IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
CENTRAL DIVISION

EXPRESS SCRIPTS, INC.; EXPRESS SCRIPTS PHARMACY, INC.; ESI MAIL PHARMACY SERVICE, INC; EXPRESS SCRIPTS SPECIALTY DISTRIBUTION SERVICES, INC.; ACCREDO HEALTH GROUP, INC.; LYNNFIELD DRUG, INC. d/b/a FREEDOM FERTILITY PHARMACY; LYNNFIELD COMPOUNDING CENTER, INC. d/b/a FREEDOM FP FERTILITY PHARMACY; and VILLAGE FERTILITY PHARMACY, LLC,

Plaintiffs,

v.

RODNEY RICHMOND, BRIAN JOLLY, DEBBIE MACK, LENORA NEWSOME, CLINT BOONE, WALTER LYN FRUCHEY, HAROLD H. SIMPSON, and BETH ANN DAVENPORT, in their official capacities as board members of the Arkansas State Board of Pharmacy; and JOHN C. KIRTLEY, in his official capacity as executive director of the Arkansas State Board of Pharmacy,

Defendants.

Case No. 4:25CV520-BSM

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

This case assigned to District Judge Miller
and to Magistrate Judge Ervin

On April 16, 2025, Arkansas Governor Sanders signed into law Act 624, a statute innocuously – but deceivingly – titled "An Act To Prohibit A Pharmacy Benefits Manager From Obtaining Certain Pharmacy Permits." What Act 624 *actually* does is harm Arkansans by banishing from the state any pharmacy that is affiliated through common ownership with a pharmacy benefits manager ("PBM"). This includes multiple pharmacies affiliated with Express

Scripts, Inc. ("ESI"), a PBM. For decades, each of those pharmacies has provided high-quality, safe, reliable, convenient, and affordable mail-order pharmacy services to tens of thousands of Arkansans. If left to stand, the law will have devastating consequences across Arkansas – including forcing numerous pharmacies operating in the state out of business, costing the more than 600 Arkansans employed at those pharmacies their jobs, and creating pharmacy "deserts" for the nearly 40% of Arkansans who live in rural areas that often lack brick-and-mortar pharmacies. The law will also dangerously limit patient choice and deny access to lifesaving drugs at affordable prices by high-quality pharmacy providers. And it will create mass confusion among Arkansans about where and how they can receive needed prescription medications, irreparably breaking bonds that patients have formed over many years with their pharmacists and pharmacy-provided home-visit nurses. Because of these grave harms, and because the law violates multiple provisions of federal law, Plaintiffs bring this action to have Act 624 enjoined and declared unlawful.

INTRODUCTION

1. Millions of Americans nationwide and hundreds of thousands of Arkansans rely on PBM-affiliated pharmacies for their prescription medications. For example, Plaintiffs Express Scripts Pharmacy, Inc. ("ESP") and ESI Mail Pharmacy Service, Inc. ("ESI Mail," and together with ESP, "Express Scripts Pharmacy") delivered more than 700,000 prescriptions to more than 45,000 patients throughout Arkansas in 2024 alone. Express Scripts Pharmacy's mail-order service is a vital pharmacy resource for Arkansans, many of whom live in rural areas that often lack brick-and-mortar pharmacies. Express Scripts Pharmacy has also served for more than 20 years as the principal mail-order pharmacy provider for the U.S. Department of Defense's TRICARE program, which provides healthcare services to military members, retirees,

and families. Last year, Express Scripts Pharmacy dispensed more than 386,000 prescriptions to over 20,000 TRICARE beneficiaries in Arkansas.

2. Another PBM-affiliated pharmacy – Plaintiff Accredo Health Group, Inc. ("Accredo Specialty Pharmacy" or "Accredo") – serves thousands of Arkansans who have complex and chronic medical conditions, including cancer, bleeding disorders, multiple sclerosis, and numerous rare diseases. Accredo not only provides safe and convenient access to specialty medications (which can be expensive, require specialized storage and handling, clinical monitoring, and frequent dose adjustments); it also offers personalized clinical counseling and support from specialized pharmacists, nurses, dieticians, and social workers. In 2024, Accredo shipped almost 70,000 prescriptions to over 5,700 patients in Arkansas, with more than 10,000 of those prescriptions going to TRICARE beneficiaries. In addition, Accredo's specially trained nurses provided over 3,000 hours of care to Arkansan patients in their homes last year.

3. A third PBM-affiliated pharmacy group – Plaintiffs Lynnfield Drug, Inc. d/b/a Freedom Fertility Pharmacy and Lynnfield Compounding Center, Inc. d/b/a Freedom Fertility FP Pharmacy (collectively referred to as "Freedom Fertility") – is the nation's leading fertility pharmacy. Freedom Fertility serves hundreds of Arkansans, delivering more than 1,500 prescriptions to patients across the state in 2024 to help them grow their families.

4. In all, more than 50,000 Arkansans rely on ESI-affiliated pharmacies today, including individuals with commercial prescription drug benefits through their employers or insurers, seniors, military service members, their families, and other beneficiaries. These Arkansans run the gamut from those who may simply require a routine maintenance medication to sustain their health and vitality to those with complex and grave medical conditions, whose

very lives depend on continuous access to medication provided by specialty pharmacies, and everyone in between.

5. Act 624 (attached as Exhibit A) imperils the health of all these individuals – for the exclusive benefit of Arkansas-based pharmacies who spearheaded the legislation in order to increase their market share by eliminating out-of-state competition. Indeed, Act 624's text, context, and legislative history make abundantly clear that the statute's purpose and effect is to protect local pharmacies domiciled in Arkansas from out-of-state competition, and to do so by punishing specific out-of-state competitors. To Plaintiffs' knowledge, *all* PBM-affiliated pharmacies operating in Arkansas are domiciled within the United States but outside Arkansas, meaning that only out-of-state (but American) entities will be denied a permit under Act 624. The statute's preamble, moreover, makes explicit that the law's purpose is to prevent "locally-operated pharmacies" from going "out of business." And the legislative history is replete with evidence that the statute's intended effect is to "safeguard the future of independent community pharmacies" by banishing PBMs as punishment for "tak[ing] pharmacy services out of our local communities."

6. If a state legislature may banish major out-of-state competitors out of concern for local, independent business interests, it could apply similar protectionist approaches in other sectors. Imagine, for example, a bill that bans out-of-state movie streaming services such as Netflix from serving customers in Arkansas because movie streaming services compete with local, independent movie theaters. Myriad examples of similar protectionist legislation involving a range of businesses, from grocery and hardware stores to gas stations, are easy to envision.

7. To be sure, Act 624 states that its purpose is to "eliminat[e] certain anticompetitive business tactics." Act 624 §1(b). But that is entirely pretextual. None of the "anticompetitive business tactics" the statute purports to prevent are real – and in any event, they are all already prohibited under current Arkansas law. For example, one state statute prohibits PBMs from "[r]eimburs[ing] a pharmacy or pharmacist in the state an amount less than the amount that the [PBM] reimburses a [PBM] affiliate for providing the same pharmacist services." Ark. Code §23-92-506(b)(4)(A). Nothing in the legislative record identifies any purportedly anticompetitive practice addressed by Act 624 that is not already prohibited under Arkansas law.

8. ESI and its affiliated pharmacies cannot avoid the harm that Act 624 inflicts by simply parting ways. Dismantling the organization in this way is not practical or feasible, because ESI and its affiliated pharmacies have long-standing, deeply-interwoven common ownership and business relationships. They have worked tirelessly to improve these synergies to provide best-in-class integrated PBM and pharmacy services to plan sponsors and their members. And these tight-knit relationships are precisely what enable ESI to provide critical, safe, and affordable pharmacy services to tens of thousands of Arkansans, creating efficiencies that lead to lower prices, improved patient care, and better patient service.

9. Act 624's illegitimate purpose and effect render it unconstitutional several times over.

10. First, the U.S. Constitution's Commerce Clause, and in particular the negative component of that clause that is known as the dormant Commerce Clause, "prohibits the enforcement of state laws 'driven by economic protectionism – that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.'" *National*

Pork Producers Council v. Ross, 598 U.S. 356, 369 (2023) (quoting *Department of Revenue of Kentucky v. Davis*, 553 U.S. 328, 337-338 (2008)). Because Act 624 is just such protectionist legislation, it is unconstitutional under the dormant Commerce Clause.

11. Second, a state law violates the Constitution's Privileges and Immunities Clause if it is "enacted for the protectionist purpose of burdening out-of-state citizens" by depriving them of "the privilege of pursuing [their professional] calling." *McBurney v. Young*, 569 U.S. 221, 227 (2013). Act 624 does exactly that: it burdens exclusively out-of-state entities (PBMs with affiliated pharmacies) by prohibiting them from working and providing services in Arkansas.

12. Third, Act 624 accomplishes its protectionist purpose by singling out PBMs and PBM-affiliated pharmacies for punishment. In particular, legislative history reveals that the law was motivated by a desire to punish the nation's three largest PBMs, including ESI. Act 624 thus violates the Constitution's Bill of Attainder Clause, which bars "legislative punishment … of specifically designated persons or groups," *United States v. Brown*, 381 U.S. 437, 447 (1965), including punishment in the form of "banishment" or "barring designated individuals or groups from participation in specified employments or vocations," *Nixon v. Administrator of General Services*, 433 U.S. 425, 474 (1977).

13. Finally, as applied to ESI, Express Scripts Pharmacy, Accredo Specialty Pharmacy, and Freedom Fertility, Act 624 is preempted by the federal statutes and regulations governing the U.S. Defense Department's TRICARE program, which delivers military health benefits through private contractors. Act 624's substantial interference with the TRICARE program is not an incidental, unforeseen consequence of the law; indeed, as a lawmaker who championed the bill explained, the law was *designed* to "tell the federal government" how to administer the TRICARE program in Arkansas and with whom it can and cannot partner in the

state. *Hearing on H.B. 1150 Before the Arkansas Senate Insurance and Commerce Committee*, Apr. 8, 2025 ("*Senate Hearing*") at 11:08:15 AM (statement of Sen. Boyd), *available at* https://sg001-harmony.sliq.net/00284/Harmony/en/PowerBrowser/PowerBrowserV2/20250408/-1/31028?mediaStartTime=20250408102505#info.*

14. But TRICARE's enabling statute includes an express preemption clause that exempts TRICARE contractors from state laws that are inconsistent with, or obstacles to the implementation of, a TRICARE contract. *See* 10 U.S.C. §1103(a). ESI's TRICARE contract with the federal government requires ESI to provide mail-order pharmacy services to TRICARE beneficiaries nationwide (including in Arkansas), and ESI has selected – and the federal government has approved – Express Scripts Pharmacy, Accredo Specialty Pharmacy, and Freedom Fertility to provide those services.

15. Because Act 624 is unconstitutionally protectionist, unconstitutionally punitive, and preempted by federal law, enforcement of the statute must be enjoined.

PARTIES

16. Plaintiff Express Scripts, Inc. ("ESI") is a Delaware corporation that has its principal place of business at 1 Express Way, Saint Louis, MO 63121.

17. Plaintiff Express Scripts Pharmacy, Inc. ("ESP") is a Delaware corporation that has its principal place of business at 4600 North Hanley Road, Saint Louis, MO 63134.

18. Plaintiff ESI Mail Pharmacy Service, Inc. ("ESI Mail") is a Delaware corporation that has its principal place of business at 4600 North Hanley Road, Saint Louis, MO 63134.

* All URLs cited in this complaint were visited on May 29, 2025.

19. Plaintiff Express Scripts Specialty Distribution Services, Inc. ("ESSDS") is a Delaware corporation that has its principal place of business at 4600 North Hanley Road, Suite B, Saint Louis, MO 63134.

20. Plaintiff Accredo Health Group, Inc. ("Accredo Specialty Pharmacy" or "Accredo") is a Delaware corporation that has its principal place of business at 1620 Century Center Parkway, Suite 109, Memphis, TN 38134.

21. Plaintiffs Lynnfield Drug, Inc. d/b/a Freedom Fertility Pharmacy and Lynnfield Compounding Center, Inc. d/b/a Freedom Fertility FP Pharmacy (collectively, "Freedom Fertility") are each a Florida corporation that has its principal place of business at 374 Merrimac Street, Newburyport, MA 01950.

22. Plaintiff Village Fertility Pharmacy, LLC ("Village Fertility") is a Delaware corporation with its principal place of business at 335 Bear Hill Road, Suite 1, Waltham, MA 02451.

23. Defendants Rodney Richmond, Brian Jolly, Debbie Mack, Lenora Newsome, Clint Boone, Walter Lyn Fruchey, Harold Simpson, and Beth Ann Davenport are board members of the Arkansas State Board of Pharmacy. Each is sued in his or her official capacity. As such, each is a resident of Arkansas.

24. Defendant John C. Kirtley is the executive director of the Arkansas State Board of Pharmacy. He is sued in his official capacity and, as such, is a resident of Arkansas.

JURISDICTION AND VENUE

25. This action arises under the Constitution and the federal statute establishing the TRICARE program. This Court has subject matter jurisdiction under 28 U.S.C. §1331. The

Court is authorized to issue the relief sought pursuant to the Civil Rights Act of 1871, 42 U.S.C. §1983, and the Declaratory Judgment Act, 28 U.S.C. §§2201-2202.

26. Venue is proper in this district under 28 U.S.C. §1391(b)(1) because all Defendants are officers of the Arkansas State Board of Pharmacy, located at 322 South Main Street, Suite 600, Little Rock, Arkansas, and are sued in their official capacity. As such, all Defendants are residents of Arkansas and reside in this district. Venue is also proper under 28 U.S.C. §1391(b)(2) because a substantial part of the events or omissions giving rise to the claims in this action occurred in this district.

FACTUAL ALLEGATIONS

I. PBMs Lower The Cost Of Prescription Drugs And Streamline Pharmacy Operations For Health Plan Sponsors And Patients

27. Most Americans do not pay the list price for their prescription drugs. Instead, most prescription drug purchases are paid for, in part, through health insurance plans that offer a prescription drug benefit. The sponsors of these plans include employers, labor unions, and insurers, as well as federal, state, and municipal governments and government programs, such as Medicare, Medicaid, and workers' compensation.

28. Health plan sponsors frequently contract with PBMs to help manage prescription drug benefits for the plan, including by providing administrative services to improve the efficiency and quality of benefits and by negotiating lower costs for prescription drugs. PBMs are the only entities in the prescription drug supply chain whose purpose is to help plan sponsors and their members pay less for prescription drugs, countering the trend of higher drug prices being set by pharmaceutical manufacturers.

29. Indeed, Arkansas itself contracts with a PBM to manage prescription drug benefits for state employees. *See Employee Benefits: Pharmacy FAQs*, Arkansas Department of

Transformation & Shared Services, *available at* https://transform.ar.gov/employee-benefits/faq/pharmacy. As the state's website explains, that PBM "negotiates costs between drug manufacturers, pharmacies, and health care insurance providers," "process[es] pharmacy claims," and reviews prior authorizations for certain medications. *Id.* Thus, like thousands of other health plan sponsors across the nation, Arkansas has recognized the value of working with a PBM to deliver critical drug benefits.

30. When a member of a health plan that works with a PBM visits or contacts a pharmacy to fill a prescription, the pharmacy (through an electronic system) checks with the plan's PBM to determine the member's coverage and co-pay information. The PBM also performs thousands of health and safety checks regarding the prescription for potential contraindications and drug interactions for the member, and will then provide a message back to the pharmacy about the status of the member's prescription claim within seconds. After the member pays the co-payment (if any) and receives the prescription, the PBM reimburses the pharmacy for the medication at a contractually determined rate (which is often also established by state law, as it is in Arkansas). The health plan, in turn, reimburses the PBM for the prescription at a contractually determined rate.

31. The discounts, savings, and efficiencies that PBMs secure for health plan sponsors allow them to reduce premiums and out-of-pocket costs for members.

32. One primary way PBMs create savings for health plan sponsors and their members is by negotiating reimbursement rates with pharmacies. By negotiating lower reimbursement rates, PBMs lower the cost of prescription drug coverage for plan sponsors and for their members. Cantrell, *It Is Time For A More Nuanced Discussion About Pharmacy*

Benefit Managers, 30 J. Managed Care & Specialty Pharmacy 1345, 1346 (2024), *available at* https://doi.org/10.18553/jmcp.2024.24311.

33. Another way PBMs create savings is by negotiating with drug manufacturers to obtain discounts on prescription drugs. By aggregating volume over multiple plan sponsors and specializing in the bargaining process, PBMs negotiate larger discounts than individual plan sponsors could. These discounts save patients tens of billions of dollars every year. Mulligan, *The Value of Pharmacy Benefit Management* at 2, National Bureau of Economic Research Working Paper 30231 (2022), *available at* https://www.nber.org/papers/w30231.

34. PBMs also provide numerous other services that improve the quality of benefits and create efficiencies for health plan sponsors and their members, such as processing prescription claims. Carlton et al., *PBMs and Prescription Drug Distribution: An Economic Consideration of Criticisms Levied Against Pharmacy Benefit Managers* at 11, 17-18, Compass Lexecon (Apr. 2025) ("Carlton Report"), *available at* https://carltonreport.org. For example, ESI adjudicates over a billion prescription claims each year from its network pharmacies, with each prescription undergoing more than 18,000 safety, quality, and benefit checks within seconds of being submitted at the pharmacy counter. ESI's affiliated pharmacies also dispense medications with a near-perfect accuracy rate. Express Scripts Pharmacy dispenses medications with 99.9990% accuracy nationwide and 99.9992% accuracy in Arkansas. Accredo's accuracy rate is 99.9985% nationwide and 99.9902% in Arkansas. ESSDS's accuracy rate is 99.9989% nationwide and 100% in Arkansas. And Freedom Fertility's accuracy rate is 99.9964% nationwide and 100% in Arkansas. *See, e.g.*, Express Scripts, *Why you should choose Express Scripts® Pharmacy*, *available at* https://militaryrx.express-scripts.com/blog/why-you-should-

choose-express-scriptsr-pharmacy#:~:text=Express%20Scripts%C2%AE%20Pharmacy%20dispenses,Looking%20to%20track%20your%20order%3F.

35. Some PBMs – including the nation's three largest (ESI, CVS Caremark, and OptumRx) – own or share common ownership with pharmacies. Such PBM-affiliated pharmacies offer simplified payment procedures, streamlined claims processing, aggregated information regarding drug safety and efficacy, and other efficiencies that make access to prescription drugs more convenient and affordable, creating more positive patient experiences.

36. Today, millions of Americans and hundreds of thousands of Arkansans – including military members, seniors, patients with specialty drug needs, and families pursuing fertility treatments – choose to fill their prescriptions at PBM-affiliated pharmacies.

37. PBM-affiliated pharmacies have not, however, displaced independent pharmacies. To the contrary, the number of independent pharmacies has increased in recent years, both nationwide and in Arkansas. Carlton Report at 101-102; *Senate Hearing* at 11:53:30 AM (statement of Sen. Irvin).

38. PBM-affiliated pharmacies compete with one another and with independent and non-PBM-affiliated chain pharmacies in a diverse market that serves patients with diverse medical needs. This competition occurs in Arkansas today and as a result, offers more diverse and robust pharmacy services to residents in the state.

39. Although PBMs can perform a number of valuable services for health plan sponsors, it is those plan sponsors – not PBMs – that exercise control over how to design their pharmacy drug benefits and how to allocate their resources. This includes wide discretion over (1) the list of drugs, or "formulary" that will be covered under a plan; (2) the types of pharmacies that will be included in a plan's pharmacy network; (3) whether there are premiums and the

amount of those premiums; (4) whether there are deductibles and the amount of those deductibles; (5) whether there are co-insurance or co-pay obligations and the amount of those obligations; (6) whether utilization management will be applied to any particular drug therapy or condition; and (7) the degree to which a plan uses programs to mitigate members' list price exposure.

40. As part of their benefit design, plan sponsors often consider cost-effective ways to create safe and effective access to pharmacy services to maximize the health and vitality of their members. One of these solutions has been the use of mail-order pharmacy services. Health plans that cover members in multiple states – for example, plans sponsored by larger regional or nationwide employers – often select a single mail-order pharmacy that can serve members throughout the United States, an arrangement that relies on those mail-order pharmacies being able to offer services on a nationwide basis. Typically, members pay reduced co-payments if they opt to use mail-order pharmacy services.

II. PHARMACIES AFFILIATED WITH ESI SERVE TENS OF THOUSANDS OF PATIENTS ACROSS ARKANSAS

41. Plaintiff pharmacies (Express Scripts Pharmacy, ESSDS, Accredo Specialty Pharmacy, Freedom Fertility, and Village Fertility) are each affiliated (by common ownership) with Plaintiff ESI, a PBM. As noted, each has offered safe, reliable, and convenient mail-order pharmacy services to patients throughout Arkansas for years, and most have done so for over two decades.

42. Express Scripts Pharmacy is a nationally accredited home-delivery pharmacy that delivered more than 700,000 prescriptions to over 45,000 patients throughout Arkansas last year alone. Doctors submit prescriptions to Express Scripts Pharmacy electronically, and patients can conveniently refill and renew prescriptions by phone or on the pharmacy's website or mobile

app. Express Scripts Pharmacy offers free standard shipping and uses packaging that is confidential, tamper-evident, and weather-resistant. For medications that require specific temperature control, it uses special packaging and coolant packs, adjusting for current and forecasted climate conditions. Pharmacists and patient-care advocates are available for live conversations with patients 24 hours a day, seven days a week. This mail-order service is a vital resource for Arkansans, more than 40% of whom live in rural areas and may not have easy access to a brick-and-mortar pharmacy. Express Scripts Pharmacy has been licensed to operate in Arkansas since 1997 and has always been in good standing.

43. Express Scripts Pharmacy's weather-resistant packaging and other capabilities also allow it to provide medications during emergencies. And it has a track record of doing so. For example, it administered an emergency prescription program for the Department of Health and Human Services in Puerto Rico following Hurricane Maria. *See* Express Scripts, *Emergency Prescription Assistance Program (EPAP) due to Hurricane Maria in Puerto Rico* (Oct. 4, 2017), *available at* https://nj211.org/sites/default/files/documents/2017-10/expresscomm-epap-puertorico-oct2017.pdf.

