WARSTOPPER PROGRAM

Comprehensive Cost Estimate Needed to Evaluate Potential Expanded Access to Emergency Medications



Report to Congressional Committees

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July 2024

WARSTOPPER PROGRAM

Comprehensive Cost Estimate Needed to Evaluate Potential Expanded Access to Emergency Medications

Why GAO Did This Study

DLA created the Warstopper Program to ensure access to items that are in high demand during wartime but low demand in peacetime, including medications. DOD used the program during the COVID-19 pandemic to obtain large quantities of medical materiel. The pandemic highlighted vulnerabilities in the nation's medical supply chain. Correspondingly, House Report 117-118 directed DLA to study the feasibility of expanding the program to include medications for all Military Health System users and included a provision for GAO to review the Warstopper Program.

This report examines the extent to which DLA (1) established goals, objectives, and performance measures for the Warstopper Program, and (2) followed best practices for economic analyses in its report assessing the feasibility of expanding the program.

GAO compared the Warstopper Program with key practices to help manage and assess the results of federal efforts, and key attributes for successful measures. GAO also assessed DLA's Warstopper Program expansion feasibility report against best practices for economic analyses.

What GAO Recommends

GAO is recommending that DLA develop (1) well-defined program goals for the Warstopper Program, (2) performance measures that align to these goals, and (3) an update for Congress that provides a cost estimate that includes all costs related to expansion of the program and a sensitivity analysis. DOD concurred with the recommendations.

What GAO Found

The Defense Logistics Agency (DLA) does not have clearly defined or outcome-oriented goals or effective performance measures for its Warstopper Program, a program designed to prevent shortages of critical items during wartime or other operations.

- DLA's program goals are not outcome-oriented and do not have quantifiable targets to assess program performance. The Warstopper Program goals identify focus areas but are not outcome-oriented statements of aim or purpose that provide direction to the program. For example, one of the Warstopper Program goals is Information Technology, but this program goal does not convey the desired outcome DLA is seeking to achieve. While DLA has strategic objectives associated with each focus area, it has not divided these strategic objectives into specific, quantifiable performance goals with associated performance measures.
- DLA's Warstopper Program performance measures limit a full assessment of performance. In 2023, DLA used three performance measures to monitor the Warstopper Program's performance, but its measures are not balanced across program goals and do not cover all the program's core program activities.

Without well-defined program goals and effective performance measures that align to the goals, DLA cannot adequately assess program performance and accurately report its achievements to decision-makers and stakeholders.

GAO Assessment of the Program Goals, Strategic Objectives, Performance Goals, and Performance Measures of the Warstopper Program

Program goals	Strategic objectives	Performance goals	Performance measures
Are not outcome- oriented statements of aim or purpose.	Generally identify intended outcomes.	Have not been identified.	Do not cover all core program activities.

Source: GAO analysis of Defense Logistics Agency (DLA) information. | GAO-24-106109

DLA determined that it is feasible to expand the Warstopper Program to include medications for all users of the Military Health System (active duty personnel and their families; retirees; and reservists). However, DLA's assessment did not include all costs related to expanding the Warstopper Program. Furthermore, DLA's assessment did not include a sensitivity analysis, which would have examined how changes to key assumptions might affect the costs, benefits, and risks related to expanding the program. These elements are key parts of effective economic analyses. According to DLA officials, they did not include all costs because they did not have sufficient information to determine all costs, such as the number of people and where they are located. Subsequently, this information has become available. Without a sensitivity analysis, decision-makers may not be able to assess risks associated with the assumptions used in the analysis, or the range of costs and benefits. By developing an updated cost estimate that is based on all costs related to expansion of the Warstopper Program, and accompanied by a sensitivity analysis, DLA could provide more useful, fulsome information to Congress as it decides whether to expand the program.

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Abbreviations

DHA Defense Health Agency
DLA Defense Logistics Agency
DOD Department of Defense

FDA Food and Drug Administration

FY Fiscal Year

GPRA Government Performance and Results Act HHS Department of Health and Human Services

MHS Military Health System

NDAA National Defense Authorization Act

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July 29, 2024

The Honorable Jack Reed Chairman The Honorable Roger Wicker Ranking Member Committee on Armed Services United States Senate

The Honorable Mike Rogers Chairman The Honorable Adam Smith Ranking Member Committee on Armed Services House of Representatives

The Defense Logistics Agency (DLA) created its Warstopper Program to ensure access to items that are in high demand during wartime but low demand in peacetime, including medications. To do this, the Warstopper Program makes investments in industrial production capacity to ensure that, in the case of a large-scale contingency operation, those items are available in sufficient quantities to meet the needs of the military.\(^1\) According to DLA officials, during the COVID-19 pandemic, the Department of Defense (DOD) used contracts put in place by the Warstopper Program to obtain large quantities of medical materiel, such as masks, gloves, ventilators, and other critical items, that were in short supply for hospitals and federal agencies.\(^2\) Nevertheless, the COVID-19 pandemic highlighted vulnerabilities in the nation's medical supply chain and, according to DLA officials, the need to employ more industrial readiness approaches across the government.

In August 2020, the President issued an executive order directing agencies to take steps toward the goal of strengthening domestic drug manufacturing and supply chains.³ In September 2021, we reported on DLA's pandemic response and cited DLA lessons learned in the areas of procurement, policy, and coordination.⁴ DLA

¹In response to lessons learned about supply chain issues during Operation Desert Storm, Congress directed DOD—via the conference report accompanying the National Defense Authorization Act for Fiscal Years 1992 and 1993—to ensure the maintenance and stability of the industrial base for critical items referred to as "war stoppers." H.R. Rep. No. 102-311, at 521 (1991) (Conf. Rep.). To accomplish this, DLA established the Warstopper Program within its Industrial Capabilities Program. Generally, Warstopper Program items are those that are critical to carrying out military missions, have large surge or mobilization requirements, and for which peacetime demand is insufficient to maintain industrial capacity. Examples include chemical protective suits, nerve agent antidote autoinjectors, meals-ready-to-eat, specialty fuels, and medications.

²DLA also reported using the Warstopper Program to support medical contingencies as part of the 2015 Ebola outbreak, to provide medical equipment to the USNS Comfort and USNS Mercy in 2017, and also to support earthquake relief efforts in Haiti in 2021.

³Exec. Order No. 13,944, Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, 85 Fed. Reg. 49,929 (Aug. 6, 2020).

⁴GAO, COVID-19: Defense-Wide Working Capital Fund Cash Management and Defense Logistics Agency Pandemic Response, GAO-21-104590 (Washington, D.C.: Sept. 22, 2021).

recommended, among other things, that DOD conduct a bottom-up review with the wider pandemic response community to determine the provisioning and prioritization of critical supply items for the Warstopper Program.⁵

The House Armed Services Committee report that accompanied a bill for the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2022 noted the contributions of the Warstopper Program to the COVID-19 response and expressed concerns about ensuring medical supply stability for service members and all Military Health System (MHS) users.⁶ Specifically, the committee directed DLA, in consultation with the Defense Health Agency (DHA), to assess the feasibility of expanding the Warstopper Program to cover commonly used pharmaceutical items for the approximately 9.6 million MHS users. DLA and DHA were to provide a report to the Senate and House Committees on Armed Services by April 1, 2022.

The committee report also included a provision that we review the Warstopper Program.⁷ This report evaluates the extent to which DLA (1) established goals, objectives, and performance measures for the Warstopper Program, and (2) followed best practices for economic analyses in its report assessing the feasibility of expanding the Warstopper Program.

To address our first objective, we reviewed DLA briefings, program documents, and internal reports, including the Warstopper Program annual reports, reports on the program's historical return-on-investment, and risk assessments of specific items, to identify DLA's program goals, strategic objectives, and performance measures for the Warstopper Program. We also interviewed DLA officials regarding the program's goals, strategic objectives, and performance measures. We compared DLA's goals and objectives to our key practices to help manage and assess the results of federal efforts, such as the Warstopper Program.⁸ We also assessed the Warstopper Program performance measures against key attributes of successful performance measures.⁹

To address our second objective, we reviewed DLA's report on the feasibility of expanding the Warstopper Program, as well as associated workpapers and analyses.¹⁰ We also interviewed DLA and DHA officials who

⁵DLA officials we spoke with during our review did not know whether DOD took any action related to those recommendations.

⁶H.R. Rep. No. 117-118, at 186 (2021). The Military Health System is a complex organization that is responsible for providing health care to more than 9.6 million beneficiaries. Eligible beneficiaries—or users—include active-duty personnel and their dependents (i.e., spouses, children), certain Reserve and National Guard personnel and their dependents, and retirees and their dependents and survivors. The Military Health System provides health care to service members and other beneficiaries through its own hospitals and clinics and a private sector care system of civilian providers to augment care when needed.

⁷H.R. Rep. No. 117-118, at 186-87 (2021).

