

West Virginia's Voluntary Nonopioid Advance Directive: Ethical and Practical Concerns

by

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Kevin Augusto Rivera, M.A.

University of Pittsburgh, 2019

The West Virginia voluntary nonopioid advance directive (VNOAD) is a document indicating a person's advance refusal of any discussion, offer, or administration of opioids by a healthcare provider. This thesis argues that, despite the worthy legislative intent behind its implementation in West Virginia—namely, to address the opioid epidemic by reducing the prescribing of opioids—the VNOAD not only fails to address the epidemic and its underlying etiology, but also presents multiple ethical and practical concerns. Because it neither requires discussion with a clinician, nor even the involvement and consent of the person to whom it applies, the VNOAD is contrary to the requirements and ethical values of informed consent. Because the VNOAD, once executed, prevents clinicians from discussing opioids with the patient, it undermines ideals of transparent clinician-patient communication and can prevent patients from receiving standard of care and from having their healthcare needs met. For clinicians, a patient's executed VNOAD can give rise to distress and exposure to legal liability. This thesis discusses these ethical and practical concerns.

The introduction recounts the origin of the VNOAD in West Virginia and presents the structure of the thesis. The second section analyzes the VNOAD in comparison to traditional advance directives and physicians' orders regarding life sustaining treatment, as well as the notion of a Ulysses contract. The third section presents the ethical and practical problems presented by the VNOAD as it has been designed and implemented in West Virginia, though

the problems likely afflict most NOADs. These problems include undermining physician-patient communication and informed consent, not respecting patient autonomy, not serving the health interests of patients, and risking distress on the part of patients, their family members, and clinicians. The fourth section suggests what might be done to address some of these problems.

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Preface

I am indebted to Dr. Lisa Parker for advising me through this project; it certainly would not exist without her guidance. I also owe a great deal of gratitude to my committee members, Dr. Valerie Satkoske and Dr. David Kappel, for their time, advice, and support in helping me complete this paper, as well as to my partner for her support and understanding throughout the writing process. A special thank you to my family, in particular my mother who made me the man I am today. I would be remiss if I did not also thank one of my closest friends, Ryan Bowers, for often being a sounding board and always having an interest in my success.

1.0 Introduction

1.1 The Nonopioid Advance Directive and its Implementation in West Virginia

On March 9, 2018, West Virginia Senate Bill 273, the Opioid Reduction Act, was passed, and went into effect 90 days later. It was introduced at the request of Governor Jim Justice (West Virginia Department of Health & Human Resources, 2018). Among its provisions—including, opioid prescription limitations, chronic pain clinic referral policy, required reporting of abnormal prescribing practices, and drug scheduling—the bill provided that the Office of Drug Control Policy, which had been created in 2017, establish a voluntary nonopioid advanced directive (VNOAD) form. The West Virginia VNOAD was included under article 54, and the form appears to be a wholesale borrowing from Massachusetts’ form (Satkoske, 2019). The form, which is to be filed in an individual’s medical record, may be used to “indicate to a health care practitioner that an individual may not be administered or offered a prescription or medication order for an opioid” (West Virginia-ARTICLE 54, SECTION 16-54-2 subsection b). (Though I discuss below reasons that the WV VNOAD should not be termed an advance directive in the traditional sense, here I note that the term used in the WV legislation and form is also erroneous. ARTICLE 54. OPIOID REDUCTION ACT. §16-54-2 refers to a “voluntary nonopioid advanced directive form,” while the proper term would include ‘advance’ not ‘advanced’.)

Legislators in different states (e.g., Connecticut and Alaska), and their residents currently suffering from substance use disorder (SUD), have become interested in the execution of nonopioid advance directives (NOADs) (Associated Press, 2017). For clarity, VNOAD will be the acronym used when talking specifically about the West Virginia document and NOAD will be

used when talking about this type of advance directive in other states or in general terms. By executing a NOAD a person refuses discussion, offer, or administration of opioids, even when such drugs are medically indicated. The main population intended to use the VNOAD are individuals with substance use disorder (SUD), who may execute a NOAD as part of their treatment plan to manage their disorder. However, one may also imagine some people without SUD seeking to execute a NOAD with the belief that it will help them avoid developing addiction, perhaps, partially because of the attention opioid addiction has received and because of the stigma associated with addiction and opioid use.

In West Virginia, the introduction of Senate Bill 273 was prompted by a desire to reduce the rate of deaths due to overdoses in West Virginia, which had the highest rate of any state in 2016 at 52.0 per 100,000 people. At the time, that rate was projected to increase by 2017, so the government chose to respond with this bill and include the implementation of the VNOAD (Rice, J.C. & Power, M.L., 2018). The bill came after a strong wave of bipartisan support to curtail the opioid epidemic, and its high death toll, demonstrated by the passage of the federal Opioid Crisis Response Act of 2018 (Facher, L., 2018). As US Representative from West Virginia Shelly Moore Capito said, “When thinking about ‘next steps’ for fighting the opioid epidemic, one of the first things I realized was that the formula for state funding was not providing adequate resources to the hardest hit states; and I worked to make sure that funding formula was changed.” Now as a US Senator, Capito reported that, at the time she supported the bill so that small states with the highest rates of opioid overdose could get more aid (Capito, 2018). West Virginia Senator Joe Manchin made similar statements at the time. He stated, “West Virginia has the highest overdose rate per capita of any state in our nation and the impacts of this epidemic can be felt [by] every[one] [in] our state... [The bill’s] language more than tripled the amount of funding coming to our state.”

Initially, state funding received through the Opioid Crisis Response Act was based solely upon the number of opioid related deaths per state, rather than opioid death rates per capita. Language based on per capita rate rather than absolute number of deaths more clearly reflects, given its small population, the degree to which WV has been affected by the opioid crisis, especially when compared with other states (Manchin, 2018).

In response to a request for information regarding the efficacy of the VNOAD, the West Virginia Bureau for Public Health (WVBPH) stated (erroneously) that the information is protected under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Common Rule governing research (42 CFR 2). (Disclosure of aggregate data would not, in fact, violate either HIPAA or 42 CFR 2.) Therefore, information like the association between implementation of the law and the number of opioid prescriptions being written or filled, or the number of individuals being diagnosed with substance use disorder (SUD), is not available. De-identified or aggregate data has also not been collected to their knowledge, perhaps due to the difficulty of doing so because of concern for privacy rights and individuals' concerns about revealing that they have employed a VNOAD. Additionally, the WVBPH expressed doubt that any meaningful data analysis existed and reported that no current raw data had been collected to test whether the intent had been successfully supported by the VNOAD. Moreover, simply learning whether the rate of opioid prescription has been significantly reduced in WV since the introduction of the VNOAD will not demonstrate a direct effect of the document; at most there could be an association between the document's introduction and prescription rates. The number of opioid prescriptions being written and/or filled is influenced by many factors.

The implementation of the VNOAD demonstrates the state's interest in promoting the general welfare of its citizens. However, it remains an open question whether the execution of the

document by an individual, leads to positive effects for the person utilizing it and indeed whether its general use reduces the incidence of opioid-related SUD and overdose deaths. Presumably, West Virginia's Governor, Jim Justice, who introduced the bill with the VNOAD provision, and those who supported it, believe in the potential the document has to achieve positive outcomes.

1.2 Overview of This Paper's Goal and Structure

This paper will focus on the Voluntary NOAD currently available in West Virginia and its possible effects on different populations; the paper will also address aspects of other state's similar directives when relevant. It will analyze the ethical considerations involved in employing NOADs and will argue against the use of NOADs for several reasons. First, VNOADs interfere with physician—patient communication. Second, the creation of the VNOAD and subsequent development of norms may lead to social pressures on patients to execute such documents. Third, because VNOADs focus on interventions, rather than patient goals and values, they suffer from the same failings as intervention-focused advance directives used to direct care during a patient's decisional incapacity. Thus, it serves as a suboptimal means of achieving patient's healthcare goals. The VNOAD may even prove detrimental for patients with SUD, as execution of a VNOAD may be too blunt an instrument to achieve their goals and may not promote their health-related well-being. Fourth, there are issues surrounding the revocation of a VNOAD. The process for revocation and reasons supporting revocation, including conditions warranting automatic revocation or nullification of the document, are not clearly delineated. Failure to enable revocation could also lead to patient distress, undermine patient quality of life, patient autonomy, and is contrary to the requirements of informed consent. Fifth, the VNOAD will likely lead to physician

distress, as physicians struggle between seeing patients in pain and the legal liability they would incur if they were to violate the VNOAD's prohibition of discussion of opioids. Sixth, family distress may also arise when a loved one has a terminal condition, is in severe pain, and has a VNOAD that prevents adequate palliative care. Seventh, issues and questions of how appropriate the VNOAD is to West Virginia's population will be analyzed. The final section will discuss the ill effects the VNOAD may have on other populations who employ the document—namely, patient's with opioid allergies and patients with deep fear of addiction but no SUD.

This paper's analysis will unfold within a total of five sections. Section 2 compares the VNOAD to traditional advance directives, the POST, and the Ulysses contract. Section 3 outlines and discusses the VNOAD's ethical and practical concerns. Section 4 suggests how some of these problems could be mitigated. Section 5 concludes that the VNOAD is a poor tool and summaries interventions that could improve it and its use.