44. ESSDS is a nationally accredited specialty pharmacy that serves Arkansans who suffer from complex sleep disorders. Last year it dispensed more than 5,400 medications to over 270 Arkansans. Its dedicated staff consists of specially trained pharmacists, nurses, reimbursement specialists, and patient-service coordinators. ESSDS has been licensed to operate in Arkansas since 2000 and has always been in good standing.

45. Accredo Specialty Pharmacy is a nationally accredited specialty pharmacy that serves Arkansans with complex and chronic conditions, including cancer, hepatitis C, HIV, rheumatoid arthritis, multiple sclerosis, and many other more rare diseases. Last year it

dispensed almost 70,000 medications to over 5,700 patients. It is one of a limited number of pharmacies with the URAC Center of Excellence Rare Disease accreditation. Accredo, *Rare Disease Therapeutic Resource Center*, *available at* https://www.accredo.com/raretherapies/prescribers.

46. Many of the specialty medications Accredo offers are part of an exclusive or limited distribution channel, meaning that the drug's manufacturer has chosen to make it available only through a single specialty pharmacy (exclusive distribution) or a small number of specialty pharmacies (limited distribution). Drug manufacturers establish exclusive and limited distribution networks to ensure patient safety, for example by choosing to work with pharmacies that have the expertise necessary to provide specialized patient support and to meet stringent storage and handling protocols. Accredo is the exclusive distributor for 20 medications treating a range of conditions, including certain types of cancer and spinal-muscular atrophy. Some Accredo patients therefore critically need medicines that they cannot get anywhere else. Accredo is also proud to be able to dispense other limited distribution medications (medications treating conditions like pulmonary arterial hypertension, hemophilia, and muscular dystrophy) because of the high-quality clinical services and support it provides.

47. Given that specialty medications are typically expensive, moreover, Accredo provides billing specialists to help patients navigate out-of-pocket costs and connect them with co-pay assistance where available. In addition to convenient and affordable access to specialty medications and related items (such as infusion pumps and other devices often needed to administer the medications), Accredo offers personalized clinical counseling and therapeutic-care services from specially trained pharmacists, nurses, dieticians, and social workers to help patients manage their complex conditions and treatments. For instance, Accredo's more than

600 specialty-trained infusion nurses provide face-to-face care in the comfort of patients' homes. Accredo aims to partner patients with the same nurse for each home visit, resulting in strong bonds between patients and their caregivers, which can lead to better adherence to medication and improved health outcomes.

48. In 2024, Accredo shipped nearly 70,000 prescriptions to Arkansas patients, and specially trained nurses provided over 3,000 hours of care to patients in their homes in the state. Accredo has been licensed to operate in Arkansas since 2002 and has always been in good standing.

49. Freedom Fertility is a nationally accredited pharmacy and the nation's leading fertility pharmacy. With over 30 years of experience supporting women's health and dispensing fertility medications, Freedom Fertility provides comprehensive expertise and resources to families pursuing IVF and other fertility treatments. Freedom Fertility serves more than one hundred Arkansans, delivering over 1,500 prescriptions to patients across the state in 2024. Freedom Fertility has been licensed to operate in Arkansas (under the names Lynnfield Drug, Inc. and Lynnfield Compounding Center, Inc.) since 2003 and has always been in good standing.

50. Village Fertility is a nationally accredited pharmacy dedicated to supporting patients on the path to parenthood by providing accessible, affordable, and personalized fertility care. Village Fertility has more than 30 years of experience in the fertility industry and serves more than 200 Arkansans. Village Fertility has been licensed to operate in Arkansas since 2018 and has always been in good standing.

III. THE U.S. DEPARTMENT OF DEFENSE RELIES ON ESI-AFFILIATED PHARMACIES TO PROVIDE PHARMACY SERVICES TO MILITARY MEMBERS, RETIREES, AND THEIR FAMILIES THROUGH THE TRICARE PROGRAM

51. Under Title 10, Chapter 55 of the U.S. Code, the Department of Defense ("DoD") operates a healthcare program, known as TRICARE, through which it provides statutory

healthcare entitlements to military service members, retirees, and families. TRICARE offers healthcare benefits to approximately 9.6 million beneficiaries in all 50 states and overseas. Through TRICARE, beneficiaries can receive healthcare services in military treatment facilities ("MTFs"), such as DoD-operated hospitals and clinics, or via networks of participating civilian healthcare providers. The Defense Health Agency ("DHA"), which administers TRICARE, contracts with several managed care support organizations, a pharmacy benefits manager, and a dental-insurance organization to deliver healthcare entitlements.

52. Section 1074g of Title 10 of the U.S. Code requires DoD to "establish an effective, efficient, [and] integrated pharmacy benefits program" as part of TRICARE, a program known as the TRICARE Pharmacy Benefits Program. *See also* 32 C.F.R. §199.21(a)(1). By statute, this program must satisfy a host of requirements. 10 U.S.C. §1074g. For example, the program must make prescription drugs available to TRICARE beneficiaries through MTF pharmacies, a retail pharmacy network, and a national mail-order pharmacy program. *Id.* §1074g(a)(2)(E).

53. To administer TRICARE, DHA contracts with private health insurance and healthcare delivery companies. In awarding contracts, DoD must ensure that TRICARE "provide[s] a stable program of benefits," and it may award contracts only to "the offeror or offerors that will provide the best value to the United States to the maximum extent consistent with furnishing high-quality health care in a manner that protects the fiscal and other interests of the United States." 10 U.S.C. §§1073(b), 1073a(a).

54. Pursuant to these authorities, DHA has contracted with ESI since 2002 for the delivery of pharmacy services to TRICARE beneficiaries. The current contract, known as TPharm5, requires ESI to perform a number of functions mandated by section 1074g. As

relevant here, ESI must "establish and maintain a retail pharmacy network throughout the 50 United States" and must provide national mail-order pharmacy services to dispense and deliver medications to TRICARE beneficiaries. TPharm5 §C.3.3.1; *see also id.* at §§C.1, C.6.1.1; 10 U.S.C. §1074(a)(2)(E)(ii), (iii). The contract requires nationwide mail-order services to be provided through "the Contractor's Mail Order Pharmacy" and "the Contractor's mail order facilities." TPharm5 §C.6.1, C.6.1.1. Excerpts of the contract are attached as Exhibit B.

55. ESI carries out its contractual obligation to provide national mail-order pharmacy services through Express Scripts Pharmacy, its in-house mail-order pharmacy. In this role, Express Scripts Pharmacy maintains a stock of medications on DoD's behalf and distributes medications from that stock to fill orders by TRICARE beneficiaries. TPharm5 §C6.1.

56. ESI informed DoD of its intent to use Express Scripts Pharmacy as TRICARE's mail-order pharmacy when ESI applied for its TRICARE contract; Express Scripts Pharmacy is the entity described as the "Contractor's Mail Order Facility" under the contract. TPharm5 §C.6.1. DoD thus specifically and expressly contemplated Express Scripts Pharmacy's involvement when it granted the TRICARE contract to ESI in 2002.

57. In addition, the TPharm5 contract provides that the "TRICARE Mail Order Pharmacy … program … includes any network pharmacy designated by the Contractor and approved by the Government that can dispense specialty agents" by mail order. TPharm5 §C.6.1. Accredo and Freedom Fertility have been "designated" by ESI and, as of March 1, 2024, "approved" by the government to dispense specialty agents by mail order under this provision. The relevant excerpt of the contract modification designating Accredo and Freedom Fertility is attached as Exhibit C.

58. The TRICARE statute generally requires TRICARE beneficiaries "to refill non-generic prescription maintenance medications through military treatment facility pharmacies or the national mail-order pharmacy program." 10 U.S.C. §1074g(a)(9)(A). The TPharm5 contract requires ESI to carry out this requirement. *See* TPharm5 § C.6.6.

59. To achieve savings in dispensing pharmaceutical agents (both specialty and non-specialty) and supplies, the TPharm5 contract requires ESI to maximize the use of replenishment of dispensed items in lieu of being reimbursed for the costs of these items. TPharm5 §§C.4.7, C.6.1. This permits the government to negotiate lower costs using the Federal Supply Schedule through the National Prime Vendor ("NPV") contract. The Defense Logistics Agency – Troop Support ("DLA-TS") manages the NPV contract. TPharm5 §§C.4.7, C.6.8, C.6.8.3, C.6.8.5.

60. When the government awarded the latest version of the NPV contract in 2022, DLA-TS announced the immense savings of the replenishment program, explaining that the "increased cost avoidance" it afforded was "[t]he biggest benefit" of "this generation of the contract." DLA-TS also lauded the increased availability of difficult-to-source specialty medications, stating: "An additional benefit is the improved access to medications that may have been previously difficult to acquire. 'This contract will expand product availability to specialty pharmaceuticals….'" DLA Troop Support Public Affairs, *Next Generation Pharmaceutical Contract Provides Major Benefits for Military Customers*, Defense Logistics Agency, *available at* https://www.dla.mil/About-DLA/News/News-Article-View/Article/3109778/next-generation-pharmaceutical-contract-provides-major-benefits-for-military-cu.

61. Co-pays for TRICARE members are established by Congress. TRICARE members save money and pay lower co-pays for 90-day supplies of medications dispensed via mail order. For example, the cost-sharing amount for a 30-day supply of a retail generic will be

$16 in 2026. The cost-sharing amount for a 30-day supply of a retail brand will be $48. In 2026, the cost-sharing amount for a 90-day supply of a mail-order generic will be $14 and the cost-sharing amount for a 90-day supply of a mail-order brand will be $44. 10 U.S.C. §1074g(a)(6)(A).

62. Because of these aspects of the TRICARE statute and TPharm5 contract, prohibiting ESI from using Express Scripts Pharmacy, Accredo, and Freedom Fertility will increase costs to the government, limit TRICARE beneficiary access to specialty medications, and at least triple the cost-sharing burden on TRICARE beneficiaries if they are required to transfer their prescriptions to retail pharmacies.

63. The fact that Express Scripts Pharmacy, Accredo, and Freedom Fertility are ESI's in-house pharmacies eliminates transaction costs and other inefficiencies that would otherwise exist in ESI's administration of mail-order pharmacy services for TRICARE beneficiaries. DoD thus appropriately determined that the selection of Express Scripts Pharmacy, Accredo, and Freedom Fertility satisfies its statutory mandate to award contracts to contractors that will "provide the best value" to TRICARE beneficiaries and the government. 10 U.S.C. §1073a(a).

IV. ACT 624 WOULD BANISH PBM-AFFILIATED PHARMACIES FROM ARKANSAS, TO DEVASTATING EFFECT

64. Act 624, signed into law on April 16, 2025, marks an unprecedented step in Arkansas's regulation of PBMs, taking direct aim at a business model that serves millions of patients nationwide – and hundreds of thousands in Arkansas – who depend on convenient and reliable access to affordable prescriptions.

65. If it takes effect, Act 624 will prohibit PBM-affiliated pharmacies from operating in Arkansas.

66. First, Act 624 defines "[p]harmacy benefits manager" to include any PBM-affiliated pharmacy – specifically, the law sweeps into the statutory definition any entity (such as a pharmacy) that is "managed by a [PBM] or is a subsidiary of a [PBM]" or "[h]as a direct or indirect ownership interest in a [PBM]." Act 624 §2(a)(2)(B), to be codified as Ark. Code Ann. §17-92-416(a)(2)(B).

67. Second, the statute declares that PBMs (defined to include PBM-affiliated pharmacies) cannot hold pharmacy permits in Arkansas. The statue provides: "A [PBM] shall not acquire direct or indirect interest in, or otherwise hold, directly or indirectly a permit … for the retail sale of drugs or medicines in this state." Act 624 §2(b), to be codified as Ark. Code Ann. §17-92-416(b). Act 624 bars PBM-affiliated pharmacies from operating brick-and-mortar establishments and from obtaining "a pharmacy permit for a mail-order pharmacy." *Id.* §2(a)(1)(B), to be codified as Ark. Code Ann. §17-92-416(a)(1)(B).

68. Third, Act 624 requires the Arkansas State Board of Pharmacy to enforce this prohibition on PBM-affiliated pharmacies. Beginning on January 1, 2026, the Board must "either revoke or not renew a permit of an entity that violates" Act 624. Act 624 §2(c), to be codified as Ark. Code Ann. §17-92-416(c).

69. Fourth, Act 624 requires PBM-affiliated pharmacies operating in Arkansas to inform their patients that they are being banished from the state. Such pharmacies, after receiving written notice from the Board that their continued operation in Arkansas will violate Act 624, must, by November 2, 2025, "provide written notice … to each patient and each patient's prescribing healthcare provider that has used the pharmacy within the previous twelve … months that the pharmacy can no longer dispense retail drugs to the patient on or after January 1, 2026." Act 624 §2(c)(1)(A), to be codified as Ark. Code Ann. §17-92-417(c)(1)(A).

70. The practical effects of Act 624 would be catastrophic for both patients and pharmacists across Arkansas. As the President of the Arkansas Chamber of Commerce testified at the Senate hearing on H.B. 1150 (the bill that became Act 624), the law is expected to force over 40 pharmacies across Arkansas to shutter, putting the more than 600 Arkansans employed at those pharmacies out of work. *Senate Hearing* at 11:41:03 AM (statement of Randy Zook, President, Arkansas Chamber of Commerce).

71. The shuttering of PBM-affiliated pharmacies across Arkansas would also force thousands of patients and their families, including seniors, to change their pharmacies, possibly requiring them to trek across their town or county to fill prescriptions. Even the law's proponents recognize that the resulting closures may create pharmacy "deserts" – particularly in rural areas. *Senate Hearing* at 11:24:23 AM (statement of Jason Finley, Director of Pharmacy, Birch Tree Communities, Inc.).

72. The closure of dozens of pharmacies across the state would also create mass confusion among Arkansans who need prescription medications to sustain their health, and break important bonds between patients and their pharmacists.

73. Act 624's proponents do not dispute that the law will result in pharmacy closures and job losses. To the contrary, a senator speaking in support of Act 624 embraced those consequences, declaring that Arkansas has "more pharmacies than we probably need." *Senate Hearing* at 12:05:30 PM (statement of Sen. Boyd).

74. Act 624 not only shutters brick-and-mortar pharmacies; it also affects the availability of critical mail-order services. The law's banishment of ESI-affiliated pharmacies alone would be harmful for Arkansans. As discussed, Express Scripts Pharmacy's mail-order service is a vital resource for Arkansans – more than 40% of whom live in rural areas and thus

lack easy access to brick-and-mortar pharmacies. And Accredo, Freedom Fertility, and ESSDS provided access to hundreds of high-touch specialty medications and care to over 6,000 patients in 2024.

75. Without Express Scripts Pharmacy, Accredo, Freedom Fertility, and ESSDS, Arkansans with complex and chronic conditions could face dangerous changes to their care, losing the pharmacists they trust as well as the nurses with experience visiting their homes to administer treatment. And without Freedom Fertility and Village Fertility, hundreds of individuals trying to build their families could have their fertility treatments disrupted, potentially mid-cycle – which could lead to failed treatment.

76. Moreover, banishing Express Scripts Pharmacy, Accredo, and Freedom Fertility from Arkansas would prevent TRICARE from providing vital mail-order pharmacy services to military service members, veterans, and families in the state. Since the beginning of 2025, over 18,000 Arkansan TRICARE beneficiaries have received over 144,000 medications through Express Scripts Pharmacy. And for beneficiaries who live in rural areas, mail-order services are often the only practical means through which they can acquire their medications. That is why federal law requires the TRICARE Pharmacy Benefit Program to provide mail-order pharmacy services *nationwide*. 10 U.S.C. §1074g(a)(2)(E)(iii). Without mail-order services, affected beneficiaries would be forced to travel to an MTF or in-network retail pharmacy to acquire their medications. For TRICARE beneficiaries who live in remote areas or have mobility limitations, that travel may be impractical or even impossible. The options are even more limited for beneficiaries who need to refill non-generic prescription maintenance medications; by statute, they generally can do so only at MTF pharmacies or via mail order. *See id.* §1074g(a)(9)(A).

Those beneficiaries will thus be forced to travel to the one military pharmacy in the state to acquire their medications.

77. By eliminating TRICARE beneficiaries' access to mail-order services in Arkansas, Act 624 jeopardizes these patients' access to care and severely interferes with DoD's ability to fulfill its statutory obligation to provide beneficiaries with "effective" and "efficient" pharmacy benefits services, 10 U.S.C. §1074g(a)(1).

78. At the Senate hearing on Act 624, a senator conveyed the views of one veteran opposed to the bill, who explained that "U.S. military retirees get [their] meds … from TRICARE's mail-order pharmacy called Express Scripts," and "Express Scripts would fall under this law … since [it] ha[s] pharmacies and [a] pharmacy benefit manager[]." *Senate Hearing* at 11:01:00 AM (statement of Sen. Irvin). Explaining that he "get[s] a biological shot every four weeks to keep [him] alive through Express Scripts," the veteran asked that the legislature "please … pull this bill down and exempt … TRICARE." *Id.* at 11:01:29 AM.

79. Act 624's proponents have acknowledged that the law's application to ESI would eliminate Arkansan TRICARE beneficiaries' access to mail-order prescriptions. For instance, testifying to a Senate committee in support of the legislation, the CEO of the Arkansas Pharmacists Association conceded that, because of the new law, "veterans will not be able to receive their prescriptions through mail-order pharmacies owned by Express Scripts, which is an exclusive relationship within the TRICARE benefit." *Senate Hearing* at 10:32:45 AM (statement of John Vinson, CEO, Arkansas Pharmacists Association).

80. Act 624's impact on TRICARE is a feature, not a defect or an incidental consequence, of the statute. As one senator who supported the bill explained, Act 624 represents an effort to "use state power to get … the federal government to do" "what [Arkansas] want[s]."

Senate Hearing at 11:08:08 AM (statement of Sen. Boyd). In that senator's words, Act 624 purports to "tell the federal government" how to administer TRICARE in Arkansas. *Id.* at 11:08:15 AM.

V. ACT 624'S PURPOSE AND EFFECT ARE TO PROTECT LOCALLY OWNED PHARMACIES FROM OUT-OF-STATE COMPETITION WHILE PUNISHING PBMS SIMPLY FOR OWNING PHARMACIES

81. The text, context, and legislative history of Act 624 make clear that its purpose and effect are to protect pharmacies domiciled in Arkansas from out-of-state competition – and in particular to do so at the expense of the "big 3" PBMs (ESI, CVS Caremark, and OptumRx).

82. To start, Act 624's preamble makes plain that the law's purpose is to prevent "locally-operated pharmacies" from going "out of business." Act 624 §1(a)(2).

83. Moreover, the fact that *all* PBM-affiliated pharmacies are (on information and belief) domiciled outside of Arkansas means that only out-of-state entities – *i.e.*, no businesses domiciled in Arkansas – will be denied a permit under Act 624.

84. In fact, Act 624 was affirmatively tailored to bar only out-of-state businesses. As originally drafted, the bill would also have impacted in-state interests, barring permits not only to pharmacies affiliated with a PBM, but also to pharmacies affiliated with a "healthcare payor," defined under Arkansas law to include "[a]n entity that provides or administers a self-funded health benefit plan," Ark. Code §23-92-503(3)(D). In February 2025, however, the bill was amended to remove the prohibition on pharmacies affiliated with a "healthcare payor." Amendment No. 1 to House Bill 1150, *available at* https://arkleg.state.ar.us/Home/FTPDocument?path=%2FAMEND%2F2025R%2FPublic%2FHB1150-H1.pdf. And the following month, the bill was further amended to specify that the ban on PBM-affiliated pharmacies "does not apply to a pharmacy employer" that administers its own pharmacy benefits when "[t]he pharmacy employer is the sole Arkansas client of the [PBM]" and "[e]xclusively

services the employees and dependents of the pharmacy employer while utilizing the affiliated [PBM] in this state." Amendment No. 2 to House Bill 1150, *available at* https://arkleg.state.ar.us/Home/FTPDocument?path=%2FAMEND%2F2025R%2FPublic%2FHB1150-H2.pdf. As a result of these amendments, the impact of Act 624 fell exclusively on out-of-state PBMs and their affiliated pharmacies, to the exclusion of in-state pharmacy interests, including the Arkansas independent pharmacies the law was intended to protect, as well as the state's largest employer.

85. Statements by the legislature's principal proponents of Act 624 confirm that the statute's intended effect is to protect in-state pharmacies from out-of-state competition. For instance, the lead House sponsor explained on a podcast that "supporting these independent neighborhood pharmacies is a really big part of why we're running H.B. 1150." The PUTTcast, *Arkansas HB 1150: Combatting PBM Anticompetitive Practices with State Legislation*, at 2:27 (Feb. 5, 2025) ("*PUTTcast*") (statement of Rep. Moore), *available at* https://www.youtube.com/watch?v=1T9p6VAMULI. On the same podcast, the bill's lead Senate sponsor made an anecdotal case for the legislation by noting that an "independent pharmacy in [his] county [had gone] out of business." *Id.* at 7:25 (statement of Sen. Hammer).

86. Sounding the same theme, the press release Governor Sanders issued to announce her signature on the bill explained that the legislation's purpose is to prevent PBMs from "attacking our state." Press Release, Governor Sanders, *Sanders Signs Legislation to Ban Anti-Competitive PBM Practices* (Apr. 16, 2025), *available at* https://governor.arkansas.gov/news_post/sanders-signs-legislation-to-ban-anti-competitive-pbm-practices/. In the same press release, the Arkansas Attorney General lamented that PBM-affiliated pharmacies were "crushing independent pharmacies" in local markets. *Id.* The word "local" appears 21 times in the press

release, including in statements to the effect that Act 624 will make it more likely that patients will "get their medication locally" rather than from "an out of state mail order pharmacy." *Id.*

87. Act 624's in-state protectionist character is no surprise given that support for the legislation was spearheaded by the Arkansas Pharmacists Association. Press Release, Arkansas Pharmacists Association, *Two New Bills To Tackle PBM Anti-Competitive Practices Announced during APA's News Conference Thursday* (Jan. 16, 2025), *available at* https://arrx.org/two-new-bills-to-tackle-pbm-anti-competitive-practices-announced-during-apas-news-conference-thursday. That group describes itself as "the voice of Arkansas Pharmacy," *Membership*, Arkansas Pharmacists Association, *available at* https://arrx.org/membership, and defines its mission as advancing a "business environment for our members to be successful," *About*, Arkansas Pharmacists Association, *available at* https://arrx.org/about. For instance, the association's CEO appeared on a podcast to promote the legislation alongside the bill's lead legislative sponsors. *PUTTcast* at 2:27. Moreover, at the Senate hearing on the bill, the lead witness in support of the legislation hailed from the American Pharmacy Cooperative, a member-owned association whose membership includes 80 independent Arkansas pharmacies. *Senate Hearing* at 10:54:02 AM (statement of Greg Reybold, Vice President of HealthCare Policy and General Counsel, American Pharmacy Cooperative).