⁸GAO, *Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts*, GAO-23-105460 (Washington, D.C.: July 12, 2023). To develop the key practices, we reviewed (1) federal laws and guidance related to evidence-building and performance-management activities and (2) its related past reports since 1996. We identified and distilled several hundred relevant actions into the key practices. We refined the practices and actions, as appropriate, based on input from cognizant officials at 24 major federal agencies and Office of Management and Budget staff.

⁹GAO, Sexual Harassment and Assault: The Army Should Take Steps to Enhance Program Oversight, Evaluate Effectiveness, and Identify Reporting Barriers, GAO-22-104673 (Washington, D.C.: May 27, 2022); Defense Health Care Reform: Additional Implementation Details Would Increase Transparency of DOD's Plans and Enhance Accountability, GAO-14-49 (Washington, D.C.: Nov. 6, 2013); Tax Administration: IRS Needs to Further Refine Its Tax Filing Season Performance Measures, GAO-03-143 (Washington, D.C.: Nov. 22, 2002).

¹⁰Defense Logistics Agency, *Report on the Warstopper Program As Requested by the House Report 117-118, at 186* (May 2023). In this report, we refer to this product as the "Warstopper Program expansion feasibility report."

developed the report, as well as officials with the Department of the Army, Department of the Navy, and the Department of the Air Force to determine any input they provided for the report.¹¹ We assessed the Warstopper Program expansion feasibility report and associated workpapers against our best practices for economic analyses.¹² We suspended the work between January 2023 and May 2023 because DLA was delayed in providing its report to Congress on the feasibility of expanding the Warstopper Program. See appendix 1 for more details about our scope and methodology.

We conducted this performance audit from June 2022 to July 2024. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Industrial Capability Program and the Warstopper Program

DLA established the Industrial Capability Program to assess the capabilities of suppliers to meet the military services' and combatant commanders' wartime requirements. According to DLA, DOD's Industrial Capability Program is an outgrowth of Industrial Preparedness Programs established under the Defense Production Act of 1950. Presidential executive orders and DOD guidance helped to further define and refine DLA and DOD responsibilities as the program evolved. Industrial Capability Program uses capability assessment plans to identify the capability of industry to meet wartime sustainment requirements and identify critical shortfalls requiring the implementation of industrial preparedness measures. Successful execution of the Industrial Capability Program directly impacts DLA's ability to deliver DLA-managed items at the right time, place, and price during wartime.

The Warstopper Program. DLA created the Warstopper Program as part of its Industrial Capability Program to address military supply chain vulnerabilities identified during Operation Desert Storm in 1991. In the conference report accompanying the NDAA for Fiscal Years 1992 and 1993, Congress directed DOD to take steps to ensure the maintenance and stability of the industrial base for a list of items that are critical and in high

¹¹Within the Department of the Navy, we met with military service officials from both the Navy and the U.S. Marine Corps.

¹²GAO, Assessment Methodology for Economic Analysis, GAO-18-151SP (Washington, D.C.: Apr. 10, 2018).

¹³DOD defines combatant commands as a unified or specified command with a broad continuing mission under a single commander. Combatant commands typically have geographic or functional responsibilities.

¹⁴The Defense Production Act of 1950, enacted as Pub. L. No. 81-774 (1950), is presently codified at 50 U.S.C. §§ 4501-4568.

¹⁵Exec. Order No. 12,919, *National Defense Industrial Resources Preparedness*, 59 Fed. Reg. 29,525 (Jun. 3, 1994); Exec. Order No. 13,603, *National Defense Resources Preparedness*, 77 Fed. Reg. 16,651 (Mar. 16, 2012); Department of Defense (DOD) Directive 4400.01E, *Defense Production Act Programs* (Oct. 12, 2001) (incorporating change 1, Aug. 31, 2018).

demand during military operations but are otherwise in low demand during peacetime.¹⁶ The Warstopper Program operates like an insurance policy for the military services, according to DLA officials. Figure 1 shows some of the items covered by the Warstopper Program, such as boots, masks, gloves, medications, and meals-ready-to-eat.

Figure 1: Select Items Covered by the Warstopper Program



Sources (left to right): U.S. Air Force/John Ingle; U.S. Army National Guard/Specialist Christopher Shannon II; and U.S. Air Force/Staff Sergeant Sean Campbell. | GAO-24-106109

According to DLA, the military services are required to have enough materiel on hand to conduct the first 30 days of operations in the event of a contingency. Beyond day 30 of a contingency, DLA is responsible for surge and sustainment. DLA noted that the Warstopper Program helps DLA fulfill this role by investing money to establish contracts for items that the military services identify as being at risk of a shortfall or shortage. The Nerve agent antidote auto-injectors are an example of this type of item, which would generally not be needed during peacetime but critical to have for the force in large quantities during wartime. Currently, there are three main ways in which DLA identifies items for Warstopper Program contracts: 1) congressionally mandated items; 2) medical items; and 3) non-medical items.

Congressionally mandated items. According to DLA officials, this category includes specific items that DLA contracts for as part of the Warstopper Program based on shortages in past military campaigns, such as Operation Desert Storm. When items are congressionally identified for inclusion in the Warstopper Program, the program evaluates the items for shortfalls, investigates the capability of industry to provide the needed

¹⁶H.R. Rep. No. 102-311, at 521 (1991) (Conf. Rep.).

¹⁷According to DLA, these investments and contracts may take the form of an industrial base maintenance contract, a corporate exigency contract, a vendor-managed inventory contract, purchase of critical path lead-time materials, or an investment in industrial equipment that modernizes critical industrial processes.

quantities, and determines an appropriate risk response strategy. According to DLA officials, sometimes the solution is a Warstopper Program contract.

Medical items. DLA works with the military services to identify potential shortfalls in medical items needed for contingency or emergency scenarios. The military services develop a Medical Contingency File, which identifies the medical material requirements that would be needed in a surge scenario. The manufacturers and distributors use existing commercial inventories to support the medical surge requirements.¹⁸

Non-medical items. DLA manages and maintains the surge and sustainment planning requirements for the military services. These planning requirements are derived mostly from the military services, but include some items identified by DLA using its own historical data, results of exercises, and industrial base studies. DLA industrial specialists monitor the database and make adjustments based on changing inventory and updates from the military services. At-risk items are identified when there is a shortfall between the military services' surge requirements and the capacity of industry to produce those items.¹⁹

Military Health System

The MHS provides health care to approximately 9.6 million military personnel, retirees, and family members through military treatment facilities and certain civilian health care providers. Its mission also includes ensuring that DOD's approximately 1.6 million active duty and 331,000 reserve-component personnel are healthy so they can complete their national security missions, and that all active and reserve medical personnel in uniform are trained and ready to provide medical care in support of operational forces around the world. Responsibility within the MHS is shared among various entities, including the Defense Health Agency, which is generally responsible for health care delivery, and the military departments, which are primarily responsible for ensuring the medical readiness of military personnel.

Federal Efforts to Address Medication Shortages

Our prior work identified the availability of medications as a persistent public health threat and recommended that federal agencies take various actions to better identify medication shortages and mitigate their effects.²¹ For example, in 2021 we found that federal agencies do not have access to quality information about the original sources of some drugs and pharmaceutical inputs, and this absence of complete and accessible

¹⁸The conference report accompanying the National Defense Authorization Act for Fiscal Year 2024 included language encouraging DLA to coordinate annually with customers in the military departments to conduct responsiveness testing of the DLA's contingency contracts for pharmaceuticals and to include the results of that testing, as reported by customers in the military departments, in the annual reports of the Warstopper Program. H.R. Rep. No. 118-301, at 1037 (2023) (Conf. Rep.).

¹⁹According to DLA, at least annually, the information in the Surge and Sustainment Database is sent to the Sustainment Readiness Criteria system, which is a collection of applications that assess industrial base capacity and risk for various items. The shortfall between the industrial base capacity to provide items and the information in the Surge and Sustainment Database related to military service requirements represents the candidates for Warstopper contracts.

²⁰GAO, Defense Health Care: Improved Monitoring Could Help Ensure Completion of Mandated Reforms, GAO-23-105710 (Washington, D.C.: June 22, 2023).

