another statement, this one reminding doctors of their professional responsibilities and the accountability to which they are held, and the potential consequences of activities that puts patients at risk:

"Physicians who generate and spread COVID-19 vaccine misinformation or disinformation are risking disciplinary action by state medical boards, including the suspension or revocation of their medical license. Due to their specialized knowledge and training, licensed physicians possess a high degree of public trust and therefore have a powerful platform in society, whether they recognize it or not. They also have an ethical and professional responsibility to practice medicine in the best interests of their patients and must share information that is factual, scientifically grounded and consensus-driven for the betterment of public health. Spreading inaccurate COVID-19 vaccine information contradicts that responsibility, threatens to further erode public trust in the medical profession and puts all patients at risk."

⁴ Saswato Ray, *What Vaccine Misinformation Really Tells Us.* HARV. POL. REV., (August 28, 2021), https://harvardpolitics.com/vaccines-social-media/

⁵ The U.S. Surgeon General's Advisory states unequivocally: "Health misinformation is a serious threat to public health" because it "has caused confusion and led people to decline COVID-19 vaccines, reject public health measures such as masking and physical distancing, and use unproven treatments." Vivek H. Murthy, *Confronting Health Misinformation*, OFFICE OF THE SURGEON GENERAL OF THE UNITED STATES, (2021), at 16.

⁶ Knowles H. (December 5, 2020) A doctor derided mask-wearing. His license has been suspended. *The Washington Post*, https://www.washingtonpost.com/nation/2020/12/05/doctor-steven-latulippe-license-suspended/

This report follows months of discussion and deliberation by the Committee and outside experts in law and ethics, and summarizes the Committee's views of misinformation and disinformation. This report offers several recommendations (listed at the end of this guidance for easy reference) for state and territorial medical and osteopathic boards (hereinafter referred to as "state medical boards") to consider as they seek to fulfill their primary and statutory mission to protect the public, especially in the setting of a global pandemic that – despite the introduction of more than half a dozen vaccines that have helped limit disease severity and death – remains a potent threat across the United States and around the world.

Section 1: Key Terms

Medical Misinformation

Health-related information or claims that are false, inaccurate or misleading, according to the best available scientific evidence at the time.⁷

Disinformation

Misinformation that is spread intentionally to serve a malicious purpose, such as financial gain or political advantage.⁸

Scientific Evidence

Information from peer-reviewed journals, methodologically-sound clinical trials, nationally or internationally recognized clinical practice guidelines, or other consensus-based documents that receive broad acceptance from the medical and/or scientific communities. Where evidence does not exist in these forms, there must still be a plausible basis in theory or prevailing and consensus-based, peer-acknowledged practice to justify any proposed treatment.

Section 2: Principles

Beneficence

In providing care, proposing treatments to patients or sharing medical advice, physicians must always act in such a way that provides benefit to the patient first, without allowing competing considerations, beliefs or interests to take precedence.

Non-maleficence

Physicians have a duty to refrain from acting in a way that harms patients or the public.

Justice

⁷ Office of the U.S. Surgeon General, "A Community Toolkit for Addressing Health Misinformation," 2021.

⁸ *Ibid*.

Physicians must remain objective and impartial in the delivery of information and in selecting or curating information that is deemed relevant to patient care and public health. If a treatment is recommended over alternatives, the recommendation must be based in scientific evidence, rather than opinion or motives that do not benefit the patient's health or that of the public. Providing treatment or treatment recommendations that could reasonably be considered below the standard of care puts patients at undue risk. This is fundamentally unjust.

Autonomy

Physicians have a professional responsibility to respect a patient's right to determine for themselves which treatments or other health decisions are in their best interests. Physicians are encouraged to guide patients towards responsible and beneficent decisions, helping to assess values and preferences, but must not allow their own biases or other non-medical considerations to influence patients' decisions regarding their health.

While respect for patient autonomy is an essential component of the physician-patient relationship, neither the patient's autonomy, nor the physician's professional autonomy, is absolute. Only reasonable requests on the part of the patient should be granted, and only scientifically justified treatment options should be recommended by the physician.

Professionalism

Physicians have a responsibility to approach medical practice in an altruistic manner, placing the needs of their patients and the health of the public above their own goals or motives. This entails a duty to be honest and truthful in all patient interactions, as well as those where the physician is acting or speaking in a professional capacity. This is essential for maintaining trust within the physician-patient relationship and for maintaining society's trust in the medical profession.