2.0 Comparison of VNOAD to Other Instruments for Directing Care

2.1 Traditional Advance Directives

A healthcare advance directive is an oral or written statement of a person's wishes for her or his medical treatment that becomes effective when a clinician deems a patient to lack decision-making capacity in the relevant domain. Lacking decision-making capacity or being deemed incompetent "denotes those who are to be placed under the guidance and control of another... [In that case,] information will be provided to a third party authorized to decide on the incompetent's behalf, and the decision will be reached by that party" (Faden & Beauchamp, 1986). Generally, advance directives are created by people to ensure that their future medical treatment, if and when they become incompetent, aligns with their values. In this manner, the advance directive plays a role in the decision-making process, along with the third party. The three types of directives that will be discussed are: oral statements (and informal written comments), the Living Will, and the Durable Power of Attorney (Meisel, 1992).

Advance directives are most ethically justifiable when they are goal-oriented, rather than intervention-specific, because they allow for flexibility in their future application in light of changing health conditions, technologies, and intervention modalities, while implementing the patient's persistent values and care goals. In order to be optimally ethically justified and effective, advance directive documents should: (i) name a surrogate decision maker, and (ii) state goals and values that should ideally inform the surrogate decisionmaker's decision-making. Advance directives are considered valid when they have been executed by an individual who is reasonably

informed, acting voluntarily in issuing them, and competent to make decisions about the future care they would like to receive if deemed incompetent (Beauchamp & Childress, 2009).

Medical decisions made by competent patients at the time when a medical need presents itself are the most likely to reflect the patients' values. Because they are written in advance of their need, advance directives likely speak to scenarios or interventions with imperfect contextualization to the present situation. An advance directive that is updated when changes in the author's values or medical condition occur should be considered to have the strongest authority as it is most likely to reflect current values of the patient-author. Such directives would best serve patient wishes and best guide a surrogate decision-maker in mirroring contemporaneous patient decision-making. Naming a surrogate decision-maker, as well as stating goals and values along with relevant updating, promote the patient's precedent-autonomy and well-being.

In cases where explicit statements have not been recorded in writing regarding specific medical care interventions, prior oral statements (heard by family or a close friend) regarding the relevant health state or intervention can be used to inform patient care when the patient is deemed incompetent. Relying on oral advance directives may raise questions about accuracy of the surrogate's reporting, as well as questions about how carefully considered a patient's previous oral comment may have been. Written advance directives provide a fixed statement to be interpreted, and the act of writing instructions or executing legal documents demonstrates some degree of seriousness on the part of the patient.

A living will is an instructional advance directive; it is a document expressing explicit wishes of the patient regarding end-of-life care. Following a living will respects a patient's autonomy by implementing the patient's own wishes regarding healthcare, and presumably promotes the patient's well-being as she or he conceives it. Relying on a living will may also

facilitate timely decision-making and alleviate doubt healthcare agents or family may have had in making those decisions had there not been a living will. The drawback is that a living will without declaration of a proxy is not very flexible in responding to medical scenarios not encompassed by the document; implementation of the living will may benefit from a proxy contextualizing the wishes to the particular scenario.

Another advance directive is a Durable Health Care Power of Attorney or Medical Power of Attorney (MPOA), as it is called in West Virginia. This is a legal document that names a surrogate decision maker for purposes of healthcare decision-making. Like the living will, it comes into effect if the individual is incapacitated and requires medical care decisions to be made to direct care. The person named as a surrogate in a MPOA is responsible for guiding care so that it aligns with any instructional advance directives or, more generally with the patient's values, and for making decisions not already clear from explicit prior statements or written direction (Mayo Clinic, 2014). The surrogate must interpret the instructional advance directive and contextualize it to the present circumstance or employ substituted judgment to construct what the patient would want, based on what is known about the patient's values and preferences. According to Beauchamp and Childress, "the standard of substituted judgement should be used for once-competent patients only if reason exists to believe that the surrogate decision maker can make a judgement as the patient would have made it. In such cases, the surrogate should have such a deep and relevant familiarity with the patient that the particular judgement made reflects the patient's views and values" (2009, pp. 117-120). If the patient's likely preference cannot be discerned, then the surrogate must make decisions that are in the patient's best interests. In contrast to the substituted judgment standard, the best interest standard in decision-making is not predicated on the patient's

values but is based on the culture's generally accepted values and views of what is conducive to quality of life.

These advance directive documents allow those employing them—a physician implementing a living will or a surrogate decision maker named in a MPOA—to contextualize the directive to the current scenario, treatment options, and decisions to be made. Insofar as the advance directive states the patient's values, priorities, and goals of care, the surrogate may truly apply the patient's values in selecting treatment. In contrast, advance directives that are purely intervention-focused—for example, a series of checkboxes asking the patient to consent/refuse antibiotics, CPR, mechanical ventilation—are less useful for constructing what the patient would want, where he or she competent, in specific circumstances. Because every medical scenario is unique, there is a high risk that the patient would not have been able to take all relevant information into account in framing an intervention-focused advance directive. Therefore, an ideal instructional advance directive would be goal-oriented, as opposed to strictly intervention-oriented. Furthermore, updating advance directives enable a person to reassess how well the directives align with her/his current life circumstances and values, and then either change or reaffirm their content.

2.2 Comparison of the VNOAD to Traditional Advance Directives

The West Virginia VNOAD differs from traditional advance directives in several ethically relevant ways. First, the VNOAD (see figure 1) need not be executed by the patient while competent but may instead be completed by a patient's guardian or health care agent, apparently without the patient being consulted or concurring. Unlike traditional advance directives, the

VNOAD need not be the result of a patient's autonomous authorization. In this way, the VNOAD fails to respect or promote patient autonomy.

Second, unlike traditional advance directives, the VNOAD seems to be effective—i.e., to guide the patient's care—whether or not the patient is competent to make decisions for him/herself at the time such care guidance is needed. The VNOAD is effective upon signing, and while it may be revoked at any time, it is intended to constrain healthcare professionals from that point forward from even discussing opioids. While healthcare professionals are not prohibited by the VNOAD from asking the patient about the existence of the VNOAD to ascertain that the patient still affirms its provisions, it is perhaps likely that healthcare professionals will be reluctant to make that inquiry once they are aware that a patient has a VNOAD. They may confuse discussing opioids and discussing the VNOAD, and mistakenly believe they are prohibited from raising either in discussion. They may not want to engage with a patient's SUD, which they may assume a patient has simply because the patient has a VNOAD. Stigma surrounding opioid use and SUD may make it difficult for a patient with a NOAD to revoke it or to have that revocation taken seriously. The possibility that the VNOAD's provisions would lead to the overriding of a competent patient's contemporaneous decision-making (e.g., a request for pain medication) is contrary to respect for patient autonomy and may be contrary to the patient's well-being.

Third, the VNOAD does not state a patient's goals for care or values, or even her/his preferences, except to state that the patient prefers not to be offered opioids. The document does not state the specific goals the patient sought through its execution and may prevent exploration of those goals by prohibiting the discussion of opioids. Awareness of patient goals helps orient healthcare teams and enables development to care plans. The VNOAD's singular goal of prohibiting discussion and prescription of opioids can conflict with unstated patient goals, as

managing their care and even managing SUD may not necessitate complete avoidance of opiates. By failing to include any opportunity to state goals and values, but instead focusing on the single intervention of opioid prescription/administration, the VNOAD does not respect patient autonomy and promote well-being in the way that traditional advance directives attempt to balance patient self-determination and well-being (Buchanan and Brock, 1989).

Even for the patient who is executing the document on his or her own behalf, the extent of what the patient is refusing by signing a VNOAD depends on comma usage within the sentence previously discussed. The sentence reads: “I <state your name> certify that I am refusing at my own insistence the offer or administration of any opioid medications including in an emergency situation where I am unable to speak for myself.” This could mean the patient refuses

a) offer or administration of opioids[,] including in an emergency situation[,] where I am unable to speak for myself. This means that the patient should not be offered/administered opioids in any situation so long as the patient cannot speak for him/herself at that time, and this includes in emergency situations. If this is the correct reading, then the patient’s refusal by means of the VNOAD is only effective when the patient cannot speak for him/herself. On this reading, the sentence could be rewritten as: “I <state your name> certify that I am refusing at my own insistence the offer or administration of any opioid medications where I am unable to speak for myself, including in an emergency situation.”

b) offer or administration of opioids[,] including in an emergency situation where I am unable to speak for myself. This means that the patient refuses the offer or administration of opioids and should not be offered/administered opioids; further, it is emphasized that this applies to emergencies when the patient cannot speak for him/herself. If this is the correct reading, then

the patient's refusal by means of the VNOAD is effective in any situation—whether or not the patient can speak for him/herself, and whether or not it is an emergency.

While interpretation (a) would be more respectful of patient autonomy, it appears that the VNOAD is commonly used during times of competence, and not only at times of incompetence, as would be implied by the fact that it also denies discussion of opioid administration with the patient, a scenario unlikely to need delineating if the patient is always expected to be incompetent at the time the healthcare professional follows the VNOAD.