²¹See GAO, *High-Risk Series: Efforts Made to Achieve Progress Need to Be Maintained and Expanded to Fully Address All Areas*, GAO-23-106203 (Washington, D.C.: Apr. 20, 2023); *COVID-19: Critical Vaccine Distribution, Supply Chain, Program Integrity, and Other Challenges Require Focused Federal Attention*, GAO-21-265 (Washington, D.C.: Jan. 28, 2021); and *Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability*, GAO-14-194 (Washington, D.C.: Feb. 10, 2014).

supply chain information for medications can impede federal efforts to identify and mitigate shortages related to these drugs. We recommended that the Food and Drug Administration (FDA) obtain complete and accessible information about supply chains for medications, and improve its coordination with drug manufacturers and federal agencies—including DOD and the Department of Veterans Affairs. The FDA has since partially implemented this recommendation as of April 2024.²²

The White House, as well as federal agencies, have taken several actions in recent years to help address medication shortages and other supply chain vulnerabilities. For example, in August 2020, the President issued Executive Order 13944, which directed federal agencies to identify vulnerabilities in the pharmaceutical supply chain and increase purchasing of critical medications that are manufactured in the U.S.²³ In 2023, the President announced the White House Council on Supply Chain Resilience, which will help implement a government-wide strategy to build enduring supply chain resilience. The President also announced that the government would draw on authorities within the Defense Production Act to boost domestic manufacturing of critical medications, strengthen existing supply chains, and address medication shortages.²⁴ In 2024, the Department of Health and Human Services announced a new position, the Supply Chain Resilience and Shortage Coordinator, to help strengthen the implementation of federal strategies to enhance supply chain resilience for medications and other medical products.²⁵

Additionally, DHA issued guidance for managing pandemic stockpiles stored at military medical treatment facilities. This guidance directed DHA's components, the combatant commands, and the military departments to establish procedures, assign responsibilities, and provide direction related to responding to public health emergencies caused by pandemics. The DHA guidance focuses specifically on inventory management and accountability of pandemic stockpiles.²⁶

Warstopper Program Goals Are Not Clearly Defined, and Performance Measures Do Not Fully Assess Results

The Warstopper Program has established goals, but these goals are not clearly defined, and DLA has not established targets to measure its progress achieving its goals. Furthermore, DLA's performance measures for the Warstopper Program do not link to all the program's goals, resulting in DLA not being able to fully assess

²²FDA is an agency within the Department of Health and Human Services (HHS). In response to our recommendation, HHS neither agreed nor disagreed. In February 2024, FDA issued guidance advising manufacturers on reporting the amounts of each drug they manufacture for commercial distribution, which was required by the Coronavirus Aid, Relief, and Economic Security Act in 2020. We are in the process of reviewing these efforts to determine if its implementation satisfies the intent of our recommendation.

²³Exec. Order 13,944, Combating Public Health Emergencies and Strengthening National Security by Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States, 85 Fed. Reg. 49,929 (Aug. 6, 2020).

²⁴The White House, Fact Sheet: President Biden Announces New Actions to Strengthen America's Supply Chains, Lower Costs for Families, and Secure Key Sectors (Nov. 27, 2023).

²⁵Department of Health and Human Services, *Policy Considerations to Prevent Drug Shortages and Mitigate Supply Chain Vulnerabilities in the United States* (Apr. 2, 2024).

²⁶Defense Health Agency Procedures Manual 6430.10, Pandemic Stockpile Management, (Dec. 6, 2022).

the results of the program. See figure 2 for a summary of our assessment of the Warstopper Program's goals, strategic objectives, performance goals, and performance measures.

Figure 2: GAO Assessment of the Extent to which the Warstopper Program Meets Key Practices Developing Goals, Objectives, and Performance Measures

Program goals Strategic objectives Performance goals Performance measures · DLA does identify program goals · Each Warstopper Program focus · DLA does not identify DLA adopted three performance for the Warstopper Program area has an associated strategic performance goals for each of measures for the Warstopper its program goals or strategic DLA also calls its Warstopper objective Program in fiscal year 2023 Program goals "focus areas" DLA's strategic objectives for the objectives These performance measures These program goals/focus do not link to all of the Warstopper Warstopper Program generally areas—such as Industrial Base identify the outcomes or impacts Program's goals and objectives Analysis, Program Management, the agency intends to achieve and Information Technology—are not outcome-oriented statements of aim or purpose Source: GAO analysis of Defense Logistics Agency (DLA) information. | GAO-24-106109

Warstopper Program Goals Are Not Clearly Defined or Outcome-Oriented

In its annual report for fiscal year 2022, DLA identified six goals for the Warstopper Program, but these goals are not clearly defined or outcome-oriented.²⁷ DLA has generally used the same six program goals for the past 10 years.²⁸ According to annual reports provided by DLA, each program goal has a corresponding strategic objective. These strategic objectives are high-level statements of what Warstopper Program leadership hopes to accomplish for the associated goal in a given fiscal year. Table 1 identifies the Warstopper Program goals and associated strategic objectives for fiscal year 2023.

Program goal	Strategic objective
Industrial Base Analysis	Leverage industrial base analyses as a value add to the timely acquisition of materiel for the warfighter
Industrial Base Acquisition Support and Guidance	Maintain a system of communicating to, and supporting of the acquisition community
Industrial Preparedness Measures	Establish and maintain stable business practices for making best value solution to mitigate industrial base risks
Information Technology	Implement and maintain information technology applications as the pre-eminent system of record for tactical industrial base and wartime surge decision that is fully integrating with the enterprise systems
Program Management	Provide program management to effectively communicate the program and to support workforce development and innovation

²⁷DLA, *FY22 Warstopper Program Annual Report* (Feb. 29, 2023). Those goals are 1) Industrial Base Analysis, 2) Industrial Base Acquisition Support and Guidance, 3) Industrial Preparedness Measures, 4) Information Technology, 5) Program Management, and 6) Customer Engagement.

²⁸DLA added the Industrial Preparedness Measures program goal in fiscal year 2014, and there have also been minor terminology changes over the years. For example, the Industrial Base Acquisition Support and Guidance program goal was previously called "Acquisition" and "Industrial Base Acquisition."

Program goal	Strategic objective
Customer Engagement	Establish and maintain a system of communicating with internal and external customers

Source: GAO analysis of DLA data. | GAO-24-106109

Note: Data from Fiscal Year 2022 Defense Logistics Agency Warstopper Program Annual Report.

We have previously identified key practices to help manage and assess the results of federal program efforts, including the development of program goals.²⁹ Specifically, goals should communicate the results that an organization seeks to achieve and allow decision-makers, staff, and stakeholders to assess performance by comparing planned and actual results. Program goals should be outcome-oriented statements of purpose or intent that indicate either long-term or near-term outcomes a program hopes to accomplish. Each program goal should lead to at least one strategic objective, which indicates how a program intends to accomplish its goal, as well as quantitative targets and timeframes against which performance can be measured. To ensure progress can be assessed, each strategic objective should be broken down into one or more specific and quantifiable performance goals with associated performance measures.

The program goals for the Warstopper Program do not reflect our definition of a well-defined strategic goal because they do not clearly define a sense of direction, or the outcome DLA is seeking to achieve. For example, one of the Warstopper Program goals is Information Technology, but this statement does not convey the desired outcome DLA is seeking to achieve related to information technology. While the Warstopper Program goals help officials organize the program's strategic objectives and activities, they do not lend themselves to identifying quantitative targets and timeframes against which performance can be measured.

The strategic objectives for the Warstopper Program generally identify an aim or purpose for each of the program goals. These objectives give a sense of the direction and describe what the Warstopper Program officials hope to achieve in those areas. For example:

- The strategic objective for the Industrial Preparedness Measures program goal is to establish and maintain stable business practices for making best value solutions to mitigate industrial base risks.
- The strategic objective for the Customer Engagement program goal is to establish and maintain a system of communicating with internal and external customers.

However, each strategic objective also should be broken down into one or more performance goals that clearly define a quantifiable target it aims to achieve in a given timeframe.³⁰ The Warstopper Program has not identified performance goals with targets.

DLA's Warstopper Program has not fully implemented key practices to help manage and assess program results by developing program goals that are clear, well-defined, outcome-oriented, and reflect the mission and function of the Warstopper Program. Further, DLA's Warstopper Program has not developed performance goals with targets that are specific and quantifiable. DLA officials said that the current program goals and strategic objectives have provided sufficient direction necessary to operate the Warstopper Program effectively.

²⁹GAO, Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts, GAO-23-105460 (Washington, D.C.: July 12, 2023).

³⁰GAO-23-105460.

DLA officials acknowledged that the Warstopper Program goals could be more clearly defined, and said they are working to write these goals more clearly. With clearly defined program goals that identify a desired outcome or purpose, as well as clearly defined performance goals with targets that are specific and quantifiable, DLA would be better positioned to communicate to internal and external stakeholders what it is seeking to achieve with its Warstopper Program.