Section 3: Medical Professionalism and Misinformation

There are several ethical arguments that support the importance of conveying truthful and accurate information to patients and the public, many of which are referenced in documents such as the American Osteopathic Association's Osteopathic Oath and the American Medical Association's Code of Medical Ethics (revised, 2017). The Declaration of Geneva, adopted by the World Medical Association in 2017, concisely outlines a physician's professional duty and ethical responsibilities.⁹

In this modern Hippocratic Oath, physicians pledge to:

Dedicate [their] life to the service of humanity... practice [their] profession with conscience and dignity and in accordance with good medical practice... share [their] medical knowledge for the benefit of the patient and the advancement of healthcare...and not use[their] medical knowledge to violate human rights and civil liberties, even under threat.¹⁰

⁹ Parsa-Parsi RW. The Revised Declaration of Geneva: A Modern-Day Physician's Pledge. *JAMA*. 1971–1972 (2017);318(20).

¹⁰ *Id. supra*, note 38.

Trust and respect are foundational for the physician-patient relationship. These qualities support the physician's duty to act in the patient's best interests and provide decisions and recommendations that aim to benefit them and keep them free from harm. Medical practice is fundamentally about caring for patients, and care cannot be provided safely without respect for the inherent value of patients as human beings with dignity and rights. ¹¹ Physicians, therefore, have an ethical duty to honestly inform their patients about potential illnesses and available treatment options. ¹²

Medical professionalism dictates that physicians base the care they provide on the best scientific evidence available at the time, while being truthful and transparent about the sources of their recommendations to foster trust in delivering ethical medical care. While there are gray areas in many aspects of the practice of medicine, which is inherently dynamic and constantly evolving, physicians must exercise care and ensure that any recommendations or prescriptions, especially in a fast-changing pandemic, have a compelling and evidence-based foundation in the medical literature.

Section 4: Practice Considerations for Licensees

Physicians regularly make commendable and heroic efforts to protect and enhance the health of their patients, which has been amply demonstrated during the COVID-19 pandemic. The intent of this policy is not to overburden physicians with new or additional requirements but to support their efforts through guidance about how best to carry out their professional responsibilities in combating misinformation and safeguarding public health.

Conveying Medical Information

The primary purpose for proposing treatments or conveying medical information and advice about a disease or medical condition must always be to benefit the health of the patient or public. A patient's interests must not be supplanted by the personal goals of the physician, whether they are political, economic or otherwise. Physicians have a duty to "adhere to...professional responsibilities at all times, including in situations that may seem to be outside of the traditional clinical sphere," such as when sharing medical information on social media.¹³

When medical information is conveyed, whether in a clinical setting or in public through electronic means or otherwise, it must be based upon the best available scientific evidence. Where no such evidence exists, physicians must proceed very cautiously and only when there is a compelling rationale for the proposed treatment and justification of its use in relation to the patient's symptoms or condition. Novel, experimental or unproven interventions should only be considered and proposed when traditional, accepted and proven treatment modalities have been

¹¹ AMA Principles of Medical Ethics.

¹² ABIM Foundation, ACP–ASIM Foundation, and European Federation of Internal Medicine, Medical Professionalism in the New Millennium: A Physician Charter, *Annals of Internal Medicine*, 5 Feb 2002, Vol. 136, Issue 3, 243-246.

¹³ "Social Media and Electronic Communications," THE FED. STATE. MED. BD. (*April 2019*), https://www.fsmb.org/siteassets/advocacy/policies/social-media-and-electronic-communications.pdf

tried and failed. In such instances, there must still be a basis in theory or peer-acknowledged support for such practices. ¹⁴ If justification based on scientific evidence is not present, disciplinary action by a state medical board may be warranted. The use of FDA-approved drug products is permissible when such use is based upon scientific evidence or sound medical opinion. Efforts should be made to ensure that information about off-label prescribing is independently derived, peer reviewed, scientifically sound, truthful and not misleading. 15 Offlabel prescribing of medication, ordinarily permitted by law, is not an appropriate defense or cover for rogue practices occurring without accompanying rationale or justification based in science.

Standards of care may evolve as novel scientific discoveries occur and as new evidence becomes available. Physicians are expected to be mindful of these evolving standards and avoid making treatment recommendations based on outdated, disproven or otherwise false information.

