United States Government Accountability Office

Report to Congressional Committees

October 2014

COMPOUNDED DRUGS

TRICARE's Payment Practices Should Be More Consistent with Regulations

GAO-15-64

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GAO Highlights

Highlights of GAO-15-64, a report to congressional committees

Why GAO Did This Study

DOD offers comprehensive health care coverage—pharmacy and medical benefits—to eligible beneficiaries through its TRICARE program. As part of its benefits package, TRICARE pays for compounded drugs. Traditionally, a drug is compounded through the process of mixing, combining, or altering ingredients, to create a customized drug tailored to the medical needs of an individual patient upon receipt of a prescription. Concerns exist about the safety and the rising costs of compounded drugs.

The National Defense Authorization Act for Fiscal Year 2014, mandated that GAO review TRICARE's payment for compounded drugs. For this report, GAO examined (1) the number and cost of compounded drugs paid for by TRICARE in fiscal year 2013, and (2) TRICARE's payment practices for compounded drugs and how they compare to other federal health care programs. GAO reviewed and analyzed TRICARE data on compounded drugs and reviewed, analyzed, and compared federal laws, regulations, and other documents pertaining to pharmacy and medical benefits under TRICARE, Medicare, and the VA health care system. GAO also interviewed program and contractor officials.

What GAO Recommends

GAO recommends that DOD align TRICARE's payment practices for compounded drugs with applicable regulations governing the TRICARE program. DOD concurred with GAO's recommendation and VA generally agreed with GAO's conclusions. HHS and VA provided technical comments that GAO incorporated as appropriate.

View GAO-15-64. For more information, contact John E. Dicken at (202) 512-7114 or dickenj@gao.gov.

What GAO Found

The Department of Defense's (DOD) TRICARE program paid for about 465,000 compounded drug prescriptions through its pharmacy benefit in fiscal year 2013; these prescriptions represented 0.3 percent of all prescription drugs paid for through TRICARE's pharmacy benefit in that year. Most of these compounded drug prescriptions were dispensed in retail pharmacies and to retirees and their family members. Compounded drug prescriptions paid for by TRICARE's pharmacy benefit cost $259 million in fiscal year 2013—accounting for about 3 percent of the total cost of all prescription drugs paid for through TRICARE's pharmacy benefit—up from $5 million in fiscal year 2004, and were largely driven by compounded drug prescriptions containing bulk drug substances. Bulk drug substances are typically raw powders that are generally not approved by the Food and Drug Administration (FDA)—the agency within the Department of Health and Human Services (HHS) responsible for assuring the safety and effectiveness of drugs and approving them for marketing in the United States. TRICARE could not identify compounded drug prescriptions paid for through its medical benefit, which pays for drugs administered to patients in outpatient or inpatient settings, because claim forms for outpatient and inpatient drugs lack specific billing codes.

TRICARE's payment practices for certain compounded drugs under its pharmacy and medical benefit are inconsistent with TRICARE regulations and are typically more generous than those of Medicare and the Department of Veterans Affairs (VA). Through its pharmacy benefit, TRICARE pays for compounded drugs that contain bulk drug substances in a manner that is inconsistent with its regulations, which stipulate that TRICARE is to pay for FDA-approved drugs only. In contrast, Medicare and VA have more restrictive payment practices for compounded drugs provided through their pharmacy benefits. By paying for compounded drugs containing bulk drug substances, TRICARE incurred additional costs. DOD officials told us that they are considering denying payment for compounded drugs that include bulk drug substances. TRICARE also pays for compounded drugs administered to patients through its medical benefit but does not determine whether these drugs contain bulk drug substances, in which case payment practices may be inconsistent with TRICARE's regulations. TRICARE's payment practices for these drugs are similar to Medicare's, but more generous than VA's.

Though compounded drugs represent a small share of TRICARE's overall drug costs, its costs for these drugs have risen significantly in recent years. Moreover, because most of these drugs contain bulk drug substances generally not approved by FDA, TRICARE's practice of paying for them is inconsistent with its regulations and results in added costs for the program.