Fourth, the VNOAD does not contemplate particular medical circumstances in which opioids may be medically indicated or provide nuanced guidance; it simply seeks to prevent opioid use. There are justifiable uses of opioids, such as palliative measures toward the end of life, immensely painful emergency scenarios, therapeutic opioid use for SUD treatment, and pain secondary to cancer or other conditions in which the pain is not controllable by other nonopioid interventions. End-of-life care is a circumstance in which pain should be treated—with opioids, if necessary—without concern about a patient's history of SUD, active SUD, or concern for development of SUD, unless the dying patient genuinely does not want opioids and expresses that preference. An active VNOAD would prevent administration of opioids in these circumstances, if the patient is not competent to revoke it, or if the guardian or healthcare representative is not present or is unwilling to do so.

Relatedly, the VNOAD also does not appoint a surrogate who could use the patient's preference not to be given opioids as guidance for contemporaneous decision-making regarding opioids in a particular circumstance. Even a surrogate named in a MPOA is not permitted to contextualize the VNOAD to situations to allow use of opioids in some cases, but not others. The VNOAD cannot be used to engage in circumstance-specific balancing in the way that a surrogate,

appointed by the patient through a MPOA can exercise judgment when interpreting the patient's living will. Instead the surrogate can only revoke or fail to revoke the NOAD, just as the patient can do, because the document does not allow for contextualization of patient preferences to the patient's current medical needs.

The VNOAD does apparently allow for the surrogate to revoke the document, but in this regard the document's language is again confusing. The document has a surrogate sign as if the surrogate were executing his or her own VNOAD: "I <state your name> guardian/health care agent certify that I am refusing at my own insistence the offer or administration of any opioid medications including in an emergency situation where I am unable to speak for myself." This is strange, as the guardian or health agent appears to be talking about his or her own refusal. The structure of the sentence, with its "I-language," implies that the powers granted to the patient are also given to the guardian or health care agent. These would include the ability to execute and to revoke the document. This ambiguity should be addressed by West Virginia, because, as written, the sentence does not make sense with the result that it is unclear under what conditions the refusal is effective. It seems that the document controls care of the patient when the surrogate is unable to speak for him/herself.

THIS IS AN OFFICIAL WEST VIRGINIA HEALTH ALERT NUMBER WV148-07-05-2018
Distributed via the WV Health Alert Network – July 5, 2018



TO: West Virginia Healthcare Providers, Hospitals and other Healthcare Facilities
FROM: Rahul Gupta, MD, MPH, MBA, FACP - Commissioner and State Health Officer
WVDHHR, Bureau for Public Health
DATE: July 5, 2018

LOCAL HEALTH DEPARTMENTS: PLEASE DISTRIBUTE TO COMMUNITY HEALTH PROVIDERS, HOSPITAL-BASED PHYSICIANS, INFECTION CONTROL PREVENTIONISTS, LABORATORY DIRECTORS, AND OTHER APPLICABLE PARTNERS

OTHER RECIPIENTS: PLEASE DISTRIBUTE TO ASSOCIATION MEMBERS, STAFF, ETC.

Purpose

The purpose of this Health Advisory is to provide guidance regarding the Voluntary NonOpioid Advanced Directive (VNOAD) form as established in Senate Bill 273, the Opioid Reduction Act of 2017 ("Act"), specifically W.Va. Code §16-54-2.

Background

The Act sets out a process enabling individuals to decline, in advance, any treatment option that includes opioids. The West Virginia Department of Health and Human Resources (WVDHHR) is actively working with the Office of Drug Control Policy (ODCP) to ensure West Virginia residents and the substance use disorder (SUD) treatment communities are aware that this new resource is available in the fight to eliminate opioid misuse.

Under the Act, the ODCP is responsible for creating the VNOAD and publishing the form on the WVDHHR website for public use. Any person who wishes to decline future treatment with opioids may complete the VNOAD and give it to their health care practitioner or responding emergency medical services (EMS) personnel, who must file it in the patient's medical record. The patient, a medical power of attorney representative, or a surrogate may revoke the Directive, orally or in writing, for any reason.

Voluntary NonOpioid Advanced Directive (VNOAD) Form

The VNOAD form, developed by the ODCP, is attached to this Health Advisory. It is also available on the WVDHHR website at <https://dhr.wv.gov/office-of-drug-control-policy>. If a person does not want opioids to be administered to him/her or offered a prescription or medication order for an opioid, he/she may complete and present the signed VNOAD form to a health care practitioner or responding EMS personnel at any time.

The ODCP encourages patients to complete the VNOAD in consultation with their primary care provider or SUD treatment provider. However, consultation is not necessary to the validity of the VNOAD.

Provider Responsibilities

If a health care practitioner receives a signed VNOAD form, it must be filed in the patient's medical record and shall be transferred with the patient from one practitioner to another or from one health care facility to another.

This message was directly distributed by the West Virginia Bureau for Public Health to local health departments and professional associations. Receiving entities are responsible for further disseminating the information as appropriate to the target audience.

Categories of Health Alert messages:

Health Alert: Conveys the highest level of importance. Warrants immediate action or attention.

Health Advisory: Provides important information for a specific incident or situation. May not require immediate action.

Health Update: Provides updated information regarding an incident or situation. Unlikely to require immediate action.

Figure 1 VNOAD Image

Prior to prescribing, administering, or offering an opioid drug product to a patient, a practitioner should check the patient's medical record to determine whether a VNOAD has been filed. In the case of response to an emergency situation, EMS personnel should ask the patient or patient's on-scene representative(s) if the patient has such. Unless revoked by the patient verbally or in writing, a provider should consider a signed VNOAD as the patient's non-consent to opioid treatment.

Any violation of the Act is grounds for disciplinary action by the board that regulates the health care practitioner who commits the violation and may subject the health care practitioner to civil and criminal liability.

Emergencies

A practitioner, without actual knowledge of a VNOAD and who prescribes an opioid in a medical emergency situation, is not civilly or criminally liable for failing to act in accordance with the VNOAD unless the act or omission was the result of the practitioner's gross negligence or willful misconduct. A medical emergency situation is an acute injury or illness that poses an immediate risk to a person's life or long-term health.

Contact Information

All questions or concerns regarding this information should be directed to the ODCP at (304) 558-0684.

Resources

CDC Guideline Information for Prescribers:

<http://www.cdc.gov/drugoverdose/prescribing/providers.html>

CDC Guideline for Prescribing Opioids for Chronic Pain:

<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

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West Virginia Health Advisory Number **WV148-07-05-2018**

Figure 1 VNOAD Image (continued)



West Virginia Department of Health and Human Resources Voluntary NonOpioid Advanced Directive

PATIENT'S LAST NAME		PATIENT'S MIDDLE NAME OR INITIAL	
PATIENT'S FIRST NAME		PATIENT'S MIDDLE NAME OR INITIAL	
DATE OF BIRTH (MM/DD/YYYY)			
STREET OR RESIDENTIAL ADDRESS			
CITY		STATE	ZIP CODE (5 or 9 digits)
LAST NAME OF GUARDIAN OR HEALTH CARE AGENT (if applicable)		MIDDLE NAME OR INITIAL	
FIRST NAME OF GUARDIAN OR HEALTH CARE AGENT		MIDDLE NAME OR INITIAL	
PATIENT/GUARDIAN/HEALTH CARE AGENT STATEMENT (SIGNATURE AND DATE REQUIRED)			
<p>I <input type="checkbox"/> patient <input type="checkbox"/> guardian <input type="checkbox"/> health care agent certify that I am refusing at my own insistence the offer or administration of any opioid medications including in an emergency situation where I am unable to speak for myself. I understand the risks and benefits of my refusal, and hereby release the health care provider(s) or emergency medical service(s), their administration and personnel, from any responsibility for all consequences, which may result by my abstinence under these circumstances. I further certify my understanding that I may effectively revoke this certification at any time orally or in writing.</p> <p>I hereby direct that health care provider(s) or emergency medical service(s), their administration and personnel, comply with the West Virginia Department of Health and Human Resources Voluntary NonOpioid Advanced Directive (VNOAD) regulations and guidance with regard to the above named patient.</p>			
Signature of Patient/Guardian/Health Care Agent			Date
SIGNATURE AND DATES (ALWAYS REQUIRED)			
<p>I am a health care practitioner for the above-named patient. I verify that the above-named patient has a current and valid VNOAD, issued on </p>			
Signature of Health Care Practitioner			
Print Name of Health Care Practitioner		Effective Date of VNOAD Certification	
Address of Health Care Practitioner			
Telephone Number of Health Care Practitioner			

First Copy: To be kept by patient
 Second Copy: To be kept in patient's permanent medical record

If the person completing this form is currently enrolled in substance use treatment, appropriate consents must comply with HIPAA and 42 CFR Part 2.
 For More Information: 304-538-8886 | dhr.wv.gov

06/2018

Figure 1 VNOAD Image (continued)

2.3 West Virginia Physician Orders for Scope of Treatment

The West Virginia Physician Orders for Scope of Treatment (POST) differs from advance directives in that it is a medical order. The POST is an order by a physician, completed after conversation with the person completing the form. A physician's signature (or a/n PA/APRN's signature in WV) validates the orders. The POST is portable, i.e., it is supposed to "travel with" the patient to all healthcare settings, for example, from hospital to nursing facility, to the patient's home to the Emergency Department.