In crisis or emergency circumstances, standards of care may need to be altered to accommodate emergent or urgent circumstances. However, a scientific basis between a condition and proposed treatment is still necessary. Even in the absence of scientific evidence, physicians must not propose treatments that present significant, foreseeable and unjustified or unacceptable risk of harm to patients.

Patients have a right to be informed about any treatments proposed for them. Physicians have a corresponding duty to clearly convey all relevant information about their proposed treatments. their risks and benefits (including the risks and benefits of not treating them), and reasonable alternatives. Such information must be based on scientific evidence and prevailing standards of care, and duly documented in the medical record. Informed consent fails and a patient's autonomy is negated when the patient consents to a management or treatment plan that is based on misinformation or disinformation.

Encountering and addressing misinformation in a clinical setting

Due to the abundance of health-related misinformation that is available to patients online, on television, on radio and in print, physicians are bound to encounter misinformed patients and may face difficulties in convincing patients about the falsity of particular viewpoints regarding the efficacy of certain treatment options. It is noteworthy that public polling continues to demonstrate that doctors are among the most trusted groups 16 and can leverage and increase this trust by engaging respectfully and honestly with patients in conversations that aim to equip them with accurate information.

When encountering misinformation in a clinical setting, physicians are encouraged to listen respectfully to their patients before reacting to the information being shared. If a patient feels dismissed when conveying a viewpoint or describing information they have received, this may

¹⁴ Federation of State Medical Boards, Policy on Regenerative and Stem Cell Therapy Practices, 2018.

¹⁵ American Medical Association Policy H-120.988: Patient Access to Treatments Prescribed by Their Physicians

¹⁶ University of Chicago Harris School of Public Policy and The Associated Press-NORC Center for Public Affairs Research.

encourage them to shut down and retreat to what they perceive to be a more accepting community, which may often be where they obtained such misinformation in the first place. Physicians should, therefore, respond at a level that is appropriate for the patient, acknowledge the patient's concerns and engage them in a discussion about their values and health goals. Ideally, the physician will be in a position to help the patient understand that if they value living a healthy life that is free from illness, they ought to also value treatment options that are most likely to help them achieve these goals. Once a common understanding of patient goals has been established, the patient may be more open to hearing about alternative, better established treatment options from their physician.

Physicians are encouraged to anticipate these difficult conversations by being prepared with easily accessible information for conditions about which patients are frequently misinformed. Options for conveying this information can include pamphlets or handouts in outpatient settings and clinics or links to practice websites. Physicians are also encouraged to maintain their competence and become more knowledgeable of basic principles of statistics, epidemiology, and public health in order to accurately and effectively convey crucial health information to patients, particularly where there may be potential for misinformation.

In addition to requests for treatments based on misinformation, physicians are likely to receive requests from patients for medical exemptions from public health requirements, such as masking or vaccination, that may not be based in medical need. While denying such requests may result in frustrations on the part of the patient and even breakdown of the physician-patient relationship, physicians should not offer exemptions that are not based in medical need or not made within the context of an established physician-patient relationship. Physicians may also receive requests to alter medical records or death certificates in ways that would make them inaccurate, either by removing or adding a diagnosis or cause of death. Such requests violate a physician's ethical and legal duties to accurately document patient encounters or properly certify deaths and should be denied.

Section 5: Considerations for State Medical Boards

State medical boards have long dealt with complaints about physicians related to false information, false claims of efficacy and false advertising. However, in an age where misinformation can be widely spread online in an instant to a vast number of recipients, boards can expect to receive complaints about misinformation and disinformation with increasing frequency and are encouraged to address complaints expeditiously when there is risk of immediate and widespread harm to public health. A recent survey of state medical boards by the FSMB revealed that two thirds of the 58 state medical boards who responded had seen an increase in complaints about licensees disseminating false or misleading information since the onset of the COVID-19 pandemic.¹⁷

In fulfilment of their mission to protect patients, several state medical boards have already taken disciplinary action against licensees for their role in spreading disinformation and several others

¹⁷ Two-Thirds of State Medical Boards See Increase in COVID-19 Disinformation Complaints, Federation of State Medical Boards, (December 9, 2021), https://www.fsmb.org/advocacy/news-releases/two-thirds-of-state-medical-boards-see-increase-in-covid-19-disinformation-complaints/

are pursuing investigations, though the specifics of those ongoing investigations are not known as they are usually confidential and not made public until a disciplinary action is taken. While some of these investigations may result in further disciplinary actions, some state medical boards have faced criticism from their state government or frustrated segments of the public and media outlets because of certain actions or perception of inaction on their part.

