

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “VA National For-
5 mulary Act of 2025”.

1 **SEC. 2. CODIFICATION AND IMPROVEMENT OF DEPART-**
2 **MENT OF VETERANS AFFAIRS NATIONAL**
3 **FORMULARY.**

4 (a) IN GENERAL.—Chapter 73 of title 38, United
5 States Code, is amended by adding at the end the fol-
6 lowing new subchapter:

7 “SUBCHAPTER VI—NATIONAL FORMULARY
8 “§ 7385. **National formulary**

9 “(a) ESTABLISHMENT.—The Secretary shall main-
10 tain a national formulary that shall consist of a list of
11 all drugs and supplies that shall be available by prescrip-
12 tion through all medical facilities of the Department. The
13 Pharmacy Benefits Management Service of the Depart-
14 ment shall be responsible for managing the national for-
15 mulary.

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

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

1 “(A) the drug is provided under the nonfor-
2 mulary medication request process under section
3 7387 of this title; or

4 “(B) the Under Secretary for Health (or the
5 Under Secretary’s designee at the national level) has
6 explicitly approved a waiver allowing a Veterans In-
7 tegrated Service Network or facility to carry the
8 drug for a defined patient population or clinical pro-
9 gram.

10 “(3)(A) The Director of a Veterans Integrated Serv-
11 ice Network or of a medical facility may request a waiver
12 under paragraph (2)(B) through the Pharmacy Benefits
13 Management Services.

14 “(B) The Secretary shall establish a centralized re-
15 view process for considering such waiver requests, which
16 shall include an assessment of clinical need, safety, and
17 cost-effectiveness. A waiver issued under this paragraph
18 shall be time-limited and reviewed periodically for con-
19 tinuing necessity.

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

24 “(c) PUBLIC COMMUNICATION OF FORMULARY DECI-
25 SIONS.—(1) The Secretary shall communicate regularly

1 with the general public regarding the management of the
2 national formulary. Such communication may include pub-
3 lic briefings or online announcements to explain formulary
4 decisions.

5 “(2) In the case of any change to the national for-
6 mulary that the Secretary determines may significantly af-
7 fect veteran care or access (including the exclusion of a
8 medication that was previously commonly used, or the ad-
9 dition of a new high-cost therapy with usage restrictions),
10 the Secretary shall publish a summary of the rationale for
11 the change (including consideration of clinical evidence
12 and outcomes) and, when feasible, hold a public briefing
13 or stakeholder call to discuss the change and address ques-
14 tions.

15 “(d) REPORTING REQUIREMENTS.—(1) The Sec-
16 retary shall submit to the Committees on Veterans’ Affairs
17 of the Senate and House of Representatives an annual ap-
18 peals report that includes a detailed description of nonfor-
19 mulary decisions and appeals made during the year cov-
20 ered by the report.

21 “(2) Not less frequently than annually during the
22 five-year period beginning on the date of the enactment
23 of this section, the Secretary shall submit to the Commit-
24 tees on Veterans’ Affairs of the Senate and House of Rep-
25 resentatives, and make publicly available, a report that in-

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

7 **“§ 7386. Pharmacy and Therapeutics Committee**

8 “(a) ESTABLISHMENT.—There is established within
9 the Veterans Health Administration a Pharmacy and
10 Therapeutics Committee (in this section referred to as the
11 ‘Committee’) to support the Pharmacy Benefits Manage-
12 ment Services in managing the national formulary of the
13 Department.

14 “(b) COMPOSITION.—The members of the Committee
15 shall be selected by the Secretary and shall be physicians
16 from major clinical specialties, clinical pharmacists, and
17 pharmacoeconomists who are employees of the Depart-
18 ment. In selecting members of the Committee, the Sec-
19 retary shall ensure the inclusion of individuals with exper-
20 tise in geriatric care and mental health care for veterans.

21 “(c) CONFLICTS OF INTEREST.—(1) The Secretary
22 shall ensure that each member of the Committee is free
23 of any conflict of interest with the pharmaceutical indus-
24 try.