Warstopper Program Performance Measures Reflect Some Positive Attributes, but Do Not Fully Assess Its Results

The Warstopper Program's performance measures reflect some positive attributes of successful performance measures, but do not fully assess the results of the program. Our prior work has shown that performance measures should align with and assess the progress towards near-term, quantitative performance goals.³¹ As discussed above, the Warstopper Program does not have clear, measurable performance goals. Clear, measurable goals can facilitate the development of effective performance measures to assess program performance. We have previously reported that agencies should use performance measures—at least one per performance goal—to monitor and report on a program's accomplishments and progress toward its goals, and successful performance measures should reflect certain key attributes.³²

For fiscal year 2023, DLA used three performance measures to monitor the Warstopper Program's performance.³³

- **Return-on-investment.** This measures the cost to purchase and store the materiel needed in a surge and sustainment situation versus the cost of the Warstopper Program's investments for access to the same amount of materiel. The annual target for this performance measure is 4:1, according to Warstopper Program officials, which means for every dollar the Warstopper Program invests in a contract for access to materiel, there would be four dollars of cost avoidance for the military services not to purchase and hold the same materiel.³⁴ In fiscal year 2022, the Warstopper Program reported that its return-on-investment was over 10:1, and the cumulative return-on-investment for the program since inception is over 9:1.
- Industrial readiness performance. This measures the dollar value of sales completed using Warstopper Program funded contracts. The target for this performance measure is \$23 million in sales annually, which the Warstopper Program achieved as a result of \$34.6-44.2 million in sales on its contracts annually from fiscal year 2020 to fiscal year 2022.

³¹GAO-23-105460.

³²GAO, Defense Health Care Reform: Additional Implementation Details Would Increase Transparency of DOD's Plans and Enhance Accountability, GAO-14-49 (Washington, D.C.: Nov. 6, 2013).

³³For fiscal year 2022, DLA used four performance measures to evaluate the Warstopper Program, but officials decided to discontinue using one of those measures. DLA discontinued its use of the Sustainment of Capabilities and Capacities performance measure. This measured efforts to sustain critical warfighter capability and capacity by comparing the Warstopper Program investment costs of those particular contracts against the cost to extend production or support, or according to DLA officials, working with the military services to develop a new item or source in the worst-case scenario. The officials added that they discontinued the use of this performance measure because this method was not a value-added way of measuring the impact of the efforts. For our analysis, we did not include the sustainment of capabilities/capacities performance measure since DLA discontinued the use of it.

³⁴Warstopper Program officials stated that program funds do not supplement or augment the War Reserve funding of the military services.

• **Risk analyses.** This measures the number of industrial base risk assessments that the Warstopper Program completes each fiscal year. Level-1 risk assessments determine and verify if an industrial base issue exists. If a risk is identified, DLA conducts a Level-2 risk assessment, which assesses the risk and identifies any potential mitigation options, such as acquisition strategies or Warstopper investments. DLA officials stated that a Warstopper investment is not always the right mitigation strategy. For fiscal year 2022, the most recent year for which DLA provided data, DLA's target was 35 Level-1 risk assessments and eight Level-2 risk assessments. The Warstopper Program completed 44 Level-1 assessments and three Level-2 assessments.

The Warstopper Program's performance measures demonstrated some, but not all, of the 10 attributes of successful performance measures as shown in table 2. Specifically, the performance measures fully met three of the attributes of successful performance measures, partially met five, and did not meet two.³⁵ Appendix II contains additional information about these attributes.

Table 2: GAO Assessment of the Defense Logistics Agency's (DLA) Warstopper Program Performance Measures Against 10 Key Attributes of Successful Performance Measures

Attribute and definition	GAO assessment	Summary
Balance—A suite of measures ensures that an organization's various priorities are covered.	did not meet	The Warstopper Program's three performance measures are not balanced across the program goals. Specifically, the "risk analyses" performance measure aligns with three program goals, the "return-on-investment" measure aligns with one program goal, and the "industrial readiness performance" measure does not clearly align with any program goals.
Baseline and trend data — Measure has a baseline and trend data associated with it to identify, monitor, and report changes in performance and to help ensure that performance is viewed in context.	partially met	Despite changes in the "return-on-investment" calculation over time, the Warstopper Program reports that it will be using 2018 as a baseline going forward because it is the most recent year in which 100 percent of Warstopper funds have been canceled. The subsequent years will establish the trend data. However, the terminology and rigor associated with the "risk analyses" performance measure has evolved over time and continues to evolve, according to program officials, making it difficult to establish a baseline or track trend data over time.
Clarity—Measure is clearly stated, and the name and definition are consistent with the methodology used to calculate it.	partially met	The "risk analyses" performance measure is consistent with its methodology and clearly identifies what is being measured. However, the "return-on-investment" performance measure is not clearly named because it is not what its name conveys. Instead, it is a measure of cost avoidance.
Core program activities— Measures cover the activities that an entity is expected to perform to support the intent of the program.	did not meet	Not all of the Warstopper's program goals have a corresponding performance measure. For example, the Warstopper Program goals of Industrial Preparedness Measures and Customer Engagement did not have associated performance measures in FY 2023.

³⁵We provided an assessment of "fully met" when we found evidence of all elements that comprise the specific attribute for all performance measures. A rating of "partially met" meant that we found evidence for some, but not all, of the elements that comprise the specific attribute for at least one of the performance measures. We provided an assessment of "did not meet" when we found evidence that collectively, the performance measures did not reflect the elements of a specific attribute.

Attribute and definition	GAO assessment	Summary
Government-wide activities— Each measure covers a priority such as quality, timeliness, and cost of service.	partially met	We found that none of the Warstopper Program performance measures address the government-wide priority of timeliness. However, its performance measures do somewhat address other priorities. For example, Warstopper Program investments are part of the calculation of its "return-on-investment" performance measure, which reflects the cost of the service the program provides.
Limited overlap—Measures provide new information beyond that provided by other measures.	fully met	All of the Warstopper Program performance measures provide new information. The "return-on-investment" performance measure tracks the ratio of the cost to purchase and hold the materiel for surge requirements against the Warstopper Program contracts for access to materiel. The "industrial readiness performance" measure tracks the dollar value of sales on Warstopper Program contracts. The "risk analyses" performance measure tracks the number of risk analyses the program completes in a given fiscal year.
Linkage —Measure is aligned with division and agency-wide goals and mission and is clearly communicated throughout the organization.	partially met	The Warstopper Program does establish the linkage between some of its activities for the program and lines of effort for the broader Industrial Capability Program. While many of these activities relate to the "risk analyses" performance measure, the linkage for "return-on-investment" and "industrial readiness performance" is not apparent.
Measurable target—Measure has a numerical goal.	fully met	All of DLA's Warstopper Program performance measures have measurable targets. For example, the target annual "return-on-investment" ratio is 4:1, and the target dollar value in sales for the "industrial readiness performance" measure is \$23 million per year.
Objectivity—Measure is reasonably free from significant bias or manipulation.	fully met	Warstopper Program performance measures appear to be reasonably free from bias. For example, the program uses documented data sources to calculate its three performance measures.
Reliability—Measure is likely to produce the same result under similar conditions.	partially met	The "return-on-investment" and "risk analyses" performance measures appear to be reliable. However, the "industrial readiness performance" measure was not reliable. For that measure, the program was reporting inflated sales data due to an error in the formula it used to calculate the sales. Warstopper Program officials stated that they have corrected this error.

Legend: ●=Fully met⊖=Partially met○=Did not meet

Source: GAO analysis of DLA information against key attributes of performance measures. I GAO-24-106109

Note: Attributes of successful performance measures are identified in GAO reports Sexual Harassment and Assault: The Army Should Take Steps to Enhance Program Oversight, Evaluate Effectiveness, and Identify Reporting Barriers, GAO-22-104673 (Washington, D.C.: May 27, 2022); Defense Health Care Reform: Additional Implementation Details Would Increase Transparency of DOD's Plans and Enhance Accountability, GAO-14-49 (Washington, D.C.: Nov. 6, 2013); Tax Administration: IRS Needs to Further Refine Its Tax Filing Season Performance Measures, GAO-03-143 (Washington, D.C.: Nov. 22, 2002).

The Warstopper Program performance measures partially meet five key attributes. For example, we determined that the return-on-investment and risk analyses performance measures were reliable, but the industrial readiness performance measure was not. In its fiscal year 2022 annual report for the Warstopper Program, DLA cited Warstopper Program medical contract sales of \$125.8 million in fiscal year 2020 and \$87.4 million in fiscal year 2021. However, the source data indicated the actual sales numbers were \$44.2 million in fiscal year 2020 and \$34.6 million in fiscal year 2021. DLA officials acknowledged there was a tabulation error, which caused orders to be counted multiple times and resulted in the higher numbers in DLA's fiscal year 2022 annual report for the Warstopper Program. The officials added that these incorrect numbers were not circulated outside of the program and said they have corrected the error going forward based on our analysis.

The Warstopper Program performance measures do not meet two key attributes—balance and core program activities.

- DLA's Warstopper Program performance measures are not balanced in a way that ensures its various priorities are covered. According to DLA officials, the risk analyses performance measure is the primary means of measuring the success of half of the Warstopper Program's goals (three of six goals). The return-on-investment performance measure is the primary performance measure for one of its program goals, while the industrial readiness performance measure is not the primary performance measure for any of the Warstopper Program goals, according to DLA officials. By using the risk analyses performance measure for three of its goals rather than using a unique performance measure for each of its goals, DLA may skew perceptions of the Warstopper Program's performance and prevent managers from understanding the effectiveness of the program.
- The performance measures do not cover the core program activities that the Warstopper Program is expected to perform to support the intent of the program. Specifically, the Warstopper Program has not developed one or more performance measures for each unique program goal and corresponding strategic objective. Federal agencies should have at least one performance measure for each performance goal to assess progress toward achieving the goal.³⁶ However, the Warstopper Program does not have a performance measure for two of its goals. Further, one performance measure is used for three different goals. Table 3 illustrates how the Warstopper Program's performance measures do not demonstrate balance among its respective program goals or address all the program's core activities.