Legal Grounds for Disciplinary Action

As state medical boards screen and triage complaints about misinformation and disinformation and adjudicate cases, they may have concerns about facing challenges on First Amendment grounds for disciplinary action that restricts a physician's right to speech. In the face of such concerns, the following section outlines several considerations for boards as they consider appropriate regulatory decisions.

State Medical Practice Acts vary in the ways in which unprofessional conduct is described and by the authority afforded state medical boards to take disciplinary action against licensees for spreading disinformation. Some medical practice acts provide broad latitude to boards in describing grounds for disciplinary action that includes deceit, fraud, intentional misrepresentation, dishonesty and other similar grounds. 18 In some cases, however, boards may be limited to only considering those infractions that occur within the context of a physicianpatient relationship or only during the provision of medical care to patients. In yet other cases, the medical practice act may clearly reference conduct that is likely to "deceive, defraud, or harm the public or any member thereof." 19 A few state statutes include language that explicitly includes conduct or speech which occurs both in private and public. 20

Regardless of varying verbiage in statutes, state medical board expectations of licensees generally are the same regardless of the type of information being conveyed: "Physicians must be accurate and not intentionally misleading in providing descriptions of their training, skills, or treatments they are able to competently offer to patients."²¹

Prohibitions on disseminating misinformation are already expressly written, or implied, in many state statutes regulating the practice of medicine. However, adopting a specific policy on misinformation is encouraged in light of the increased prevalence of, and harm caused by, physician-disseminated misinformation in this ongoing pandemic.

Additional grounds for disciplinary action that could relate to the dissemination of misinformation but are not necessarily directly related to fraud or deceit could include:

- o Failure to adequately obtain informed consent by not providing adequate or truthful information to patients about proposed treatments
- o Failure to adhere to an applicable standard of care

¹⁹ Kentucky - KRS 311.595(9) – italics added

¹⁸ See, e.g., Alaska AS§ 08.64.326

²⁰ See, e.g., Louisiana LRS Title 37, Chapter 15: §1285

²¹ Federation of State Medical Boards, "Position Statement on Sale of Goods by Physicians and Physician Advertising," Adopted April, 2017.

- Engaging in conduct that is likely to bring the profession into disrepute (unprofessional conduct)
- Engaging in unethical conduct by harming the public²²
- Using experimental forms of therapy without proper informed patient consent, without conforming to generally accepted criteria or standard protocols, or without proper periodic peer review of results²³

In assessing a licensee's alleged infraction, state medical boards may wish to consider which factors addressed in the above examples are relevant and addressed in their Medical Practice Acts as bases for imposing disciplinary action. Potential questions and considerations for the board include:

- O Did the spread of disinformation occur during the course of provision of care or in the context of an established physician-patient relationship?
- o Did the infraction involve conduct on the part of the licensee, or speech only?
- Was the licensee acting in a professional capacity or as a private citizen?
- Does disinformation (in public or private) indicate high likelihood that the same disinformation is being provided to patients?
- O Did the infraction result in harm to the health of the licensee's patient(s) or did it result in broader harms to the public health?
- o Was demonstrable harm involved? Was it direct or indirect harm?
- O Did the licensee knowingly disseminate disinformation? That is, can intent be established?

State medical boards may also wish to consider whether there may be options available that do not involve disciplinary action but which could help a licensee better understand the ethical basis of their duty to convey accurate information to patients and the public. It may be more effective in certain circumstances to engage licensees in conversation, provide informal and non-public notices and seek educational and remedial options, rather than proceed with disciplinary action. This approach is likely more appropriate in instances where licensees unknowingly spread misinformation without malicious intent.

There are many ways in which physicians' speech in clinical settings and in public is already subject to reasonable restrictions. To ensure informed consent, many state laws already regulate physician speech and prohibit misinformation. Further, in the interest of patient privacy, HIPAA regulates the types of disclosures physicians can make in the clinic and in public communication. In the interest of consumer protection, the Federal Food, Drug, and Cosmetic Act (FDCA) and the Federal Tort Claims Act (FTCA) restrict health claims made in connection with advertisements for drugs and physician services; both prohibit misinformation in the commercial context.²⁴

²² N.H. Rev. Stat. Ann. § 153-A:13. ("Engaging in unethical conduct including... conduct likely to deceive, defraud, or harm the public.")

