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119TH CONGRESS
1ST SESSION

H. R. 6580

To amend title 38, United States Code, to make certain improvements in the administration of the national formulary of the Department of Veterans Affairs, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 10, 2025

Mrs. MILLER-MEEKS introduced the following bill; which was referred to the Committee on Veterans' Affairs

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A BILL

To amend title 38, United States Code, to make certain improvements in the administration of the national formulary of the Department of Veterans Affairs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''VA National Formulary Act of 2025''.

SEC. 2. CODIFICATION AND IMPROVEMENT OF DEPARTMENT OF VETERANS AFFAIRS NATIONAL FORMULARY.

(a) IN GENERAL.—Chapter 73 of title 38, United States Code, is amended by adding at the end the following new subchapter:

''SUBCHAPTER VI—NATIONAL FORMULARY

''§ 7385. National formulary

''(a) ESTABLISHMENT.—The Secretary shall maintain a national formulary that shall consist of a list of all drugs and supplies that shall be available by prescription through all medical facilities of the Department. The Pharmacy Benefits Management Service of the Department shall be responsible for managing the national formulary.

''(b) LOCAL FORMULARY RESTRICTIONS.—(1) The national formulary shall be implemented uniformly across all Department medical facilities. Except as provided in paragraph (2), no Veterans Integrated Service Network or individual medical center may maintain a local formulary that includes a drug or medication not listed on the national formulary.

''(2) A drug that is not on the national formulary may be provided to a veteran if—

''(A) the drug is provided under the nonformulary medication request process under section 7387 of this title; or

''(B) the Under Secretary for Health (or the Under Secretary's designee at the national level) has explicitly approved a waiver allowing a Veterans Integrated Service Network or facility to carry the drug for a defined patient population or clinical program.

''(3)(A) The Director of a Veterans Integrated Service Network or of a medical facility may request a waiver under paragraph (2)(B) through the Pharmacy Benefits Management Services.

''(B) The Secretary shall establish a centralized review process for considering such waiver requests, which shall include an assessment of clinical need, safety, and cost-effectiveness. A waiver issued under this paragraph shall be time-limited and reviewed periodically for continuing necessity.

''(C) Nothing in this subsection shall be construed to limit the ability of a clinician to prescribe a nonformulary drug for a veteran when medically necessary in accordance with section 7387 of this title.

''(c) PUBLIC COMMUNICATION OF FORMULARY DECISIONS.—(1) The Secretary shall communicate regularly

with the general public regarding the management of the national formulary. Such communication may include public briefings or online announcements to explain formulary decisions.

''(2) In the case of any change to the national formulary that the Secretary determines may significantly affect veteran care or access (including the exclusion of a medication that was previously commonly used, or the addition of a new high-cost therapy with usage restrictions), the Secretary shall publish a summary of the rationale for the change (including consideration of clinical evidence and outcomes) and, when feasible, hold a public briefing or stakeholder call to discuss the change and address questions.

''(d) REPORTING REQUIREMENTS.—(1) The Secretary shall submit to the Committees on Veterans' Affairs of the Senate and House of Representatives an annual appeals report that includes a detailed description of nonformulary decisions and appeals made during the year covered by the report.

''(2) Not less frequently than annually during the five-year period beginning on the date of the enactment of this section, the Secretary shall submit to the Committees on Veterans' Affairs of the Senate and House of Representatives, and make publicly available, a report that in-

cludes a summary of any changes made to the national formulary of the Department during the preceding year. Each such report shall include a list of all drugs added to or removed from the formulary, and any modifications to usage criteria or prior authorization requirements, during the year covered by the report.

"§ 7386. Pharmacy and Therapeutics Committee

''(a) ESTABLISHMENT.—There is established within the Veterans Health Administration a Pharmacy and Therapeutics Committee (in this section referred to as the 'Committee') to support the Pharmacy Benefits Management Services in managing the national formulary of the Department.

''(b) COMPOSITION.—The members of the Committee shall be selected by the Secretary and shall be physicians from major clinical specialties, clinical pharmacists, and pharmacoeconomists who are employees of the Department. In selecting members of the Committee, the Secretary shall ensure the inclusion of individuals with expertise in geriatric care and mental health care for veterans.

''(c) CONFLICTS OF INTEREST.—(1) The Secretary shall ensure that each member of the Committee is free of any conflict of interest with the pharmaceutical industry.

''(2) The Secretary shall—

''(A) require each member of the Committee to annually disclose financial interests; and

''(B) prohibit the participation by any member in formulary decisions for which the member has a financial conflict of interest.

''(d) TIMELY REVIEW OF NEW MEDICATIONS.—The Committee shall meet not less often than monthly (or bi-monthly) to review newly approved drugs by the Food and Drug Administration. The goal of the Committee with respect to each such newly approved drug shall be to make a national formulary inclusion or exclusion decision by not later than 120 days after the date on which the drug is approved, to the extent practicable.

