Need Mental Health Care? Sign Here: Signature Consent for Psychotropic Medication

Every thought you produce, anything you say, any action you do, it bears your signature.
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Fed Pract. 2026;43(8).
Published online August 10.
doi:10.12788/fp.0754

Almost everyone has been asked to sign a consent form to receive medical care. Some of us diligently read every word (usually on a tablet these days) and deliberate about proceeding. Many more of us either skim or just sign.

Seldom, if ever, does the person holding the tablet ask if we have any questions. I recall taking my mother, an older veteran, to a community ophthalmologist for cataract surgery years ago and being appalled when a nonclinical clerk handled the informed consent process. That experience is not uncommon. In many clinical settings outside the Veterans Health Administration (VHA), signing the consent form has become *pro forma* and perfunctory. Yet when we get blood drawn for routine laboratory tests or an X-ray of our foot taken to see if we broke a toe playing pickleball, we are generally not asked for explicit consent. There is a legal and ethical standard for routine, low-risk, or simple treatments and procedures when patients provide implicit consent. There is also a legal standard for oral consent that the clinician documents in the clinical note, which is usually sufficient.

Federal law and US Department of Veterans Affairs (VA) policy have set a higher standard for informed consent than many academic or community health care systems.[2] Now, 35 veterans groups are demanding Congress pass a bill they think will provide even greater protection through the use of signature consent.[3] The Written Informed Consent Act is bipartisan legislation that would expand the Veterans Health Administration informed consent directive to apply to broad classes of psychiatric medications.[4]

The directive—VHA Directive 1004.01 (3) Informed Consent for Clinical Treatments and Procedures—already requires signature consent for treatments and procedures that meet ≥ 1 of the following criteria: 1) Require sedation; 2) Require anesthesia or narcotic analgesia; 3) May produce significant discomfort for the patient; 4) May produce significant risk of complication or morbidity; or 5) Require injections of any substance into a joint space or body cavity.

VHA clinical subject matter experts determine which treatments and procedures meet the risk threshold for signature consent; VHA keeps an internal list. The policy also includes a stipulation that a clinician may obtain signature consent for a treatment or procedure not listed, if they believe medical conditions present an elevated risk (eg, a patient with a comorbidity or genetic disorder that increases the risk associated with a potential medication).

Most importantly for this column, the policy contains this sentence, at least for now: "Signature consent is not permitted for treatments and procedures that do not meet the criteria outlined in paragraph 4.d.(1)(a) as the extra documentation burden on the patient is ethically unjustifiable."[5]

From a technical ethics language standpoint, the title of the bill doesn't accurately convey its purpose. Consent can be written and still not require a signature. It is the latter concern that the veterans' groups and legislators believe will "leav[e] no doubt about what information veterans are or are not provided."[3] Primarily, the groups want veterans to be informed about the potential risks of what they refer to as "mind-altering drugs." Many mental health professionals would object to this term as nonscientific and stigmatizing. The bill requires that veterans receive written information about adverse events (AEs) that may occur with these medications, which is already the norm. In the wake of the opioid epidemic, VA prudently requires signature consent for high-risk opioid drugs. The veterans groups backing the legislation and the congressional representatives supporting it want to expand that provision to psychiatric

medications they think present similar threats to veteran well-being.[6]

The American Psychiatric Association, American Psychological Association Services, National Association of Social Workers, American Academy of Family Physicians, American Academy of Neurology, and American College of Obstetricians & Gynecologists jointly submitted a letter to Congress detailing the administrative weight this burden has on clinicians and patients and the potential threats to the health and life of patients with mental health conditions it presents. The organizations stressed that extant VHA policy already requires signature consent when there are salient or particularized risks and underscored that some psychotropic medications may already fall under the signature umbrella. They object to blanket inclusion of almost every class of psychiatric medications, including antidepressants, antipsychotics, mood stabilizers, and anxiolytics that, in their view, do not present a risk so significant and unusual that they require signature informed consent.[7]

Mental health professionals inside and out of VHA are concerned the bill will have unintended consequences that undermine its ostensible purpose of enhancing shared decision-making in mental health care. Mental health care, especially for members of the uniformed services and veterans, is already stigmatized; requiring a signature may amplify the aversion to seek it.[8] It may also communicate to already wary veterans that drugs that could literally be lifesaving, may present a level of risk that is not supported scientifically despite what social media tells them. Rather than increasing the already overtaxed mental health practitioners and pharmacists with more administrative tasks, the money and time this bill will cost could be directed toward meeting the shortage of VHA mental health professionals, a far more serious risk to the well-being of veterans.[9] More profoundly, the bill would supplant professional judgment borne of years of training and experience for each individual patient with a generalized bureaucratic approach to prescribing medications for veterans with complex psychosocial, medical, and mental health presentations.

The bill is intended to address what the veterans groups and some media outlets feel is the current dangerous prescribing of multiple psychiatric medications for anxiety, depression, and posttraumatic stress disorder to veterans without fully educating and counseling patients about potential AEs (eg, suicidal ideation, agitation).[3] The bill is a response to tragic narratives of veterans—some who died by suicide, others who lived with severe distress and an inability to function—that they or their families or advocates attribute to psychiatric medication-related AEs.[10]

These stories deserve our utmost empathy and engagement. Mental health professionals acknowledge the clinical ethics obligation to safely and responsibly discontinue medications that are inappropriately prescribed.[11] Nor is this a duty unique to psychiatry. During my years as a consultation-liaison psychiatrist, I would tell my trainees that our job was to "hoover" (my term for deprescribing) the medication list to reflect a more rational pharmacotherapy. However, that problem is complicated and far too multidetermined to be reduced to the addition of a signature on a consent form.

There is no strong evidence that signature consent improves the quality of the clinicians' disclosure or the patient's understanding of key information about a medication. Nor is there overwhelming data that it does not. Some experts in health law and ethics caution it is more likely both parties will focus on the signature and the form rather than the personalized conversation. No requirement can ever replace the therapeutic alliance which is more crucial in mental health care than in any other area of medicine.[12]

As the epigraph argues, it is the integrity of the professional, the patient's trust in the practitioners' commitment to their well-being, and the mutual trust between them that is essential to ensure veterans are given the information needed to fully and authentically provide informed consent based on their own values and preferences for psychotropic medications.

Disclaimer

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