88. Any doubt about Act 624's local protectionist purpose was erased by the testimony of the legislation's proponents during the Senate hearing on the bill. The overwhelming theme of that testimony was concern for the protection of "local pharmacies," *Senate Hearing* at 10:40:06 AM (statement of John Vinson), based in Arkansans' "home communities." *Id.* at 10:39:34 AM (statement of Brittany Sanders, President, Arkansas Pharmacists Association). For example, one supporter of the bill testified that it was necessary

to "safeguard the future of independent community pharmacies" because PBM-affiliated pharmacies "have made it nearly impossible for small pharmacies … to survive." *Id.* at 11:22:27 AM, 11:23:30 AM (statement of Brandi Chane, Pharmacists United for Truth and Transparency). Other witnesses likewise lamented that "independent pharmacies continue to close," *id.* at 11:13:00 AM (statement of Greg Reybold), and explained that Act 624 would counteract PBMs that "take pharmacy services out of our local communities," *id.* at 10:32:24 AM (statement of John Vinson). And yet another witness asserted that the "problem" that Act 624 would "take care of" is that "opportunity has not always been there for independent pharmacies." *Id.* at 11:30:18 AM (statement of Jason Finley).

89. As a senator opposed to Act 624 explained, meanwhile, the legislation is plainly designed to benefit pharmacies based in Arkansas by "getting rid of [their] competition"; in other words, Act 624 "us[es] the government in an anticompetitive way to pick winners and losers." *Senate Hearing* at 11:13:20 AM (statement of Sen. Irvin).

90. Act 624 seeks to accomplish its in-state protectionist purpose by punishing PBMs. The law specifically identifies PBMs as its target. *See* Act 624 §2(b), to be codified as Ark. Code Ann. §17-92-416(b). In particular, Act 624 is intended to punish the "big 3" PBMs: ESI, CVS Caremark, and OptumRx. The law's preamble even mentions a Federal Trade Commission report focused on these "three largest PBMs." FTC, Office of Policy Planning, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* at 1 (July 2024), *available at* https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf. And that report refers to the "Big 3" more than 40 times. Moreover, during the Senate hearing on the legislation, the bill's lead Senate sponsor specifically named "CVS, Optum, and Express Scripts," *Senate Hearing* at 10:25:45 AM

(statement of Sen. Hammer), and a supporter of the law testified that legislators should not be worried about Act 624's anticompetitive effects because "we're talking about three of the biggest companies on earth," *id.* at 11:15:46 AM (statement of Greg Reybold).

91. To the extent Act 624 purports to be aimed at "eliminating certain anticompetitive business tactics" supposedly engaged in by PBMs, Act 624 §1(b), that purpose is pretextual. To start, the supposedly "anticompetitive business tactics" mentioned in the statute are illusory. As noted, the number of non-PBM-affiliated pharmacies has *increased* in recent years, both nationwide and in Arkansas. Carlton Report at 101; *Senate Hearing* at 11:53:30 AM (statement of Sen. Irvin). And the fiscal-impact statement for Act 624 acknowledges that the law will result in "less competition," not more. *Pricing Approach and Comments* (Mar. 17, 2025), *available at* https://arkleg.state.ar.us/Home/FTPDocument?path=%2FAssembly%2F2025%2F2025R%2FFiscal+Impacts%2FHB1150-Other1.pdf.

92. In any event, the supposed "anticompetitive business tactics" that Act 624 purports to prevent are (as part of Arkansas's years-long extensive regulation of PBMs) already illegal in the state. Specifically, Act 624 purportedly seeks to "minimize conflicts of interest by stopping the pharmacy benefits managers acting as a 'fox guarding the henhouse' by being both a price setter and price taker," Act 624 §1(a)(3). State law already addresses that purported concern several times over.

93. For example, Arkansas Act 900, enacted in 2015, requires PBMs to reimburse Arkansas pharmacies at a price equal to or greater than what the pharmacy paid to buy the drug. The law accomplishes this by requiring PBMs to (1) timely update their reimbursement rates when a drug's wholesale price increases, Ark. Code §17-92-507(c)(2); (2) provide administrative appeal procedures for pharmacies to challenge reimbursement rates that are below a pharmacy's

acquisition costs, *id.* §17-92-507(c)(4)(A)(i)(*b*); and (3) increase their reimbursement rates to cover the lowest price at which a pharmacy can obtain a drug from its typical wholesaler, *id.* §17-92-507(c)(4)(C)(i)(*b*).

94. Arkansas further regulated PBMs in 2018 with Act 1, known as the Arkansas Pharmacy Benefits Manager Licensure Act, which vests comprehensive regulatory authority over PBMs in the Arkansas Insurance Department and the Insurance Commissioner, *see generally* Ark. Code §§23-92-501 et seq. This law provides that PBMs "shall not … [r]eimburse a pharmacy or pharmacist in the state an amount less than the amount that the [PBM] reimburses a [PBM] affiliate for providing the same pharmacist services." *Id.* §23-92-506(b)(4)(A). It further mandates that PBMs may not (1) "charge a pharmacist or pharmacy a fee related to the adjudication of a claim" without permission from the Insurance Commissioner, *id.* §23-92-506(b)(2); (2) "[p]ay or reimburse a pharmacy or pharmacist for the ingredient drug product component of pharmacist services less than the national average drug acquisition cost or, if the national average drug acquisition cost is unavailable, the wholesale acquisition cost," *id.* §23-92-506(b)(5)(A); or (3) "require pharmacy accreditation standards or certification requirements inconsistent with, more stringent than, or in addition to requirements of the" State Board of Pharmacy without permission from the Board and the Insurance Commissioner, *id.* §23-92-506(b)(9).

95. As the President of the Arkansas Chamber of Commerce testified at the Senate hearing on Act 624, "according to the last audit by the Arkansas Insurance Department, the PBMs were complying" with "all of these laws." *Senate Hearing* at 11:39:32 AM (statement of Randy Zook). This explains why the lead witness in support of the legislation had to resort to citing findings from a *Mississippi* audit of PBMs and their affiliated pharmacies, rather than any

evidence of PBM or PBM-affiliate practices in Arkansas. *Id.* at 10:55:20 AM (statement of Greg Reybold).

96. Act 624's proponents were well aware of Arkansas's existing prohibitions on PBMs, as the following exchange from the Senate hearing on the bill illustrates:

> Senator Irvin: "You know that it is against the law in the state of Arkansas for a PBM-affiliate pharmacy to pay themselves more than an independent pharmacy, correct?"
>
> Witness in support of Act 624: "Correct."

Senate Hearing at 11:04:02 AM (exchange between Sen. Irvin and Greg Reybold).

97. As the President of the Arkansas Chamber of Commerce summarized at the Senate hearing, therefore, Arkansas already has "regulations on the PBM industry to prevent predatory practices such as paying an affiliate pharmacy more than other pharmacies; from steering patients to affiliated pharmacies, including mail-order pharmacies; and from paying below the national average drug acquisition cost." *Senate Hearing* at 11:39:10 AM (statement of Randy Zook). In light of this statutory backdrop, he explained, "the obvious intent of" Act 624 is not to curb anticompetitive practices, but rather "to eliminate competition" for in-state pharmacies. *Id.* at 11:38:21 AM. In his words, the law "is a punitive measure to remove competition from the market, plain and simple." *Id.* at 11:40:09 AM.

VI. PLAINTIFFS WILL BE IRREPARABLY HARMED BY ACT 624

98. Defendants' enforcement of Act 624 will cause Plaintiffs irreparable harm.

99. Under Act 624, Plaintiffs will have to send a written notice to each of their patients and each patient's prescribing healthcare provider, stating that Plaintiffs "can no longer dispense retail drugs to the patient." Act 624 §2(c)(1)(A), to be codified as Ark. Code Ann. §17-92-417(c)(1)(A). Plaintiffs will then have their pharmacy permits revoked, permits which several have held in good faith for decades, making it unlawful for them to continue operating in

Arkansas. *See* Act 624 §2(c), to be codified as Ark. Code Ann. §17-92-416(c); *see also* Ark. Code §17-92-404 (requiring pharmacy permit); *id.* §17-92-405 (describing penalties for violations).

100. Act 624 will cause irreparable harm by leading to an enormous and unrecoverable loss of business and goodwill for Plaintiffs. Enforcement of the law will forever damage the relationships that Plaintiffs have formed with their patients in Arkansas as well as their patients' prescribing healthcare providers. Patients and providers who receive the required notice will learn that Plaintiffs "can no longer dispense retail drugs" in Arkansas, leading to confusion and panic and ultimately the permanent loss of Plaintiffs' customers in the state. This destruction of Plaintiffs' patient and provider relationships will be further cemented by the revocation of Plaintiffs' licenses, which will force Plaintiffs to cease operations in Arkansas.

101. Beyond the harm it will inflict on Plaintiffs' relationships in Arkansas, Act 624 will create widespread uncertainty among Plaintiffs' patients and providers nationwide. Existing and potential customers in other states will see that Plaintiffs were required to abruptly end their relationships with customers in Arkansas, damaging Plaintiffs' reputation and imperiling Plaintiffs' business prospects and ability to serve patients throughout the country.

102. The damage that Act 624 will cause Plaintiffs cannot be reversed. Even if eventually permitted to resume operations in Arkansas, Plaintiffs will be unable to win back many of their patients (including because of the burdens associated with switching pharmacies yet again) or completely restore their damaged reputation. Once the required notices are issued and Plaintiffs' permits revoked, no monetary damages will be able to fully repair the resulting lost business relationships and goodwill that Plaintiffs have built in Arkansas and across the country.

COUNT ONE
(Dormant Commerce Clause, U.S. Const. art. 1, §8; 42 U.S.C. §1983)

103. Plaintiffs incorporate and re-allege paragraphs 1 through 102 as if fully set forth herein.

104. The Constitution's Commerce Clause vests Congress with the power to "regulate Commerce … among the several States." U.S. Const. art. I, §8, cl. 3.

105. Within the Commerce Clause, the Supreme Court has recognized a "dormant Commerce Clause," which "state laws offend … when they seek to 'build up domestic commerce' through 'burdens upon the industry and business of other States,' regardless of whether Congress has spoken." *National Pork*, 598 U.S. at 369 (quoting *Guy v. Baltimore*, 100 U.S. 434, 443 (1879)).

106. A state thus violates the dormant Commerce Clause when it "discriminat[es] against interstate commerce." *Northwest Airlines, Inc. v. County of Kent*, 510 U.S. 355, 373 n.18 (1994). Indeed, this "antidiscrimination principle lies at the 'very core' of [the Supreme Court's] dormant Commerce Clause jurisprudence." *National Pork*, 598 U.S. at 369. Specifically, "the Commerce Clause prohibits the enforcement of state laws 'driven by economic protectionism – that is, regulatory measures designed to benefit in-state economic interests by burdening out-of-state competitors.'" *Id.* (quoting *Davis*, 553 U.S. at 337-338).

107. Act 624 violates the dormant Commerce Clause because it discriminates against out-of-state commerce in order to benefit in-state economic interests. The text, context, and legislative history of Act 624 all make clear that its purpose and effect are to protect pharmacies domiciled in Arkansas from out-of-state competition – by burdening PBMs and their affiliated pharmacies, which are all domiciled outside of Arkansas. Act 624 was plainly driven by local

protectionism, and it has the effect of barring only out-of-state entities from holding pharmacy permits.

108. Because Act 624 violates the dormant Commerce Clause, it is facially invalid and cannot be enforced against Plaintiffs.

COUNT TWO
(Privileges and Immunities Clause, U.S. Const. amend. XIV; 42 U.S.C. §1983)

109. Plaintiffs incorporate and re-allege paragraphs 1 through 102 as if fully set forth herein.

110. The Constitution's Privileges and Immunities Clause provides that "[t]he Citizens of each State [are] entitled to all Privileges and Immunities of Citizens in the several States." U.S. Const. art. IV, §2, cl. 1.

111. The Privileges and Immunities Clause protects the right of citizens to "ply their trade, practice their occupation, or pursue a common calling." *Hicklin v. Orbeck,* 437 U.S. 518, 524 (1978). A state law "violat[es] the privilege of pursuing a common calling" if it was "enacted for the protectionist purpose of burdening out-of-state citizens." *McBurney*, 569 U.S. at 227. For example, the Supreme Court has struck down a statute imposing unequal licensing restrictions on out-of-state entities where the purpose and effect of the law was to exclude non-residents. *See id.* at 227-228 (citing *Toomer v. Witsell*, 334 U.S. 385, 395 (1948)).

112. Act 624 violates the Privileges and Immunities Clause because it was enacted for the purpose of protecting in-state entities while burdening out-of-state entities by depriving those entities of the privilege to ply their trade in Arkansas. The text, context, and legislative history of Act 624 all demonstrate that it was enacted to protect pharmacies domiciled in Arkansas from out-of-state competition by burdening PBMs and their affiliated pharmacies, all of which are domiciled outside of Arkansas.

113. Because Act 624 violates the Privileges and Immunities Clause, it is facially invalid and cannot be enforced against Plaintiffs.

COUNT THREE
(Bill of Attainder Clause, U.S. Const. art. I, §10; 42 U.S.C. §1983)

114. Plaintiffs incorporate and re-allege paragraphs 1 through 102 as if fully set forth herein.

115. The Constitution provides that "[n]o State shall … pass any Bill of Attainder." U.S. Const. art. I, §10, cl. 1. This clause bars "legislative punishment, of any form or severity, of specifically designated persons or groups." *Brown*, 381 U.S. at 447.

116. Act 624 is a bill of attainder because it (1) singles out PBM-affiliated pharmacies, (2) imposes a forbidden punishment on them, and (3) imposes that punishment without a judicial trial. *Palmer v. Clarke*, 408 F.3d 423, 433 (8th Cir. 2005).

117. First, Act 624 singles out PBM-affiliated pharmacies, including pharmacies owned by ESI. It specifically targets PBMs (defined to include PBM-affiliated pharmacies). Act 624 §2, to be codified as Ark. Code Ann. §17-92-416(b). In addition, its preamble identifies a Federal Trade Commission report focused on the "big 3" PBMs – again, ESI, CVS Caremark, and OptumRx – as motivation for the law's enactment. *See id.* §1(a)(2). Legislative history further confirms that Act 624 is aimed, in particular, at the nation's three leading PBMs.

118. Second, Act 624 imposes a "forbidden punishment" on PBMs and PBM-affiliated pharmacies, whether assessed under a "historical test, a functional test, [or] a motivational test," *WMX Technologies, Inc. v. Gasconade County*, 105 F.3d 1195, 1202 (8th Cir. 1997). It impermissibly punishes under the historical test because it "banish[es]" PBM-affiliated pharmacies from Arkansas and "bar[s]" PBMs and their affiliated pharmacies "from participation in specified employments or vocations," *Nixon*, 433 U.S. at 474 – namely, the

provision of pharmacy services. It unlawfully punishes under the functional test because the statute's banishment of PBM-affiliated pharmacies from the state cannot "reasonably … be said to further nonpunitive legislative purposes." *Id.* at 475. The type of anticompetitive conduct that Act 624 purports to address is already illegal in Arkansas, and local economic protectionism is not a legitimate government interest. Finally, Act 624 inflicts a forbidden punishment under the motivational test, as the law's preamble and legislative history plainly show that Act 624's purpose was to punish PBMs for perceived past anticompetitive conduct.

119. Third, Act 624 punishes PBMs through legislative means, not a judicial trial.

120. Because Act 624 violates the Constitution's ban on any state enacting a bill of attainder, it is facially invalid and cannot be enforced against Plaintiffs.

COUNT FOUR
(TRICARE Preemption, U.S. Const. art. VI, cl. 2; 10 U.S.C. §1103; 32 C.F.R. §199.17)

121. Plaintiffs incorporate paragraphs 1 through 102 as if fully set forth herein.

122. The Supremacy Clause states: "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof … shall be the supreme Law of the Land … any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

123. Under the Supremacy Clause, "state law is preempted" whenever "federal law 'imposes restrictions or confers rights on private actors' and 'a state law confers rights or imposes restrictions that conflict with the federal law.'" *Kansas v. Garcia*, 589 U.S. 191, 202 (2020) (quoting *Murphy v. National Collegiate Athletic Association*, 584 U.S. 453, 477 (2018)).

124. Pursuant to the Supremacy Clause and federal statute, ESI's contract with the federal government to manage DoD's TRICARE Pharmacy Benefits Program preempts the application of Act 624 to ESI, Express Scripts Pharmacy, Accredo, and Freedom Fertility.

125. Indeed, TRICARE's enabling statute includes a preemption provision that expressly exempts its contractors from state laws and regulations. Specifically, the federal statute provides that state laws or regulations "relating to … health care delivery … shall not apply to any [TRICARE] contract" if the Secretary of Defense determines that (1) the state laws or regulations are "inconsistent with a specific provision of the contract or a regulation promulgated" to administer TRICARE, or (2) preemption is "necessary to implement or administer the provisions of the contract or to achieve any other important federal interest." 10 U.S.C. §1103(a). Under this authority, the Defense Secretary has "determined that" it is necessary to preempt "any State or local law relating to … health care delivery," and thus such laws "do[] not apply in connection with TRICARE." 32 C.F.R. §199.17(a)(7)(i)-(ii). Other federal regulations similarly provide that state laws and regulations "relating to … health care delivery" "do[] not apply in connection with TRICARE pharmacy contracts." *Id.* §199.21(o)(2).

126. These provisions of federal law preempt Act 624 because Act 624 "relat[es] to … health care delivery" and interferes with mail-order services that ESI is obligated to provide to TRICARE beneficiaries. ESI's TRICARE contract requires it to fill prescriptions by mail for military service members nationwide, using "the Contractor's Mail Order Pharmacy" and "the Contractor's mail order facilities." TPharm5 §§C.6.1, 6.1.1. Requiring ESI not to use Express Scripts Pharmacy, its "Mail Order Pharmacy," would conflict with these contractual provisions and force ESI and the government to choose a different pharmacy from the one contemplated by the contract for national mail-order services.

127. In addition, under section C.6.1.1 of the TPharm5 contract, ESI has designated, and the government has "approved," Accredo and Freedom Fertility to "dispense specialty [pharmaceutical] agents … under a mail order" to TRICARE beneficiaries. Requiring ESI not to

use these pharmacies would force ESI to designate (and the government to approve) a different mail-order pharmacy under the contract for dispensing specialty medications.

128. Removing Express Scripts Pharmacy, Accredo, and Freedom Fertility as TRICARE's mail-order pharmacies would be impractical, as those pharmacies maintain and distribute a nationwide stock of medications on behalf of DoD. It would also increase costs for the TRICARE pharmacy program, since those pharmacies' status as ESI's in-house pharmacies eliminates transaction costs and other inefficiencies, enabling them to "provide the best value to the United States," 10 U.S.C. §1073a(a), in the administration of the TRICARE program. And it would undermine the uniformity of the TRICARE program and inhibit DoD's obligation to ensure nationwide consistency in the provision of health benefits to military personnel. *See id.* §1074g(a)(2)(E)(iii) (requiring DoD to establish a "*national* mail-order pharmacy program" (emphasis added)).

129. Because Act 624 is preempted by federal law, the Supremacy Clause prohibits the Arkansas State Board of Pharmacy from revoking or failing to renew Express Scripts Pharmacy's, Accredo's, or Freedom Fertility's pharmacy permits under the provisions of Act 624.

130. In the alternative, federal law preempts any action taken by Arkansas to condition ESI's, Express Scripts Pharmacy's, Accredo's, or Freedom Fertility's provision of mail-order pharmacy services to TRICARE beneficiaries on their possession of an Arkansas pharmacy permit.

131. Accordingly, Plaintiffs are entitled to a declaration that Act 624 is preempted to the extent its application would prevent ESI, Express Scripts Pharmacy, Accredo, or Freedom

Fertility from carrying out their functions as part of the federal TRICARE program, along with an injunction against such application.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

a) Declare that Act 624 violates the Constitution's dormant Commerce Clause;

b) Declare that Act 624 violates the Constitution's Privileges and Immunities Clause;

c) Declare that Act 624 violates the Constitution's Article I, Section 10 Bill of Attainder Clause;

d) Declare that Act 624 is preempted by federal law as applied to Express Scripts Pharmacy, Accredo, and Freedom Fertility or, in the alternative, that Express Scripts Pharmacy, Accredo, and Freedom Fertility are not required to hold an Arkansas pharmacy permit to carry out their functions under ESI's TRICARE contract;

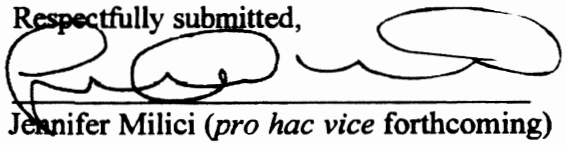
e) Preliminarily and permanently enjoin Defendants, their agents, successors in office, and all persons acting in concert with them from taking any action to enforce Act 624 against Plaintiffs;

f) Award Plaintiffs their attorneys' fees and costs incurred in bringing this action, including attorneys' fees and costs under 42 U.S.C. §1988(b) for successful claims against state officials under 42 U.S.C. §1983; and

g) Award Plaintiffs all other relief as the Court deems just and proper.