''(e) EVIDENCE-BASED DECISION MAKING.—The Committee shall make decisions with respect to the national formulary of the Department based on evidence-based drug monographs, clinical data (including data on real-world use and outcomes), and pharmacoeconomic analyses of cost-effectiveness. In making such decisions, the Committee shall consider the applicable clinical practice guidelines of the Department and of the Department of Defense to ensure alignment with best practices in veteran care.

''(f) TRANSPARENCY OF DECISIONS.—For each significant addition to or removal from the national for-

mulary of the Department, the Secretary shall make publicly available on an appropriate website of the Department a summary of the clinical rationale for the addition or removal, including a description of the evidence and guidelines considered. Such summaries may not include proprietary pricing information or trade secrets.

"§ 7387. Nonformulary drug request process

''(a) ELECTRONIC REQUEST SYSTEM.—The Secretary shall acquire or develop and implement a standardized electronic system for handling requests by clinicians of the Department for drugs not included in the national formulary of the Department. This system shall be integrated with the electronic health record system of the Department to allow treating clinicians to submit nonformulary drug requests as part of the prescribing workflow.

''(b) TIMELINESS OF DECISIONS.—The Secretary shall establish a process to ensure that any request by a Department clinician for a nonformulary drug is decided upon promptly. Under such process, an initial decision on a nonformulary request shall be communicated to the requesting clinician within 96 hours after the request is submitted. In any case where a nonformulary request is denied, the veteran (and the requesting clinician) shall be informed of the denial and of the right to appeal under subsection (e). If an appeal is filed, a decision with respect

to the appeal shall be rendered not later than seven days after the date on which the appeal is submitted.

''(c) CONSISTENT CRITERIA AND APPROVAL STANDARDS.—The Secretary shall establish uniform criteria for evaluating nonformulary drug requests, which shall be applied across all Veterans Integrated Service Networks (herinafter referred to as 'VISNs') and medical facilities of the Department to ensure consistency. Such criteria shall be evidence-based and shall be made available to Department clinicians.

''(d) PORTABILITY OF APPROVALS.—An approval for a nonformulary drug under this section shall be valid throughout the Veterans Health Administration. In the case of a veteran for whom a nonformulary drug has been approved and who chooses to receive hospital care or medical services at a different medical center or VISN of the Department, the nonformulary approval (including any established renewal date or duration of approval) shall remain in effect at the new location, subject to the same clinical conditions or monitoring requirements that were originally imposed.

''(e) APPEALS PROCESS.—(1) The Secretary shall establish a tiered appeals process for nonformulary drug decisions. At a minimum, such process shall provide—

''(A) an opportunity for review of an initial denial by a secondary clinical reviewer or pharmacy committee at the regional or VISN level; and

''(B) a further opportunity for appeal to a national-level authority within the Pharmacy Benefits Management Services of the Department, whose decision shall be final within the Department.

''(2) The Secretary shall ensure that all clinicians of the Department are informed of the appeals process and that appeals are resolved within the timeframe specified in subsection (b).

''§ 7388. Formulary management and drug therapy programs

''(a) PERIODIC THERAPEUTIC CLASS REVIEWS.—In order to maintain a clinically appropriate and up-to-date formulary, the Secretary shall require regular reviews of groups of drugs by therapeutic class.

''(b) MEDICATION THERAPY MANAGEMENT AND DRUG USE REVIEW.—(1) The Secretary shall provide drug therapy management for veterans, with a particular focus on polypharmacy and high-risk medications.

''(2) As part of such drug therapy management, clinical pharmacy specialists shall provide comprehensive drug reviews for veterans who are on complex regimens of drugs or are at increased risk of adverse drug events.

''(3) The Secretary shall—

''(A) conduct regular reviews of drug use to identify trends, including inappropriate prescribing, drug duplication, or need for dose optimization; and

''(B) provide interventions, including provider education or patient outreach, based on the results of such reviews in order to improve therapeutic outcomes and promote drug safety and adherence.''.

(b) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by adding at the end the following new items:

''SUBCHAPTER VI—NATIONAL FORMULARY

''7385. National formulary.
''7386. Pharmacy and Therapeutics Committee.
''7387. Nonformulary drug request process.
''7388. Formulary management and drug therapy programs.''.

SEC. 3. DEPARTMENT OF VETERANS AFFAIRS PHARMACEUTICAL PURCHASING AGREEMENTS.

(a) FORMULARY-BASED PRICING AND VALUE-BASED AGREEMENTS.—

(1) IN GENERAL.—Subchapter II of chapter 81 of title 38, United States Code, is amended by inserting after section 8129 the following new section:

''§ 8130. Pharmaceutical purchasing agreements and value-based initiatives

''(a) NEGOTIATION OF SUPPLEMENTAL DISCOUNTS.—(1) In addition to the limitations on the prices

of drugs in effect pursuant to section 8126 of this title, the Secretary may negotiate additional discounts or price concessions with manufacturers of drugs procured by the Department.