Table 3: Primary Performance Measure for Each Defense Logistics Agency (DLA) Warstopper Program Goal, Fiscal Year 2023

Program goal	Primary performance measure
Industrial Base Analysis	Risk analyses
Industrial Base Acquisition and Support	Risk analyses
Industrial Preparedness Measures	None
Information Technology	Risk analyses
Program Management	Return-on-investment
Customer Engagement	None

Source: GAO analysis of Defense Logistics Agency information. | GAO-24-106109

In developing Warstopper Program performance measures, DLA has not fully implemented key practices as they relate to performance measures.³⁷ DLA officials also acknowledged that current performance measures do not fully assess the extent to which the Warstopper Program achieves its goals and strategic objectives. The officials added that they are working to develop performance measures to better assess the Warstopper Program's effectiveness, but these efforts are not yet completed. By developing performance measures that reflect key attributes of successful performance measures—to include unique measures that align to each

³⁶ GAO-23-105460.

³⁷GAO-23-105460. The key practices identified in this product, to include defining goals and setting quantitative targets against which performance can be measured, are a means of helping agencies implement the Government Performance and Results Act of 1993 (GPRA), as amended by the GPRA Modernization Act of 2010 and the Foundations for Evidence-Based Policymaking Act of 2018. GAO, *Tax Administration: IRS Needs to Further Refine Its Tax Filing Season Performance Measures, GAO-03-143* (Washington, D.C.: Nov. 22, 2002); *GPRA Performance Reports, GAO/GGD-96-66R* (Washington, D.C.: Feb. 14, 1996); *Missile Defense: Opportunity to Refocus on Strengthening Acquisition Management, GAO-13-432* (Washington, D.C.: Apr. 26, 2013); *Performance Measurement and Evaluation: Definitions and Relationships, GAO-11-646SP* (Washington, D.C.: May 2, 2011); and *Agency Performance Plans: Examples of Practices That Can Improve Usefulness to Decisionmakers, GAO/GGD/AIMD-99-69* (Washington, D.C.: Feb. 26, 1999).

program goal and are balanced—DLA can better evaluate the Warstopper Program's progress and more clearly communicate its accomplishments and any challenges.

DLA's Report Concluded Warstopper Program Expansion Is Feasible, but Did Not Include All Costs and a Sensitivity Analysis

DLA Concluded Warstopper Program Expansion Is Feasible, but Not without Risks

In response to House Report 117-118, accompanying a bill for the National Defense Authorization Act for Fiscal Year 2022,³⁸ DLA performed an assessment analyzing the feasibility of expanding the Warstopper Program to include 30 generic medications at risk of shortage for all users of the MHS as identified by a May 2022 Health and Human Services report.³⁹ According to DHA officials, these medications were selected because they are at risk of shortage and are used for critical care treatment.⁴⁰ Examples of these medications are morphine sulfate, epinephrine, and vancomycin. DLA performed the assessment by sending questionnaires to and conducting interviews with industry partners, as well as examining open-source information.

DLA and DHA formed a working group to establish the methodology for conducting the congressionally directed assessment. One of the primary objectives of the report was to develop a rough cost estimate needed to provide the 6-month supply of medications to all MHS users. To develop this cost estimate, DLA used the same tool and a similar process that the military services use to create their Medical Contingency Files for the Warstopper Program.⁴¹ DLA determined it would cost approximately \$12.7 million to maintain a 6-month supply of the 30 medications for a 5-year period, including initial investment costs. To develop a cost estimate that included 30 medications, DLA developed two scenarios and added the costs together as shown in table 4. The working group selected two emergency scenarios with a domestic focus that would require the medications at risk of shortage—an airborne contagion scenario and a major hurricane scenario. The working group did not select a pandemic scenario because, according to officials, there was no existing scenario upon which to model the requirements, and the COVID-19 pandemic was still ongoing.

³⁸H.R. Rep. No. 117-118, at 186-87 (2021).

³⁹Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response, *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* (May 2022). Defense Logistics Agency, *Report on the Warstopper Program As requested by the House Report 117-118, p.186 accompanying H.R. 4350, the National Defense Authorization Act for Fiscal Year 2022* (May 2023). A generic medication is approved by FDA as the same—or bioequivalent—to a previously approved brand-name medication in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use under section 505(j) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 355(j).

⁴⁰Officials used a report from the Department of Health and Human Services that identified essential medications, and which of those might be at risk of shortage. Department of Health and Human Services, *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* (May 2022).

⁴¹This tool is called the Medical Contingency Requirements Workflow. It contains pre-loaded scenarios based on historical data, which allows the military services to project their requirements in a surge scenario and produce their respective Medical Contingency Files. According to Warstopper Program officials, this tool was used because DHA did not have a corresponding model or data set for the MHS population.

Table 4: Medical Health Emergencies Used for the Defense Logistics Agency Warstopper Program Expansion Report, and Associated Data

Medical health emergency	Military Health System population-at-risk	Medications at risk of shortage (of 30)	Cost for coverage (5 years)
Airborne contagion	389,498	3	\$91,817
Major hurricane	1,718,793	27	\$12,613,021
Totals	2,108,291	30	\$12,704,838

Source: GAO analysis of Defense Logistics Agency data. I GAO-24-106109

DLA concluded that expansion of the Warstopper Program to include at least 30 medications at risk of shortage for all MHS users is feasible, but not without risk to the original mission of the program to support deployed warfighters in times of emergency. One of those risks would be competition for the same medications between deployed service members and all other MHS users during a national or global health emergency, according to DLA officials. Specifically, DLA officials stated that, as of the time of our review, the agency had contracts for the 30 medications at risk of shortage that it used for its cost estimate. DLA officials added that 28 out of those 30 medications are covered by Warstopper Program contracts. However, according to DLA and DHA officials, the demand resulting from a domestic health emergency affecting many MHS users occurring simultaneously with an overseas contingency involving deployed warfighters could overwhelm private industry's ability to provide the needed quantity of medications. This could result in questions of whom to prioritize when distributing the limited amounts of medications available.

Moreover, DLA determined that an expansion of the Warstopper Program to include medications at risk of shortage for all users of the MHS would be challenging. Specifically, DLA officials stated that manufacturers interviewed as part of the assessment expressed concern and, in some cases, reluctance to participate in a program that added production and storage requirements to provide medications both to service members and all the remaining MHS users. Specifically, to guarantee access for a larger population, such as all MHS users, vendors would need to produce a larger volume of medications. According to DLA officials, some vendors expressed concern that if the medications were not ordered on a Warstopper contract, they would not be able to sell the increased volume of medications to other customers before the medications expire. The officials added that at least two vendors stated they would not be inclined to participate in an expansion.

In the report, DLA recommended that if the Warstopper Program were to be expanded, a multi-year, phased-approach should be used to allow time for planning, assessing, and minimizing the impact to the Warstopper Program's original mission of supporting deployed service members over time.⁴² Ensuring warfighters have continued access to these same generic medications would be essential, while also supporting the larger quantities required for MHS users, the report concludes. DLA officials also confirmed that no additional statutory authorities would be required to expand the program, which could be implemented through existing authorities and normal interagency processes.

⁴²The seven phases proposed by DLA are 1) DHA full deployment of MHS Genesis to ensure accurate requirements data; 2) Develop initial requirements and forecast planning; 3) Update internal issuances to include procedures; 4) Long-term funding commitments and resources (e.g. manpower); 5) Evaluate implementation decisions; 6) Implement and assess; 7) Maintenance.

DLA's Report Included Most of the Information That Best Practices Suggest, but Not All Costs and a Sensitivity Analysis

DLA's Warstopper Program expansion feasibility report included most of the information that is considered best practice to include in an economic analysis, but the report did not consider all costs related to expansion. Further, DLA did not conduct a sensitivity analysis to validate its methodology and assumptions.⁴³

We previously developed criteria necessary to conduct an economic analysis that informs decision-makers and stakeholders about the economic effects of a public action, such as DLA's assessment of the feasibility of expanding the Warstopper Program.⁴⁴ These criteria are a synthesis of elements and practices derived from several agencies, including the Office of Management and Budget and DOD. These elements include objective and scope, methodology, analysis of effects, documentation, and transparency. See table 5 for the best practices and the elements that comprise them.