The POST may include orders regarding resuscitation, intubation, antibiotic and general pharmaceutical usage, nutrition and hydration interventions, the desired place to be treated, and can identify an authorized surrogate. The patient, or the patient's previously designated surrogate holding a MPOA, or in some cases a guardian, provides a signature to make the orders effective and, of greatest ethical importance, to demonstrate he or she was part of the conversation leading to the orders and agrees that the orders listed are in accordance with the patient's values and wishes. The POST is intervention-focused, rather than goals-of-care-focused, but a POST form is to be completed only near the end of life, so the medical circumstances contemplated by the orders are more circumscribed than an advance directive executed at possibly a great length of time before presentation of illness. Like an advance directive, the POST can be updated if the patient's circumstances do change, though the WV POST form (see figure 2), for example, states that updating of the orders should be sought if "time permits" following a change in medical condition.

The POST, and other states' variations of it, was developed by patient advocates who felt that the best way to protect a patient's interests at the end of life was to incorporate a patient's healthcare decisions within a physician's medical order. Experience shows that POSTs (or other iterations of the same document) are more likely to be honored in the healthcare setting than are

advance directives, as the orders—being physician orders—are more widely applicable throughout different medical environments (Furrow, et al., 2018, pg. 377). The general consensus with research conducted on the POST appears to prove the POST to be more effective in having patient end-of-life wishes being honored. In example, in a retrospective cohort study of 2,027 West Virginians, the study researched whether an AD or POST was more effective in achieving an out-of-hospital death (OHD) for patients in hospice. Patients with only advance directives had an OHD 56.9% of the time as opposed to patients with a POST form with either limited or full intervention orders who had an OHD 88.4% and 75.9% of the time, respectively (Pedraza, et al., 2016). As noted previously, the effectiveness of the VNOAD is apparently not being tracked by the WVBPH.

In West Virginia, the POST document, or similar documents in other states, is currently used predominantly by the elderly and principally in skilled nursing facilities. In fact, in some skilled nursing facilities, the mandatory offer of the POST may be misinterpreted as mandating completion of the POST by all their patients:

“A number of states require hospitals or long-term care facilities to offer POLST to certain groups of patients. This requirement parallels the duty under the Patient Self-Determination Act (PSDA) to ‘provide written information ... concerning . . . right to formulate advance directives.’ For example, Maryland requires that completion of its MOLST form be offered to patients in assisted living and nursing facilities, hospices, home health agencies, and dialysis centers, as well as to hospital inpatients being transferred to long-term care. Utah requires a similar range of facilities to determine, on admission, whether each individual has a POLST. These facilities must determine which individuals without a POLST should be offered the opportunity to complete one. Such requirements encourage widespread clinical implementation of POLST, but surveys of states and facilities implementing POLST raise concerns that healthcare facilities, especially nursing

homes, misinterpret ‘mandatory offer’ to mean all residents must have a POLST form.” (Pope, T.M., & Hexum, M. 2012).

The Nursing Home Model Policy for the WV POST, posted on West Virginia University’s Center for Health Ethics and Law page, explicitly states that the POST cannot be mandated by anyone but rather is strictly voluntary (WVU Center for Health Ethics and Law, accessed 2019). Any requirement that a person complete a POST form would be contrary to promotion of the patient’s rights of self-determination.

HIPAA PERMITS DISCLOSURE OF POST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY				
West Virginia Physician Orders for Scope of Treatment (POST) This is a Physician Order Sheet based on the person's medical condition and wishes. Any section not completed indicates full treatment for that section. When need occurs, <u>first</u> follow these orders, <u>then</u> contact physician. Faxed or electronic versions in the e-Directive Registry are legal if copied on bright pink paper.		Last Name/First/Middle Initial		
		Mailing Address		
		City/State/Zip		
		Date of Birth (mm/dd/yyyy)	Last 4 SSN □□□□	Gender □ M □ F
A Check One Box Only	CARDIOPULMONARY RESUSCITATION (CPR): Person has no pulse <u>and</u> is not breathing.			
	<input type="checkbox"/> Resuscitate (CPR) <input type="checkbox"/> Do Not Attempt Resuscitation (DNR/no CPR)			
When not in cardiopulmonary arrest, follow orders in B, C, and D.				
B Check One Box Only	MEDICAL INTERVENTIONS: Person has pulse <u>and/or</u> is breathing.			
	<input type="checkbox"/> Comfort Measures Treat with dignity and respect. Keep clean, warm, and dry. Use medication by any route, positioning, wound care and other measures to relieve pain and suffering. Use oxygen, suction and manual treatment of airway obstruction as needed for comfort. Do not transfer to hospital for life-sustaining treatment. <u>Transfer only</u> if comfort needs cannot be met in current location. Treatment Plan: Maximize comfort through symptom management.			
	<input type="checkbox"/> Limited Additional Interventions Includes care described above. Use medical treatment, antibiotics, IV fluids and cardiac monitoring as indicated. Do not use intubation or mechanical ventilation. <u>Transfer to hospital</u> if indicated. Avoid intensive care unit. Treatment Plan: Provide basic medical treatments.			
	<input type="checkbox"/> Full Interventions includes care above. Use intubation, advanced airway interventions, mechanical ventilation, and cardioversion as indicated. <u>Transfer to hospital</u> if indicated. Include intensive care unit. Treatment Plan: Full treatment including life support measures in the intensive care unit. Additional Orders: _____			
C Check One Box Only in Each Column	MEDICALLY ADMINISTERED FLUIDS AND NUTRITION: Oral fluids and nutrition must be offered as tolerated.			
	<input type="checkbox"/> No IV fluids (provide other measures to assure comfort)		<input type="checkbox"/> No feeding tube	
	<input type="checkbox"/> IV fluids for a trial period of no longer than _____		<input type="checkbox"/> Feeding tube for a trial period of no longer than _____	
	<input type="checkbox"/> IV fluids long-term if indicated		<input type="checkbox"/> Feeding tube long-term	
Additional Orders: _____				
D	Discussed with: <input type="checkbox"/> Patient/Resident <input type="checkbox"/> Health care surrogate <input type="checkbox"/> MPOA representative <input type="checkbox"/> Spouse <input type="checkbox"/> Court-appointed guardian <input type="checkbox"/> Parent of Minor <input type="checkbox"/> Other: _____ (Specify)			
	Authorization <input type="checkbox"/> INITIAL BOX if you agree with the following statement: If I lose decision making capacity and my condition significantly deteriorates, I give permission to my MPOA representative/surrogate to make decisions and to complete a new form with my physician in accordance with my expressed wishes for such a condition or, if these wishes are unknown or not reasonably ascertainable, my best interests.			
	Registry Opt-In <input type="checkbox"/> INITIAL BOX if you agree to have your POST form, do not resuscitate card, living will and medical power of attorney form (if completed) submitted to the WV e-Directive Registry and released to treating health care providers. REGISTRY FAX - 844-616-1415			
	Signature of Patient/Resident, Parent of Minor, or Guardian/MPOA Representative/Surrogate (Mandatory)			Date
	Signature of Physician			
Physician Name (Print Full Name)		Physician Phone Number		
Physician Signature (Mandatory)		Date and Time		
FORM SHALL ACCOMPANY PATIENT/RESIDENT WHEN TRANSFERRED OR DISCHARGED				
©Center for End-of-Life Care, Robert C. Byrd Health Sciences Center of West Virginia University, P.O. Box 9022, Morgantown, WV 26506, 1-877-209-8086 2015				
e-Directive Registry FAX 844-616-1415			№ 468666	

Figure 2 West Virginia POST Image

HIPAA PERMITS DISCLOSURE OF POST TO OTHER HEALTH CARE PROFESSIONALS AS NECESSARY				
				Last Name/First/Middle Initial
E	Patient/Resident (Parent for Minor Child) Preferences as a Guide for this POST Form			
	Advance Directive (Living Will or MPOA)	<input type="checkbox"/> NO	<input type="checkbox"/> YES - Attach copy	
	Organ and Tissue Document of Gift	<input type="checkbox"/> NO	<input type="checkbox"/> YES - Attach copy of documentation	
	Court-appointed Guardian	<input type="checkbox"/> NO	<input type="checkbox"/> YES - Attach copy of documentation	
	Health Care Surrogate Selection	<input type="checkbox"/> NO	<input type="checkbox"/> YES - Attach copy of documentation	
MPOA/Surrogate/Court-appointed Guardian/Parent of Minor Contact Information				
Name		Address		Phone
Person Preparing Form				
Signature of Person Preparing Form		Preparer Name (Print)		Date Prepared
F	Review of this POST Form			
	Date of Review	Reviewer	Physician Signature	Location of Review
				<input type="checkbox"/> No Change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, no new form
				<input type="checkbox"/> No Change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, no new form
				<input type="checkbox"/> No Change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, no new form
				<input type="checkbox"/> No Change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, no new form
				<input type="checkbox"/> No Change <input type="checkbox"/> FORM VOIDED, new form completed <input type="checkbox"/> FORM VOIDED, no new form
Review of POST Form				
<p>This form should be reviewed if there is substantial change in patient/resident health status or patient/resident treatment preferences. According to state law, the form <u>must</u> be reviewed if the patient/resident is transferred from one health care setting to another. If this form is to be voided, write the word "VOID" in large letters on the front of the form. After voiding the form, a new form may be completed. <i>If no new form is completed, note that full treatment and resuscitation may be provided.</i> FAX voided form and newly completed form to the Registry. Additional forms can be obtained by calling 877-209-8086 or ordered online from the WV Center for End-of-Life Care website at www.wvendoflife.org/Request-Information.</p>				
Instructions for Submission to the WV e-Directive Registry (if Opt-In Box is initialed)				
<p>FAX a copy of BOTH sides of the POST form to the e-Directive Registry at 844-616-1415. Copy form on your copy machine and adjust the lightness/darkness to contrast depending on your machine so that the form is readable prior to FAXing to the Registry. If you have questions about submission of this POST form or other advance directive documents to the Registry, call 877-209-8086. If you are using POST forms that were printed prior to 2010 and wish to submit them to the Registry, please complete a Sign-Up Form that contains the additional demographic information needed to identify the patient/resident in the Registry. The Sign-Up Form can be downloaded at www.wvendoflife.org/e-Directive-Registry.</p>				
FORM SHALL ACCOMPANY PATIENT/RESIDENT WHEN TRANSFERRED OR DISCHARGED				
<p>©Center for End-of-Life Care, Robert C. Byrd Health Sciences Center of West Virginia University, P.O. Box 9022, Morgantown, WV 26506, 1-877-209-8086 2015 e-Directive Registry FAX 844-616-1415</p>				