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Abbreviations

AWP	average wholesale price
CMS	Centers for Medicare & Medicaid Services
DHA	Defense Health Agency
DOD	Department of Defense
DQSA	Drug Quality and Security Act
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
HCPCS	Healthcare Common Procedure Coding System
HHS	Department of Health and Human Services
MTF	military treatment facility
NCPDP	National Council for Prescription Drug Programs
NDC	national drug code
PBM	pharmacy benefit manager
USP	U.S. Pharmacopeial Convention
VA	Department of Veterans Affairs
VAMC	VA medical center

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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Congressional Committees

The Department of Defense (DOD) offered comprehensive health care coverage—including pharmacy and medical benefits—to nearly 9.6 million eligible beneficiaries through its TRICARE program in fiscal year 2013.[1] As part of its pharmacy and medical benefits, TRICARE pays for compounded drugs. Traditionally, a drug is compounded through the process of mixing, combining, or altering ingredients to create a customized drug tailored to the medical needs of an individual patient upon receipt of a prescription.[2] Drug compounding is typically used to prepare prescription drugs that are not commercially available; for example, a pharmacist may prepare a liquid formulation for a patient who has trouble swallowing pills or tailor a drug for a patient who is allergic to an ingredient in a commercially available prescription drug. Drug compounding is practiced in a variety of pharmacy settings, including retail pharmacies, mail-order pharmacies, and home infusion pharmacies, as well as hospital pharmacies. Compounded drugs may be dispensed directly to patients in pharmacy settings, or administered to patients in inpatient or outpatient settings, such as hospitals or physician offices.

Compounded drugs are not approved by the Food and Drug Administration (FDA)—the agency within the Department of Health and Human Services (HHS) responsible for assuring the safety and effectiveness of drugs and approving them for marketing in the United

[1]Eligible beneficiaries include active duty personnel and their dependents, Reserve and National Guard personnel and their dependents, and retirees and their dependents and survivors. TRICARE beneficiaries may obtain pharmacy benefits at network and non-network retail pharmacies, TRICARE's mail-order pharmacy, and military treatment facility (MTF) pharmacies. MTFs are DOD-operated hospitals and clinics located on military bases throughout the United States and overseas. TRICARE's medical benefits include services that beneficiaries receive in outpatient settings—including civilian physicians' offices and MTFs—and services they receive in inpatient settings—including civilian hospitals, skilled nursing facilities, and MTFs. For the purposes of this report, when we discuss outpatient settings, we are primarily referring to physician offices.

[2]Drug compounding does not generally include mixing or reconstituting approved products in accordance with the manufacturer's instructions or the product's approved labeling. Some pharmacies engage in repackaging of drugs, such as taking a multidose vial of a drug and transferring it to single dose vials or syringes. Repackaging of drugs was outside the scope of our report.

States. Compounded drugs may contain ingredients that are FDA-approved products. These drugs may also contain bulk drug substances, which are typically raw powders that are generally not FDA approved.[3] Traditionally, the practice of drug compounding has been regulated by state pharmacy regulatory bodies (e.g., boards of pharmacies). FDA and others have raised concerns that some pharmacies are going beyond the traditional practice of preparing compounded drugs for individual patients by producing large quantities of compounded drugs without prescriptions for individual patients, and selling these drugs to facilities in multiple states with no assurance of their having met the safety and legal requirements with which drug manufacturers must comply.[4] In addition, in 2012, an outbreak of fungal meningitis linked to contaminated compounded drugs raised concerns about the safety and quality of compounded drugs. In July 2013, we reported on FDA's oversight of entities that compound drugs and found that FDA's oversight was limited.[5]

DOD officials have expressed concern over the significant increase in costs for compounded drugs—particularly those that include bulk drug substances—dispensed directly to TRICARE beneficiaries in pharmacies. In June 2013, DOD informed beneficiaries that TRICARE would no longer pay for drugs dispensed by retail pharmacies that contain bulk drug substances. However, due to beneficiary complaints and enactment of

[3]FDA regulations define a bulk drug substance as any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances. 21 C.F.R. 207.3(4) (2014).