Economic analysis best		
practice	Elements comprising each best practice	
Objective and scope	An explanation of the action examined and the rationale and justification for the action. The analysis states its objective. The scope of the analysis is designed to address this objective.	
Methodology	An examination of the effects of the action by comparing alternatives, using one of them as the baseline. All relevant alternatives should be considered, including that of no action. The analysis is performed in a way that identifies the important economic effects for each alternative considered, their timing, and whether they are direct or ancillary effects.	
Analysis of effects	The important economic effects (costs) are quantified and monetized using net present value, or related outcome measures, to compare the effects across alternatives. The analysis controls for inflation and uses economically justified discount rates. Where important economic effects cannot be quantified, the analysis explains how they affect the comparison of alternatives.	
Documentation	In addition to being clearly written with a plain language summary, the analysis identifies the following: clearly labeled tables that describe the data used and results, a conclusion that is consistent with these results, citations for all sources used, documentation that the analysis complies with a robust quality assurance process and, where applicable, the Information Quality Act. The analysis also discloses the use and contributions of contractors and outside consultants.	
Transparency	The analysis includes a description and justification of the analytical choices, assumptions, and data used, as well as an assessment of how plausible adjustments and/or statistical variability affect the results (a sensitivity or uncertainty analysis). The analysis also includes the key limitations of the data used.	

Source: GAO, Assessment Methodology, Economic Analysis, GAO-18-151SP (Washington, D.C.: Apr. 10, 2018). | GAO-24-106109

DLA's report included most of the information related to best practices in an economic analysis. For example, DLA's report identifies

⁴³A sensitivity analysis examines the effects that changes to key assumptions have on the analytic outcome and are helpful to understand risks and costs. It is a tool that can be used for assessing the extent to which costs and benefits are sensitive to changes in key factors and can provide a range of costs and benefits that may provide a better guide or indicator than a single estimate.

⁴⁴GAO, Assessment Methodology, Economic Analysis, GAO-18-151SP (Washington, D.C.: Apr. 10, 2018).

- the objective as being to analyze the feasibility of expanding the Warstopper Program in response to the committee direction;⁴⁵
- the scope of analysis, which was to evaluate the feasibility of expanding the Warstopper Program framework for incorporation of a risk assessment of the essential medications described in the *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* report, May 2022;
- four goals for its report, which were to produce 1) a rough cost estimate to expand the program, 2) an expansion concept of operations, 3) other expansion and management considerations, and 4) a supply chain analysis;
- details of its methodology, such as its outreach to pharmaceutical companies, its use of open-source material, and how it used medical health emergency scenarios to identify the potential medications at risk of shortage;
- documentation of many of the sources that it used through footnotes and significant decisions through the inclusion of meeting notes; and
- transparency in the way that it identified many of the assumptions, such as the assumed populationsat-risk in each medical health emergency scenario and the level of care that would be required.

DLA analyzed the effects of expansion by identifying the risks of expansion—namely that expanding coverage to all MHS users may limit the warfighters' ability to access the same resources—as well as some of the costs. As previously discussed, those costs included the estimated expense involved with establishing contracts and initial investments for a 6-month supply of 30 medications over a 5-year period using the airborne contagion and major hurricane scenarios—\$12.7 million.⁴⁶

However, DLA's report does not include all costs related to expansion. For example, the costs do not include

- any costs of updating the priority list of medications as changes over time occur. The report states that it is reasonable that the priority list of medications at risk of shortage will change over time, and that the analysis to identify the priority critical medications with shortages will need to be done on a yearly basis to keep the medical readiness coverage relevant to the congressional and Warstopper Program intent;
- any costs of a multi-year implementation process for expanding the program. The expansion report identifies a multi-year process for expansion implementation; and
- inflation costs over the 5-year period used in the Warstopper Program expansion feasibility report.

Warstopper Program officials acknowledged that the report did not include all costs related to expanding the program. According to DLA officials, DHA was not able to provide data on MHS users, including actual types and volumes of medications used and the number of users by location. This information was not available because DHA was deploying its new MHS Genesis system at the time of the assessment, according to DHA

⁴⁵H.R. Rep. No. 117-118, at 186-87 (2021).

⁴⁶The Warstopper Program expansion feasibility report states that the costs of the airborne contagion scenario is about \$92,000 over 5 years to assure access to three medications at risk of shortage for over 389,000 MHS users. The report also presents the costs of the hurricane scenario as about \$12.6 million over 5 years to assure access to 27 medications at risk of shortage for over 1.7 million users of the MHS.

and DLA officials.⁴⁷ Warstopper Program officials stated that without complete requirements from DHA and agreed upon models, they could not provide a reliable estimate for implementation costs due to the unknown variables. This would not have been data-driven, but rather an educated guess, according to the officials. DLA officials also stated that had MHS Genesis been available, its assessment would have been able to produce a more comprehensive cost estimate. Without those data, DLA and DHA relied on scenarios from an existing DLA tool, the Medical Contingency Requirements Workflow, which contains different scenarios built with historical data and parameters.

Furthermore, the report did not include a sensitivity analysis, which would have clearly identified the various limitations of its assumptions and tested if or how the changes to various assumptions would affect the results. For example, DLA's analysis and cost estimate is based on a certain percentage of the population being at risk for the respective medical health emergencies. However, DLA only projected one population-at-risk number for each scenario—approximately 390,000 MHS users for the airborne contagion scenario, and approximately 1.7 million MHS users for the major hurricane scenario.

DLA officials stated that they did not perform a sensitivity analysis because they were limited in the inputs that they could use for such an analysis. The inputs were limited to population and International Classification of Diseases codes, which prevented them from performing a sensitivity analysis, according to DLA officials.⁴⁸ DLA officials stated that, because they did not have requirements data and were making certain assumptions in order to arrive at a cost estimate, making additional assumptions as part of a sensitivity analysis would have introduced more uncertainty around the estimate. However, a sensitivity analysis is a tool that can help decision-makers understand the range of costs, benefits, and risks when conducting a feasibility assessment.

In March 2024, DHA deployed MHS Genesis to its final location. This will allow DLA to have access to requirements data that could improve the accuracy of assumptions and estimates, as well as facilitate the development of a sensitivity analysis, resulting in an overall improved feasibility assessment. By developing a cost estimate that is based on MHS Genesis or other actual requirements and includes all costs related to expansion of the Warstopper Program, as well as providing a sensitivity analysis, DLA would better position Congress to evaluate possible expansion of the Warstopper Program to include medications at risk of shortage for all MHS users.

Conclusions

DLA's Warstopper Program plays a critical role in helping to ensure warfighters have the materiel they need during a contingency while also avoiding the cost of stockpiling and maintaining items such as medications, chemical protective suits and gloves, and meals-ready-to-eat.

⁴⁷MHS Genesis is the Military Health System's new electronic health record. When fully deployed, MHS Genesis will provide a single health record for service members, retirees, and their families. According to DLA officials, the system had been deployed to less than 50 percent of the DOD providers and locations at the beginning of the assessment. DHA fully deployed the system in March 2024.

⁴⁸International Classification of Disease codes are a means of diagnosing, recording, and analyzing data and statistics related to health conditions regardless of country or culture. Established by the World Health Organization, these codes also aid in decision support, resource allocation, reimbursement, guidelines, and allow for the counting of medicine services and encounters. As an example, DLA's report identifies the ICD code for its airborne contagion scenario as 487.1 – Influenza with other respiratory manifestations.

However, DLA does not have clearly defined program goals and performance goals for the Warstopper Program that align with key practices to help manage and assess program results. DLA officials acknowledged that the Warstopper Program's goals could be more clearly defined. By developing outcome-oriented program goals that provide direction for the Warstopper Program, as well as performance goals that are specific and quantifiable, DLA would be better positioned to communicate to internal and external stakeholders what it is seeking to achieve.

Clear, measurable goals can also facilitate the development of effective performance measures to assess program performance. While DLA has established some performance measures for the Warstopper Program, DLA cannot fully assess the program's progress toward achieving its goals and strategic objectives. By developing unique performance measures that align to each program goal and reflect other key attributes of successful performance measures, DLA can better evaluate the Warstopper Program's progress and more clearly communicate its accomplishments.

The potential expansion of the Warstopper Program to include at least 30 medications at risk of shortage for all MHS users represents a significant expansion of the program. DLA's Warstopper Program expansion feasibility report contained many elements required of an economic analysis that aims to provide relevant information to decision-makers. However, the report did not include all costs associated with the expansion nor did DLA conduct a sensitivity analysis of the scenarios it assessed. Now that DLA has access to more complete requirements data, developing a cost estimate that includes all costs related to expansion of the Warstopper Program and conducting a sensitivity analysis that demonstrates how adjustments to the assumptions affect the cost estimates could provide more useful information to Congress.