May 29, 2025

Respectfully submitted,



Jennifer Milici (*pro hac vice* forthcoming)
Daniel S. Volchok (*pro hac vice* forthcoming)
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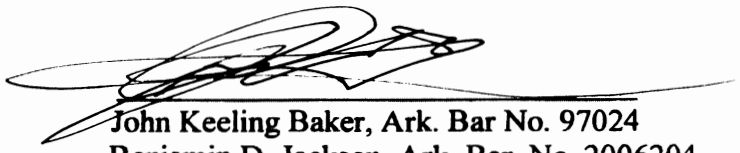

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Exhibit A

Stricken language would be deleted from and underlined language would be added to present law.
Act 624 of the Regular Session

State of Arkansas *As Engrossed: H2/11/25 H3/18/25 H4/1/25*
95th General Assembly **A Bill**
Regular Session, 2025 HOUSE BILL 1150

By: Representatives J. Moore, *Ennett, Wooten, Achor, Lundstrum, Gramlich, R. Scott Richardson, Joey Carr, Vaught, Rose, Hawk, Ladyman, Bentley, J. Mayberry, Duffield*
By: Senators K. Hammer, *J. Petty, Caldwell, G. Leding, C. Tucker, M. Johnson, J. Scott, D. Sullivan*

For An Act To Be Entitled

AN ACT TO PROHIBIT A PHARMACY BENEFITS MANAGER FROM OBTAINING CERTAIN PHARMACY PERMITS; AND FOR OTHER PURPOSES.

Subtitle

TO PROHIBIT A PHARMACY BENEFITS MANAGER FROM OBTAINING CERTAIN PHARMACY PERMITS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. DO NOT CODIFY. Legislative findings and intent.

(a) The General Assembly finds that:

(1) It is beneficial to the State of Arkansas to support patient access to prescription drugs and pharmacy services at fair prices in a market that supports optimal patient care;

(2) The Federal Trade Commission and the United States House Committee on Oversight and Government Reform have found evidence of anticompetitive business tactics that have driven locally-operated pharmacies out of business, limiting patient choices and inflating drug prices at pharmacies owned by pharmacy benefits managers; and

(3) The State of Arkansas wishes to minimize conflicts of interest by stopping the pharmacy benefits managers acting as a "fox guarding the henhouse" by being both a price setter and price taker.

(b) It is the intent of the General Assembly that the State of Arkansas shall improve healthcare delivery in the pharmacy market for patients by eliminating certain anticompetitive business tactics as a basic

tenet of this act.

SECTION 2. Arkansas Code Title 17, Chapter 92, Subchapter 4, is amended to add *additional sections* to read as follows:

17-92-416. Prohibition on certain pharmacy permits for retail sale of drugs or medicines — Definitions.

(a) As used in this section:

(1)(A) "Permit" means a permit issued under § 17-92-405.

(B) "Permit" includes a pharmacy permit for a mail-order pharmacy; and

(2)(A) "Pharmacy benefits manager" means the same as defined in § 23-92-503.

(B) "Pharmacy benefits manager" includes an entity that:

(i) Is managed by a pharmacy benefits manager or is a subsidiary of a pharmacy benefits manager; or

(ii) Has a direct or indirect ownership interest in a pharmacy benefits manager.

(b) A pharmacy benefits manager shall not acquire direct or indirect interest in, or otherwise hold, directly or indirectly, a permit under § 17-92-405 for the retail sale of drugs or medicines in this state.

(c) On and after the effective date of this act, the Arkansas State *Board of Pharmacy shall either revoke or not renew a permit of an entity that violates this section.*

(d)(1) The board may issue a limited use permit for certain rare, orphan, or limited distribution drugs that are otherwise unavailable in the market to a patient or a pharmacy that would otherwise be prohibited under this section.

(2)(A)(i) The board may assess the need for rare, orphan, or limited distribution drugs for a limited use permit for certain rare, orphan, or limited distribution drugs under subdivision (d)(1) of this section before revocation or renewal of an existing retail permit for a pharmacy.

(ii) If the assessment made by the board in subdivision (d)(2)(A)(i) of this section determines that a rare, orphan, or limited distribution drug is otherwise unavailable in the market to a patient or pharmacy that would otherwise be prohibited in this section, the board shall convert the retail permit for the prohibited pharmacy to a limited use permit for that pharmacy for a period of no less than ninety (90) days.

(B) This subsection shall expire on September 1, 2027.

(3)(A) Before the effective date of this section, the board shall adopt a written policy to implement subdivision (d)(1) of this section.

(B) The written policy under subdivision (d)(3)(A) of this section shall establish:

(i) The process in which a patient, pharmacy, or healthcare provider may notify the board of a rare, orphan, or limited distribution drug unavailable in the market;

(ii) The process in which a pharmacy may request a limited use permit under subdivision (d)(1) of this section;

(iii) The timeline in which the board must make a decision; and

(iv) The process for emergency determinations due to patient need.

(e) The board may extend the use of a retail permit or issue a renewal of a retail permit for a pharmacy that offers same-day patient access for pharmacist services, a prescription for a controlled substance, mental health services, or other critical patient healthcare services for a period of time as determined by the board if there is a pending sale of the pharmacy to an eligible buyer.

(f) This section does not apply to a pharmacy employer and a pharmacy that:

(1) Has direct or indirect interest in a pharmacy benefits manager;

(2) The pharmacy employer is the sole Arkansas client of the pharmacy benefits manager that the pharmacy employer has a direct or indirect interest in; and

(3) Exclusively services the employees and dependents of the pharmacy employer while utilizing the affiliated pharmacy benefits manager in this state.

17-92-417. Notice required.

(a)(1) The Arkansas State Board of Pharmacy shall conduct an initial assessment of each active retail pharmacy permit that was issued under § 17-92-405 as of July 1, 2025, and shall send written notice to each pharmacy permit holder that the board reasonably believes will violate § 17-92-416 at

least ninety (90) days before January 1, 2026.

(2) As used in subdivision (a)(1) of this section, "written notice" means actual notice to the pharmacy permit holder via mail or email.

(b) The written notice required under subdivision (a)(1) of this section shall include:

(1) A list of each pharmacy benefits manager that holds a direct or indirect interest in, or otherwise holds, directly or indirectly, a permit under § 17-92-405 for the retail sale of drugs or medicines in this state held by the pharmacy permit holder;

(2) A phone number and email address that is monitored by the board during regular business hours; and

(3)(A) A list of Arkansas pharmacies that hold an active retail pharmacy permit that are not reasonably expected to violate § 17-92-416 as of January 1, 2026.

(B) The list in subdivision (b)(3)(A) of this section shall include:

(i) The name of the pharmacy;

(ii) The phone number of the pharmacy;

(iii) The physical address of the pharmacy;

(iv) The website of the pharmacy, if known; and

(v) An email address for the pharmacy, if known.

(C) If the board has a searchable website that includes the information required in subdivision (b)(3)(B) of this section, the board may provide the website information in lieu of the list.

(c)(1)(A) A pharmacy permit holder with written notice from the board in subdivision (a)(1) of this section shall provide written notice at least sixty (60) days before January 1, 2026, to each patient and each patient's prescribing healthcare provider that has used the pharmacy within the previous twelve (12) months that the pharmacy can no longer dispense retail drugs to the patient on or after January 1, 2026.

(B) As used in subdivision (c)(1)(A) of this section, "written notice" means actual notice to the patient via mail, email, or through the pharmacy's patient portal.

(2) Written notice required in subdivision (c)(1)(A) of this section shall include the information under subdivisions (b)(2) and (b)(3) of this section provided by the board to the pharmacy permit holder.

SECTION 3. DO NOT CODIFY. Effective date.

This act is effective on and after January 1, 2026.

/s/J. Moore

APPROVED: 4/16/25

Exhibit B

SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES
	C-9	1 379

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NUMBER
HT940221C0007	HT940220R0002	☐ SEALED BID (IFB) ☒ NEGOTIATED (RFP)	07/13/2020	21-PHAR-0028

7. ISSUED BY	CODE	8. ADDRESS OFFER TO (If other than Item 7)
DEFENSE HEALTH AGENCY DEFENSE HEALTH AGENCY AURORA 16401 E CENTRETECH PARKWAY AURORA CO 80011	HT9402	

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder".

SOLICITATION

9. Sealed offers in original and _____ copies to furnish the supplies or services in the Schedule will be received at the place specified in Item 8, or if hand carried, in the depository located in Mail Room, Defense Health Agency-Aurora, 16401 E Centretech Parkway, Aurora CO 80011 until 1200 MTN (Hour) local time 06/04/2021 (Date)

CAUTION: LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in this solicitation.

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE (NO COLLECT CALLS) AREA CODE	NUMBER	EXT.	C. E-MAIL ADDRESS
	(b) (6)	[redacted]	[redacted]		[redacted]

11. TABLE OF CONTENTS

(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
		PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES	
☒	A	SOLICITATION/CONTRACT FORM	1	☒	I	CONTRACT CLAUSES	156
☒	B	SUPPLIES OR SERVICES AND PRICES/COSTS	2			PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.	
☒	C	DESCRIPTION/SPECS./WORK STATEMENT	22	☒	J	LIST OF ATTACHMENTS	171
☒	D	PACKAGING AND MARKING	104			PART IV - REPRESENTATIONS AND INSTRUCTIONS	
☒	E	INSPECTION AND ACCEPTANCE	105	☐	K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
☒	F	DELIVERIES OR PERFORMANCE	108				
☒	G	CONTRACT ADMINISTRATION DATA	111	☐	L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
☒	H	SPECIAL CONTRACT REQUIREMENTS	134	☐	M	EVALUATION FACTORS FOR AWARD	

OFFER (Must be fully completed by offeror)

NOTE: Item 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within _____ calendar days (60 calendar days unless a different period is inserted by the offeror) from the date for receipt of offers specified above, to furnish any or all items upon which prices are offered at the price set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT (See Section I, Clause No. 52.232-8)	10 CALENDAR DAYS (%)	20 CALENDAR DAYS (%)	30 CALENDAR DAYS (%)	CALENDAR DAYS (%)

14. ACKNOWLEDGEMENT OF AMENDMENTS (The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE
	0001-0005	10/3/20		
	0006	5/11/21		

15A. NAME AND ADDRESS OF OFFEROR	CODE	1WPW1	FACILITY	16. NAME AND TITLE OF PERSON AUTHORIZED TO SIGN OFFER (Type or print)
	Express Scripts, Inc. 1 Express Way St. Louis, MO 63121			(b) (6) (b) (6) (b) (6)

15B. TELEPHONE NUMBER AREA CODE	NUMBER	EXT.	15C. CHECK IF REMITTANCE ADDRESS ☐ IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE
[redacted]	[redacted]			(b) (6) digital signature	8/3/21

AWARD (To be completed by government)

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION
	$4,286,902,274.40	9720200130.1889.102000

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION:	23. SUBMIT INVOICES TO ADDRESS SHOWN IN (4 copies unless otherwise specified)	ITEM
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 253 (c) ( )		

24. ADMINISTERED BY (If other than Item 7)	CODE	25. PAYMENT WILL BE MADE BY	CODE
See Schedule G	HT9402	See Schedule G	HT9402

26. NAME OF CONTRACTING OFFICER (Type or print)	27. UNITED STATES OF AMERICA	28. AWARD DATE
[redacted]	(b) (6)	20210805

IMPORTANT - Award will be made on this Form, or on Standard Form 26, or by other authorized official written notice.

AUTHORIZED FOR LOCAL REPRODUCTION
Previous edition is unusable

STANDARD FORM 33 (Rev. 9-97)
Prescribed by GSA - FAR (48 CFR) 53.214(c)

SECTION C
STATEMENT OF WORK

C.1. Program Description

TRICARE is the Department of Defense (DoD) health care program administered by the Defense Health Agency (DHA) by means of the Military Health System (MHS) for approximately 9.5 million active duty and retired members of the Uniformed Services, and their spouses and children, including TRICARE for Life beneficiaries. The TRICARE Pharmacy Program is authorized under 10 U.S.C. §1074g and 32 C.F.R. 199.21.

The mission of the MHS is to enhance DoD readiness and national security by providing health support for the full range of military operations. The MHS must be prepared not only to provide a high quality, cost-effective health care benefit to its eligible members during peacetime, but also must be prepared to support the armed forces during exercises, contingencies, operations other than war, and in wartime. The MHS provides quality medical care through: (1) a network of health care providers and pharmacies in the United States and its territories; and (2) direct care Military Treatment Facilities (MTFs) – (hospitals, clinics, and pharmacies) in the United States and overseas. The direct care system cannot support the total demand for health care services and is focused on maintaining the clinical skills of military staff to support medical readiness. TRICARE augments the direct care system through a civilian network of providers and facilities serving its eligible members. TRICARE provides a world-class pharmacy benefit to all eligible beneficiaries through the integration of state of the art technologies to enhance patient safety, efficiency, and cost-effectiveness. DoD administers an integrated TRICARE Pharmacy Benefits Program offering pharmacy services through MTFs, retail network pharmacies, retail non-network pharmacies, or delivery through the TRICARE Mail Order Pharmacy (TMOP). Retail network pharmacy services are currently available in all 50 states and the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands.

Features of the pharmacy benefits program include the use of the DoD Uniform Formulary, a tiered cost sharing structure, and a preference for generic over branded products. The DoD formulary is managed by the DoD Pharmacy and Therapeutics (P&T) Committee, which establishes the basic program benefits. Prescriptions for selected pharmaceutical agents may be subject to prior authorization (PA) or utilization review requirements to assure Medical Necessity (MN), clinical appropriateness, and/or cost-effectiveness. DoD has established tiered cost-sharing by which beneficiaries partially defray costs of administering the pharmacy benefits program. Cost-sharing amounts differ based on the classification of a pharmaceutical agent as generic, formulary, or non-formulary, in conjunction with the Point of Service (POS) from which the agent is acquired. The mail order and retail portions of this benefit are open to all eligible TRICARE beneficiaries.

Pharmacy benefits management functions under this contract include the following: perform claims adjudication, administer a retail pharmacy network, operate TMOP, process reimbursements for claims filled at retail network and non-network pharmacies, perform clinical reviews, and provide beneficiary and pharmacy support services. The Contractor shall transmit all claim information to the Government's designated Pharmacy Data Warehouse (PDW).

SECTION C
STATEMENT OF WORK

C.1.1. Overall Program Objectives

The following objectives identify the desired outcomes of this contract and are supported by the technical requirements in Section C:

- Maximize patient safety through the utilization of best practices.
- Apply the prescription drug benefit consistently and comprehensively in an effective, efficient, and accurate manner.
- Execute a fiscally responsible pharmacy program.
- Establish and maintain a high level of customer and beneficiary satisfaction.
- Provide flexible, effective and collaborative management and quality control for all services and functions.

C.1.2. Definitions

Definitions specific to this contract, or not otherwise in Appendix A of the TRICARE Operations Manual, are provided in J-1.

C.1.3. Government Furnished Information

C.1.3.1. The Contractor shall interface with the Defense Enrollment Eligibility Reporting System (DEERS), according to the requirements established in the TRICARE Systems Manual.

C.1.3.2. The Government will provide licenses for the Contractor to access and use DEERS applications.

C.1.3.3. The Government will provide the Contractor with access to a medical pricing catalog which will be used for replenishment, at TMOP and for adjudicating MHS Genesis claims.

C.1.3.4. The Government will provide initial Interface Control Documents (ICDs) and some additional technical specifications for the following systems:

- PDW
- Forensic Toxicology Drug Testing Laboratory Information Management System (FTDTL IMS)
- Immunization Tracking System
- Theater Medical Data Store (TMDS)
- MHS GENESIS

C.1.3.5. The Government will provide a quarterly data file for beneficiary mailings related to formulary changes, described under C.9.3.3.

C.1.3.6. The Government will provide a quarterly file of beneficiary zip codes for use in evaluating and reporting on compliance with network access standards.

C.1.3.7. The DHA Communications will design, develop, and print beneficiary educational materials, including written materials, briefings, and other methods of publicizing the TRICARE

benefit, excluding letters and other communication pieces required under this contract. The Government will provide an electronic portal where printed items can be ordered by the Contractor.

C.1.3.8. The Government will provide the PDW Data Dictionary and Data Schema, as described under C.11.8.

C.1.3.9. Before the start of pharmacy services, the Government will provide (via previous contractors) batch files containing all retail, mail, and MTF claims along with Prior Authorization (PA) and MN determinations for the past two year period. The Government (via the outgoing contractor) will also provide an Other Health Insurance (OHI) data file.

C.1.4. Requirements Documents

C.1.4.1. Statutory and Regulatory Authority

- 10 U.S.C. §1074g Pharmacy Benefits Program
- 32 C.F.R. 199 Civilian Health and Medical Program of the Uniform Services (CHAMPUS)
- 10 U.S.C. §1086 Contracts for Health Benefits for Certain Members, Former Members, and Their Dependents
- 38 U.S.C. §8126 Limitation on Prices of Drugs Procured by Department and Certain other Federal Agencies

When changes are made to the above statutes or regulations, they are automatically incorporated into the contract requirements.

C.1.4.2. TRICARE Manuals.

C.1.4.2.1. The Contractor shall utilize the current version of the TRICARE Manuals T-2017, published at Attachment J-3, line 11. The manuals are applicable in their entirety.

C.1.4.2.2. The Contractor shall routinely review proposed, pending, and published manual changes and discuss concerns with the Contracting Officer Representative (COR).

C.1.4.2.3. When a new manual change is pending publication (identified with a change number and date), the COR and Contractor shall coordinate to confirm the applicability of a change to the contract.

C.1.4.2.3.1. To the extent practicable, for those manual changes that apply to the contract, the Government and Contractor will negotiate in good faith a bilateral agreement incorporating the change into the contract. This in no way precludes the Government's exercise of its rights to execute unilateral change orders as circumstances may require.

C.1.4.2.3.2. Those manual changes that do not apply to the contract will be incorporated into the contract as part of the next modification to incorporate an applicable change (i.e. Manual Changes 1-4 that do not apply will be incorporated at the same time as Manual Change 5, which does apply).

C.1.4.2.4. In the event of conflict, the TRICARE Policy Manual shall take precedence over the other three TRICARE Manuals. The TRICARE Reimbursement Manual shall take precedence over the TRICARE Systems Manual and the TRICARE Operations Manual. The TRICARE Systems Manual shall take precedence over the TRICARE Operations Manual.

In the event of a conflict between language found within the TRICARE Manuals and the contract, the contract prevails.

C.2. General Claims Processing.

C.2.1. The Contractor shall accept and process claims submitted by retail network pharmacies, TMOP, MTF pharmacies, Veteran Affairs (VA) pharmacies, Indian Health Services (IHS) pharmacies, by beneficiaries for direct reimbursement (including non-network), to include batch files submitted from the Department of Veterans Affairs (DVA) and State Medicaid Agencies.

C.2.2. Unless stated otherwise, the Contractor shall include claims adjudication processes outlined in C.2, consisting of eligibility check, application of the correct copayment, identification of OHI, benefit design edits, Drug Utilization Review (DUR) and application of catastrophic cap and deductible updates.

C.2.3. The Contractor shall maintain a complete patient profile, inclusive of all claims processed within the scope of this contract.

C.2.4. Appeal Rights. The Contractor shall not accept appeals from Active Duty Service Members (ADSMs). ADSM are not authorized as appealing parties for TRICARE cost-sharing determinations. ADSM should be directed to their local MTF for review of access to care issues.

C.2.5. [redacted]

C.2.5.1. If the Contractor receives a prescription or supporting documentation (e.g., paper claim, PA request) for a beneficiary with Contractor-administered OHI, the Contractor shall internally transfer to its commercial operation in lieu of rejecting or returning to source.

C.2.5.2. [redacted]

C.2.6. Claims Processing System

C.2.6.1. The Contractor shall provide 24 hours a day, 7 days a week claims processing for all locations, including overseas MTFs.

C.2.6.2. The Contractor's claims processing system shall be available no less than 99.5% of the time, excluding external downtime (e.g., DEERS, B2B Gateway, etc.). The system is considered to be unavailable when the rate of certain claims rejects exceeds 10% for at least 30 minutes. These

C.2.9.6. The Contractor shall document their policies for the application of OHI information in claims processing, including the use of different types of DEERS records and how discrepancies are resolved. This documentation will be made available for the Government's review upon request.

C.2.9.7. The Contractor shall provide reporting to the Government on OHI development (CDRL Q110) and cost avoidance (CDRL Q111).

C.2.10. Claims Processing System Documentation

C.2.10.1. The Contractor shall develop and maintain comprehensive documentation of all aspects of claims processing. This documentation shall include the items listed below as well as any supplemental information provided by the Contractor. The sum of all this documentation shall allow the Government to correctly determine how any given claims processing scenario will adjudicate. Updated versions of any of these documents shall be made available to the Government upon request.

C.2.10.2. The Contractor shall maintain all payer sheets used in the transmission of DoD claims from all POS.

C.2.10.3. The Contractor shall maintain a benefit design document and provide the Government with access to the current version via a web-based platform. The Contractor's presentation of the benefit design within this document shall remain consistent with the elements of the document initially provided by the Government and shall be in a format agreed to by the Government. The benefit design shall contain formulary and benefit restrictions based on beneficiary category, enrollment category, POS, medication by category, and any other factors, including but not limited to:

- MTF Basic and Extended Core Formularies
- Compound inclusions and exclusions
- Covered over-the-counter (OTCs)
- Federal Ceiling Price (FCP) Non-Compliant Retail Exclusions
- Non-Formulary Drugs
- PA
- Step-Therapy Drugs
- Self-Administered Injectables
- Smoking Cessation Drugs
- Specialty Drugs
- Covered Vaccines
- Non-covered Drugs
- Quantity Limit (QL) Restrictions
- Age restrictions

C.3. Retail Prescriptions

C.3.1. Retail Prescription Claims

C.3.1.1. The Contractor shall accept and process all claims for pharmaceutical agents and supplies covered under the TRICARE pharmacy benefit, and purchased from a licensed pharmacy in the 50

United States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa and Guam.

C.3.1.2. The Contractor shall limit retail claims for covered drugs under 10 U.S.C. §1074g, 32 C.F.R. 199.21, and other applicable regulations. Network pharmacies may submit claims for covered supply items using the National Drug Code (NDC) numbers assigned to them. Reimbursement of retail pharmacy claims will be made in accordance with G.3.6.2.

