WEST VIRGINIA LEGISLATURE

2020 REGULAR SESSION

Introduced

Senate Bill 681

BY SENATORS TRUMP, MARONEY, AND RUCKER

[Introduced January 31, 2020; referred

to the Committee on Health and Human Resources]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §33-15F-1, §33-15F-2, §33-15F-3, §33-15F-4, §33-15F-5, §33-15F-6, §33-15F-7, and §33-15F-8, all relating to creating the Persistent Symptoms Act; making findings; setting forth the rights of health insurance providers and patients; establishing the access to approved and indicated or investigational drugs, biological products, and devices for patients who suffer from persistent symptoms; limiting causes of action; setting forth the effect on health care coverage; and defining terms.

Be it enacted by the Legislature of West Virginia:

ARTICLE 15F. PERSISTENT SYMPTOMS ACT.

§33-15F-1. Short title.

This article shall be known and may be cited as the Persistent Symptoms Act.

§33-15F-2. Findings.

The Legislature finds and declares that:

(1) Medical practice guidelines provide information to help doctors with physiology descriptions, applicable diagnostics, and recommended therapies to return patients to their healthy conditions. However, some guidelines maintain persistent symptoms and do not return patients to health;

(2) The process of approval for investigational drugs, biological products and devices in the United States protects future patients from premature, ineffective, and unsafe medications and treatments over the long run, but the process often takes many years;

(3) Patients who have persistent symptoms do not have the luxury of waiting for a medical association to eliminate the maintenance of persistent symptoms in their guideline or accessing available investigational drugs, biological products and devices not recommended by applicable medical practice guidelines;

(4) Patients who have persistent symptoms have two fundamental rights to attempt to pursue the improvement of their own lives by accessing available Food and Drug Administration

approved and indicated drugs, biological products or products, grand-fathered by the Food, Drug, and Cosmetic Act of 1938 and devices or by accessing investigational drugs that have only passed the Food and Drug Administration first approval stage requirements;

(5) The use of available approved or grandfathered and indicated drugs, biological products and devices or the use of investigational drugs, biological products and devices is a decision that should be made by the patient with a persistent symptoms in consultation with the patient's health care provider and the patient's health care team, if applicable;

(6) The decision to use an approved and indicated drug, biological product or device, or investigational drug, biological product or device should be made with full awareness of the potential risks, benefits, and consequences to the patient and the patient's family, wherein said consequences shall include the disruption of the patient's family and well-being of the patient's family and ability to be a productive citizen; and

(7) Diseases known to produce persistent symptoms are the persistent symptoms of hypothyroidism and chronic Lyme disease, which have the common characteristics of ignored critical physiology, prescribed inadequate diagnostics and therapy, and prescribed effective drugs.

§33-15F-3. Definitions.

For the purposes of this article:

"Approved and indicated drug, biological product or device" means a drug, biological product or device that has been approved and indicated for general use by the United States Food and Drug Administration or grandfathered by the Food, Drug, and Cosmetic Act of 1938.

"Eligible patient" means a person who has:

(A) Persistent symptoms without medical practice guideline recommended therapy attested to by the patient's treating physician;

(B) Considered all other treatment options currently approved by the United States Food and Drug Administration or as grandfathered by the Food, Drug, and Cosmetic Act of 1938;

(C) Been unable to participate in a clinical trial for the persistent symptoms within 100 miles of the patient's home address for the persistent symptoms, or not been accepted to the clinical trial within one week of completion of the clinical trial application process;

(D) Received a recommendation from his or her physician for an approved and indicated drug, biological product or device, or investigational drug, biological product or device;

(E) Given written, informed consent encompassing the physiological action and medical benefit of the use of the approved and indicated drug, biological product or device, or investigational drug, biological product or device, or if the patient is a minor or lacks the mental capacity to provide informed consent, a parent or legal guardian has given written, informed consent on the patient's behalf; and

(F) Documentation from his or her physician that he or she meets the requirements of this subdivision.

"Eligible patient" does not include a person being treated as an inpatient in a hospital licensed or certified pursuant to §16-5B-1 of this code.

"Investigational drug, biological product or device" means a drug, biological product or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration and remains under investigation in a United States Food and Drug Administration-approved clinical trial.

"Persistent symptoms" means the continuing or chronic symptoms of a disease that, without appropriate interventions, will continue with significantly reduced quality of life until death.