Figure 2 West Virginia POST Image (continued)

2.4 Comparison of the POST and the VNOAD

The POST and VNOAD have instructive, ethically relevant similarities and differences. Though the VNOAD is not a physician's order, by law it is to be included in the patient's medical record and is to be signed by a patient's healthcare provider. Both documents are designed to be portable and implemented within all settings of healthcare including an Emergency Department, skilled nursing facility, rehabilitation facility, and outside the healthcare setting to direct EMS care in the prehospital setting.

Both the VNOAD and the POST can be executed on behalf of a patient by a surrogate—perhaps without the patient's knowledge or without taking the patient's values into account. Though, most importantly, in contrast to the VNOAD, a surrogate can only execute the POST if the patient is incompetent. Notably, that surrogate must have been appointed by the patient while the patient was competent. The West Virginia Nursing Home Model Policy notes that the POST may only be completed by the resident patient, if the patient still has capacity. In contrast, it is not clear whether a surrogate or guardian could execute a VNOAD on behalf of a competent person; it appears that this may be possible. Both documents are immediately effective or actionable. Thus, it is especially problematic that the VNOAD could be executed without a competent person's knowledge.

2.5 Examination of the VNOAD as a Type of Ulysses Contract

A Ulysses contract is meant to help an individual achieve particular goals despite external or internal pressures. The concept of a Ulysses contract derives from the story of Ulysses, who is

also known as Odysseus in Greek mythology. During his voyage, Ulysses is curious to hear the music of the Sirens, but those who heard the Siren songs never survived. He instructs his crew to put beeswax in their ears to avoid hearing the music, and to tie him down tightly to the mast of the boat, so that he would not need to wear beeswax to avoid being lured by the Sirens' music to steer the ship onto rocks. He knew he would hear their music, lose control, and beg his crew to let him free, thus leading him to steer the ship, fatally, onto the rocks. As a result of this knowledge, he makes a pact with the crew that his contemporaneous stated wishes are to be ignored until he is no longer enamored by the Sirens, until his mind is clear and he again reasons as his authentic self and not a sailor under the influence of the Sirens' songs. Due to being tied up, Ulysses was able to both hear the sirens and remain on deck; the ship survived having its captain hear the Sirens' songs. The ethical justification for the conceptual Ulysses contract is that the current competent, authentic-self executes a Ulysses contract to constrain his or her future behavior when she or he is not competent or is being unduly pressured resulting in him or her not acting voluntarily in accordance with his/her authentic values.

In healthcare, this quasi-contract is designed to empower a proxy to override present requests by the patient, even if he or she is considered legally competent, through the document's previously agreed upon orders (signed into effect by the patient when clearly competent) (Spellecy, 2004). This type of contract may be used in mental healthcare for those suffering from conditions such as mania and schizophrenia. For example, a patient with schizophrenia whose condition is currently controlled by anti-psychotics can sign this contract agreeing to be hospitalized if he or she were to begin hallucinating, perhaps due to medication non-compliance. In the case of patients who have SUD, a Ulysses contract would specify behaviors that likely indicate active substance

use by the individual signing the contract. The contract would then specify that another individual should intervene in some way, perhaps by committing the person to a treatment facility.

If executed by a competent patient, a NOAD can be viewed as a type of Ulysses contract. While a Ulysses contract is generally not legally binding—Arizona is the only state to have something similar to a Ulysses contract be legally recognized (Spellecy, R., 2004)—a NOAD is legally binding in all states in which they have been created. By executing the contract, the person tries to constrain his or her future behavior (i.e., opioid consumption); however, unlike the Ulysses contract the NOAD constrains the healthcare professional’s behavior. Like other Ulysses contracts, a NOAD would be executed by a person when competent and would become effective immediately. Unlike the typical Ulysses contract, the NOAD would constrain future actions of others, rather than the person executing the NOAD (e.g., recommendations and prescribing by healthcare professionals). Like the Ulysses contract, the NOAD would be effective whether or not the patient was competent at the future time contemplated and would function to override the patient’s stated preferences at that time.

In some ways, NOADs are similar to opioid contracts executed between a patient with SUD and his or her clinician. Opioid contracts, however, are executed in the course of SUD treatment between treating clinicians and the patient, and specify particular consequences that will follow from particular patient behaviors (e.g., unprescribed resumption of opioid use). While they are designed to constrain the behavior of patients with SUD and describe clinician behavioral responses to proscribed behaviors, they do not seek to prevent the medically indicated prescribing of opioids. Daniel Buchman and Anita Ho (2013) comment on opioid contracts as creating an adversarial environment that could harm the physician-patient therapeutic relationship. The

VNOAD, or NOADs in general, may lead to similar adversarial interactions and may preempt therapeutically useful interactions to achieve trusting communication and adequate pain relief.

3.0 An Examination of the VNOAD's Ethical Shortcomings

3.1 Interference with Physician-Patient Communication and Informed Consent

The VNOAD undermines the goal of transparency in healthcare communication for patients who execute them. The VNOAD is designed not only to prevent healthcare professionals from administering opioids, but also from discussing opioids as a treatment option for those who have executed a VNOAD. The VNOAD thus prevents fulfillment of the information requirement of both informed consent and prevents provision of standard of care, which is contrary to patients' health-related well-being. What exacerbates these ethical concerns even further is the fact that a physician consultation is not necessary to execute a VNOAD; a physician need only sign it to certify it has been included in the patient's medical record.

One may think that because patients already know that opioids will not be discussed, if they have employed a VNOAD, that there is sufficient transparency in the patient's future medical encounters and disclosure during the informed consent process. Such a belief is false on two counts. First, the patient's surrogate may have executed the document without the patient's knowledge. Second, even if the patient executed the VNOAD her/himself, there may have been a lack of informed consent, in so far as the patient may not have realized the range of conditions in which treatment with opioids would have been standard of care, but would not be discussed, offered, or administered because of the valid VNOAD. Discussion with a healthcare professional is important in order to identify the patient's reasoning in seeking to execute a VNOAD—including understanding not only what a VNOAD is, but also what it entails—as well as to ensure that the patient is voluntarily executing the VNOAD. Of course, because the patient need not be

involved—a guardian or healthcare agent may execute the VNOAD—there is actually no requirement that the patient give informed consent to its implementation.

3.2 Social Pressures and Concern for the Voluntary Informed Consent to VNOADs

As the VNOAD is publicized and becomes more commonplace it is possible that people, particularly those with SUD, will sense an increased pressure to sign one into effect. Patients with SUD and without a VNOAD may be (mistakenly) seen as not making their strongest effort to recover. Two wrongful harms are involved. First, extrinsic pressures to comply with pressure to execute a VNOAD is contrary to informed consent, and refusal of medical interventions that may be appropriate is contrary to patient well-being. Second, increased stigmatization of SUD patients not only for their condition, but also their lack of a VNOAD, would be wrong and contrary to their recovery. With increased acceptance and popularity of NOADs, there may be increased risk of rehabilitation facilities implementing their execution as a requirement of treatment, exerting pressure on patients to execute them, or “firing” patients who refuse. This would be detrimental to the health of those patients, contrary to the public health goal of increasing SUD rehabilitation, and contrary to respect for patient autonomy and the voluntariness requirement of informed consent.

3.3 The VNOAD as Contrary to Patient Well-being and Justice

The VNOAD is a suboptimal means of achieving the goals of patients with SUD who employ the document to avoid relapse for several reasons. First, it is only specific to the medical setting. Even after executing a VNOAD, patients with SUD can still pursue opioids outside of the healthcare setting, perhaps seeking even more dangerous opioid options such as heroin. Importantly, “four out of five heroin addicts come to the drugs... through prescribed opioids” (Bruder, 2018). Unfortunately, the VNOAD does not get at the true etiology of opioid misuse, as it is only a tool to deter prescribing of opioids to patients. Patients with active SUD still remain with down regulated dopamine receptors in the brain, a lessened sense of pleasure, learned drug seeking habits, and extreme cravings from past drug experiences that motivate them to find opioids. Brains may begin transitioning back to a state prior to drug use, but this can take time (Volkow & Morales, 2015).

Second, within healthcare settings, opioid prescribing guidelines could achieve the results sought through the VNOAD, while still permitting judicious use of opioids when no other pain relief is effective. This is important for reasons of both well-being and justice. People with SUD have the same interest in pain relief that others do. According to Norman Daniels (2008), “Whatever our chosen goals or tasks, we need our health and, therefore, appropriate health care.” Though a person’s goals can change with changes in health, as Daniels points out, the degrees of freedom to flourish and pursue goals are reduced with diminished health. Because pain can impair an individual’s ability to function it reduces an individual’s health-related and overall well-being. The VNOAD with its absolute bar of opioid use does not promote health-related well-being.