C.3.1.3. When access to specific drugs at retail pharmacies is restricted under the law, the Contractor shall facilitate either a change in the beneficiary's current prescription to an approved pharmaceutical or supply, or shift the beneficiary's prescription to TMOP. Covered drugs that are restricted at retail and their respective implementation dates are published at in DoD P&T Committee Meeting Minutes (Attachment J-3, Line 1).

C.3.1.4. When claims are received for covered drugs furnished in geographical locations not covered under this contract, the Contractor shall forward them to the TRICARE Contractor responsible for processing claims for those locations as specified in the TOM, Chapter 8, Section 2.

C.3.1.5. The Contractor shall complete real-time, online Coordination of Benefits (COB) in accordance with National Council of Prescription Drug Program (NCPDP_ D.0 standards (or most current version) for those claims filled in retail network pharmacies where OHI has been identified, to include Medicare Part D claims. The Government will provide the COB and Medicare Part D billing transaction segments to include the required values. The Contractor is required to track Medicare Part D True Out-Of-Pocket expenses (TROOP) and total drug expenditures for each TRICARE beneficiary who is also enrolled in Medicare Part D. The Contractor shall provide this information to the Centers for Medicare & Medicaid Services (CMS) designated TROOP facilitator.

C.3.1.6. The Contractor shall reimburse claims in accordance with the TRM, Chapter 4.

C.3.1.7. The Contractor shall process claims submitted by Department of VA pharmacies for beneficiaries who are TRICARE-eligible as primary payer. The double coverage provisions in TOM, Chapter 23, Section 3 and TRM, Chapter 4 are waived for beneficiaries with Medicare Part D. VA benefits are not considered OHI.

C.3.1.8. If requested by the beneficiary and allowable under federal and state law, the Contractor may authorize the dispensing of up to a 90-day supply prescription as a single transaction at a retail pharmacy. In these cases, the pharmacy shall collect a copayment for each 30-day increment. The Contractor must make this option available at all retail network pharmacies.

C.3.1.9. The Contractor shall ensure that claims for prescriptions filled but not dispensed are reversed within ten (10) calendar days of the date the original claim was submitted. When reversals are processed more than ten (10) calendar days after the date the original claim was submitted, the Contractor shall adjust or cancel the TRICARE Encounter Data (TED) record.

C.3.1.10. The Contractor shall process batch claims in the most current NCPDP batch format. The Contractor may receive batch claims from a variety of sources (e.g., State Medicaid agencies, clearinghouses, DVA) and the Contractor shall process these claims regardless of the electronic media (e.g., CD ROM, tapes) through which they are submitted. All batch claims shall be processed

within 14 days of receipt. The Contractor shall process claims from state agencies in accordance with TRM Chapter 1 Section 20. Notwithstanding the above, Medicaid subrogation electronic batch claims shall be processed within two business days.

C.3.1.11. The Contractor shall report the actual amount paid to the retail pharmacy. On the TED, this will be populated as the Amount Paid by Government Contractor, per the TSM.

C.3.2. Paper Claims

C.3.2.1. The Contractor shall process paper claims submitted by beneficiaries, also known as Direct Member Reimbursement (DMR) claims, and those submitted by pharmacies, known as assignment of benefit claims, in accordance with TOM, Chapter 23, Section 3, Paragraph 1.2 and Chapter 8, Section 1, Paragraph 3.1. The Contractor shall accept claims submitted using any of the specified forms. Electronic submission of paper claims is only allowed under an approved Office of Management and Budget (OMB) format.

C.3.2.2. Upon request, the Contractor shall mail the current version of the DD2642 claim form to beneficiaries.

C.3.2.3. The Contractor shall reimburse paper claims for non-network pharmacy services in accordance with the TRM, Chapter 1, Section 15, minus applicable copayments and deductibles.

C.3.2.4. The Contractor shall process these paper claims using the most current NCPDP format.

C.3.2.5. The Contractor shall monitor paper claims processing and work with retail network pharmacies to reduce the volume of network paper claims. Network pharmacies should be using online coordination of benefits in most cases and the Contractor shall work with any pharmacies with higher than average rates of paper claims to transition them to online processing.

C.3.2.5.1. The Contractor shall require all retail network pharmacies to utilize online Coordination of Benefits.

C.3.2.6. The Contractor shall not report or bill manual corrections to retail pharmacy claims as paper claims.

C.3.2.7. The Contractor shall process claims for beneficiaries who are required by their OHI to use their designated mail order pharmacy or other non-network pharmacy using network cost shares. Non-network copayments and deductibles are not applicable to these claims.

C.3.2.8. The Contractor shall routinely audit paper claims to look for scenarios such as high cost claims, high cumulative claims value, and high volume of claims. All such reviews and audits shall be performed at the beneficiary and family level.

C.3.2.9. Measured on a monthly basis, paper claims shall meet the following minimum standards:

C.3.2.9.1. 95% of paper claims shall be processed to completion within [redacted] calendar days of receipt.

C.3.2.9.2. 100% of paper claims shall be processed to completion within [redacted] calendar days of receipt.

C.3.2.10. The Contractor shall provide reporting on paper claims volumes, processing times, denials and appeals (CDRL Q050). Paper claims are considered to be processed to completion as of their TED record Create Date.

C.3.2.11. The Contractor shall provide notification to the beneficiary must be in writing for denied paper claims. The notification must explain why the claims were denied and detail the beneficiary's appeal rights.

C.3.2.12. Under the TRICARE benefit, the Contractor shall not process paper claims for prescriptions filled at MTF pharmacies. If necessary, the Contractor may forward the claims to its commercial services section for review as a claim payable by a commercial insurance plan.

C.3.3. Retail Pharmacy Network

C.3.3.1. The Contractor shall establish and maintain a retail pharmacy network throughout the 50 United States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam. The Contractor shall provide network retail pharmacy services in American Samoa and the Northern Mariana Islands when they become eligible.

C.3.3.2. Retail Network Access. The Contractor's retail pharmacy network shall meet the following:

C.3.3.2.1. Access Requirements, as measured by beneficiary zip code:

C.3.3.2.1.1. At least [redacted] pharmacy within 15 minutes driving time of [redacted] of the beneficiaries;

C.3.3.2.1.2. At least [redacted] pharmacies within 15 minutes driving time of [redacted] of the beneficiaries; and

C.3.3.2.1.3. At least [redacted] pharmacy within 30 minutes driving time of [redacted] of the beneficiaries.

C.3.3.2.2. No fewer than 35,000 retail network pharmacies.

C.3.3.2.3. Exclusions

C.3.3.2.3.1. MTF, VA, Public Health Service (PHS), and Indian Health Service (IHS) pharmacies shall not be considered as retail network pharmacies for purposes of this requirement.

C.3.3.2.3.2. Beneficiaries residing on military installations shall be excluded from this metric. The Government will provide a list of zip codes of military installations for the Contractor's use in calculating this metric.

C.3.3.3. The Contractor shall use commercially available software or web tools to calculate this metric and the methodology shall be made available to the Government for audit upon request.

C.3.3.4. The Contractor shall provide reports identifying retail network pharmacies and the total network size (CDRL M040), network access relative to the above metrics (CDRL M041), [redacted]

C.3.3.5. The Contractor shall provide a plan describing how beneficiaries not meeting the access standards will have access to pharmacy services. (CDRL A110)

C.3.3.6. All network pharmacies shall be fully licensed in accordance with applicable Federal and State laws and have a current NCPDP number. Pharmacies providing pharmaceuticals solely through internet or mail order pharmacies shall not be included in the retail network. Retail pharmacies who offer to mail prescriptions to beneficiaries as part of their business may be included in the network subject to the retail pharmacy specifications listed herein.

C.3.3.7. At a minimum, the retail pharmacies shall provide TRICARE beneficiaries the same quality of services provided to beneficiaries of other commercial clients, to the extent allowed by Federal regulation and this contract.

C.3.3.8. The Contractor shall ensure that all pharmacies document the receipt of the medication by the beneficiary or the individual authorized by the beneficiary, in accordance with all applicable State and Federal Laws. The Contractor shall ensure that network pharmacies have procedures to reasonably assess the validity of prescriptions ordered by telephone.

C.3.3.9. Changes to the Retail Pharmacy Network

The Contractor shall have a plan for communicating to beneficiaries when a pharmacy is removed from the network. As part of the plan, the Contractor shall do the following in the event of network changes:

- Provide the Government with the names of all pharmacies selected for removal from the network at a minimum of [redacted] days prior to the effective date of the changes.
- Identify and provide advance notification to beneficiaries who have filled prescriptions at the designated pharmacies during the previous six (6) months. The Contractor shall ensure that the beneficiary receives the letter at a minimum of 30 days prior to the effective date of the change.
- Provide the Government with samples of all beneficiary correspondence related to the change in the network for comment. The Government shall have no less than 14 days to review.
- Monitor and track prescription fills by impacted beneficiaries in specific categories (CDRL R020).
- Make changes to the plan as necessary to ensure successful communications with the all beneficiaries and minimize disruption of therapy.

C.3.3.9.1. In situations where a pharmacy fails to meet credentialing standards or there are indications of potential fraud that does not meet the standard requirements for case development per TOM Chapter 13, the Contractor may remove the pharmacy from the network without providing advance notification to the Government or beneficiaries. For other situations that justify short-notice removal of a pharmacy, the Contractor shall contact the Government for approval. The Contractor shall notify the impacted beneficiaries within 14 days after the pharmacy is removed.

SECTION C
STATEMENT OF WORK

C.4. Specialty Agents and Clinical Services

C.4.1. The Government will provide an initial list of pharmaceutical agents considered specialty agents. The Contractor shall propose updates to the list based on changes in the market, evolution of clinical practices, limited access, cost effectiveness, clinical support considerations, and overall benefit to the TRICARE Pharmacy Program for Government approval.

C.4.2. The Contractor shall provide the methodology under which drugs are evaluated and proposed for the addition or removal from the specialty agent list.

C.4.3. Network Pharmacies Capable of Dispensing Specialty Agents. All network pharmacies that can dispense specialty agents shall be fully licensed in accordance with applicable Federal and State laws and have a current NCPDP number. When not dispensed by an MTF pharmacy or a VA pharmacy, all covered specialty agents, including limited distribution agents, shall be accessible to beneficiaries at network retail cost shares or mail order cost share if the TMOP dispenses the specialty agent. The Contractor shall not deny cost sharing or reimbursement for claims associated with specialty agents filled at network pharmacies unless the specialty agent is enrolled in Expanded Use of MTF and TMOP (C.6.6), subject to benefit design restrictions (C.7.3.1) or non-compliant with pricing agreements per C.8.8.

C.4.3.1. The Contractor shall provide notification to the Government of any changes to the network per C.3.3.9.

C.4.4. Access. The Contractor shall make all specialty agents as defined by C.4.1 available to TRICARE beneficiaries in the pharmacy network. If requested by the Government, the Contractor shall facilitate in the movement of specialty prescriptions from MTF pharmacies to TMOP or other network pharmacies.

C.4.4.1. To avoid beneficiary and provider confusion, the Contractor shall provide beneficiary and prescriber education on obtaining specialty agents through the network pharmacies if requested by beneficiaries and/or providers. This shall include but is not limited to:

- Education on accessing agents that have access restrictions (limited distribution agents).
- Assistance in transferring prescriptions or obtaining new prescriptions.
- Education on all options in the pharmacy network for obtaining a prescription for specialty agents and benefits of these options within the pharmacy network to allow beneficiaries and providers to make an informed choice.
- Assist in a waiver request if appropriate per C.6.6.
- On-boarding and registration activities at TMOP and Contractor Selected Retail Network Pharmacies, when appropriate.

C.4.5. Patient Support at TMOP and Contractor Selected Retail Network Pharmacies. The Contractor shall ensure support for beneficiaries who receive specialty agents is in accordance with pharmacy best practice standards. At a minimum, the Contractor shall provide medication administration support (e.g. proactive patient consultation, therapy evaluation and call center support,) that minimizes adverse events. The Contractor shall maximize adherence as appropriate,

improve well-being, and promote beneficiary satisfaction as measured by widely recognized industry benchmarks.

C.4.5.1. Where applicable and if available, the Contractor shall educate beneficiaries on manufacturer supported programs that may augment, but not replace, those services offered by the network pharmacies.

C.4.5.2. At TMOP and Contractor selected retail network pharmacies, the Contractor shall provide delivery management services to include timely delivery of medications to align with treatment schedules, delivery tracking and waste prevention.

C.4.5.3. The Contractor shall ensure beneficiaries receive accompanying supplies for specialty agents dispensed at TMOP and Contractor selected retail network pharmacies, including those required for administration, disposal or any other purposes in accordance with pharmacy best practices.

C.4.5.4. At TMOP and Contractor selected retail network pharmacies, the Contractor shall work with the MCSC(s) to coordinate drug administration when appropriate (C.15.1.16.4). If required, this shall include the administration or disposal of drugs, healthcare provider support or other available services as deemed appropriate.

C.4.6. Programmatic Support. The Contractor shall optimize the specialty services provided in the areas of cost controls, utilization strategies and incorporation of commercial best practices that aligns with the TRICARE benefit design. Utilization strategies will align with those noted under C.7.2.1.

C.4.7. Replenishment at TMOP. The Contractor shall maximize replenishment of specialty agents from the National Prime Vendor (NPV) contract. The Defense Logistics Agency-Troop Support (DLA-TS) manages the NPV contract (C.6.8.9).

C.4.7.1. Replenishment will be provided (owed) to the Contractor when all of the following conditions are met: 1) specialty agents are dispensed from the TMOP to TRICARE eligible beneficiaries; 2) specialty agents are available for replenishment from the NPV; and 3) specialty agents are not acquired through the Market Priced Pharmaceutical Program per C.4.7.6.

C.4.7.1.1 The Government will work with the Contractor to determine which non-specialty agents are eligible for replenishment at pharmacies designated as replenishment pharmacies and to dispense specialty agents per C.6.1. Non-specialty agents determined to be replenishable by the Government will follow the mail order requirements in C.6. and G.3.5.7.3.

C.4.7.2. The Contractor shall request replenishment in accordance with C.6.8. Any deviation in ordering product for replenishment from the NPV shall be requested per CDRL R130. Requests for deviations shall be consolidated by the Contractor for submission to the Government.

C.4.7.3. The Contractor shall ensure pharmacies receiving replenishment acknowledge receipt of replenished inventory from the NPV per C.6.8.20 and report any discrepancies per C.6.8.21.

C.4.7.4. The Contractor shall ensure pharmacies receiving replenishment continuously monitor availability for cost effective products for replenishment and provide recommendations to the government per CDRL W011.

C.4.7.5. Non-specialty and specialty agents which are not replenished from the NPV will follow retail prescriptions claims processing per C.3.1.

C.4.7.6. The Contractor may identify opportunities for the Market Price Pharmaceutical Program per C.6.8.22. Opportunities shall be accounted for in CDRL R140.

C.4.7.7. The Contractor shall track and report volume of dispensed specialty agents and the replenishment of specialty agents ordered and received from the NPV and provide auditable reconciliation reporting per C.6.8.7.

C.4.7.7.1. The Contractor shall identify its preferred Returns Management Reverse Distributor (Reverse Distributor) to the Government and further distinguish between returns for which replacement of a pharmaceutical is expected from the NPV per C.6.4.

C.4.7.8. For non-replenished specialty agents, the costs will be reimbursed (see Section G.3.6.1). Non-replenished agents are subject to cost control measures under the retail network specialty guarantee (See Section H.3.3). In instances where a specialty agent is not replenished in a timely manner, as agreed upon by the Government and the Contractor, the Contractor will coordinate with the Government to determine the best course of action for continued efforts towards replenishment of specialty agents. This may include but is not limited to: (1) the use of the Contractor's inventory until replenishment is available through the NPV (C.6.8.13); or (2) utilizing the Market Price Pharmaceutical Program (C.4.7.6 and C.6.8.22). Any replenishment owed at the end of each option period will be reconciled per C.6.8.7.

C.4.7.8.1. If a specialty agent becomes non-replenished from a previous replenished status, the Contractor will provide education to beneficiaries and/or providers on where the medication can be accessed and if benefit restrictions or co-pay changes may occur.

C.4.7.8.2. If a specialty agent is unavailable at TMOP or the Contractor selected retail network pharmacies, the Contractor shall ensure the beneficiary is informed of the situation and will educate the beneficiary and/or provider of their options in obtaining the medication, as well as facilitate in the transfer of that prescription. If appropriate, the Contractor will work with the beneficiary's provider to find alternative therapies which may be available at TMOP or the Contractor selected retail network pharmacies.

C.4.8. Reporting. The Contractor shall provide a report on the dispensing of specialty prescriptions and clinical services provided (CDRL Q150).

C.5. MTF Pharmacy Claims

C.5.1. The Contractor shall support claims submissions from MTF Pharmacies using MHS GENESIS.

C.5.1.1. Reserved.

C.5.4.8. The Contractor shall adjudicate all MHS GENESIS claims and shall reject claims that do not pass edits. The Contractor may return a paid claim with advisory messaging in lieu of rejection or exclude specific drugs from such rejects as directed by the Government. The Government may identify specific information to be included in the messaging for advisories or rejects. Commercial standard edits shall apply unless otherwise indicated.

C.5.4.9. The Contractor shall accept the ingredient cost submitted on the claim for MHS GENESIS claims. No adjustments or discounts shall be applied.

C.5.4.10. The Contractor shall monitor MHS GENESIS rejects and, on a weekly basis, report NDCs which trigger rejects in the indicated categories. (CDRL W030)

C.5.4.10.1. The Contractor shall coordinate with DHA and/or the MHS GENESIS Contractor to ensure alignment between their drug file and that used by MHS GENESIS, including the handling of new and termed NDCs.

C.6. Mail Order Pharmacy

C.6.1. Mail Order Pharmacy Prescriptions. The TRICARE Mail Order Pharmacy (TMOP) program, as administered under the terms of this contract, is the Contractor's Mail Order Pharmacy and includes any network pharmacy designated by the Contractor and approved by the Government that can dispense specialty agents (C. 4. 1.) under a mail order National Provider Identifier (NPI) code which allows claims to follow the TRICARE mail order benefit design, and mail order cost- share for TRICARE eligible beneficiaries. These pharmacies shall receive replenishment inventory from the NPV. All requirements for administration of the TMOP under this contract shall be applicable to the dispensing of specialty agents by a designated network pharmacy with a mail order NPI code unless otherwise specified.

C.6.1.1. The Contractor's mail order facilities shall dispense and deliver medications to TRICARE beneficiaries consistent with the requirements that apply to the overall standard operations of TMOP outlined below. For beneficiaries in deployed theaters of operation, the Contractor shall dispense medications as indicated in Section C.6.7.

C.6.1.2. The Contractor shall accept prescription orders at TMOP by written (original or facsimile), electronic (supporting digital signature including e-prescribing), or telephonic submission.

C.6.1.2.1. The Contractor shall notify the beneficiary when a prescription order is received directly from a healthcare provider and process the prescription in accordance with the beneficiary's need (e.g. fill, pend the prescription, etc.).

C.6.1.3. The Contractor shall only accept prescriptions written by healthcare providers licensed in the U.S. with prescriptive authority as delegated by state and federal law. A provider who meets the applicable standards of state or federal licensure but who operates by the Indian Health Service, an Indian tribe, tribal organization, or urban Indian organization would meet the requirements of having prescriptive authority under DHA rules.

C.6.1.4. The Contractor shall have procedures in place to reasonably assess the validity of prescription orders.

C.6.1.5. For all medications dispensed through TMOP, the Contractor's tracking and dispensing procedures shall comply with Federal and State law and all applicable state boards of pharmacy requirements.

C.6.1.6. For beneficiaries receiving prescription medications through the TMOP, the Contractor shall provide 24 hours a day, 7 days a week access to a pharmacist by phone.

C.6.1.7. The Contractor shall not collect sales tax on prescriptions dispensed by TMOP.

C.6.1.8. The Contractor shall not dispense TMOP prescriptions to a beneficiary with OHI, unless one of the following exceptions applies:

1. The OHI does not cover the prescribed agent, either by the benefit design or denied coverage review.

2. The beneficiary has exhausted the benefits under the OHI.

C.6.1.8.1. Under these exceptions, to receive TRICARE coverage of pharmaceuticals dispensed through the TMOP, beneficiaries with OHI must submit documentation to the Contractor showing the OHI does not cover the prescribed item, or documentation such as an Explanation of Benefits (EOB) indicating their coverage has been exhausted. In cases where the Contractor is also the PBM for the OHI, it may provide such documentation in place of the beneficiary. The Contractor will then update the beneficiary's profile with this information and process the prescription(s) accordingly.

C.6.1.9. The Contractor's TMOP prescription processing and written notification of denied orders for non-specialty agents shall meet the following minimum standards:

C.6.1.9.1. 98% of Mail Order prescriptions not requiring intervention or clarification shall be shipped in four (4) business days from receiving the prescription.

C.6.1.9.2. 100% of Mail order prescriptions shall be shipped, scheduled for delivery, returned, or denied within ten (10) calendar days of receipt, date stamped in accordance with TOM Chapter 8, Section 1.

C.6.1.9.2.1. Exceptions to the above prescription processing standard are as follows:

- Prescriptions under the Deployment Prescription Program (DPP) that require clarifications or intervention. These will not be included in the calculation of mail order pharmacy processing time; and
- Prescriptions for specialty agents which will follow delivery protocol specific to treatment needs per C.4.5.2.

C.6.1.9.3. Prescriptions dispensed from the TMOP shall be accurate 100% of the time, measured monthly.

C.6.1.10. In the event the Contractor fails to mail any prescription that did not require clarification or intervention within ten (10) business days for non-specialty agents or per beneficiary's need in the

case of specialty agents, the Contractor shall automatically provide next day delivery service at no additional charge to the beneficiary.

C.6.1.11. The Contractor shall provide reporting of mail order volumes and processing times (CDRL Q040).

C.6.1.12. The Contractor shall contact the prescriber for each TMOP prescription received requiring intervention or clarification.

C.6.1.13. If the Contractor is unable to obtain a response from a prescriber within two (2) business days for a non-specialty agent or within an appropriate time necessary to dispense a specialty agent given a beneficiary's need, the Contractor shall contact the beneficiary telephonically or by electronic means, based on the beneficiary's indicated preferences, to provide order status.