[4]In general, compounded drugs meeting certain criteria are exempt from certain requirements under the Federal Food, Drug, and Cosmetic Act (FDCA), including new drug approval, current good manufacturing, and certain labeling requirements. 21 U.S.C. § 353a.

[5]See GAO-13-702, *Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight*, (Washington, D.C.: Jul. 31, 2013).

new legislation concerning compounded drug safety and quality, DOD postponed this change.[6]

The National Defense Authorization Act for Fiscal Year 2014 mandates that we examine TRICARE's payment for compounded drugs. This report examines (1) the number and cost of compounded drugs paid for by TRICARE in fiscal year 2013, and (2) TRICARE's payment practices for compounded drugs and how they compare to other federal health care programs. In addition, we provide information on DOD's pharmacy accreditation standards for helping to ensure the safety of compounded drugs provided to TRICARE beneficiaries in appendix I.[7]

To examine the number and cost of compounded drugs paid for by TRICARE in fiscal year 2013, we requested DOD's Defense Health Agency (DHA) to provide fiscal year 2013 data on compounded drug prescriptions provided to beneficiaries through TRICARE's pharmacy and medical benefits.[8] We analyzed the available data to determine the number of compounded drug prescriptions provided to TRICARE beneficiaries by beneficiary category (i.e., active duty and non-active duty personnel, retirees, and dependents) and by setting (i.e., retail, mail-order, and military treatment facility (MTF) pharmacies; and civilian outpatient, inpatient, and MTF providers) and examined the total cost of compounded drug prescriptions, which included TRICARE's reimbursements to providers and beneficiary copayments.[9] Furthermore, we interviewed DHA officials about how they ensure the accuracy of the

[6]The Drug Quality and Security Act of 2013 (DQSA) amended the FDCA to clarify FDA's authority over compounded drugs and create a category of compounders, known as "outsourcing facilities," that engage in the compounding of sterile drugs, elect to register as an outsourcing facility, and comply with certain requirements, including current good manufacturing practice and adverse event reporting requirements, as well as risk-based inspections. Pub. L. No 113-54, tit. I, 127 Stat. 587 (Nov. 2013).

[7]We are separately reviewing payment practices for compounded drugs for Medicare, Medicaid, and private health insurance plans and expect to issue a report in early fall 2014.

[8]DOD's DHA manages TRICARE and executes TRICARE policies.

[9]DHA's Pharmacy Data Transaction Service maintains a centralized data repository of all transactions that occur in pharmacy settings, which include retail pharmacies, TRICARE's mail-order pharmacy, and MTF pharmacies. We did not examine transactions from non-network retail pharmacies because data were not available. In addition, we did not examine DOD's drug procurement practices at MTFs as this was outside the scope of this report.

data and to obtain additional information on compounded drug utilization and costs. Based on reviewing documentation describing these data, interviewing DHA officials about steps they take to help ensure data accuracy, and manually reviewing the data to examine them for obvious errors and omissions, we determined that the data were sufficiently reliable for our purposes.

To examine TRICARE's payment practices for compounded drugs and how they compare to other federal health care programs, we reviewed federal laws and regulations governing pharmacy and medical benefits under TRICARE, Medicare, and the Department of Veterans Affairs (VA) health care system; available agency documentation that describes each program's payment policy for compounded drugs under their pharmacy and medical benefits; and available agency documentation on how payment is calculated to reimburse pharmacy and medical providers for compounded drugs in these programs.[10] We selected Medicare and the VA health care system for our comparison to TRICARE because they are two of the largest federal health care programs in the United States.[11] We also conducted interviews with officials from:

- DHA, DOD's pharmacy benefits manager (PBM)—Express Scripts[12]—and DOD's managed care support contractors and their subcontractor,[13] which are collectively responsible for managing

[10]Medicare is the federal program that provides coverage of health services for people aged 65 and older and certain other individuals. The VA health care system provides health care benefits, including prescription drugs, to veterans and certain family members of veterans. VA provides drug benefits to family members of veterans under certain circumstances, such as through the Civilian Health and Medical Program of the Department of Veterans Affairs. We excluded VA family member programs from the scope of our review.