Moreover, contrary to the requirements of justice, the VNOAD may lead to the treatment of patients with SUD differently from other patients for irrelevant, and thus unjust reasons. Insofar

as they are encouraged or forced to have a NOAD to obtain SUD treatment, the imposition of this inappropriate and irrelevant barrier to treatment for their disorder is unfair. Insofar as their VNOAD prevents them from having appropriate, standard of care treatment for other conditions, like pain, the VNOAD leads to this injustice.

Pain can not only be debilitating but can also lead to or exacerbate ill health. Untreated post-surgical pain, for example, can delay appropriate healing time (Erlenwein, et al., 2015). Of the people who have VNOADs due to their SUD, it is likely some may be on medication due to chronic pain, and while they may be able to get off of medication to keep substance free and withstand some discomfort, they may later sustain an injury, need surgery, or develop cancer, and now their level of pain would indicate opioid usage. Pre-existing or chronic pain is an established risk factor for severe postoperative pain: “a history of chronic pain was associated with slower postoperative mobilization, poorer physical function, and greater psychological distress in addition to increased postoperative pain intensity. The comorbidity of a chronic pain disorder resulted in greater pain intensity after surgery, and also impeded postoperative rehabilitation” (Erlenwein, et al., 2015). As a matter of justice, people with SUD have as much entitlement to effective pain management as those without the disorder. Acute pain control is an issue independent of the chronic issue of SUD, and both should be remedied.

3.4 The VNOAD: Problems Surrounding Execution and Revocation

Guidance in the law regarding the VNOAD’s implementation and revocation is so minimal as to be ethically inadequate. There is no clear requirement of counseling prior to executing a VNOAD. A patient may not understand its provisions or carefully consider reasons to execute the

document, and patients executing a VNOAD should be afforded the decision support, information, and rights associated with other medical decision-making, including the conditions for giving informed consent.

It should be noted that some people mistakenly believe that people with SUD are specifically incompetent in regard to decisions involving opioids. People may have this mistaken belief for at least two reasons. First, they may think this because opioids may impair judgement and decision-making ability, and thus undermine the *informed* aspect of being able to give informed consent. Second, people may think that people with SUD may lack autonomy with regard to resisting craving for opioids and thus render them incapable of making *voluntary* decisions regarding the substances their diseases cause them to crave. If accurate, these views would, however, be contrary to the intended voluntary nature of the VNOAD. Embracing these views—namely, of people with SUD as lacking autonomy or decisional capacity—would also undermine the rationale for allowing patients with SUD to execute VNOADs—namely, respect for patient autonomy. If people with SUD are considered incompetent to accept opioids why would they not also be considered incompetent to refuse opioids as well? Moreover, insofar as voluntary and active participation in treatment is a necessary feature of successful treatment for SUD, it would fail to be conducive to patient well-being to assume that people with SUD cannot make autonomous decisions regarding their care.

Similarly, prior to executing the document, patients would likely want to know what their physicians would believe to be justifiable reasons to revoke a VNOAD, especially because once it has been signed into effect, it functions to prevent physicians from discussing opioids. Neither patients nor clinicians are provided guidance regarding how to facilitate revocation in situations where the patient already knows—at the time of executing the VNOAD—that she or he would like

the VNOAD to be revoked or nullified, for instance if the patient were to develop dementia, associated loss of decisional capacity, and extreme pain. Contemplating such a case, even a person who is currently very concerned about developing SUD or experiencing SUD relapse, may not care about the risk of active SUD or may prefer to trade-off that risk in favor of effective pain control. The document's instructions do not indicate any way to establish conditions for automatic revocation of the executed VNOAD.

3.5 Physician Distress and Legal Liability

Physician distress is another potential negative byproduct of the VNOAD. In cases where a physician has strong reason to believe the patient could greatly benefit from opioids with minimal likelihood of resulting harm (i.e., acute pain in scenarios associated with emergency medical care), the VNOAD's prevention of the discussion of opioid use may quite reasonably cause the physician (and other clinicians) distress. Physicians may especially experience distress when they know or suspect that the VNOAD was executed by someone else (a guardian or healthcare agent), and even more if it was done without the knowledge of the patient. While physicians may try to avoid a situation in which their patients do not know they have an active VNOAD, when this situation occurs, the physician's hands are essentially tied.

Physicians' ethical obligations to prevent suffering and to obtain informed consent may conflict with their legal requirement to respect the provisions of a VNOAD. There are serious legal consequences from violating the VNOAD and mentioning, offering, or administering opioids. The VNOAD document explicitly states, "any violation of the act is grounds for disciplinary action... and may subject the health care practitioner to civil and criminal liability." The law does not allow

healthcare providers to ensure for themselves that informed consent was acquired. In the contemporaneous context, the existence of the VNOAD prevents informed consent by preventing disclosure and recommendation of relevant treatment options, including opioid use.

Additional sources of distress and legal liability also arise because patients may not know that opioids could be indicated to treat their pain (since VNOAD prevents their physician from disclosing this fact), or patients may be inappropriately focused on avoiding opioids increasing the risk that they would use extreme measures to address their pain. A person with unbearable pain could feel forced toward suicidality, particularly if they thought their pain was an immutable part of their life from then on. If an individual committed suicide after seeing his physician and failing to receive adequate pain control, could there be a basis for a malpractice lawsuit? Recommending adequate pain control is standard of care; failing to make that recommendation would seem to open a physician to suit, even if the existence of the patient's VNOAD would ultimately serve as a defense. The VNOAD only addresses potential legal liability if the physician violates the VNOAD's terms; it does not address the ethical and legal conflict a physician faces between the VNOAD and standard of care, or between the VNOAD and the patient's well-being.

It is also not clear whether all physicians are mandated to upload a completed VNOAD when approached to do so. The obligation to upload the document is underneath the "Provider Responsibilities" category. The VNOAD document reads as follows, "If a health care practitioner receives a signed VNOAD form, it must be filed in the patient's medical record and shall be transferred with the patient from one practitioner to another or from one health care facility to another." Physicians only sign the VNOAD to indicate that they have uploaded the document, not to make it effective. The language "must be filed in a patient's medical record," creates an

obligation for the physician. It is not clear, however, whether physicians would be legally liable if they refused to upload the document.

Further, it is not clear whether it would be ethical for a physician to refuse to continue to treat a patient if he or she has a VNOAD. Perhaps physicians could turn away patients, citing the ethical and legal bind in which VNOADs place them; however, this presents the usual ethical concerns that “firing” or refusing to treat a patient presents: concerns about patient abandonment, about undue pressures on patients to comply with physician wishes, and about groups of patients being “orphaned” by refusing physicians. In terms of firing pediatric patients due to families being refusers of infant vaccines, Dr. Stan Block notes legal liability in his reasoning to fire patients due to possible lawsuits from the families of other children that may become exposed to disease at his office. He writes, “we believe it is our ethical duty to tell all of our families that we have tried to vaccinate all of the children being seen in our office to the fullest extent possible according to the CDC vaccine schedule. We should be able to reassure all of our families that highly contagious infectious disease hazards...have been optimally minimized in our offices by our diligent vaccine efforts” (2015). While physicians with patients who have VNOADs are not at risk to be sued by other patients due to exposure, there may be lawsuits that come from the patient themselves or their families due to opioid complaints. Block reports that if appropriate measures are taken to transition care then a patient need not be “orphaned” but rather can still have continuous care. Dr. Mark Wicclair takes the position that “at best [dismissal of a patient is] in a gray zone of professional and unprofessional conduct and should be avoided” (2013). He notes the only substantial reason for dismissing a patient to be that the physician feels other doctors are better equipped to treat the patient due to the physician’s lack of clinical skills and/or substantial deficiencies in the patient-physician relationship leading to a counterproductive, destructive,

and/or harmful result. Even so, Dr. Wicclair notes that the physician ought to recommend another physician and facilitate the patient's transfer.

Furthermore, if the physician has strong reason to believe the patient either did not have capacity when signing the VNOAD into effect or was not fully informed of what it entailed, the physician may face an ethical quandary and experience distress. As in any other case (except emergency care) in which a physician believes the patient fails to understand the medical decision to which she or he is consenting, the physician has an ethical obligation to intervene and to attempt to inform the patient and elicit an informed consent or refusal. Yet the terms of the VNOAD preclude discussion of opioids, their risks and benefits, and the indications for their use, which would be necessary information for a person to make an informed decision regarding executing or affirming execution of a VNOAD. The physician is "between a rock and a hard place." This gives rise to potential legal liability and stress.

The medical field is already stressful, with estimates placing the percentage of physicians experiencing burnout in the United States at around 30 to 40 percent (Dyrbye & Shanafelt, 2011). If the use of VNOADs results in the aforementioned scenarios, they are likely to increase the level of burnout and emotional distress amongst physicians, resulting in more poor outcomes for all parties within the medical field. "Many aspects of patient care may be compromised by burnout. Physicians who have burnout are more likely to report making recent medical errors, score lower on instruments measuring empathy, and plan to retire early and have higher job dissatisfaction, which has been associated with reduced patient satisfaction with medical care and patient adherence to treatment plans" (Dyrbye, & Shanafelt, 2011). Not implementing NOADs within a healthcare system would avoid introducing an additional source of physician stress and burnout.