Recommendations for Executive Action

We are making a total of three recommendations to the Secretary of Defense. Specifically:

The Secretary of Defense should ensure that the Director of the Defense Logistics Agency revise the program goals for the Warstopper Program in a way that reflects the mission and function of the program and are outcome-oriented. (Recommendation 1)

The Secretary of Defense should ensure that the Director of the Defense Logistics Agency, upon completion of revised program goals, develops one or more performance goals with quantifiable targets for each program goal, and unique performance measures that align to each program goal and reflect other key attributes of successful performance measures. (Recommendation 2)

The Secretary of Defense should ensure that the Director of the Defense Logistics Agency, in coordination with the Director of the Defense Health Agency, provide Congress an updated cost estimate for expanding the Warstopper Program that is based on actual requirements data and includes (1) all costs related to possible expansion, and (2) a sensitivity analysis. Additionally, the update should include any new or different conclusions based on the updated cost estimate. (Recommendation 3)

Agency Comments

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We provided a draft of this report to DOD for review and comment. In written comments, reproduced in appendix III, DOD concurred with all the recommendations. DOD also provided technical comments, which we incorporated into the report as appropriate.

We are sending copies of this report to the Secretary of Defense; the Director of the Defense Logistics Agency; and the Director of the Defense Health Agency. In addition, the report is available at no charge on the GAO website at https://www.gao.gov.

If you or your staff have any questions about this report, please contact Alissa Czyz at (202) 512-3058 or CzyzA@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in Appendix IV.

Alissa H. Czyz

Director, Defense Capabilities and Management

Appendix I: Scope and Methodology

Methodology for Assessing the Warstopper's Program Goals, Strategic Objectives, Performance Goals, and Performance Measures

To address our first objective, we reviewed Defense Logistics Agency (DLA) briefings, the Warstopper Program annual reports, return-on-investment reports, risk assessments, and other program documents to identify DLA's program goals, strategic objectives, and performance measures for the Warstopper Program.¹ We also interviewed DLA officials for additional clarity and context related to the program's goals, strategic objectives, and performance measures. We compared DLA's program management system for the Warstopper Program to our key practices to help manage and assess the results of federal efforts, such as the Warstopper Program.² Specifically, a GAO analyst performed an initial assessment, and a GAO subject matter expert with specialized knowledge of the criteria reviewed the assessment to ensure the criteria was accurately applied.

Our past work identified 13 key practices that can help executive branch leaders and employees at any organizational level—such as an individual project or program, component agency or office, department, or cross-agency effort—build and use evidence to manage the organization's performance. To develop the 13 key practices, we reviewed our past reports on evidence-building and performance management activities since 1996 and identified several hundred relevant actions. We distilled those actions into the 13 key practices using input from officials at 24 major federal agencies, Office of Management and Budget staff responsible for providing government-wide direction and guidance, and the results from a survey of federal managers that we conducted in 2020. In addition, the 13 key practices can help inform Congress's oversight of the Executive Branch's evidence-building and performance management activities, including implementation of relevant legislative requirements from the Government Performance and Results Act of 1993 (GPRA), as amended by the GPRA Modernization Act of 2010, and the Foundations for Evidence-Based Policymaking Act of 2018.³

Our past work breaks a program's performance management system down into various topic areas, the first of which is Plan for Results. The first best practice in this first topic area is Define Goals. We used this best practice and its associated criteria to assess the Warstopper Program's goals and strategic objectives.

We also assessed the Warstopper Program's performance measures against key attributes for performance measures. A GAO analyst analyzed each of the three performance measures that DLA used in fiscal year 2023 to determine if the measure reflected each of the 10 attributes. If all three performance measures reflected the attribute, we rated that attribute as "fully met." If some of the Warstopper Program's performance measures reflected the attribute but others did not, we rated the attribute as "partially met." In instances where none of the program's performance measures reflected the attribute, or as a whole they did not reflect the attribute, we rated that attribute as "not met." A GAO subject matter expert reviewed the analysis and the evidence to ensure the standards were consistently applied.

¹GAO did not evaluate DLA's contracting approach or the return-on-investment calculation as part of this review.

²GAO, Evidence-Based Policymaking: Practices to Help Manage and Assess the Results of Federal Efforts, GAO-23-105460 (Washington, D.C.: July 12, 2023).

³Pub. L. No. 103-62 (1993); Pub. L. No. 111-352 (2011); Pub. L. No. 115-435 (2019).

Methodology for Analyzing DLA Warstopper Program Expansion Feasibility Report

To address our second objective, we reviewed DLA's report on the feasibility of expanding the Warstopper Program, as well as associated workpapers and analyses. We also interviewed DLA and Defense Health Agency (DHA) officials who produced the report, as well as officials with the Department of the Army, Department of the Navy, and the Department of the Air Force to determine any input they provided for the report. A GAO analyst and an economist assessed the report and associated workpapers against our best practices for economic analyses to determine whether the Department of Defense (DOD) fully met, partially met, or did not meet those criteria. A rating of fully met meant that DLA included all elements of a particular practice. A rating of partially met meant that the agency may have partially or fully addressed one part of a best practice, but not another part of the best practice. A rating of not met meant that DLA did not include any elements of a particular best practice.

We used our assessment methodology for economic analyses, which was developed by reviewing documents from the various federal agencies and international partners, including DOD, as well as consulting with experts on economic analysis of public actions. The five resulting best practices identified by us are not intended to be exhaustive or to supplant or alter relevant federal and agency requirements for economic analysis. Instead, their intent is to establish a sound baseline framework for the assessment of an economic analysis. DOD has its own instruction that identifies best practices for its offices to use when developing economic analyses—DOD Instruction 7041.03.6 This instruction identifies seven elements for DOD offices to include when performing an economic analysis. Those elements are 1) Objective, 2) Assumptions, 3) Alternatives, 4) Costs and Benefits, 5) Comparison of Alternatives, 6) Sensitivity and Uncertainty Analyses, and 7) Results and Recommendations.

We compared the elements of our criteria to the elements in the DOD Instruction to ensure consistency. Using the descriptions of each best practice or element found in the respective document, we found that the best practices and the elements are consistent with each other. The specific correlation between the two can be found in Table 6.

Table 6: Crosswalk Retweet	n GAN Rost Practices and DNN	Elements for Economic Analyses

GAO best practice	Department of Defense (DOD) element	
Objective and Scope	Objective	
Methodology	 Alternatives 	
	 Comparison of Alternatives 	
Analysis of Effects	Costs and Benefits	
Transparency	 Assumptions 	
	 Sensitivity and Uncertainty Analysis 	
Documentation	Results and Recommendations	

Source: GAO-18-151SP. | GAO-24-106109

⁴Within the Department of the Navy, we met with military service officials from both the Navy and the U.S. Marine Corps.

⁵GAO, Assessment Methodology for Economic Analysis, GAO-18-151SP (Washington, D.C.: Apr. 10, 2018).

⁶Department of Defense Instruction 7041.03, *Economic Analysis for Decision-Making*, (Sept. 9, 2015) (incorporating Change 1, Oct. 2, 2017).

Appendix I: Scope and Methodology

We conducted this performance audit from June 2022 to July 2024. We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Key Attributes of Successful Performance Measures

We assessed the Warstopper Program performance measures against key attributes of performance measures identified in prior GAO reports. Performance goals and measures that successfully address important and varied aspects of program performance are key to a results-oriented, balanced work environment. Measuring performance allows organizations to track the progress they are making toward their goals and gives managers critical information on which to base decisions for improving their programs. Detailed explanations of each attribute are below.

Balance

Balance exists when a suite of measures ensures that an organization's various priorities are covered. Performance measurement efforts that overemphasize one or two priorities at the expense of others may skew the agency's performance and keep its managers from understanding the effectiveness of their program.

Baseline and Trend Data

Providing baseline and trend data could enable decision-makers to assess an agency's performance more fully because the data show progress over time and because decision-makers can use historical data to assess performance, including whether performance achieved in the fiscal year covered by the report was reasonable. Including baseline and trend data in annual performance reports can help agencies ensure that their reports are complete, and that performance is viewed in context. Such data can show whether performance goals are realistic given the past performance of an agency or program.

Clarity

A measure has clarity when it is clearly stated, and the name and definition are consistent with the methodology used for calculating the measure. A measure that is not clearly stated (i.e., contains extraneous or omits key data elements) or that has a name or definition that is inconsistent with how it is calculated can confuse users and could cause managers or other stakeholders to think that performance was better or worse than it actually was.

Core Program Activities

Core program activities are the activities that an entity is expected to perform to support the intent of the program. Performance measures should be scoped to evaluate the core program activities. Limiting the number of performance measures to the core program activities will help identify performance that contributes to goal achievement. At the same time, however, there should be enough performance measures to ensure

¹GAO, *Tax Administration: IRS Needs to Further Refine Its Tax Filing Season Performance Measures*, GAO-03-143 (Washington, D.C.: Nov. 22, 2002); *GPRA Performance Reports*, GAO/GGD-96-66R (Washington, D.C.: Feb. 14, 1996).

that managers have the information they need about performance in all the core program activities. Without such information, the possibility of achieving program goals is less likely.