25 “(2) The Secretary shall—

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

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

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

14 “(e) **EVIDENCE-BASED DECISION MAKING.**—The
15 Committee shall make decisions with respect to the na-
16 tional formulary of the Department based on evidence-
17 based drug monographs, clinical data (including data on
18 real-world use and outcomes), and pharmacoeconomic
19 analyses of cost-effectiveness. In making such decisions,
20 the Committee shall consider the applicable clinical prac-
21 tice guidelines of the Department and of the Department
22 of Defense to ensure alignment with best practices in vet-
23 eran care.

24 “(f) **TRANSPARENCY OF DECISIONS.**—For each sig-
25 nificant addition to or removal from the national for-

1 mulary of the Department, the Secretary shall make pub-
2 licly available on an appropriate website of the Depart-
3 ment a summary of the clinical rationale for the addition
4 or removal, including a description of the evidence and
5 guidelines considered. Such summaries may not include
6 proprietary pricing information or trade secrets.

7 **“§ 7387. Nonformulary drug request process**

8 “(a) ELECTRONIC REQUEST SYSTEM.—The Sec-
9 retary shall acquire or develop and implement a standard-
10 ized electronic system for handling requests by clinicians
11 of the Department for drugs not included in the national
12 formulary of the Department. This system shall be inte-
13 grated with the electronic health record system of the De-
14 partment to allow treating clinicians to submit nonfor-
15 mulary drug requests as part of the prescribing workflow.

16 “(b) TIMELINESS OF DECISIONS.—The Secretary
17 shall establish a process to ensure that any request by a
18 Department clinician for a nonformulary drug is decided
19 upon promptly. Under such process, an initial decision on
20 a nonformulary request shall be communicated to the re-
21 questing clinician within 96 hours after the request is sub-
22 mitted. In any case where a nonformulary request is de-
23 nied, the veteran (and the requesting clinician) shall be
24 informed of the denial and of the right to appeal under
25 subsection (e). If an appeal is filed, a decision with respect

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

3 “(c) CONSISTENT CRITERIA AND APPROVAL STAND-
4 ARDS.—The Secretary shall establish uniform criteria for
5 evaluating nonformulary drug requests, which shall be ap-
6 plied across all Veterans Integrated Service Networks
7 (herinafter referred to as ‘VISNs’) and medical facilities
8 of the Department to ensure consistency. Such criteria
9 shall be evidence-based and shall be made available to De-
10 partment clinicians.

11 “(d) PORTABILITY OF APPROVALS.—An approval for
12 a nonformulary drug under this section shall be valid
13 throughout the Veterans Health Administration. In the
14 case of a veteran for whom a nonformulary drug has been
15 approved and who chooses to receive hospital care or med-
16 ical services at a different medical center or VISN of the
17 Department, the nonformulary approval (including any es-
18 tablished renewal date or duration of approval) shall re-
19 main in effect at the new location, subject to the same
20 clinical conditions or monitoring requirements that were
21 originally imposed.

22 “(e) APPEALS PROCESS.—(1) The Secretary shall es-
23 tablish a tiered appeals process for nonformulary drug de-
24 cisions. At a minimum, such process shall provide—

1 “(3) The Secretary shall—

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

5 “(B) provide interventions, including provider
6 education or patient outreach, based on the results
7 of such reviews in order to improve therapeutic out-
8 comes and promote drug safety and adherence.”.

9 (b) CLERICAL AMENDMENT.—The table of sections
10 at the beginning of such chapter is amended by adding
11 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.”.

12 **SEC. 3. DEPARTMENT OF VETERANS AFFAIRS PHARMA-**
13 **CEUTICAL PURCHASING AGREEMENTS.**

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

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

19 **“§ 8130. Pharmaceutical purchasing agreements and**
20 **value-based initiatives**

21 “(a) NEGOTIATION OF SUPPLEMENTAL DIS-
22 COUNTS.—(1) In addition to the limitations on the prices

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

5 “(2) In conducting negotiations under this para-
6 graph, the Secretary may—

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

10 “(B) enter into an agreement with a manufac-
11 turer under which the manufacturer offers a dis-
12 counted price or rebate for a drug in exchange for
13 preferred status for the drug on the national for-
14 mulary of the Department, if the Secretary deter-
15 mines the agreement will provide clinically appro-
16 priate outcomes for veterans and net cost savings or
17 value to the Department.