[11]We did not include Medicaid in this comparison as it is a federal-state program, with payment largely set by individual states.

[12]PBMs are responsible for developing and maintaining health plan formularies—lists of medications that health care providers are encouraged to prescribe—contracting with retail pharmacies, negotiating rebates with drug manufacturers and discounts with retail pharmacies, and processing and paying prescription drug claims. TRICARE's PBM, Express Scripts, provides beneficiaries with access to TRICARE's retail pharmacy network, operates the mail-order pharmacy for beneficiaries, and provides administrative services, such as claims processing and payment.

[13]DOD's managed care support contractors and their subcontractors are responsible for administering TRICARE's civilian medical benefit and perform other activities, including outpatient and inpatient claims processing and adjudication.

TRICARE's pharmacy and medical benefits and for processing pharmacy and medical claims from civilian pharmacy, outpatient, and inpatient providers;

- The Centers for Medicare & Medicaid Services (CMS), the HHS agency responsible for managing the Medicare program, and five of the largest Medicare Part C insurers—known as Medicare Advantage organizations—which also provide Medicare Part D (Part D) coverage, and two Part D-only plan sponsors;[14]
- The Veterans Health Administration, the agency responsible for managing pharmacy and medical benefits in the VA health care system;
- Two companies that publish national drug compendia for their perspectives on payments for compounded drugs;[15] and
- FDA, which is responsible for assuring the safety and effectiveness of drugs and approving them for marketing in the United States.

To select the Medicare Advantage organizations and Part D plan sponsors, we used publicly available CMS data on Medicare Advantage and Part D enrollment as of February 2014 to identify the 10 largest Medicare Advantage organizations that offer Part D plans and Part D-only plan sponsors, by number of enrollees. We interviewed officials from 5 of these Medicare Advantage organizations and 2 Part D-only plan sponsors. These 7 Medicare Advantage organizations and Part D-only plan sponsors accounted for about 48 percent of all Medicare Advantage and Part D enrollees.[16] We reviewed related documentation on how the

[14]Medicare Part C, Medicare's managed care benefit known as Medicare Advantage, and Part D, Medicare's prescription drug benefit, are administered by insurers that offer a variety of plans in which beneficiaries can choose to enroll. Medicare Advantage plans provide medical benefits and may also provide pharmacy benefits under Part D, while Part D plans provide pharmacy benefits only.

[15]These national drug compendia provide pharmaceutical information, including drug pricing data, to hospitals, physician practices, payers, retail pharmacies, state health programs and others for the purpose of medication decision support and negotiating reimbursement rates paid to pharmacies and other providers. The two companies are First Databank and Medi-Span.

[16]The five Medicare Advantage organizations are Aetna, Blue Cross Blue Shield of Michigan, Humana, Kaiser Permanente, and WellPoint. The two Part D sponsors are CVS Caremark and Express Scripts. CVS Caremark and Express Scripts also serve as PBMs for other Part D sponsors, and Express Scripts serves as TRICARE's PBM.

data were collected and determined that these data were sufficiently reliable for our purposes. However, the results of our analysis are not generalizable to all Medicare Advantage organizations or Part D plan sponsors.

We conducted this performance audit from January 2014 to October 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Drug Compounding

Compounded drugs may include sterile and nonsterile preparations, which, like all drug products, are made up of active and inactive ingredients.[17] The active ingredient or ingredients in a compounded drug may be one or more FDA-approved products, or may be bulk drug substances. Bulk drug substances—usually raw powders—are generally not approved by FDA for marketing in the United States. Examples of bulk drug substances that may be used to make compounded drugs include baclofen, a muscle relaxer, and gabapentin, an anticonvulsant, both of which may be compounded for use in topical pain medications.