"Written, informed consent" means a written document signed by the patient and attested to by the patient's physician and a witness that, at a minimum:

(A) Explains the currently approved and/or investigational products and treatments for the disease or condition from which the patient suffers;

(B) Attests to the fact that the patient concurs with his or her physician in believing that all currently guideline recommended, and conventionally recognized treatments, are unlikely to

improve the quality of life and reduce the suffering by the patient;

(C) Clearly identifies the specific proposed approved and indicated drug, biological product or device, or investigational drug, biological product or device that the patient is seeking to use;

(D) Describes the potentially best and worst outcomes of using the approved and indicated or investigational drug, biological product or device with a realistic description of the most likely outcome, including the possibility that new, unanticipated, different or worse symptoms might result and the persistent symptoms may not be mitigated by the proposed treatment based on the physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition;

(E) Makes clear that the patient's health insurer and provider may not be obligated to pay for any care or treatments consequent to the use of the investigational drug, biological product or device;

(F) Makes clear that the patient's eligibility for hospice care may be withdrawn if the patient begins treatment and care may be reinstated if the treatment ends and the patient meets hospice eligibility requirements;

(G) Makes clear that in-home health care may be denied if treatment begins; and

(H) States that the patient understands that he or she may be liable for all expenses consequent to the use of the investigational drug, biological product or device, and that this liability extends to the patient's estate, unless there is a contract between the patient and the manufacturer of the drug, biological product or device states otherwise. However, insurance denial appeals may be based upon the approved and indicated drug may also be associated with sufficient medical science that it is not experimental.

§33-15F-4. Availability of investigational drugs, biological products or devices; costs; insurance coverage.

(a) Nothing in this article expands the coverage required by §33-15-1 *et seq.* of this code as applicable to investigational drugs, biologic products or devices.

(b) A health insurance carrier may, but is not required by this article to, provide coverage for the cost of an investigational drug, biological product or device.

(c) An insurer may deny coverage to an eligible patient from the time the eligible patient begins use of the approved and indicated drug, biologic product or device through a period not to exceed six months from the time the approved and indicated drug, biologic product or device is no longer used by the eligible patient; except that coverage may not be denied for a preexisting condition and for coverage for benefits which commenced prior to the time the eligible patient begins use of such drug, biologic product or device.

(d) If a patient dies while being treated by an approved and indicated drug, biological product or device, the patient's heirs are not liable for any outstanding debt related to the treatment or lack of insurance due to the treatment;

(e) The patient's West Virginia health insurance must cover the costs of approved and indicated drugs, biological product or device reduced by patient's insurance customary co-pays.

§33-15F-5. Action against health care provider's license or Medicare certification prohibited.

(a) Notwithstanding any other law, a licensing board may not revoke, fail to renew, suspend or take any action against a health care provider's license issued pursuant to chapter 30 of this code based solely on the health care provider's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product or device as long as the recommendations are consistent with medical standards of care. Action against a health care provider's Medicare certification based solely on the health care provider's recommendation that a patient have access to an investigational drug, biological product or device is prohibited.

(b) The healthcare provider must provide or be responsible for basic and timely care and progress checks.

(c) Any investigation of provider's decisions must comply with West Virginia and Federal Rules of Evidence, which basically invalidates the evidentiary philosophy of evidence-based

medicine.

§33-15F-6. Access to approved and indicated or investigational drugs, biological products and devices.

An official, employee, or agent of this state shall not block or attempt to block an eligible patient's access to an approved and indicated or investigational drug, biological product or device. Counseling, advice, or a recommendation consistent with medical standards of care from a licensed health care provider is not a violation of this section.

§33-15F-7. Cause of action.

No cause of action is created against physicians or manufacturers, but a cause of action may accrue against responsible medical associations. However, insurance companies do have a cause of action against medical association authors of one or more medical practice guidelines that maintain persistent symptoms until such guideline are obsoleted by a new guideline.

This article does not create a private cause of action against a manufacturer of an approved and indicated or investigational drug, biological product or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological product or device, for any harm done to the eligible patient resulting from the investigational drug, biological product or device, so long as the manufacturer or other person or entity is complying in good faith with the terms of this article, unless there was a failure to exercise reasonable care.

This article, however, allows insurance companies liable to the patients by this act to have a cause of action against medical association authors of one or more medical practice guidelines that maintain persistent symptoms until such guideline are obsoleted by a new guideline.

§33-15F-8. Effect on health care coverage.

Nothing in this section affects the mandatory health care coverage for participation in clinical trials pursuant to §33-25F-2 of this code.

NOTE: The purpose of this bill is to create the Persistent Symptoms Act. The bill makes

findings. The bill sets forth the rights of health insurance providers and patients. The bill establishes the access to approved and indicated or investigational drugs, biological products and devices for patients who suffer from persistent symptoms. The bill limits causes of action. The bill sets forth the effect on health care coverage. The bill defines terms.

Strike-throughs indicate language that would be stricken from a heading or the present law, and underscoring indicates new language that would be added.