18 “(3) Nothing in this subsection shall be construed to
19 supersede the price limitations under section 8126 of this
20 title. The Secretary shall ensure that any agreement en-
21 tered into under this subsection with respect to a drug
22 that is a covered drug under such section results in prices
23 that are lower than the maximum price allowed under such
24 section for such drug.

1 “(b) USE OF FLEXIBLE PURCHASING ARRANGE-
2 MENTS.—(1) To the extent practicable, the Secretary shall
3 use industry best practices in the procurement of drugs
4 and medical supplies, including the use of blanket pur-
5 chase agreements, ordering agreements, and other volume-
6 leveraging contracts to achieve favorable pricing.

7 “(2) The Secretary may pursue value-based pur-
8 chasing arrangements with manufacturers of drugs and
9 biological products to be included on the national for-
10 mulary. Such arrangements may include contracts under
11 which the manufacturer agrees to provide the drugs or bi-
12 ological products to the Secretary in exchange for payment
13 in an amount that is determined based upon the effective-
14 ness of the drug or biological product for veterans to
15 whom the drug or biological product is prescribed. If the
16 Secretary enters into such a contract under this para-
17 graph, the Secretary shall ensure that the contract in-
18 cludes a mechanism to monitor the effectiveness of the
19 drug or biological product and to adjust payments or re-
20 bates accordingly.

21 “(c) OUTCOME AND COST-EFFECTIVENESS EVALUA-
22 TIONS.—(1) The Secretary shall conduct periodic reviews
23 of the outcomes and budgetary effects associated with
24 major changes to the national formulary or pharma-
25 ceutical initiatives of the Department. Not later than 180

1 days after concluding a periodic review under this para-
2 graph, the Secretary shall submit to the Committees on
3 Veterans' Affairs of the Senate and House of Representa-
4 tives the results of the review.

5 “(2) Not later than one year after implementing any
6 significant action affecting the national formulary, includ-
7 ing adding a high-cost drug with usage criteria or remov-
8 ing a clinically used drug from the formulary, the Sec-
9 retary shall evaluate the effects of that action on veteran
10 health outcomes, drug use patterns, and overall costs to
11 the Department. The Secretary shall make findings from
12 such evaluations available to the Committees on Veterans'
13 Affairs of the Senate and House of Representatives and
14 use the findings to inform future formulary decisions and
15 purchasing agreements.

16 “(d) BIOLOGICAL PRODUCT DEFINED.—In this sec-
17 tion, the term ‘biological product’ has the meaning given
18 such term in section 351(i)(1) of the Public Health Service
19 Act (42 U.S.C. 262(i)(1)).”.

20 (2) CLERICAL AMENDMENT.—The table of sec-
21 tions at the beginning of such chapter is amended
22 by adding at the end the following new item:

“8130. Pharmaceutical purchasing agreements and value-based initiatives.”.

23 (b) ESTABLISHMENT OF TIERED SCHEDULE FOR CO-
24 PAYMENTS.—

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

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

10 “(2) Under the tiered schedule established under this
11 subsection, the amount of a copayment for a 30-day sup-
12 ply of a generic drug or a drug listed on the national for-
13 mulary of the Department shall be lower than amount of
14 a copayment a 30-day supply of a brand-name drug or
15 a drug not included on such national formulary.”.

16 (2) UPDATE OF CROSS-REFERENCE.—Sub-
17 section (a)(3)(D) of such section is amended by
18 striking “section 491” and inserting “section 2732”.

19 **SEC. 4. VETERANS FORMULARY ADVISORY COMMITTEE.**

20 (a) ESTABLISHMENT.—The Secretary of Veterans
21 Affairs shall establish an advisory committee, to be known
22 as the Veterans Formulary Advisory Committee (in this
23 section referred to as the “Advisory Committee”). The Ad-
24 visory Committee shall provide veteran and clinician input

1 on the national formulary of the Department of Veterans
2 Affairs.

3 (b) MEMBERSHIP.—The Advisory Committee shall
4 consist of not more than ten members and shall include
5 front-line clinical providers or pharmacists of the Depart-
6 ment who are not involved in national formulary decision-
7 making and other stakeholder representatives as the Sec-
8 retary considers appropriate.

9 (c) MEETINGS.—The Advisory Committee shall meet
10 at regular intervals (at least semiannually) and shall re-
11 view proposed formulary changes.

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

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

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