[17]Compounded drugs include nonsterile preparations, such as capsules, ointments, creams, gels, and suppositories, which are typically dispensed in pharmacy settings. Sterile compounded preparations include intravenously administered fluids and injectable drugs, which are typically administered in both inpatient and outpatient settings. Compounded sterile drugs pose special risks of contamination if not made properly and require special safeguards to prevent injury or death to patients receiving them. Active ingredients include any drug component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. An inactive ingredient, or excipient, is any component of a drug product other than the active ingredient such as a dye or water for injection. See 21 C.F.R. § 210.3(b)(3), (7), (8) (2014).

Active ingredients used to make a compounded drug—including bulk drug substances—are generally assigned national drug codes (NDC).[18] FDA maintains a publicly available list of NDCs for FDA-approved products.[19] NDCs for FDA-approved products and bulk drug substances are published in three national drug compendia, by First Databank, Medi-Span, and Truven Health Analytics. In addition, these compendia include drug pricing data by NDC, such as the average wholesale price (AWP) of FDA-approved products and bulk drug substances.[20] A single FDA-approved product or bulk substance may be distributed by multiple manufacturers, in different forms or strengths, and by varying package sizes and, hence, may have multiple NDCs associated with it. The number of bulk drug substances that First Databank has added to its database—which First Databank tracks using NDCs—has increased significantly over the last 5 years, with the number of new NDCs added from 2009 through 2013 representing an increase of approximately 58 percent.[21] (See fig. 1 for the number of NDCs for bulk drug substances that have been added to First Databank's database from 2009 through 2013.)

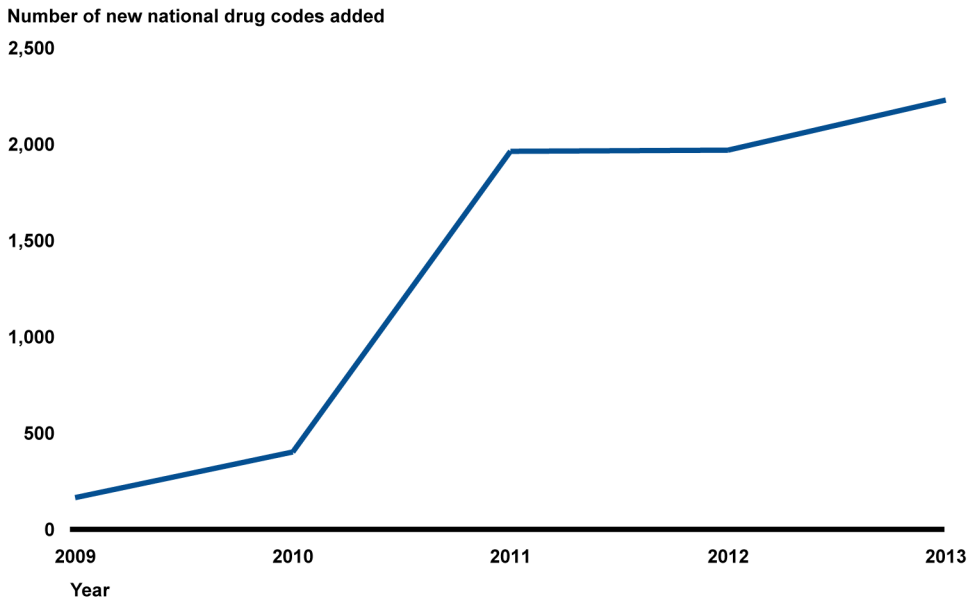
[18]NDCs are three-segment numbers that are the universal product identifiers for drugs for human use. FDA assigns the first segment of the NDC, which identifies the labeler (i.e., the firm that manufactures, repackages, or distributes a drug). The labeler assigns the second and third segments. The second segment identifies a specific strength, dosage form, and formulation (e.g., 20 mg capsules) and the third segment identifies package size and type (e.g., 100 capsules in a bottle).

[19]FDA's list of drugs approved for marketing within the United States is published annually in the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the Orange Book.

[20]Average wholesale price (AWP) is the average of the list prices that the manufacturer suggests wholesalers charge pharmacies. AWP is obtained and published by Medi-Span and Truven Health Analytics.