3.6 Family Distress

Hospital visits are stressful events for patients, and stress also extends to family, particularly those who are charged with making medical decisions on behalf of patients who cannot make decisions themselves. To mitigate such stress people should be encouraged to make thoughtful and informed end-of-life decisions in advance of the need for them. Because observing a loved one suffer is especially distressing, it is particularly important to address how an individual's pain should be managed toward the end-of-life and how to balance pain control with other patient values. "One in five Americans die using intensive care services. Therefore, ICU core competencies should include the provision of quality end-of-life care in addition to life-sustaining care" (Angus, 2004). Additionally, there is growing concern for "Post-Intensive Care Syndrome," a syndrome characterized by the anxiety or depression in relatives resulting from acute stress during a family member's hospitalization that may have resulted in death (Azoulay, 2012). Controlling a patient's pain is an important way to mitigate family stress during a relative's dying event, but the VNOAD may prevent adequate pain control and even prevent discussion of the possibility of using opioids.

3.7 NOAD Appropriateness for West Virginia

There is a question of the appropriateness of West Virginia's VNOAD within West Virginia, because the VNOAD was practically wholly borrowed from Massachusetts. Some of its specific terminology, for example, is not clearly applicable to the citizens of West Virginia; for example, it uses the word 'agent' which is not recognized in West Virginia medico-legal language.

Another difference between Massachusetts and West Virginia may be even more important. WalletHub, a credit score and financial information site, publishes reports on jobs, the economy and financial matters. It ranked educational levels of states according to several parameters. Massachusetts ranked in at #1, while West Virginia ranked 49th. West Virginia came in 50th for the number of adults with college experience or bachelor's degrees, and 48th for graduate degree holding adults (McCann, 2019). A state's development and implementation of a NOAD should consider the health literacy within the population the document is likely to be used. Specifically, regarding West Virginia, there should be consideration of whether special care should be taken when addressing SUD in with the context of poverty and low education level.

The use of a NOAD document may not be appropriate in WV if its implementation does not take sufficient account of the vulnerability of populations, or characteristics like impoverishment and low education level that are correlated with opioid drug use. Low levels of education may make it especially challenging for people to recognize the long-term broad implications of executing the VNOAD. The NOAD document may not present the same level of risk in Massachusetts, one of the most educated states in the country, because individuals there may look at the document with greater skepticism. One safeguard would be for West Virginia—indeed, for any state—to mandate that a physician-patient discussion take place prior to allowing a person to execute a NOAD and prior to a physician certifying it. A second safeguard would be to eliminate the ease with which parties other than the patient can sign a VNOAD into place.

3.8 Populations Likely to be Affected by a VNOAD

3.8.1 Opioid Allergy Population

Although the VNOAD was developed primarily for use by individuals with SUD, other patient populations may be attracted to executing a VNOAD. For patients with an opioid allergy, executing a VNOAD might seem to be beneficial, but is also likely unnecessary and suboptimal. While patients with an opioid allergy could benefit from having their medical record flagged to avoid the prescription or administration of opioids to them, there are other means of achieving this result. Their allergy could and should be recorded in their medical record. Moreover, with the existence of allergy bracelets and allergy alerts on medical order interfaces, the VNOAD for this indication seems unnecessary.

While execution of a VNOAD may achieve the result of avoiding receipt of opioids, other means are more appropriate, particularly because having a VNOAD is associated with having SUD. Thus, having a VNOAD could mark a person as having a SUD and result in stigmatization. Moreover, in the medical setting where balancing of pain control and patient management or outcome is important, there should be a clear delineation of the levels of risk and the severity of the patient's opioid-induced allergic reaction, which should be balanced against the severity of pain and health-related responses. Importantly, "morphine causes the release of histamine, frequently resulting in itching, but this is not an allergic reaction. True allergy to opioid agents (e.g. anaphylaxis) is not common but does occur" (Utah Department of Health, 2008). Furthermore, "generally, [an] allergy to one opioid agent does not mean the patient is allergic to [all] opioids; switching to an agent in another opioid drug class may [also prove] be effective" (Utah Department of Health, 2008). The VNOAD in such a case would not allow for other

beneficial paths to be discussed and optimal pain relief reached. However, an allergy alert would be more effective as it would trigger clinical judgment and patient-physician discussion, whereas the VNOAD stops it. Additionally, it is important to note that allergies may not have been recorded accurately, and clinicians should be free to determine whether a patient may eventually benefit from opioid intervention. In a scenario where opioid pain medication is indicated, it would be best to allow for a patient-physician discussion, which the VNOAD does not. For patients without clearly documented evidence of an opioid allergy, the VNOAD's complete restriction of opioid medication may prove more restrictive than beneficial. Thus, the VNOAD is actually a poor tool to address the needs of the opioid-allergic population and most likely inferior to current standard hospital measures already in place for patients with allergies.

3.8.2 Patients without SUD who Fear Addiction

For individuals who neither currently have, nor have historically had SUD, use of the VNOAD will likely be of only minimal (if any) benefit to avoid addiction or SUD. Instead, clinicians' following prescribing practice guidelines and counseling patients in regard to pain medication would better serve such individuals. SUD is a chronic illness that can often be avoided with proper pain management. It is important for physicians to help people understand the difference between acute pain and chronic pain, differences in their treatment, and the chances of developing SUD as a result of treating acute versus chronic pain. Ironically, avoiding appropriate opioid medication during a time of acute pain could potentially lead to chronic pain and greater need of opioid usage or use of higher dosages. Undertreated or untreated acute post-operative pain has been suggested to increase the patient's risk of developing chronic pain (Kehlet, Jensen, &

Woolf, 2006; Anson, 2016). Thus, there is health-related risk attending people's execution of VNOADs because they fear addiction.

Executing a VNOAD is like bringing a shotgun instead of a key to open a door. It is very much jumping the gun. Individuals using a VNOAD to avoid SUD may not realize the instrument's full implications. Signing a VNOAD results in lack of access to opioid pain control for terminal disease, post-surgical pain, and emergency scenarios. It is likely that the individual trying to avoid addiction is not considering such scenarios or is not accurately weighing the relative risks of SUD and intense or intractable pain. They may be acting out of fear of the much-publicized ill-effects of opioid misuse, or they just want their physician to be more deliberate about avoiding opioids when not absolutely necessary. For these patients, their executing a VNOAD cannot be considered an informed refusal of opioids or an informed advance directive regarding their future care.

4.0 Suggestions for Moving Forward

The VNOAD is an ethically problematic measure to address opioid misuse within the healthcare system and broader society. Having to accept the VNOAD as a reality, as well as desiring to mitigate harms toward those currently using the document, it is possible to suggest some measures to mitigate the harm of the VNOAD as currently designed and implemented.

First, a thorough physician-patient discussion should be required. This discussion should be required prior to the VNOAD being executed. The guidelines for the discussion should incorporate an acknowledgement of the VNOAD's preempting of any future discussion of opioids as a treatment option, even when medically indicated, as well as helping the patient appreciate how pain can affect quality of life and health. It should include discussion of how the failure to use opioids may be detrimental within the treatment of patients with SUD, as well as the benefits of avoiding their use. The discussion should also acknowledge stigma that the document may carry. The discussion should also describe how the VNOAD may be revoked, and conditions under which its revocation would be advisable. Second, only the incompetence (decisional incapacity) of the patient (person who is the subject of the NOAD) should permit someone other than the patient to execute a NOAD. Only if the patient lacks decisional capacity should she or he not be aware of the VNOAD. Third, within regulations creating the possibility of a NOAD, there should be stipulation of conditions or scenarios under which the VNOAD would be automatically revoked or voided. These scenarios that would automatically void the VNOAD should be thoroughly discussed with the patient or surrogate.

Requiring a thorough physician-patient discussion of the risks, potential benefits, and limitations of the VNOAD would benefit those using the VNOAD by promoting their autonomy

by helping to ensure that they give their voluntary informed consent to its execution. A thorough physician-patient discussion is also crucial for those seeking to employ the VNOAD because of their actual or presumed opioid allergy. In this case, the discussion should emphasize alternative approaches to ensuring that they are not administered opioids. Finally, a thorough physician-patient discussion may dissuade those fearful of developing SUD from executing a VNOAD, because it may lead them to realize that when opioids are prescribed appropriately and their use is well monitored, their likelihood of developing a substance use disorder is much less than they perceive. For each population—those with SUD, those who fear SUD, and those with an opioid allergy—it is critical for patients to recognize the role of opioids in pain management (and indeed, in SUD treatment) and the importance of managing pain and other extreme discomfort, as well as to develop a realistic view of the risk of developing or exacerbating SUD and the limited role of a VNOAD in addressing this concern. No physician should allow a patient to execute a VNOAD and submit it for inclusion in his or her medical record without making certain that a thorough discussion took place.