C.6.1.13.1. For intervention such as PA, MN or QL overrides, the Contractor will request beneficiary direction to process the prescription within the given benefit design, pend the prescription, return or cancel the prescription, or continue efforts to obtain a response from the provider.

C.6.1.13.2. For prescription clarification, which requires the information on the prescription to be clarified for completeness, accuracy and legibility, the Contractor will request beneficiary direction to either return or cancel the prescription or continue efforts to obtain a response from the provider. The Contractor will be held to the 10 day processing requirement per C.6.1.9 for all non-specialty agents. The Contractor shall document all calls and the beneficiary's direction.

C.6.1.14. If a medication is unavailable at Mail Order, the Contractor shall notify the beneficiary, provide options where the prescription can be filled including in-network options, and help facilitate the transfer of the prescription to the beneficiary's selected pharmacy.

C.6.1.15. The Contractor shall not return or cancel a prescription without first attempting to contact the beneficiary telephonically or by electronic means. The beneficiary shall have no less than 72 hours to provide a response before the prescription is returned or cancelled.

C.6.1.16. For all returned or cancelled prescriptions, the Contractor must provide written notification to the beneficiary explaining why the prescription was returned or cancelled.

C.6.1.17. If the Contractor is unable to fill a prescription because the medication is on backorder, the Contractor shall notify the beneficiary at the time of the order and offer to pend the prescription, transfer the prescription to a retail pharmacy, return or cancel the prescription, or contact the provider to request an alternative drug which is available. If the beneficiary opts to transfer the prescription to a retail network pharmacy, it shall be processed in accordance with C.3.1.

C.6.1.17.1. For specialty agents that are unavailable at Mail Order, the Contractor shall follow the requirements in C.4.7.8.2.

C.6.1.18. If the prescription is pended due to backorder, the Contractor shall contact the beneficiary when the medication is back in stock to request permission to fill the order.

C.6.1.18.1. The Contractor shall provide notification to the Government of items currently on backorder per CDRL W012.

C.6.1.19. The Contractor will use best commercial practices to maximize generic substitution, including attempts to convert Dispense as Written (DAW) prescriptions. TMOP prescriptions dispensed shall adhere to the Government's mandatory generic policy.

C.6.1.20. Upon receipt of a DAW prescription for a brand name product for which a generic equivalent is available, the Contractor shall contact the prescriber to change the prescription to a generic equivalent.

C.6.1.20.1. If the prescriber refuses to switch, the Contractor shall process the prescription according to government-approved PA criteria, as described in C.8.

C.6.1.20.2. If the prior authorization is denied, the Contractor shall cancel and/or return the prescription to the beneficiary.

C.6.1.20.3. If the Contractor cannot contact the prescriber, the Contractor shall notify the beneficiary per C.6.1.15.

C.6.1.21. For all denied mail order prescriptions, the Contractor shall provide notification to the beneficiary explaining why the order was denied and detailing the beneficiary's appeal rights.

C.6.1.22. At the direction of the COR, the Contractor may dispense brand in lieu of generic in instances where the brand is the lowest cost available on the medical pricing catalog, provided by the Defense Logistics Agency Troop Support (DLA-TS), for replenishment.

C.6.1.23. The Contractor may offer automatic refills but shall exclude specific agents from this service as determined by the DoD P&T Committee process. Specialty agents shall follow delivery management services per C.4.5.2 and will not be included in automatic refill programs unless otherwise specified by the DoD P&T Committee.

C.6.1.23.1. The automatic refill program shall allow beneficiaries to opt in for agents appropriate for automatic refill.

C.6.1.23.2. The Contractor shall present opt-in and opt-out options in a way that is clear and easy to understand and make their selection on all web-based tools and other beneficiary-facing communications. Confirmation will be sent to the beneficiary upon selection via the beneficiary's preferred electronic means.

C.6.1.23.3. The Contractor shall notify beneficiaries when a prescription is eligible for an automatic refill. The Contractor shall only fill the prescription after [redacted]

C.6.1.23.4. The Contractor shall not dispense prescriptions exceeding 450 days' supply over the course of any 365 day period unless an override is deemed appropriate per C.8.10. This limitation will not be applied to beneficiaries during the period they are receiving DPP dispensing(s).

C.6.1.23.5. When a prescription expires, the Contractor shall contact the beneficiary to authorize outreach to the prescriber to renew the prescription and get confirmation from the beneficiary to continue enrollment of that prescription into the automatic refill program.

C.6.1.23.6. When a drug is removed from the automatic refill program, the Contractor shall notify the beneficiary per C.9.3.

C.6.1.23.7. The Contractor shall provide reporting in accordance with CDRL M130.

C.6.1.24. The Contractor shall use clinical best practices to ensure prescriptions are processed to reflect the beneficiaries' most recent therapy. This shall include but not limited to:

- Ensuring prescriptions processed have the most current strength, dosage forms, and directions of use.
- Renewal prescriptions are pended in lieu of rejecting early submissions and beneficiaries are notified by telephone or other electronic means, based on beneficiary preference, of prescriptions received and placed in a pended status, and the anticipated processing date for each.

C.6.1.25. The Contractor shall report dispensed ingredients that are replenished at the burdened unit price from the medical pricing catalog provided by the DLA-TS. On the TED, this will be populated as the Amount Paid by Government Contractor, per the TSM. Ingredients acquired by Contractor through MPPP should reflect the acquisition cost to the Government. See Section C.6.8.22 for more information.

C.6.1.26. The Contractor shall accommodate all special requirements in regards to handling, processing or shipping of pharmaceutical agents as recommended by the Food and Drug Administration (FDA) or manufacturer for products dispensed through TMOP.

C.6.2. Mailing Prescriptions

C.6.2.1. The Contractor shall mail TMOP prescription orders to only those beneficiaries living in the 50 United States, the District of Columbia, Puerto Rico, U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and Guam, and to beneficiaries with an Army Post Office (APO), Fleet Post Office (FPO), or Diplomatic Post Office (DPO) address. The Contractor will follow best industry practices for delivering temperature sensitive products and will follow specialty handling requirements per C.6.1.26.

C.6.2.2. The Contractor shall mail TMOP prescriptions to an APO, FPO, and DPO address using, at a minimum, a delivery method equivalent to U.S. Priority Mail. All other TMOP prescriptions shall be shipped or mailed postage paid to the beneficiary in a manner which provides, at a minimum, a delivery time equivalent to First Class U.S. Mail. Prescriptions for specialty agents shall be mailed in accordance with delivery management services per C.4.5.3. as appropriate.

C.6.2.3. The Contractor shall ship TMOP prescriptions at no additional cost to the beneficiary. The Contractor may also offer pick-up at a local location, in accordance with state and federal laws.

C.6.2.4. The Contractor shall apply TMOP dispensing rules and copayments, regardless of delivery mechanism.

C.6.2.5. Upon request by the beneficiary, for non-specialty agents, the Contractor shall provide next day or other expedited delivery services to beneficiaries with a mailing address within the continental U.S. The beneficiary is responsible for the additional shipping cost at the Contractor's most favorable shipping rate.

C.6.2.6. The Contractor shall have the ability to suspend shipping to specified addresses outside the United States by postal code when directed by the Government.

C.6.2.7. The Contractor shall ship medications care of (c/o) to the beneficiary's health care provider's office, if requested by the beneficiary.

C.6.2.8. When shipping medications, the Contractor shall comply with U.S., U.S. Military, and U.S. Diplomatic Postal Service regulations.

C.6.2.9. The Contractor shall not ship prescriptions to addresses where any prior prescription or correspondence to that beneficiary has been returned undeliverable without first contacting the beneficiary and verifying the address.

C.6.2.10. With each order shipped, the Contractor shall provide information on all options for reordering a medication.

C.6.2.11. The Contractor shall be responsible for all medications dispensed by the Contractor up to the verified point of delivery to the beneficiary or to the alternate delivery location designated by the beneficiary. For non-specialty agents when using U.S. Mail, the Contractor shall allow 12 days from the original ship date for the beneficiary to receive their order. Beginning 12 days after the ship date, the Contractor shall reship the order within three days of receiving notification from the beneficiary that their order has not been received or was received in unusable condition. A beneficiary shall have up to 45 days from the original ship date to report that an order was not received and request a replacement. This shall be extended to 60 days for prescriptions sent using an APO, FPO, or DPO address. Specialty agents dispensed at TMOP shall follow the delivery model per C.4.5.2. If the Contractor determines the original order for a non-specialty or specialty agent was not received or was received in unusable condition, the Contractor shall reimburse the copayment for the original order, or may provide delivery of a replacement order with no additional copayment. Upon receipt of beneficiary notification that the original order was not received, the Contractor shall educate the beneficiary regarding the copayment for any replacement order and the potential for reinstatement of the original copayment should the original order arrive in usable condition. Following shipment of the replacement order, the Contractor shall monitor deliveries of prescription order(s) to determine the status of the original order as well as replacement orders and make outreach to the beneficiary as needed to address the ongoing issue.

C.6.2.12. If it is determined the original prescription order was not received or was received in unusable condition, the Contractor shall not receive an administrative fee, replenishment or reimbursement for the lost or damaged prescriptions. The Contractor will receive an administrative fee, replenishment or reimbursement if the replacement is the result of a circumstance in which the

Contractor has limited or no control, such as a drug recall or natural disaster. The Contractor shall report on all replacement shipments requested and fulfilled (CDRL Q041).

C.6.2.12.1. In situations where either a return is received or a request to return a prescription is received due to error(s) not caused by the Contractor or the beneficiary (see C.6.5), the Contractor shall work with the Government to determine appropriate resolution.

C.6.2.13. Order Tracking. The Contractor shall provide an electronic method for beneficiaries to monitor a prescription order from the day an order is processed to final delivery. Tracking should include updates on order processing, any processing delays, the date of expected delivery, and upon successful delivery. Additional notification would apply if an order is placed in pended status with a next eligible fill date, the order is eligible for release from pended status and the order is returned or cancelled. Beneficiaries should have an option to configure notifications if desired, based on their communication preferences.

C.6.2.14. [redacted]

C.6.2.14.1. [redacted]

C.6.2.14.2. [redacted]

C.6.2.14.3. [redacted]

C.6.3. Mail Order Pharmacy Accounts

C.6.3.1. The Contractor shall support TMOP registration by a variety of means, including but not limited to submissions in writing, via telephone, or via the Contractor's website.

C.6.3.2. For prescription orders, the Contractor shall allow beneficiaries to provide a credit card for the copayment amount.

C.6.3.3. The Contractor shall establish individual accounts for family members, and shall allow for more than one credit card to be on record for collection purposes.

C.6.3.4. The Contractor shall ensure that if a beneficiary overpays a copayment amount, the beneficiary is notified that the excess has been credited to the beneficiary's account for future prescriptions, or the overpayment is refunded to the beneficiary along with the explanation of the refund, based on the beneficiary's preference.

C.6.3.5. As a result of its own business judgment and at its own risk, the Contractor may choose to extend credit to beneficiaries so that when an insufficient copayment is received, the Contractor may

fulfill the prescription order up to the amount of the Contractor-established credit limit and credit aging parameters. As the Contractor is not acting as an agent of the Government in extending credit to beneficiaries, none of the recoupment procedures set forth in this contract or the TRICARE manuals shall be available to the Contractor to collect beneficiary copayments. Likewise, any uncollected debts from beneficiaries resulting from the extension of credit are not reimbursable under this contract. If the Contractor does not extend credit or the beneficiary has exceeded the Contractor's established credit parameters, the Contractor shall return the prescription to the beneficiary and notify the beneficiary of the correct copayment amount required.

C.6.4. Returns

C.6.4.1. Prior to the start of pharmacy services, the Contractor shall identify its preferred Returns Management Reverse Distributor (Reverse Distributor) to the Government.

C.6.4.2. The Contractor shall segregate all returned pharmaceuticals from all other pharmaceuticals in its facility.

C.6.4.3. The Contractor will further distinguish between returns for which replenishment of the pharmaceutical is expected from the NPV per C.6.8.1, and any returns leading to a replacement furnished by the Contractor.

C.6.4.4. Any returns leading to a Contractor furnished replacement may be submitted to the Contractor's Reverse Distributor; any credits arising from these returned drugs accrue to the Contractor.

C.6.4.5. For all pharmaceutical agents returned to the MOP, the TED record will be adjusted or cancelled as necessary to properly reflect co-payment, administrative fee, and replenishment. The TED adjustment/cancellation must maintain an accurate clinical record on the PDW.

C.6.4.6. The Contractor shall hold all returned pharmaceutical agents for which replenishment is expected for processing by the Government's Reverse Distributor.

C.6.4.7. The Contractor shall contact the Government's Reverse Distributor no less frequently than quarterly to arrange for a return shipping date. The Contractor will provide the Government's Reverse Distributor access to its facility(ies) for onsite inventory, packaging, and shipment of returns to the Government's Reverse Distributor's central location.

C.6.4.8. The Contractor shall submit to the COR all receipts provided by the Government's Reverse Distributor upon pick-up. The Contractor is not responsible for the cost of packaging or shipment of returns to the Reverse Distributor.

C.6.4.9. The Contractor shall work directly with the Reverse Distributor to negotiate any disputes which may arising from the processing of returnable pharmaceuticals and/or the disposal of non-returnable pharmaceuticals owned by the Contractor. In the event, a dispute cannot be resolved, the Contractor may contact the COR or the Contracting Officer for assistance.

C.6.4.10. Before dispensing any compounded medication through TMOP, the Contractor shall verify that all supplies and ingredients required to prepare the compound are available for replenishment

from the NPV, as described in C.6.8. In the event that any required products are not available, the Contractor may return the prescription to the beneficiary.

C.6.5. Error Reporting

C.6.5.1. The Contractor shall provide a report on all defects and errors that occurred at TMOP (CDRL Q042). For purposes of this report, the Government defines a medical error according to the National Coordinating Council for Medication Error Reporting & Prevention (NCC-MERP): "Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer." Examples include, but are not limited to:

- Lost or damaged prescriptions reported upon receipt, resulting in delay in processing and/or increased difficulty in transcription;
- Prescriptions entered into the incorrect patient's profile, transcribing the wrong drug or dose, or directions (sig), into the patient's profiles;
- Failing to correctly enter all elements of a prescription, e.g., refills, such that the patient may not correctly receive the correct duration of therapy; or events that may trigger an allergy or drug-drug interaction, dosed incorrectly, wrong quantity transcribed, etc.; or
- Incorrect quantity dispensed, broken medications, label, bottle or packing defects, improper storage or shipping.

All such events which are identified and corrected prior to leaving TMOP are considered defects

C.6.6. Expanded Use of MTF and TMOP

C.6.6.1. The Contractor shall apply the requirements of the Expanded Use of MTF and TMOP (NDAA Fiscal Year 2015, Section 702), in accordance with TPM, Chapter 8, Section 9.1, The Contractor shall report monthly results using the Expanded Use of MTF and TMOP Summary Report (CDRL M120).

C.6.6.2. The Contractor shall monitor and apply any changes to the list of select medications for Expanded Use of MTF and TMOP posted in accordance with TPM Chapter 8, Section 9.1.

C.6.6.3. The Contractor shall approve overrides to the Expanded Use of MTF and TMOP, which may be authorized for the situations listed below. The Contractor shall apply the waiver in the patient profile which will allow a universal override for future retail dispensing in accordance with TPM Chapter 8, Section 9.1.

C.6.6.4. The Contractor shall implement a waiver process based on personal need, hardship, emergency, or other special circumstances that requires use of a retail pharmacy, per TPM Chapter 8, Section 9.1 and criteria established by the DoD P&T Committee (February 2015). The determination shall be made using Contractor-developed, Government-reviewed criteria. Criteria shall include the follow circumstances:

- A beneficiary exhibits personal need, hardship or an emergency.
- A beneficiary residing in a nursing home or other long term care facility. Communication with the beneficiary, a relative or a caregiver, is sufficient to establish residency in a nursing home. The Contractor will allow caregivers to establish residency for multiple beneficiaries at the same time.
- Barriers exist preventing a beneficiary from receiving medications by mail (e.g., no permanent mailing address, resides in rural setting).
- Special circumstances shall include but are not limited to the following:
    - The dosing is not stable or the medication requires titration to achieve therapeutic effectiveness or safety.
    - Prescriptions for different specialty agents for a given beneficiary are split between multiple pharmacies in the network due to limited distribution.
    - Medically fragile beneficiaries (e.g. pediatric, complex and serious medical conditions, disability due to health impairment, etc.) receiving specialized care and services through a retail network pharmacy.
    - Clinical and/or situational needs that would be better served through a specific retail network pharmacy.

C.6.6.5. The Contractor shall provide a dedicated toll-free number to assist beneficiaries in transferring their prescriptions from retail pharmacies to TMOP or an MTF, based on the beneficiary's directions.

C.6.6.6. When the Contractor processes a retail network pharmacy claim for a beneficiary subject to Expanded Use of MTF and TMOP, the Contractor will communicate information regarding the options available to the beneficiary.

C.6.6.7. The Contractor shall contact the beneficiary by letter or electronic means, based on the beneficiary's preference, by the end of the following week after each of the two potential 30-day courtesy fills. The communication shall remind the beneficiary of their options for obtaining future fills (at MTF, TMOP or pay the full cost of the medication at a retail network pharmacy), and provide contact information for the Contractor's call center.

C.6.6.8. The Contractor shall provide notification explaining the beneficiary's options in the following situations:

C.6.6.8.1. The beneficiary has paid the full cost for their prescription of select maintenance medication at a retail network pharmacy.

C.6.6.8.2. The beneficiary received a rejection for their medication at a retail pharmacy and did not subsequently contact the Contractor to obtain their prescription order through TMOP.

C.6.6.9. After the two 30-day courtesy fills, the Contractor shall require beneficiaries to pay the full cost of prescriptions for select maintenance medications when dispensed at a retail network

pharmacy unless the beneficiary meets requirements for waiver or override. When a beneficiary opts to pay full price for a select medication at a retail network pharmacy, it is considered a non-covered service. A record of the dispensing shall be posted to the patient's profile. The Contractor will not reimburse paper claims submitted by beneficiaries who paid the full cost of a select medication, unless otherwise authorized by the COR subsequent to a review.

C.6.6.10. The Contractor shall not reject prescriptions filled at VA pharmacies under this program.

C.6.7. Deployment Prescription Program

C.6.7.1. The Contractor shall manage all aspects of the TMOP registration and prescription process for deploying beneficiaries and for beneficiaries at in-theater locations.

C.6.7.2. The Contractor shall provide comprehensive reporting, allowing the Government to monitor the program (CDRL M100). Deployment prescriptions include all prescriptions for TRICARE-eligible beneficiaries deployed in a theater of operation.

C.6.7.3. For beneficiaries deployed in theaters of operation, the Contractor shall provide an electronic method for beneficiaries to monitor a prescription order per C.6.2.13.

C.6.7.4. For beneficiaries deployed in theaters of operation, the Contractor shall provide prescription status notifications by electronic means or by telephone, based on the beneficiary's preference, including but not limited to prescriptions received, placed in pended status, next eligible fill date, eligible for release from pended status, prescription order shipment, as well as any prescription delays, returns or cancellations.

C.6.7.5. The Contractor shall receive DPP prescriptions via standard mail and via electronic methods (such as fax, secure server, or e-prescribing system) from any Pre-Deployment or Out-Processing Center, hereafter referred to as the "Center(s)." DPP prescriptions will also be received using these same channels from within theater.

C.6.7.6. Upon receipt of a DPP prescription, the Contractor shall verify, adjudicate, and process the prescription in accordance with the procedures outlined in C.6.7.11. DPP prescriptions may have additional restrictions (e.g., psychotropic policy, non-deployable medications, etc.), as stipulated at the Government's Deployment Prescription Program page (Attachment J-3, Line 2). Specific restrictions may vary depending on which command (e.g., CENTCOM, SOUTHCOM, PACOM, etc.) the deployment falls under. Specialty agents as defined by C.4 may be supported through the deployment program if the specialty agent is deemed eligible to be dispensed based on the restrictions above or if the beneficiary is waived from the restrictions and the specialty agent is considered suitable for shipment.

C.6.7.7. The Contractor shall develop and maintain a prescription form to be used solely for the Deployed Prescription Program, based on a template furnished by the Government. The Contractor's initial DPP prescription form, as well as any subsequent updates or modifications, must receive Government approval prior to dissemination and utilization. The Contractor's DPP prescription form must be able to be printed and completed by hand, as well as completed electronically and digitally signed.

C.6.7.8. To support DPP prescriptions, the Contractor shall establish communications with and maintain channels of communication for all Centers and regional theater pharmacists.

C.6.7.9. The Contractor shall educate the Centers and theater personnel on the most common causes for delays in prescription processing and returned prescriptions, and shall actively work with the Centers and theater personnel to maximize the volume of prescriptions received and dispensed that do not require intervention or clarification.

C.6.7.10. The Contractor will provide a dedicated team to interface with deployment centers and theater personnel, and establish channels of communication to align processes to submit/process prescriptions.

C.6.7.11. Upon receipt of a DPP prescription, the Contractor shall perform the following verification steps:

C.6.7.11.1. The Contractor shall perform a DEERS eligibility query. If a DEERS query shows the beneficiary as ineligible for MOP, the Contractor shall notify the beneficiary with explanation, and provide guidance so the beneficiary may take the appropriate steps needed to show eligibility. Activated National Guard and Reserve service members may need to submit orders to DEERS to update their active duty status.

C.6.7.11.2. The Contractor shall verify that registration is complete and legible. The Contractor shall return the prescription form to the Centers for correction as necessary. For theater prescriptions, the Contractor shall contact the beneficiary, or the provider if unable to contact beneficiary, to verify registration information.

C.6.7.11.3. The Contractor shall enter all beneficiary registration and prescription information into Contractor's system and verify that the information provided is complete and correct. If clinical issues are identified with prescription information, the Contractor shall coordinate with the Center or theater prescriber as appropriate, to resolve issues.

C.6.7.11.4. The Contractor shall verify that all prescriber identifiers are received and valid.

C.6.7.11.5. The Contractor shall screen prescriptions to be pended for completeness and perform ProDUR prior to pending. Rejections and clinical warnings that would prevent the prescription from processing when it is released from pended status should be resolved with the Center or theater prescriber and corrected in the system prior to pending the prescription. This screening is in addition to the full adjudication process that occurs prior to dispensing, when the prescription is released from pended status by the beneficiary.