[21]According to First Databank officials, manufacturers submit requests to First Databank to add NDCs for bulk drug substances to its database.

Figure 1: Number of New National Drug Codes for Bulk Drug Substances Added to First Databank's Database, 2009 through 2013



Source: First Databank. | GAO-15-64

Note: According to First Databank officials, First Databank tracks the number of bulk drug substances—which are generally not approved by FDA for marketing—added to its database by national drug code (NDC). NDCs are three-segment numbers that are the universal product identifiers for drugs for human use. A single bulk drug substance may be distributed by multiple manufacturers, in different forms or strengths, and by varying package sizes and, hence, may have multiple NDCs associated with it. According to First Databank officials, manufacturers submit requests to First Databank to add NDCs for bulk drug substances to its database.

Under section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA), a compounded drug is exempt from certain FDCA requirements, including new drug approval and certain labeling and current good manufacturing practice requirements, provided the compounded drug meets certain criteria.[22] These criteria include that the drug is compounded by a pharmacist or physician based on a valid prescription for an identified individual patient or in limited quantities in anticipation of receiving a valid prescription based on historical prescribing patterns

[22]Drug sponsors submit new drug applications to FDA when they believe there is enough evidence about the drug's safety and effectiveness to meet FDA's requirements for marketing approval. If FDA approves the application, the product may be marketed in the United States.

(known as anticipatory compounding).[23] The Drug Quality and Security Act (DQSA) of 2013 amended certain FDCA provisions as they apply to the oversight of compounded drugs to clarify the applicability of section 503A nationwide and to create a category of outsourcing facilities involved in sterile drug compounding under section 503B. Outsourcing facilities that register with FDA and provide information to the agency about the products that are compounded at the facility can qualify for exemptions from the FDCA's new drug approval and certain labeling requirements.[24] Outsourcing facilities, however, must comply with current good manufacturing practice requirements. In addition, the DQSA requires FDA to develop lists of bulk drug substances that may be used for compounding and lists of drugs that present demonstrable difficulties to compound, among others. To develop these lists, FDA has issued requests for nominations of bulk drug substances that pharmacists and outsourcing facilities may use to make compounded drugs.[25] According to FDA, inclusion of a bulk drug substance on an FDA list does not indicate that FDA has approved the drug; rather, inclusion on the list means that a pharmacist or outsourcing facility may qualify for exemptions from certain

[23]21 USC § 353a, as amended by Pub. L. No. 113-54, § 106, 127 Stat. 587, 598 (Nov. 2013).

[24]An outsourcing facility is a facility at one geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility with the FDA, and complies with all of the requirements of section 503B of the FDCA. These requirements include that the facility must comply with current good manufacturing practice requirements and must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products it compounds. An outsourcing facility can qualify for exemptions from the FDA approval requirements and the requirement to label products with adequate directions for use but not for an exemption from the current good manufacturing practice requirements.

[25]FDA initially published in the Federal Register two separate requests for nominations for inclusion on these lists in December 2013—one list to be used by individual physicians and pharmacists to compound in accordance with section 503A of the FDCA, and one list to be used by outsourcing facilities to compound in accordance with section 503B of the FDCA. To obtain more information concerning the substances nominated, the agency issued revised requests for nominations in July 2014. 79 Fed. Reg. 37747 (July 2, 2014) and 79 Fed. Reg. 37750 (July 2, 2014). The notices request interested parties submitting nominations to provide certain information about the bulk drug substances and the drug products that will be compounded with the bulk drug substance, such as the drug's historical use and information published in reports in peer-reviewed medical literature. The public was provided 90 days to nominate bulk drug substances in response to these notices.

requirements of the FDCA if they compound using bulk drug substances included on the lists.[26]