''(2) In conducting negotiations under this paragraph, the Secretary may—

''(A) take into consideration the placement or tiered status of a drug on the national formulary of the Department; and

''(B) enter into an agreement with a manufacturer under which the manufacturer offers a discounted price or rebate for a drug in exchange for preferred status for the drug on the national formulary of the Department, if the Secretary determines the agreement will provide clinically appropriate outcomes for veterans and net cost savings or value to the Department.

''(3) Nothing in this subsection shall be construed to supersede the price limitations under section 8126 of this title. The Secretary shall ensure that any agreement entered into under this subsection with respect to a drug that is a covered drug under such section results in prices that are lower than the maximum price allowed under such section for such drug.

"(b) USE OF FLEXIBLE PURCHASING ARRANGEMENTS.—(1) To the extent practicable, the Secretary shall use industry best practices in the procurement of drugs and medical supplies, including the use of blanket purchase agreements, ordering agreements, and other volume-leveraging contracts to achieve favorable pricing.

"(2) The Secretary may pursue value-based purchasing arrangements with manufacturers of drugs and biological products to be included on the national formulary. Such arrangements may include contracts under which the manufacturer agrees to provide the drugs or biological products to the Secretary in exchange for payment in an amount that is determined based upon the effectiveness of the drug or biological product for veterans to whom the drug or biological product is prescribed. If the Secretary enters into such a contract under this paragraph, the Secretary shall ensure that the contract includes a mechanism to monitor the effectiveness of the drug or biological product and to adjust payments or rebates accordingly.

"(c) OUTCOME AND COST-EFFECTIVENESS EVALUATIONS.—(1) The Secretary shall conduct periodic reviews of the outcomes and budgetary effects associated with major changes to the national formulary or pharmaceutical initiatives of the Department. Not later than 180

days after concluding a periodic review under this paragraph, the Secretary shall submit to the Committees on Veterans' Affairs of the Senate and House of Representatives the results of the review.

"(2) Not later than one year after implementing any significant action affecting the national formulary, including adding a high-cost drug with usage criteria or removing a clinically used drug from the formulary, the Secretary shall evaluate the effects of that action on veteran health outcomes, drug use patterns, and overall costs to the Department. The Secretary shall make findings from such evaluations available to the Committees on Veterans' Affairs of the Senate and House of Representatives and use the findings to inform future formulary decisions and purchasing agreements.

"(d) BIOLOGICAL PRODUCT DEFINED.—In this section, the term 'biological product' has the meaning given such term in section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1))."

(2) CLERICAL AMENDMENT.—The table of sections at the beginning of such chapter is amended by adding at the end the following new item:

"8130. Pharmaceutical purchasing agreements and value-based initiatives.".

(b) ESTABLISHMENT OF TIERED SCHEDULE FOR COPAYMENTS.—

(1) IN GENERAL.—Section 1722A of title 38, United States Code, is amended by adding at the end the following new subsection:

''(d)(1) For the purpose of encouraging the use of clinically appropriate, cost-effective drugs by veterans while maintaining access to nonformulary drugs that are medically necessary, the Secretary shall establish a tiered schedule for the amount of the copayments charged to veterans for drugs furnished under this chapter.

''(2) Under the tiered schedule established under this subsection, the amount of a copayment for a 30-day supply of a generic drug or a drug listed on the national formulary of the Department shall be lower than amount of a copayment a 30-day supply of a brand-name drug or a drug not included on such national formulary.''.

(2) UPDATE OF CROSS-REFERENCE.—Subsection (a)(3)(D) of such section is amended by striking ''section 491'' and inserting ''section 2732''.

SEC. 4. VETERANS FORMULARY ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—The Secretary of Veterans Affairs shall establish an advisory committee, to be known as the Veterans Formulary Advisory Committee (in this section referred to as the ''Advisory Committee''). The Advisory Committee shall provide veteran and clinician input

on the national formulary of the Department of Veterans Affairs.

(b) MEMBERSHIP.—The Advisory Committee shall consist of not more than ten members and shall include front-line clinical providers or pharmacists of the Department who are not involved in national formulary decision-making and other stakeholder representatives as the Secretary considers appropriate.

(c) MEETINGS.—The Advisory Committee shall meet at regular intervals (at least semiannually) and shall review proposed formulary changes.

(d) RESPONSIBILITIES.—The Advisory Committee may provide to the Secretary and to the Pharmacy and Therapeutics Committee established under section 7386 of title 38, United States Code, the independent feedback or recommendations of the Advisory Committee regarding proposed additions, removals, and restrictions pertaining to the national formulary, including with respect to any potential effects on veteran patients. Recommendations of the Advisory Committee shall be advisory in nature.

(e) TERMINATION.—The Advisory Committee shall terminate on the date that is two years after the date of the establishment of the Advisory Committee.

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