C.6.7.12. The Contractor shall notify the beneficiary via electronic means or telephone, based on the beneficiary's preference, when a pended prescription is eligible to be filled.

C.6.7.13. The Contractor shall dispense prescriptions following the standard mail order pharmacy adjudication process. For all DPP prescriptions, the appropriate overrides will be entered by the Contractor to allow the prescription to fill. These overrides may include the following:

- Max days' supply limit (up to 180 days' supply)

- Refill too soon
- MN
- PA required
- Excluded Drug
- QL
- Maximum Cost

C.6.7.14. Where clarification is required to process the prescription, the Contractor shall contact the prescriber (if originating from theater) or Center (if originating from Pre-Deployment Center) within one (1) business day to verify the prescription, and to notify the beneficiary of the issue.

C.6.7.14.1. The Contractor shall make a second attempt at seven calendar days after initial outreach if no response has been received. The Contractor shall allow up to 14 calendar days for a response.

C.6.7.14.2. For prescriptions originating in-theater, the Contractor will utilize the regional point of contacts (POCs) to assist in resolution. After attempting appropriate follow-up, the Contractor shall return and/or cancel any prescriptions that cannot be processed to the appropriate POC and notify the beneficiary and the prescriber.

C.6.7.14.3. When a delay is expected, the prescription cannot be processed, and upon successfully processing and/or shipping, the Contractor shall notify the beneficiary via electronic means or by phone based on the beneficiary's preference, within one (1) business day.

C.6.8. Pharmaceutical Agents and Supplies

C.6.8.1. The Contractor shall provide inventory of pharmaceutical agents and supplies, hereafter referred to collectively as "agents," for TMOP dispensing to TRICARE beneficiaries. The Contractor shall be responsible for ordering all agents (specialty and non-specialty). The Government shall replenish that inventory as set forth below.

C.6.8.1.1. The Contractor shall use the NPV as the primary source for replenishing pharmaceutical agents and supplies unless the Government approves dispensing of specific pharmaceutical agents from commercial sources under the MPPP (see C.6.8.22).

C.6.8.2. In order for the Government to replenish agents dispensed to TRICARE beneficiaries, the Contractor shall request replenishment for the same agents (drug, strength, and form) as dispensed.

C.6.8.3. The Contractor shall request replenishment by using the medical pricing catalog to obtain agents from the Government's contracted NPV.

C.6.8.4. To optimize replenishment, the Contractor shall provide written notification to the COR when the NPV is not able to resolve situations which may impede the replenishment process. This notification will occur via CDRL D010 or R130 and will identify each situation, including the specific agent and NDC, number of prescriptions impacted, reasons for the issue (if known), and any steps taken to locate additional sources of supply, and also provide recommendations as appropriate.

C.6.8.5. The Government compiles the pricing file from Federal Supply Schedules (FSS), Distribution and Pricing Agreements (DAPA), joint DoD/DVA national contracts, DoD contracts, and Blanket Purchase Agreements (BPA). This is currently compiled by the DLA-TS. The Contractor shall use the medical pricing file to identify, select, and price orders from the NPV for agents in package sizes that are most economical to the Government and can support utilization levels for agents which are replenished. If the Contractor is using the NPVs online ordering system, the contractor is required to select the most economical contracted agent available in the online ordering system. Orders shall be rounded down to the nearest whole package size of product needed to replenish agents dispensed. The agents will be shipped by the NPV to the Contractor's TMOP location(s) and specialty pharmacy location(s). In limited cases when required by the NPV or manufacturer, the Contractor may receive orders that are drop shipped directly from the manufacturer to the aforementioned locations.

C.6.8.5.1. The Contractor shall submit electronic orders to the NPV 24 hour, 7 days a week. Routine manual order shall be submitted Monday through Friday (normal business days) between the hours of 8:00 a.m. and 5:00 p.m. Orders must be received prior to 5:00 p.m. local distribution center time to be considered for next business day delivery. Orders received after 5:00 p.m. will be shipped two business days after the date of the order.

C.6.8.5.2. The Contractor shall be limited to two emergency shipments per month for each of the TMOP facilities at no additional transportation/handling charges to the ordering facility. Any additional emergency shipments requested by the ordering facility shall be at the expense of the ordering facility which shall include all applicable transportation and handling costs.

C.6.8.6. The Contractor shall not deviate from the procedures described above when ordering products from the NPV without prior written authorization from the COR. Requests to do so shall include the 11-digit NDC number, nomenclature of the product(s), package size, anticipated purchase quantity, unit cost per package, and anticipated total cost of the order for both the requested product and the product it will replace.

C.6.8.7. The Contractor shall track and report volume of dispensed agents and the replenishment agents ordered and received from the NPV. The Contractor shall also track and report the volume of agents dispensed from approved MPPP (see C.6.8.22) recommendations and provide auditable reconciliation reporting by 11-digit NDC number (CDRLs M110, M111, M140 and R140). The elements required for auditing will be specified by the Government. In the event that a dispensed NDC is not available for replenishment from the NPV, the Contractor will request replenishment with a therapeutically equivalent substitute product with the same drug, dose, and dosage form. In cases where therapeutic equivalent agents are used to replenish dispensed agents, the Contractor will maintain records which permit the therapeutic equivalent agents to be tracked by quantity and cost back to the original agents in the Contractor's inventory. The quantities ordered from the NPV for replenishment shall not exceed the quantities dispensed. The Contractor shall reconcile any latent replenishment owed, no more than 90 days after conclusion of each option period. If the quantity owed cannot be depleted within this timeframe, the Contractor shall notify the Contracting Officer or COR, to request an extension and provide a plan to reconcile within reasonable amount of time (CDRL A140).

C.6.8.8. The Contractor will provide written notification to the Government within 10 days if availability issues result in prescriptions being returned to the beneficiary.

C.6.8.9. The Contractor shall coordinate with the NPV and the DLA-TS as necessary to accomplish the replenishment of pharmaceutical agents. The operational processes for this coordination are between the Contractor and the NPV, but shall be consistent with NPV order monitoring requirements and the requirements established in the DLA-TS/NPV contract SPE2DX-20-R-0001, or successor contracts.

C.6.8.9.1. The maximum number of discrete contractor facilities at which the NPV can support replenishment is 12.

C.6.8.10. The Contractor shall work collaboratively with the NPV to achieve efficiencies with regards to communications, ordering and delivery practices, usage forecasting and necessary reporting to facilitate replenishment. [redacted]

C.6.8.11. The Contractor shall provide usage data to the NPV for prescriptions dispensed by TMOP. The data should allow the NPV to accurately forecast the quantities necessary to meet current usage demands. The Contractor shall notify the NPV at least 14 days prior to any situations which may impact usage demands (e.g., the movement of prescription volume between dispensing facilities, benefit design changes or any other situations that may impact usage demands) to ensure the NPV is able to support such changes. [redacted]

C.6.8.11.1. For newly marketed items of supply, the Contractor shall notify the NPV at least 30 days before changes in its usage patterns. Newly marketed items of supply are items approved by the FDA within the past six months.

C.6.8.11.2. The Contractor shall notify the NPV if any item is being removed from their usage data. The data will be removed by the NPV effective the last day of that calendar month.

C.6.8.12. The Contractor shall participate in a process to expend any credits that have accumulated with the NPV as a result of returns, pricing errors, and other adjustments. In the event of an unusually large credit, the Government may initiate an out-of-cycle request to perform the process.

C.6.8.13. As provided herein, the Contractor shall primarily dispense agents which are replenishable by the NPV. The Contractor understands that dispensed agents unreplenishable from the NPV are the responsibility of the Contractor. When an agent that is normally available from the NPV becomes unavailable, the Contractor will utilize its inventory to fill prescription orders, until NPV replenishment occurs, or a MPPP recommendation if approved by the Government under C.6.8.22.

C.6.8.14. A dispensed pharmaceutical agent that has not been replenished is deemed unreplenishable (subject to be confirmation of individual agents by the Government) in the following cases:

- If the agent is a discontinued brand product which cannot be replenished. This does not include cases in which a branded NDC has changed and an equivalent product, referenced by NDC, is available.

- If the agent is a discontinued generic product, for which a therapeutic equivalent generic product cannot be replenished.
- Where the Government has directed a change from a brand product to a generic equivalent associated with a market shift to the generic product.
- Specific medications, defined by the Government, which have limited or no commercial use but are necessary to support troop readiness or operational contingency requirements.
- Specific situations in which the Contracting Officer or the COR determine that replenishment is not appropriate.

C.6.8.15. Annual Rebaseline. Prior to the start of pharmacy services and by a date mutually agreed upon after award, and during each successive exercised option period within 60 days of CO notification, the Contractor shall submit a baseline listing of multi-source generic or branded products by 11-digit NDC for approval by the CO or COR (CDRLs W010 and W011). Each baseline listing will identify the therapeutically equivalent NDC that is the most economical to the Government and will be dispensed for each product whenever substitution is permitted by the prescriber.

C.6.8.16. Continuous Monitoring. Following the start of option period 1, the Contractor shall continuously monitor availability and pricing of all replenished products and provide weekly recommendations to the Government for the most cost-effective agents to be dispensed (CDRL W010 and W011). The Contractor shall identify the recommended change by 11-digit NDC for the Government's approval and the anticipated annual savings to the Government based on current utilization trends. The Contractor shall exclude those products acquired under a commercial market recommendation approved by the Government per C.6.8.22.1, during the period in which the Contractor is dispensing the commercial products.

C.6.8.17. Authorization for NDC change requests for agents replenished must be obtained from the CO or COR in writing (CDRL D010 and R130). The Government may direct the Contractor to make additional changes due to: 1) significant changes in drug prices, 2) the Government's award of a pharmaceutical procurement contract, or 3) other circumstances that necessitate a change. In the event, an NDC change takes longer than 30 calendar days to complete, the Contractor shall notify the Government per C.6.8.18

C.6.8.18. The Contractor shall complete each NDC change no later than 30 calendar days after being notified by the Government. The Contractor shall submit a written request for extension to the COR within10 days of receiving initial notification if the NDC change is expected to take longer than 30 calendar days. The request shall state the date the NDC change will be made and include the rationale for the extension.

C.6.8.19. In situations where NPV has supplies of government-specific inventory, the Contractor shall work with the NPV to deplete existing supplies prior to implementing an NDC change or dispensing the commercially-acquired pharmaceutical agents. The Contractor shall notify the Government if it anticipates it will be unable to deplete this inventory.

C.6.8.20. Receipt of Goods. The Contractor's facility(ies) ordering replenishment (hereby within referred to as ordering facility) shall have 48 hours after inventory is delivered by the NPV to acknowledge receipt for orders via an EDI 527 transaction (C.6.8.9). If the receipt of an order is not acknowledged within 48 hours after delivery, the ordering facility's ability to report discrepancies will be waived and all items in the order shall be considered received in full.

C.6.8.21. Discrepant Orders. The ordering facility(s) shall report all discrepancies relating to an order delivered by the NPV within 48 hours after delivery. Discrepancies include but are not limited to the following conditions:

- Products were shipped in error.
- Overages or short ships.
- Products with concealed damages or damaged in shipment.
- Products that did not meet the expiration/shelf life dating requirements of the NPV contract, unless otherwise authorized by the ordering facility or the DLA Troop Support NPV Contracting Officer.
- Products that were recalled, regardless of level of recall, except when the manufacturer's policy states otherwise, in which case the manufacturer's disposition instructions shall be followed.
- Other conditions consistent with the PPV's normal return policy.

C.6.8.21.1. TMOP facility(ies) shall report all discrepancies to the NPV customer service center within 48 hours after receiving an order. Discrepancies shall be communicated in a manner mutually agreed upon by all parties to include interactive work platforms. DLA Troop Support Discrepancy Mailbox (Attachment J-3, Line 15) shall be included on any communication to the NPV regarding discrepancies. Any discrepancies reported after 48 hours may be rejected by the NPV. In limited instances, a discrepancy may require additional research to reach a final conclusion which shall have a mutually agreed upon date between the NPV and the ordering facility. Notification of these instances and the agreed upon resolution date shall be reported to the NPV, DLA and DHA as soon as they are identified.

C.6.8.21.2. If an ordering facility receives an overage, or agent is received after the NPV cancelled the item on the order confirmation, the ordering facility shall notify the NPV and obtain disposition for the items. The NPV is to either provide a return authorization number and arrange for pickup or inform the ordering facility of other actions. The ordering facility is not authorized to keep the overage or cancelled agent. Discrepant goods will be held by the ordering facility's receiving point subject to NPV's disposition instructions.

C.6.8.21.3. The Contractor shall submit all discrepancies regarding cold chain products directly to DLA Troop Support Cold Chain Management, where it will be evaluated for product quality. When valid discrepancies are identified, DLA Troop Support Cold Chain Management will notify the NPV of the specific error and indicate when receipt for goods should not be posted by the Contractor or if a credit must be given.

C.6.8.22. Market Priced Pharmaceutical Program (MPPP)

C.6.8.22.1. The Contractor may recommend to the Government sustainment offers of Trade Agreement Act (TAA) compliant agent(s) to dispense at TMOP or specialty pharmacy(ies) where supply sources are not stable or are unavailable through the NPV(s). Such offers may address situations when: (1) the only alternative agents available from the NPV(s) are branded agents, or agents otherwise treated as brand, which are more costly to the Government compared to generic agents available in the commercial market; or (2) when there is accumulation of replenishment owed. The Government may impose additional restrictions such as minimum order thresholds (e.g., offers with an estimated duration less than 30 days).

C.6.8.22.2. The Generic Sequence Number (GSN) shall be the means of identifying the recommended drug family.

C.6.8.22.3. The Contractor's MPPP recommendation shall provide the following:

- The specific medical pricing catalog NDC and price for which a therapeutically equivalent agent is being offered.
- Evidence of market conditions which support the Contractor's recommendation based on the Government's usage demands at the time of evaluation.
- An attestation that the product is therapeutically equivalent to the comparable agent listed on the medical pricing catalog.
- An attestation that the drug is TAA compliant.
- The unit price and quantity available from the recommended commercial source.
- The proposed total cost to include drug, administrative fee, and estimated incentive.
- The expected allocation of drug, utilization between DoD and Dual-Eligible Beneficiaries.
- Cost savings of the combined drug and administrative fee when compared to the listed price on the MMC.
- The expiration date of the offer, as well as the estimated time period during which the product shall be dispensed based on current usage demands.

C.6.8.22.4. The Contractor shall advise DLA concurrently of offers they submit to the DHA Contracting Officer. The information provided to DLA shall include the NDC but shall exclude contractor pricing information.

C.6.8.22.5. If the Contractor's MPPP recommendation is approved by the Government, a provisional approval will be communicated to the Contractor, who will then communicate the specific NDC to be purchased to the Government. The Government will then use the NDC to make an independent determination of therapeutic equivalence and TAA compliance.

C.6.8.22.6. Upon the Government's confirmation of the Contractor's attestations, the parties will execute a modification identifying the pharmaceutical agent, unit price, and quantity at which the

Contractor is authorized to purchase and dispense the specified agents (M140 and R140) in lieu of ordering replenishment. The Contractor will be paid an administrative fee for each recommendation which is accepted by the Government and implemented and may request reimbursement for the cost of pharmaceutical agents (described herein) dispensed by invoicing as described in Section G.

C.6.8.22.7. If the NPV has excess quantities of government-specific inventory on hand (for the purpose of replenishment), the Contractor shall coordinate with the NPV to deplete these supplies per C.6.8.19 prior to dispensing the commercially-acquired pharmaceutical agents through the MPPP. Once the Contractor begins to dispense commercially-acquired product, all such product shall be dispensed before the resumption of dispensing product for replenishment. The Contractor shall notify the NPV, to ensure product is available to support the Government usage demands, prior to when it has completed the dispensing MPPP-acquired pharmaceutical agents and allowing for seamless transition back to use of Government replenished inventory.

C.6.8.22.8. At the request of the Government, the Contractor may submit MPPP offers to meet the requirements of MTF pharmacies. Any additional terms and conditions needed to facilitate this support may be negotiated as needed.

C.7. Formulary and Benefit Design

C.7.1. DoD Uniform Formulary

C.7.1.1. The Contractor shall comply with the provisions of the DoD Uniform Formulary and its copayment structure. Uniform Formulary changes are generally announced quarterly. Additional information may be found at in the DoD P&T Committee Minutes (Attachment J-3, Line 1) and on the TRICARE website (Attachment J-3, Line 14).

C.7.1.2. The Contractor shall participate in the formulary review process as a voting member of the Beneficiary Advisory Panel (BAP). Further information is available at the BAP website (Attachment J-3, Line 5).

C.7.1.3. When the P&T process makes changes to the formulary, such as the approval of new or revised clinical restrictions, prior authorization, medical necessity, or alters clinical and/or safety criteria, the Contractor shall accurately adopt those changes according the specified implementation date. The Contractor shall continually monitor and implement published uniform formulary changes (see Attachment J-3, Line 1).

C.7.1.4. The Contractor shall participate in person at quarterly meetings with the Government to align on implementation of benefit design changes.

C.7.1.5. Copayments based on formulary status, point of service, and beneficiary category shall be charged to beneficiaries in accordance with the TRM, Chapter 2, Addendum B.

C.7.1.6. The Contractor shall provide a report (CDRL M200) documenting the implementation of benefit design changes and the identification and correction of inaccuracies.

SECTION J
ATTACHMENT J-1 – Definitions

703 (or 703b): Refers to FY08 NDAA, section 703 that expanded Federal Ceiling Prices to the retail network. See "Federal Ceiling Prices."

Accurate: Containing all information and void of omitted information; note that clinical and financial records may not always match and may need to be adjusted independently

Accurate Clinical Record: Contains all prescriptions dispensed to patients and the actual quantities dispensed; includes medication shipped, even if reported missing by patient

Accurate Financial Record: Correct accounting of the costs paid by patients and by the Government; accounts for reversals of fees and copays and other financial adjustments

Active User: Any beneficiary using the TRICARE pharmacy benefit under this contract.

Agent: Pharmaceuticals and supplies covered by the TRICARE Pharmacy benefit, as determined by the DoD P&T Committee.

Administrative Review/Override: Any non-clinical review. Includes automated reviews conducted in the adjudication process, profile reviews conducted prior to issuing an override code in response to certain types of edits, and system-generated prior authorizations and medical necessity determinations resulting from an MTF dispensing.

Authorized Generic: Any drug approved by the FDA under a NDA that is marketed, sold or distributed under different labeling, packaging, product code, labeler code, trade name or trade mark than the listed (i.e., brand name) drug (21 USC §355). Authorized Generics as defined and maintained by the FDA will be treated as brand name drugs, unless specified by the DoD P&T Committee.

Backorder: All products within a drug, strength and form not available from the NPV or through commercial vendors to the Contractor for the fulfillment of DoD prescriptions.

Base Period of Performance: Runs from the intial start date of transition in until the start of pharmacy services. Can be found in Section F. Also referred to as "Initial Period of Performance", "Transition-In", "Start of transition" and "Start-up".

Basic Core Formulary: The Basic Core Formulary (BCF) is a list of medications required to be on formulary at all full-service military treatment facilities (MTFs). BCF medications are intended to meet the majority of the primary care needs of DoD beneficiaries. BCF status has no impact on cost-sharing at other points of service

Brand Name Drugs: A brand name drug is a drug marketed under a proprietary, trademark-protected name. Brand name drugs are usually approved by the FDA under a NDA or a BLA. Also see "Authorized Generics."

Branded Generic: A generic drug, as approved by the FDA under an ANDA, which has a proprietary name. Branded Generics as maintained by the FDA (i.e., Orange Book) and will be treated as generic drugs, unless specified by the DoD P&T Committee.

Business day: Any day in which the contractor's relevant operations are staffed.

SECTION J
ATTACHMENT J-1 – Definitions

Clarification: Any out-reach to the provider to verify prescription information for completeness, accuracy, legibility and appropriate dosing or other clinical/safety aspects. Examples of necessary information include: prescription information such as drug name and strength, package size, directions, refills, quantity, prescription date, provider's name and provider's signature or beneficiary information such as address, DOB or patient name.

Compound Medication: A compound medication includes two or more ingredients (with at least one active ingredient) mixed, combined, or altered by a pharmacy to create prescription medication tailored to the needs of an individual patient. Coverage of a compound will be determined by clinical appropriateness and the coverage of each ingredient in the compound based on the DoD Benefit Design. An active Ingredient is a chemical that has pharmacological or therapeutic activity.

Confirmed Breach: An incident in which it is known that unauthorized access could occur. For example, if a laptop containing PII/PHI is lost and the contractor knows that the PII/PHI is unencrypted, then the contractor should classify and report the incident as a confirmed breach, because unauthorized access could occur due to the lack of encryption (the contractor knows this even without knowing whether or not unauthorized access to the PII/PHI has actually occurred). If the laptop is subsequently recovered and forensic investigation reveals that files containing PII/PHI were never accessed, then the possibility of unauthorized access can be ruled out, and the contractor should re-classify the incident as a non-breach incident.

Continuity of Care: Efforts taken to ensure care is provided without gaps in therapy due to limited medication access, benefit rejects or other barriers that may prevent the patient receiving the appropriate medication for the intended diagnosis.

Contract award: Block 28 on SF-33

Clinical Review: Review conducted in response to a request for prior authorization or medical necessity, prompted by submission of the appropriate form (to include electronic methods) from the prescriber or beneficiary or a telephonic inquiry from the prescriber. Appropriateness is determined relative to criteria established by P&T or contractor-developed criteria approved by the government.

Cybersecurity Incident: A violation or imminent threat of violation of computer security policies, acceptable use policies, or standard security practices, with respect to electronic PII/PHI. A cybersecurity incident may or may not involve a breach of PII/PHI. For example, a malware infection would be a possible breach if it could cause unauthorized access to PII/PHI. However, if the malware only affects data integrity or availability (not confidentiality), then a non-breach cybersecurity incident has occurred.

Day: Unless otherwise specified, a calendar day, as defined in FAR 2.101.

DHA Privacy Office: DHA Privacy and Civil Liberties Office. The DHA Privacy Office Chief is the HIPAA Privacy and Security Officer for DHA, including the National Capital Region Medical Directorate (NCRMD).