Government-wide Priorities

Agencies should develop a range of related performance measures to address government-wide priorities, such as quality, timeliness, efficiency, cost of service, and outcome. A range is important because most program activities require managers to balance these priorities among other demands. When complex program goals are broken down into a set of component quantifiable measures, it is important to ensure that the overall measurement of performance does not become biased because measures that assess some priorities but neglect others could place the program's success at risk.

Limited Overlap

Measures overlap when the results of measures provide basically the same information. A measure that overlaps with another is unnecessary and does not benefit program management. Unnecessary or overlapping measures not only can cost money but also can cloud the bottom line in a results-oriented environment by making managers or other stakeholders sift through unnecessary or redundant information. Some measures, however, may overlap partially and provide stakeholders some new information. In those cases, management must make a judgment as to whether having the additional information is worth the cost and possible confusion it may cause.

Linkage

Performance goals and measures should align with an agency's goals and mission. A cascading or hierarchal linkage moving from top management down to the operational level is important in setting goals agencywide, and the linkage from the operational level to the agency level provides managers and staff throughout an agency with a road map that (1) shows how their day-to-day activities contribute to attaining agencywide goals and mission and (2) helps define strategies for achieving strategic and annual performance goals. As agencies develop annual performance goals, they can serve as a bridge that links long-term goals to agencies' daily operations. For example, an annual goal that is linked to a program and also to a long-term goal can be used both to (1) hold agencies and program offices accountable for achieving those goals and (2) assess the reasonableness and appropriateness of those goals for the agency as a whole. In addition, annual performance planning can be used to better define strategies for achieving strategic and annual performance goals. Linkages between goals and measures are most effective when they are clearly communicated to all staff within an agency so that everyone understands what the organization is trying to achieve and the goals it seeks to reach. Communicating goals and their associated measures is a continuous process and supports the basis for everything the agency does each day. Communication creates a "line of sight" throughout an agency so that everyone understands what the organization is trying to achieve and the goals it seeks to reach.

Measurable Target

Where appropriate, performance goals and measures should have quantifiable, numerical targets or other measurable values. Numerical targets or other measurable values facilitate future assessments of whether overall goals and objectives were achieved because comparisons can be easily made between projected

Appendix II: Key Attributes of Successful Performance Measures

performance and actual results. Some goals are self-measuring (i.e., they are expressed objectively and are quantifiable) and therefore do not require additional measures to assess progress. When goals are not self-measuring, performance measures should translate those goals into observable conditions that determine what data to collect to learn whether progress was made toward achieving goals. The measures should have a clearly apparent or commonly accepted relation to the intended performance or have been shown to be reasonable predictors of desired behaviors or events.

Objectivity

To the greatest extent possible, goals and measures should be reasonably free of significant bias or manipulation that would distort the accurate assessment of performance. They should not allow subjective considerations or judgments to dominate the outcome of the measurement. To be objective, performance goals and measures should indicate specifically what is to be observed, in which population or conditions, and in what timeframe and be free of opinion and judgment. Objectivity is important because it adds credibility to the performance goals and measures by ensuring that significant bias or manipulation will not distort the measure.

Reliability

Reliability refers to whether measures are amenable to applying standard procedures for collecting data or calculating results so that they would be likely to produce the same results if applied repeatedly to the same situation. Errors can occur at various points in the collection, maintenance, processing, and reporting of data. Significant errors would affect conclusions about the extent to which performance goals have been achieved. Likewise, errors could cause the measure to report performance at either a higher or lower level than is actually being attained. Reliability is increased when verification and validation procedures, such as checking performance data for significant errors by formal evaluation or audit, exist.

Appendix III: Comments from Department of Defense



ASSISTANT SECRETARY OF DEFENSE 3500 DEFENSE PENTAGON WASHINGTON, DC 20301-3500

JUL 0 9 2024

Ms. Alissa Czyz Director, Defense Capabilities and Management U.S. Government Accountability Office 441 G Street NW Washington, DC 20548

Dear Ms. Czyz:

This is the Department of Defense's (DoD's) response to GAO Draft Report, GAO-24-106109, 'WARSTOPPER PROGRAM: Comprehensive Cost Estimate Needed to Evaluate Potential Expanded Access to Emergency Medications,' dated May 14, 2024. The Department concurs with all three GAO recommendations. Responses to the recommendations directed at the Secretary of Defense are provided attached.

The Department's response was prepared with input from the Defense Logistics Agency in coordination with the Defense Health Agency. It describes efforts to be implemented by the Department of Defense.

The Department has prepared a sensitivity analysis and has found no controlled unclassified information in its response to the recommendation. If you have any questions, comments, or concerns, please contact the Office of the Assistant Secretary of Defense for Legislative Affairs.

Christopher J. Lowman

Enclosure: As stated

GAO DRAFT REPORT GAO-24-106109SU

"WARSTOPPER PROGRAM: COMPREHENSIVE COST ESTIMATE NEEDED TO EVALUATE POTENTIAL EXPANDED ACCESS TO EMERGENCY MEDICATIONS"

DEPARTMENT OF DEFENSE'S RESPONSE TO THE GAO'S RECOMMENDATIONS

RECOMMENDATION 1: The Secretary of Defense should ensure that the Director of the Defense Logistics Agency revise the program goals for the Warstopper Program in a way that reflects the mission and function of the program and are outcome oriented.

ASD(S) RESPONSE: Concur. While the Defense Logistics Agency's (DLA's) Warstopper Program has a defined mission and program level goals that support the Agency's Strategic Plan, DLA acknowledges the written format differed from the GAO's recommendations. DLA will ensure the program doctrine document addresses the mission and goals of the program.

RECOMMENDATION 2: The Secretary of Defense should ensure that the Director of the Defense Logistics Agency, upon completion of revised program goals, develops one or more performance goals with quantifiable targets for each program goal, and unique performance measures that align to each program goal and reflect other key attributes of successful performance measures.

ASD(S) RESPONSE: Concur. DLA's Warstopper Program self-identified the issues related to the metrics used by the program that GAO cited on pages 11, 15, and 24 of the report. The program has performance goals and completes performance reviews throughout the year. DLA acknowledges that the format used in previous fiscal year reports did not fully align with GAO's standards as outlined in the final version of report GAO-24-106109SU. DLA has begun to update its operating plans and reporting practices to address GAO's recommendations.

RECOMMENDATION 3: The Secretary of Defense should ensure that the Director of the Defense Logistics Agency, in coordination with the Director of the Defense Health Agency, provide Congress an updated cost estimate for expanding the Warstopper Program that is based on actual requirements data and includes (1) all costs related to possible expansion, and (2) a sensitivity analysis. Additionally, the update should include any new or different conclusions based on the updated cost estimate.

ASD(S) RESPONSE: Concur. Page 186 of House Armed Services Committee Report 117-118, accompanying H.R.4350, the National Defense Authorization Act for Fiscal Year 2022, Public Law No. 117-81, requested the Department to provide "an assessment of resources or authorities required to ensure access..." to a six-month supply of at least 39 pharmaceuticals, which the report to Congress accomplished. House Report 117-118 made limited scenario-based health emergency assumptions for modeling requirements because the Defense Health Agency (DHA) study members were unable to establish specific requirements (to include quantities and time-phasing). However, the analysis was sufficient to demonstrate feasibility. The Warstopper program has decades worth of data proving that providing a readiness solution for pharmaceuticals through a vendor managed process which prioritizes access is feasible and cost effective. GAO did not take exception to the soundness of these contract solutions or the cost benefit demonstrated by the program. Using Warstopper for DHA requirements is feasible, but not without warfighter risk, as indicated in the report submitted to Congress.

Warfighter readiness coverage provided through the Warstopper program is for deployed warfighters to support operational needs. It is not intended for home station military members, dependents, and veterans. Utilizing the Warstopper program to benefit a non-warfighter population has the potential risk of diluting the capability available for deployed forces and adding operational complexity to meeting warfighter needs.

DLA will coordinate with DHA to identify specific medical requirements for establishing a sixmonth supply of pharmaceuticals for Military Health System users. Based on these requirements, DLA will identify the costs related to the possible expansion of the Warstopper Program and conduct a sensitivity analysis. Additionally, the update will include any new or different conclusions based on the updated cost estimate while considering the impacts to warfighter readiness.

Accessible Text for Appendix III: Comments from Department of Defense

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Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Alissa H. Czyz, (202) 512-3058 or CzyzA@gao.gov.

Staff Acknowledgments

In addition to the contact named above, Lori Atkinson (Assistant Director), Matthew Spiers (Analyst in Charge), Namita Bhatia-Sabharwal, Robert Bullock, Elizabeth Field, Christopher Gezon, William Hadley, Rebecca Hendrickson, Robert C. Jones, Benjamin Licht, Felicia Lopez, Patricia Powell, Clarice Ransom, Theologos Voudouris, and Raymond Weyandt made key contributions to this report.

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