1. PURPOSE

The purpose of this notice is to provide interim policy while a new Right to Try directive and changes to the Investigational Drugs and Supplies regulation are being prepared. The notice establishes an interim process for approvals of eligible investigational drugs that are administered under the Right to Try Act (P.L. 115-176). **NOTE: This notice does not apply to investigational drugs prescribed and administered in clinical investigations; please refer to Veterans Health Administration (VHA) Handbook 1108.04, Investigational Drugs and Supplies, dated February 29, 2012, for VHA standards on investigational drugs used in Department of Veterans Affairs (VA) research. AUTHORITY: Title 21 United States Code (U.S.C.) § 360bbb-0a; 38 U.S.C. § 7301(b).**

2. DEFINITIONS

   a. Eligible Investigational Drug. An eligible investigational drug has completed Food and Drug Administration (FDA) approved Phase 1 clinical trial, has not been approved or licensed for use by the FDA, is in an active clinical trial under an application for approval or subject for an application for approval that has been filed with the FDA and is under ongoing active development or production that has not been discontinued by the manufacturer or placed on a clinical hold. **NOTE: This definition may only be used for purposes of this directive.**

   b. Eligible Patient. An eligible patient is a patient that is diagnosed with a life-threatening disease or condition, has exhausted approved treatment options, is unable to participate in a clinical trial involving the eligible investigational drug as certified by a physician and provides written informed consent regarding the risks associated with taking the eligible investigational drug.

   c. Life-Threatening Disease or Condition. A life-threatening disease or condition is a disease or condition where the likelihood of death is high unless the course of the disease is interrupted and a disease or condition with potentially fatal outcomes, where the end point of clinical trial analysis is survival.

3. PROCESS

To administer an eligible investigational drug to a VA medical facility eligible patient, the following steps must be followed:

   a. Before administration of an eligible investigational drug to a patient, the VA medical facility Director will execute a written agreement between the VA medical facility and a
sponsor supplying an eligible investigational drug. The VA medical facility Pharmacy Services will maintain the agreement as part of the VA medical facility’s records.

b. The VA medical facility Chief of Staff must approve any health care provider before they can order an eligible investigational drug.

c. The prescribing health care provider must provide the VA medical facility Pharmacy Service information about the eligible investigational drug, including allergies, toxicities or adverse drug reactions related to the investigational drug or the potential for interaction with other drugs, foods or dietary supplements, including a prescription for the eligible investigational drug. **NOTE:** The prescribing physician must be in good standing with their licensing organization or board and will not be compensated directly by the manufacturer.

d. The patient or the patient’s legally authorized representative must sign and date a consent form prior to dispensing an eligible investigational drug under the Right to Try Act. The consent form must be maintained as part of the VA medical facility’s Pharmacy Service records. Required elements of the consent form must include:

(1) Name of the drug,

(2) A statement that the drug is investigational but that this activity is not research as the drug is being administered under the Right to Try Act,

(3) An explanation of the purposes of the drug and a description of the procedures to be followed,

(4) A description of any reasonably foreseeable risks or discomforts to the patient,

(5) A description of any benefits to the patient that may reasonably be expected from the drug,

(6) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might benefit the patient,

(7) A statement of any costs that would be incurred by the patient for treatment with the drug and

(8) An explanation of whom to contact for answers to pertinent questions about the drug.

e. Prior to the administration of the eligible investigational drug, a local VA medical facility ethics consultation is required if there is a values-based uncertainty or conflict about prescribing or administering the eligible investigational drug.

f. The VA medical facility Pharmacy Services must be notified in writing upon administration of an eligible investigational drug by the prescribing health care provider. The VA medical facility Pharmacy Service will notify Pharmacy Benefits Management
Services. VA medical facility patients will not be charged a co-payment for eligible investigational drugs under Right to Try. If the VA medical facility is required to purchase the eligible investigation drug, consultation with the VA medical facility Pharmacy Services is required for approval on reimbursement and payments. **NOTE:** Clinical judgment, such as provider determination of medical necessity of a drug, must be applied in all scenarios of eligible investigational drug administration decisions under the scope of this notice. A VA physician is not obligated to make a request for treatment of an eligible investigational drug.

4. FOOD AND DRUG ADMINISTRATION REPORTING

Drug manufacturers are responsible for reporting the use of eligible investigational drugs administered by VA health care providers under the Right to Try Act to FDA.

5. LIABILITY

VA medical facility patients who receive eligible investigational drugs under the Right to Try Act do not release VA from liability. There is no liability against the sponsor manufacturer, prescriber, dispenser or other individual entity for acts or omissions regarding eligible investigational drugs unless the relevant conduct constitutes reckless or willful misconduct, gross negligence or an intentional tort under applicable State law. Additionally, there is no liability for a sponsor manufacturer, prescriber, dispenser or other individual entity for its determination not to provide access to an eligible investigational drug. See 21 U.S.C. § 360bbb-0a note.

6. All inquiries concerning this action should be addressed to the Office of Research and Development (10X2) at 202-443-5600.

7. This VHA notice will be archived as of July 31, 2021. However, the rescission information will remain in effect.

**BY DIRECTION OF THE OFFICE OF THE UNDER SECRETARY FOR HEALTH:**

/s/ Lucille B. Beck, PhD.
Senior Advisor to the Under Secretary for Health

**DISTRIBUTION:** Emailed to the VHA Publications Distribution List on July 27, 2020.