Direct Member Reimbursement (DMR): Beneficiary request for reimbursement of an agent. See TOM Chapter 23, Section 3 for additional information.

DoD Benefit Number (DBN): A unique identifier assigned to a beneficiary based on association with a DoD sponsor and used to determine benefits. DoD beneficiaries who have multiple sponsors will be assigned unique DBNs for each relationship (DoDI 6040.45). It is typically 11 digits.

SECTION J
ATTACHMENT J-1 – Definitions

DoD Identification Number (DOD ID): A unique 10-digit identifier assigned to each person who has a record in the DEERS database, including all military personnel, family members, employees, most contractors. The DoD identification number identifies the individual in all interactions with DoD. Also known as the EDI-PI (DoDI 6040.45).

Dual eligible beneficiaries: TRICARE beneficaries who also have Medicare Parts A and B.

Dynamic linking: A process to connect various patient idenfication numbers (e.g., patient/sponsor SSN, DBN, DoD ID) to a single patient profile, including claims history and clinical reviews, in instances when patients are detached from one sponsor and reestablished under another separate sponsor. Examples include, but are not limited do, a beneficiary divorcing one TRICARE sponsor and marrying a different TRICARE sponsor, retirement of an active duty member who becomes the dependent of the active duty member spouse, or a dependent of a TRICARE sponsor who becomes his/her own sponsor.

Electronic Claim: Any claim received through electronic submission or other digital media, including batch claims.

Extended Core Formulary: The Extended Core Formulary (ECF) includes medications in therapeutic classes that are used to support more specialized scopes of practice than those on the Basic Core Formulary (BCF). ECF status has no impact on cost-sharing at other points of service.

Federal Ceiling Price (FCP): Pricing provisions of pharmaceuticals dispensed at retail pharmacies as outlined in 38 USC §8126 and 10 USC §1074g(f) and applied as described in 32 CFR 199.21(q). Manufacturers that do not sign the Retail Refund Pricing Agreement for specific pharmaceuticals are considered non-compliant with FCP (Non-FCP compliant).

Non -FCP compliant; Retail Exclusion: Specific drugs of manufacturers that do not sign the Retail Refund Pricing Agreement.

Generic Drugs: A drug containing the identical amounts of active ingredient(s) as the reference brand drug and has been evaluated as "therapeutically equivalent" and expected to have equal effects and no difference when substituted for the brand product. Generic drugs are approved by the FDA under an Abbreviated New Drug Application (ANDA) and are proven to be bioequivalent to an innovator drug. Also see "Branded Generics".

In writing: Any means of notification as authorized by the beneficiary, including but not limited to, email, secure messaging, or a letter delivered via a common carrier.

Initial Period of Performance: A time frame in which the incoming contractor completes the phase-in transition activities during the outgoing contractor's last Option Period. Also referred to as "Base Period of Performance", "Start of transition" and "Start-up".

Innovator drug: New agent approved by the FDA under a New Drug Application (NDA) or Biologic License Application (BLA). The NDA innovator drug is further defined by their chemical types, to include, but not limited to, new molecular entity, new active ingredients, new dosage formulations, new combinations and dosage formulation. The Innovator Drug program is explained in the August 2015 DoD Pharmacy & Therapeutics (P&T) Committee meeting minutes.

SECTION J
ATTACHMENT J-1 – Definitions

Intervention: Any out-reach to the provider to request initial or additional information regarding prior authorization, medical necessity or quantity restrictions to confirm clinical and/or safety criteria.

Line-extension: A follow-on product that has the same FDA-approved indication as the parent drug and is from the same manufacturer. Line extensions may also include products with different release properties from the parent drug, for example, an immediate release preparation subsequently FDA-approved as a sustained release or extended release formulation, available from the same manufacturer as the parent drug. The line extension definition is outlined in the May 2014 and November 2016 DoD P&T Committee minutes.

Medical Necessity (MN): A request to demonstrate medical need for a Non-Formulary medication. If approved at retail or mail order, the beneficiary will receive a non-formulary medication at the appropriate tier formulary copay. At the MTF, an approval will allow access to the medication. MNs are categorized as a type of Clinical Review under this contract.

Non-covered: Agent determined to be excluded from the TRICARE Pharmacy benefit by the DoD P&T Committee due to not having a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome over other pharmaceutical agents (32 CFR 199.21(a)(3)(ii)). Also includes items excluded from the pharmacy benefit based on benefit design (eg, cosmetic,select OTCs, medical foods, etc.). Non-covered agents are not available for cost-share.

Non-formulary (NF) agent: A higher cost-share tier of agents based on reduced relative clinical effectiveness and cost effectiveness compared to other agents. Cost-share may be reduced with an approved Medical Necessity. These agents are generally not available at MTFs without a Medical Necessity.

Non-preferred agent: Generally agents that require an approved prior authorization or prior history of a preferred agent. Non-formulary agents are usually considered non-preferred.

Non-replenishable (non-replenished): Medications or supplies that are not available from the NPV to replace contractor's stock dispensed for a TRICARE prescription, due to limited distribution or NPV contract limitations. This is not the same as "Unreplenishable."

Paper Claim: A non-electronic claim request for reimbursement, usually by the beneficiary (also known as a direct member reimbursement (DMR) claim), but can also be by the pharmacy. See TOM Chapter 23, Section 3 for additional information.

Possible Breach: An incident where the possibility of unauthorized access is suspected (or should be suspected) and has not been ruled out. The following are examples that identify a possible breach:

1) A laptop containing PII/PHI is lost, and the contractor does not know if the PII/PHI on the laptop was encrypted, the incident must be classified as a possible breach; until it is determined that unauthorized access to the PII/PHI has not occurred (not a breach) or has occurred (a breach).

2) A beneficiary identifies that an expected package has not been received, a possible breach exists until the Contractor determines the package is received by the beneficiary unopened (not a breach) or opened (a breach occurred) or the Contractor determined the package was received and opened by an unauthorized recipient (a breach).

SECTION J
ATTACHMENT J-1 – Definitions

Preauthorization: Specific type of clinical review relating to the availability of certain medications through the retail pharmacy network under Federal Ceiling Price restrictions described under 32 C.F.R. 199.21(q)(2).

Preferred agent: Agents which generally do not require a prior authorization or prior history of use.

Prior Authorization (PA): See TOM, Appendix A.

Replenished (replenishment): Process by which the Contractor orders agents from the NPV to replace stock dispensed by prescription to an eligible TRICARE beneficiary.

Run-off Claims: Claims received at the outgoing contractor's facility prior to the start of pharmacy services of the incoming contractor. The outgoing contractor should process all run-off claims and forward all claims received on or after the new contract's service delivery start date to the new contractor.

Start of pharmacy services: The beginning of Option Period 1, which occurs after the base period of performance, or transition-in, is complete. Also referred to as "Start Date."

System Availability Calculation: The following terms are referenced in M030, Pharmacy Transaction Processing Report.

- **Total Time In Reporting Period (Total Time):** Total number of minutes in the month for which data is reported
- **Downtime:** The amount of time, expressed in minutes, that the claims processing system is not available
    - **External Downtime:** Amount of time the claims processing system or interface outside the Contractor's control is unavailable due (eg, DMDC, DISA). Includes both scheduled and unscheduled outages, expressed in minutes.
    - **Contractor Downtime:** Amount of time a claims processing system or interface within the Contractor's control is unavailable. Includes both scheduled and unscheduled downtime, measured in minutes
- **Concurrent Contractor and External Downtime (Concurrent Downtime):** Overlapping downtime between both the Contractor's system and/or connections and external systems. When both systems are "down" at the same time, such as during a scheduled maintenance window, the overlap is counted once (eg, both DMDC and the Contractor were down for maintenance from 12:01 AM PST to 1 AM PST, resulting in 60 minutes of concurrent downtime).
- **Net Contractor Downtime:** Downtime attributed to the Contractor after subtracting Concurrent Downtime, expressed in minutes
- **Adjusted Total Time:** Defined as the Total Time in the Reporting Period minus external downtime, measured in minutes. The denominator in the system availability calculation.
- **Constractor System Availability:** Adjusted Total Time minus Net Contractor Downtime. The numerator in the system availability calculation.

Utilization Management: Efficient management of access to care or drug therapies utilizing available benefit design tools. These may include quantity limits, prior authorizations, step therapy, and other activities to ensure appropriate care while minimizing costs.

SECTION J
ATTACHMENT J-2 – Acronym List

Note: Acronyms are generally referenced in Section C. Where an acronym is primarily used in another section of the contract, the contract section appears after the name.

ABA – American Banking Association (G)

ACHC – Accreditation Commission for Health Care

ADP – Automated Data Processing

ADSM – Active Duty Service Member

AFRICOM – United States Africa Command

AHLTA – Armed Forces Health Longitudinal Technology Application

AIS – Automated Information System

ANDA – Abbreviated New Drug Application

API(s) – Application Programming Interface(s)

APO – Army Post Office

AQL – Acceptable Quality Level (L)

ART – Assistance Reporting Tool

ARU – Automated Response Unit

ASAP – American Society for Automation in Pharmacy

ASAP – Automated Standard Application Payment System (G)

AWP – Average Wholesale Price

B2B – Business-to-Business Gateway

BAP – Beneficiary Advisory Panel

BCACs – Beneficiary Counseling and Assistance Coordinators

BCF – Basic Core Formulary

BLA – Biologic License Application

BPA – Blanket Purchase Agreements

BSR – Beneficiary Service Representative (M)

CAC – Common Access Card

CC&D – Catastrophic Cap and Deductible

CCDD – Catastrophic Cap and Deductible Database

CDC – Centers for Disease Control

CDD – Certificate of Data Destruction

SECTION J
ATTACHMENT J-2 – Acronym List

CDR – Clinical Data Repository

CDRL – Contract Data Requirements List

CENTCOM – United States Central Command

CFR – Code of Federal Regulations

CHCBP – Continued Heath Care Benefits Program

CHCS – Composite Health Care System

CHDR – Clinical Data Repository/Health Data Repository

CIT – Continuous Integrated Testing

CLIN – Contract Line Item Number

CMS – Center for Medicare and Medicaid Services

CO – Contracting Officer

COB – Coordination of Benefits

COOP – Continuity of Operations Plan

COR – Contracting Officer's Representative

CPAR – Contract Performance Assessment Report (L)

CPPA – Center for Pharmacy Practice Accreditation

CRC – Contractors Resource Center (G)

CRM – Contract Resource Management (G)

CSA – Clinical Support Agreement

CSR – Customer Service Representative (M)

DAPA – Distribution and Pricing Agreements

DAW – Dispense as Written

DBN – DoD Benefits Number

DEA – Drug Enforcement Agency

DEERS – Defense Enrollment Eligibility Reporting System

DFARS – Defense Federal Acquisition Regulation Supplement

DHA – Defense Health Agency

DHMSM – Defense Healthcare Management Systems Modernization

DISA – Defense Information Systems Agency

DLA–TS – Defense Logistics Agency Troop Support

DMDC – Defense Manpower Data Center

SECTION J
ATTACHMENT J-2 – Acronym List

DMR – Direct Member Reimbursement

DOB – Date of Birth

DoD – Department of Defense

DoDACC – Depart of Defense Activity Address Code (G)

DoDI – Department of Defense Instruction

DoD ID – Department of Defense Identification

DPO – Diplomatic Post Office

DPP – Deployment Prescription Program

DS Logon – DoD Self–service Logon

DSA – Data Sharing Agreement

DSCP – Defense Supply Center, Philadelphia (G)

DTM – Directive-Type Memorandum (H)

DT&E – Developmental Testing and Evaluation

DUA – Data Use Agreement

DUNS – Data Universal Numbering System (G)

DUR – Drug Utilization Review

DVA – Department of Veterans Affairs

ECF – Extended Core Formulary

EFT – Electronic Funds Transfer (G)

E/HPC – Enrollment/Health Plan Code (G)

EHR – Electronic Health Record

EI – Enterprise Infrastructure

EMC – Electronic Media Claim (G)

EOB – Explanation of Benefits

EOP – Explanation of Payment (H)

ePA – Electronic Prior Authorizations

eSRS – Electronic Subcontract Reporting System (M)

EUCOM – United States European Command

FAPIIS – Federal Awardee Performance and Integrity Information System (M)

FAR – Federal Acquisition Regulation

FCP – Federal Ceiling Price

SECTION J
ATTACHMENT J-2 – Acronym List

FDA – Food and Drug Administration

FDB – First Databank

FHP&R – Force Health Protection & Readiness

FI – Fiscal Intermediary (G)

FOIA – Freedom of Information Act

FPO – Fleet Post Office

FR – Federal Register

FRB – Federal Reserve Bank (G)

FSS – Federal Supply Schedule

FST – Formulary Search Tool

FTDTL – Forensic Toxicology Drug Testing Laboratory

FY – Fiscal Year

GAAP – Generally Accepted Accounting Principles (I)

GAO – Government Accountability Office (L)

GIQD – General Inquiry to DEERS

GCN – Generic Code Number

HA – Health Affairs

HDR – Health Data Repository

HHS – Health and Human Services

HIPAA – Health Insurance Portability and Accountability Act

HIT – Home Infusion Therapy

HL7IMM – Health Level 7 Immunizations

HUBZone – Historically Underutilized Business Zone (L)

I&O – Infrastructure and Operations Division

IA – Information Assurance

ICD – Interface Control Document

ICN – Internal Control Number (H)

IHS – Indian Health Service

INDOPACOM – United States Indo–Pacific Command

IPT(s) – Integrated Product Team(s) (H)

IRO – Independent Review Official (L)

SECTION J
ATTACHMENT J-2 – Acronym List

LEPS – Legacy Electronic Prescribing Solution (L)

LIMS – Laboratory Information Management System

LPO – Locally Processing Office (G)

MAJCOM – Major Command (includes AFRICOM, CENTCOM, EUCOM, INDOPACOM, NORTHCOM, SOUTHCOM)

MC-CD – Managed Care-Contracting Division (G)

MCSC – Managed Care Support Contractor

MHS – Military Health System

MMC – Medical Master Catalog

MME – Morphine Milligram Equivalents

MN – Medical Necessity

MOP – Mail Order Pharmacy

MOU – Memorandum of Understanding

MPPP – Market Price Pharmaceutical Program

MTFs – Military Treatment Facilities

NABP – National Association of Boards of Pharmacy

NAICS – North American Industry Classification System

NCC–MERP – National Coordinating Council for Medication Error Reporting and Prevention

NCPDP – National Council for Prescription Drug Programs

NDA – New Drug Application

NDAA – National Defense Authorization Act

NDC – National Drug Code

NF – Non–formulary

NIST – National Institute of Standards and Technology

NORTHCOM – United States Northern Command

NPV – National Prime Vendor

OCI – Organizational Conflict of Interest (H)

OHI – Other Health Insurance

OHI/SIT – Other Health Insurance Standard Insurance Table

OMB – Office of Management and Budget

OSD – Office of the Secretary of Defense

SECTION J
ATTACHMENT J-2 – Acronym List

OT&E – Operational Testing and Evaluation

OTC – Over-the-counter

P&T – DoD Pharmacy and Therapeutics Committee

PA – Prior Authorization

PBM – Pharmacy Benefit Management/Manager

PCM – Primary Care Manager

PCO – Procuring Contracting Officer (L)

PDMP – Prescription Drug Monitoring Program

PDW – Pharmacy Data Warehouse

PHI – Protected Health Information

PHS – Public Health Service

PIA – Privacy Impact Assessment

PII – Personally Identifiable Information

PIIA – Payment Integrity Information Act (H)

PMP – Prescription Monitoring Program

PMPM – Per Member Per Month (G)

POC – Point of Contact

POD – Pharmacy Operations Division

PoP – Period of Performance (F)

POSC – Pharmacy Operations Support Contract

PPI – Past Performance Information (L)

PPIRS – Past Performance Information Retrieval System (L)

ProDUR – Prospective Drug Utilization Review

PSF – Professional Service Fee (G)

PWS – Performance Work Statement

RPC – Retail Pharmacy Claims (F)

RTN – Routing Number (G)

SAM – System of Award Management (K)

SBCC – Service Branch Classification Code (G)

SCA – Service Contract Act (L)

SDB – Small Disadvantaged Business (L)

SECTION J
ATTACHMENT J-2 – Acronym List

SDD – Solutions Delivery Division

SDVOSB – Service Disabled Veteran Owned Small Business (L)

SF – Standard Form (L)

SFTP – Secure file transfer protocol

SLA – Service Level Agreement (L/M)

SOC1 – Service Organization Control Report (G)

SOE – State of Emergency

SOO – Statement of Objectives

SORN – System of Records Notice

SOUTHCOM – United States Southern Command

SOW – Statement of Work

SP – Special Publication

SPC – Special Processing Code (G)

SSA – Source Selection Authority (M)

SSAC – Source Selection Advisory Council (M)

SSAE – Statement on Standards for Attestation Engagements (G)

SSEB – Source Selection Evaluation Board (M)

SSN – Social Security Number

TED(s) – TRICARE Encounter Data

TEDS – TRICARE Encounter Data System

TEPRV – TRICARE Encounter Provider record

TFL – TRICARE for Life

TIN – Taxpayer Identification Number

TMDS – Theater Medical Data Store

TMIP – Theater Medical Information Program

TMOP – TRICARE Mail Order Pharmacy

TOM – TRICARE Operations Manual

TPharm – TRICARE Pharmacy Program/Contract

TPM – TRICARE Policy Manual

TRI – TEDS Record Indicator

TRM – TRICARE Reimbursement Manual

SECTION J
ATTACHMENT J-2 – Acronym List

TROOP – True Out-Of-Pocket expenses

TSM – TRICARE Systems Manual

UF – TRICARE Uniform Formulary

URAC – Utilization Review Accreditation Commission

US CERT – United States Computer Emergency Readiness Team

USC – United States Code

USTF – Uniformed Services Treatment Facility

VPN – Virtual Private Network

WAC – Wholesale Acquisition Cost (G/H)

WAWF – Wide Area Workflow (G)

WOSB – Woman-Owned Small Business (B)

Exhibit C

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
J	1 173

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (If applicable)
P00015	See Block 16C	23-PHAR-0058	22396

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
DEFENSE HEALTH AGENCY DEFENSE HEALTH AGENCY-AURORA 16401 E CENTRETECH PARKWAY AURORA CO 80011	HT9402	DEFENSE HEALTH AGENCY DEFENSE HEALTH AGENCY-AURORA 16401 E CENTRETECH PARKWAY AURORA CO 80011-9066	HT9402

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)

EXPRESS SCRIPTS INC
ATTN THOMAS JENKINS
1 EXPRESS WAY
SAINT LOUIS MO 63121

CODE 1WPW1 FACILITY CODE 1WPW1

(x) 9A. AMENDMENT OF SOLICITATION NO.

9B. DATED (SEE ITEM 11)

x 10A. MODIFICATION OF CONTRACT/ORDER NO. HT940221C0007

10B. DATED (SEE ITEM 13) 08/05/2021

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☐ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☐ is extended. ☐ is not extended.
Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning _____ copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)
9723230130.9700.102000 (FY23) Net Increase: $3,438,213.00

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
X	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A. FAR 52.243-1, Changes - Fixed Price(Aug 1987), ALT I(Apr 1984)
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☒ is not. ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this modification is to: (1) revise Section C - Statement of Work, Section F - Deliveries or Performance, Section G - Contract Administration, Section H - Special Contract Requirements and Section J-1 Contract Definitions, as needed to support the TPharm5 Revised Specialty Approach; (2) establish Sub-CLIN 1023AD to support implementation of this change; and (3) revise CLIN Descriptions (X003 / X004 and X016) to correctly describe revised specialty approach (both in regard to dispensing and incentives).

Continued ...

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print) Viktoria Reed [redacted]	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA [redacted] (Signature of Contracting Officer)	16C. DATE SIGNED 07/27/2023

SECTION F
DELIVERIES OR PERFORMANCE

R121 Transition-Out MOU
R130 Specialty_Agents Daily NDC Change Requests Report (Rev 06012023)
R140 Specialty_Agents Market Priced Pharmaceutical Program Report (Rev 06012023)
R150 Systems Integration Test Plans
R160 B2B Gateway Questionnaire
R170 Mission-Essential Contractor Services Plan
R180 MOU with TMEP Contractor

F.3.5.7. Transition.
T010 Transition-In Plan
T020 Transition-In Status Report
T030 Transition-Out Plan
T040 Transition-Out Status Report

F.4 Delivery Schedule – Contract Changes

F.4.1 MHS GENESIS Transition – Loading Prior Authorization and Medical Necessity
At the Government's direction, the Contractor will load PA and MN overrides timely, so that existing beneficiaries will receive medication (requiring overrides) at the following MTF pharmacies transitioning to MHS GENESIS without interruption, per C.8.10.2.2.3.

	Final Five GENESIS PA/MN Load Support			Quantity Limit (QL) Load Spt	
Wave / Site(s)	Modification	Sub-CLIN	Completion Date	Fielding Go-Live Date	Govt QL Listing Est Due Date (45 Days Before Start)
Portsmouth/Drum	P00006	1023AA	Jan, 2023	21-Jan-23	Immediate
Reed/Belvoir	P00006	1023AA	Mar, 2023	25-Mar-23	Immediate
Wright Patterson	P00006	1023AA	Jun, 2023	3-Jun-23	19-Apr-23
Landstuhl/Lakenheath	P00006	1023AA	Sept, 2023	23-Sep-23	9-Aug-23
Guam/S. Korea & Okinawa	P00006	1023AB	Dec, 2023	28-Oct-23	13-Sep-23

F.5. Facilities_& Associated DODAACs Authorized for Defense Logistics Agency (DLA) National Prime Vender (NPV) Replenishment:

a. Contractor TMOP Fulfillment Sites
HGC006 - TEMPE, AZ
HGC005 - ST. LOUIS, MO
HT808C – BURLINGTON, NJ

b. Regional Locations
HT800C - TEMPE, AZ
HT801C - MEMPHIS, TN
HT802C - NEW CASTLE, DE
HT803C - ORLANDO, FL
HT804C - WARRENDALE, PA
HT805C - WHITESTOWN, IN
HT806C - LYNNFIELD, MA

(End of Section F)