In cases when a surrogate executes a VNOAD, it must be ensured that the patient is at least aware that a VNOAD exists, save for patients deemed persistently incompetent. An easy way to facilitate this would be to make a mandatory policy that the patient be in the room when the VNOAD is signed into effect by a surrogate. A VNOAD executed by a surrogate should be revisited with a patient if the patient regains decisional capacity. Execution of a VNOAD by a surrogate should be a rare event, and should be permitted only in consultation with the patient's physician and only in the rare instances when executing the VNOAD is arguably in the patient's best interest or is in-keeping with the patient's values or wishes stated while still competent

Finally, there should be stipulated conditions, criteria, or medical scenarios that nullify a previously executed VNOAD, so that at least the discussion of opioids with the patient may be initiated by the physician. Scenarios that may be valid for automatic revocation or nullification of the VNOAD should include emergencies when opioid use is medically indicated, when death is imminent and opioids are necessary to promote quality of life while the patient is dying, when cancer-pain is unmanageable without opioids, in the case of post-surgical procedures that cause or are likely to cause intense pain, and when a patient has dementia and management of symptoms (e.g., pain, discomfort) is of greater concern than the patient's development of SUD or risk of SUD relapse. Importantly, the VNOAD being automatically nullified does not take away the patient's (or proxy's) right to refuse the opioid intervention. Instead, automatic nullification or revocation merely allows the physician to recommend the medication as he or she may deem fit or necessary. Stipulation of conditions under which the VNOAD is nullified would benefit those seeking to use the VNOAD to address their SUD or concern about development of SUD, by separating the chronic condition of SUD from acute conditions in which patients may benefit from short-term, well-monitored opioid use.

Michigan has employed such measures in its recent creation of a NOAD (figure 3). In Michigan, the NOAD is inactivated in emergency scenarios. The Michigan form (see figure 3) states, "this directive does not apply to... a patient [who] is being treated at a hospital, or in a setting outside of a hospital in the case of an emergency, and, in the prescriber's professional opinion, the administration of the opioid is medically necessary to treat the individual." Clearly, an emergency is a time of crisis, it is acute, and stabilization of a patient is the predominant issue. Another appropriate time for a NOAD to be inapplicable is toward the end of life or when death

is imminent. At that time, a conversation about the appropriate balance between pain control and other patient values should be initiated by the physician.

Further, when a patient is diagnosed with cancer and either the cancer itself or surgery is likely to occasion severe pain, a physician should not just be permitted, but should be required to discuss whether the patient with a NOAD wants to affirm it, i.e., to have it remain effective. This discussion can be initiated without specifically talking about, offering, or recommending opioids. The focus of the discussion can be, at least initially, whether the patient wants to maintain his or her NOAD. There is a substantial proportion of individuals suffering from cancer who require opioids to manage pain; it is estimated that about two-thirds of cancer patients in pain would have opioids indicated as part of the 3rd step on the WHO analgesic ladder (Rajagopal, et al., 2007). In addition, as cancer brings closer an ever more imminent death for the individual it is possible that their alignment of goals no longer has opioid avoidance or mitigation of SUD as higher than pain control. Particularly because SUD is a chronic condition, which terminally ill patients may not develop (or are likely not to care about if they are in hospice, for example), discussion of whether they want to continue to refuse opioids should not be overly concerning. Physicians' duties to reduce suffering and promote patient well-being support aggressive pain management, including opioid use, toward the end of life.

Furthermore, post-surgical procedures likely to cause intense pain should also be grounds for automatic VNOAD revocation or nullification, because intense pain can lead to a higher likelihood of post-surgical complications as well a slower healing process. In addition, undertreating or not treating acute pain can also lead to a higher likelihood of developing chronic pain.

Dementia should also be a condition that leads to the automatic revocation or nullification of a VNOAD. For patients with severe dementia, the reasons that led them to execute a VNOAD may no longer apply, or they may no longer be aware of them. Addiction may no longer be a fear. Concern about SUD relapse may no longer be relevant. Dementia is a terminal condition, though the process toward death may take a long time. Patients with severe dementia are likely to be well-monitored, either in a skilled nursing facility or at home by informal caregivers and family. It is highly unlikely that such a regulated environment would lead to SUD in the patient, and even if so, the team can carefully manage the patient to ween appropriately. Patients with dementia may have therapeutic reasons for opioids, such as discomfort, and their current interests in mitigating pain and discomfort are likely to outweigh previously expressed interests in living opioid-free. It is important that patients with dementia have as good a quality of life as can be offered, and without opioid use agitation may ensue and physical restraints or restrictions on movement may be employed, thereby reducing the person's quality of life. To promote the patient's quality of life and dignity, it is important to avoid such restraints and restrictions as much as possible, even if opioids need to be administered.

Lastly, insofar as a VNOAD was created to aid in SUD treatment, a person executing a VNOAD should not result in restriction of opioid usage needed as part of SUD therapy. The Michigan NOAD, for example, specifically states that the document does not apply in the context of SUD treatment. SUD clinics rely heavily on creating an environment conducive to healthcare, emphasizing strong patient-centered care. The VNOAD undermines the goals of these healthcare facilities, such as methadone clinics. As the West Virginian VNOAD is currently written, it is incompatible with therapies requiring the use of opioid substances. There is also a danger that increased usage of the VNOAD begins to invalidate therapies like buprenorphine or suboxone

treatment in the public opinion. This would be especially unfortunate because, as Harris and McElrath (2012) suggest, “social control and institutional stigma create the conditions for poor outcomes with [methadone therapy].” They cite factors such as arbitrary rules within certain healthcare settings and patients feeling that they are being held in contempt by healthcare personnel as examples of what may result in poor patient outcomes. If the popularity of VNOADs further stigmatize the use of methadone, buprenorphine, or suboxone, the underlying goal of the instrument’s development—to reduce SUD and deaths due to opioids—would be undermined.

NONOPIOID DIRECTIVE

Michigan Department of Health and Human Services
Required by MCL 333.9145 effective 3/28/2019

MUST BE INCLUDED IN THE PATIENT'S MEDICAL RECORD

Patient Name [REDACTED]	Date of Birth [REDACTED]
Other names used by patient [REDACTED]	Preferred language of patient [REDACTED]
Emergency Contact [REDACTED]	Name of primary care provider [REDACTED]
Drug allergies [REDACTED]	
<p>The patient above must not be administered an opioid or offered a prescription for an opioid while this directive is in effect.</p> <ul style="list-style-type: none">• An individual who has executed a nonopioid directive on their own behalf may revoke the directive at any time and in any way they are able to communicate their intent to revoke the form.• A guardian or patient's advocate can revoke at any time by issuing a revocation in writing and providing notice of the revocation to the individual's health professional or their delegate.• This directive does not apply to:<ul style="list-style-type: none">•• A patient receiving opioids for substance use disorder treatment;•• A patient who is in hospice;•• A patient is being treated at a hospital, or in a setting outside of a hospital in the case of an emergency, and, in the prescriber's professional opinion, the administration of the opioid is medically necessary to treat the individual.	
Signature of patient, or if the patient is a minor, parent [REDACTED]	Date [REDACTED]
Printed name of Patient [REDACTED]	Date [REDACTED]
Signature of guardian or patient's advocate, if applicable [REDACTED]	Date [REDACTED]
Printed name of parent/guardian/patient's advocate, if applicable [REDACTED]	Date [REDACTED]
The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group because of race, religion, age, national origin, color, height, weight, marital status, genetic information, sex, sexual orientation, gender identity or expression, political beliefs or disability.	

MDHHS-5793 (3-19)

Figure 3 Michigan NonOpioid Directive Image

5.0 Conclusion

Overall, the West Virginia VNOAD is a poor instrument, and its employment should be met with skepticism. Physicians should advise against patients' use of them. The VNOAD disrupts physician-patient communication, increases several aforementioned risks for patients in the healthcare setting, and undermines patient autonomy. Having a VNOAD may itself be stigmatizing even for those without SUD, and for those with SUD having a VNOAD may undermine SUD treatment protocols in which opioids are used to treat patients. The document does not further patients' overall healthcare goals, and conditions for its revocation are not clearly delineated. The document not only affects patients, but also affects physicians and other clinicians by potentially increasing their distress both as a result of the liability exposure the document presents to physicians prevented from providing standard of care and because of the stress clinicians experience watching patients suffer pain that they are prevented from attempting to control effectively. Likewise, families may experience distress in scenarios in which the patient is experiencing a great deal of pain without appropriate pain medication.

For states considering the implementation of a NOAD they would be wise to mandate that there be a thorough physician-patient discussion prior to execution of the document, as well as a process to ensure that only if a patient is incompetent (lacks decisional capacity) may a NOAD be executed by others without the patient's participation and consent. The physician-patient discussion—with the patient or with a surrogate if the patient lacks decisional capacity—should include discussion of contexts in which prescription of opioids is standard of care and alternatives to opioids if they exist, as well as disclosure of contexts in which there may be no effective alternative to opioid use. The physician should explain how pain can affect both quality of life and

health status, and how execution of a NOAD may and may not contribute to avoidance of development of SUD or SUD relapse. The physician should make a recommendation regarding how the document could benefit the patient or explain why he or she believes it is not indicated. The physician should disclose that the document may itself be stigmatizing by leading others to view the patient as having the stigmatizing condition of SUD. States should also stipulate scenarios in which the NOAD is automatically revoked (e.g., to allow discussion of the document after a cancer diagnosis, to allow appropriate pain management following surgical procedures likely to cause intense pain, and to afford appropriate comfort measures for patients diagnosed with dementia, and environments in which the NOAD's application would be restricted (e.g., in dementia or hospice care, or in SUD treatment). These measures may mitigate the harms otherwise done by use of NOADs.

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