²³ Federation of State Medical Boards, "Guidelines for the Structure and Function of a State Medical and Osteopathic Board,' Adopted May 2021.

²⁴ 15 U.S.C. § 45(a) (The FTC Act prohibits "unfair or deceptive acts or practices in or affecting commerce" "misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act."); 21 U.S.C.A. § 331 (THE FDCA prohibits "The adulteration or misbranding of

The dissemination of misinformation in the clinic or in public is a clear ethical violation—it endangers public health, undermines the quality of care, and damages the reputation of the medical profession. The harm is even greater when it comes to disinformation, as this implies the physician is knowingly misleading the public for personal gain. A policy which expressly prohibits physicians from disseminating misinformation or engaging in disinformation is thus a reasonable restriction on professional conduct. State medical boards are not ordinarily dissuaded from carrying out their long-held disciplinary procedures. There should not be an exception with respect to the spread of disinformation, particularly when its impact on patients and the health of the public is widespread and severe in an ongoing pandemic that has thus far taken the lives of nearly a million Americans in less than two years.

Section 6: Summary of Recommendations

State Medical Boards

- 1. State medical boards are encouraged to adopt a policy that clarifies board expectations regarding the dissemination of misinformation and disinformation by licensees.
- 2. State medical boards must retain their legislated authority to regulate the professional conduct of licensees in order to effectively protect the public.
- When adjudicating cases regarding misinformation and disinformation, state medical boards are encouraged to consider the full array of authorized grounds for disciplinary action in their Medical Practice Acts.
- 4. When appropriate, state medical boards should consider whether there are options that do not involve disciplinary action that could help a licensee understand the ethical basis of their duty to convey accurate information to patients and the public and change or remediate their behavior appropriately.
- 5. State medical boards should not be dissuaded from carrying out their duty to protect the public by concerns about potential challenges to disciplinary decisions when these decisions are based on sound regulatory considerations for public protection.

Licensees

6. Recommendations regarding proposed or potential treatments of a medical illness or condition must be supported by the best available scientific evidence or prevailing scientific consensus.

7. In the absence of available evidence or consensus, physicians must only proceed when there is an appropriate scientific rationale and justification for a proposed treatment, in

any food, drug, device, tobacco product, or cosmetic in interstate commerce." Misbranding includes misinformation on the label.

relation to the patient's symptoms or condition, and the risks and benefits of the approach are understood by the patient in an informed consent that is documented in the medical record. Novel, experimental and unproven interventions should only be proposed when traditional or accepted and proven treatment modalities have been exhausted.

- 8. Physicians must not propose treatments that present significant, foreseeable and unjustified or unacceptable risk of harm to patients.
- 9. Treatment recommendations should be based on scientific evidence or sound medical opinions. Physicians should be truthful and transparent, including sharing with the patient the risks and benefits of the treatment recommendations, as well as reasonable alternatives to the recommendations.
- 10. Off-label prescribing of medication, should be based upon scientific evidence or sound medical opinion. Efforts should be made to ensure that information about off-label prescribing is independently derived, peer reviewed, scientifically sound, truthful and not misleading.
- 11. Physicians must not offer exemptions from vaccinations or other preventive measures that are not based in medical need, nor should they acquiesce to patient requests to alter medical records or death certificates in ways that do not accurately reflect patient encounters, diagnoses or treatments.
- 12. Physicians are expected to remain current with evolving scientific evidence and practice standards, and avoid making treatment recommendations based on outdated, disproven or otherwise false information.
- 13. When confronted by misinformed patients, physicians are encouraged to listen respectfully to patients before reacting to the information being shared.
- 14. Physicians should anticipate difficult conversations with patients about controversial topics that are in the news by being prepared with current, evidence-based and easily accessible information for conditions and treatments about which patients may be misinformed.
- 15. Physicians are encouraged to maintain their competence or become knowledgeable in areas such as statistics, epidemiology and principles of public health, either through accredited continuing medical education or other appropriate means, in order to accurately and effectively convey important health information to patients, particularly where there is potential for misinformation.

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