Several organizations develop standards and guidelines for compounded drugs and pharmacy transactions, adherence to which may be required by law. The U.S. Pharmacopeial Convention (USP) publishes professional standards and guidelines for preparing compounded drugs.[27] According to the National Association of Boards of Pharmacy, 28 states had laws requiring full adherence to USP standards for preparing sterile compounds, as of 2013.[28] In addition, to qualify for the exemption under section 503A of the FDCA, a drug product must be compounded in compliance with these standards. The National Council for Prescription Drug Programs (NCPDP) develops standards for electronic pharmacy prescribing and billing transactions. These standards include version D.0, which allows pharmacies to submit, and insurance plans to see, the NDC for and quantity of each ingredient used to make a compounded drug on the pharmacy claim, as well as the pharmacy-submitted price per ingredient. In 2009, HHS issued a regulation requiring entities subject to the Health Insurance Portability and Accountability Act, including pharmacies and health insurers, to use version D.0 for electronic

[26]To qualify for the FDCA exemptions provided under section 503A of the act, a pharmacist or physician also may compound using bulk drug substances that comply with the standards of an applicable monograph or that are components of FDA-approved drugs. 21 U.S.C. § 353a(b)(1)(A).

[27]USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements. USP's current suite of General Chapters for compounding includes, among others, Chapter 797 Pharmaceutical Compounding—Sterile Preparations, which provides procedures and requirements for compounding sterile preparations; and Chapter 795 Pharmaceutical Compounding—Nonsterile Preparations, which provides guidance on applying good compounding practices in the preparation of nonsterile compounded formulations for dispensing or administration to humans or animals.

[28]The National Association of Boards of Pharmacy is a professional association that assists its member state boards of pharmacy and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

pharmacy transactions.[29] These entities were required to be fully compliant with version D.0 by January 1, 2012.[30]

Drug Benefits under Federal Health Care Programs

TRICARE

TRICARE offers pharmacy and medical benefits to active duty personnel and their dependents, military retirees and their dependents and survivors, as well as reservists and members of the National Guard and their dependents. TRICARE beneficiaries may obtain drugs through network and non-network retail pharmacies, MTF pharmacies, and TRICARE's mail-order pharmacy through the TRICARE pharmacy benefit. In addition, through TRICARE's medical benefit, TRICARE beneficiaries may obtain drugs in outpatient or inpatient settings, such as civilian physicians' offices and hospitals and MTFs.[31]

Medicare

Medicare Part A, Medicare's inpatient medical benefit, provides benefits for drugs administered in inpatient settings, such as hospitals. Medicare Part B, Medicare's outpatient medical benefit, provides limited benefits for drugs administered to patients in outpatient settings, such as physician offices.[32] Medicare uses contractors to process and pay Part A and Part B claims.[33] Medicare Part C—Medicare's managed care benefit, also known

[29]74 Fed. Reg. 3296, 3302 (Jan. 16, 2009) (codified at 45 C.F.R. Part 162).

[30]Prior to the implementation of the updated standard, providers typically submitted claims for compounded drugs based on the primary—and, typically, the most expensive—ingredient.

[31]DOD is required by law to make all clinically appropriate prescription drugs available to TRICARE beneficiaries and, with the exception of several classes of drugs, DOD covers all FDA-approved drugs.

[32]Medicare Part B also provides benefits for certain vaccines, such as influenza; drugs administered in hospital outpatient settings, such as part of emergency department services; and drugs administered using durable medical equipment. For the purposes of this report, when we discuss outpatient settings we are referring to drugs administered in physician offices incident to physician services.

[33]CMS established the Medicare contractors as multistate, regional contractors responsible for administering both Medicare Part A and Medicare Part B claims. For more information on Medicare contractors, see GAO, *Medicare: Contractors and Private Plans Play a Major Role in Administering Benefits*, GAO-14-417T (Washington, D.C.: Mar. 4, 2014).

as Medicare Advantage—offers beneficiaries plans that provide inpatient and outpatient drug benefits (Part A and Part B, respectively) through a network of managed care organizations. In addition, some Medicare Advantage organizations offer plans with pharmacy benefits similar to those provided under Part D. Part D provides a voluntary pharmacy benefit for Medicare beneficiaries. Beneficiaries may choose Part D plans from among those offered by private Part D plan sponsors. Part D beneficiaries may obtain drugs through retail and mail-order pharmacies.

VA Health Care System

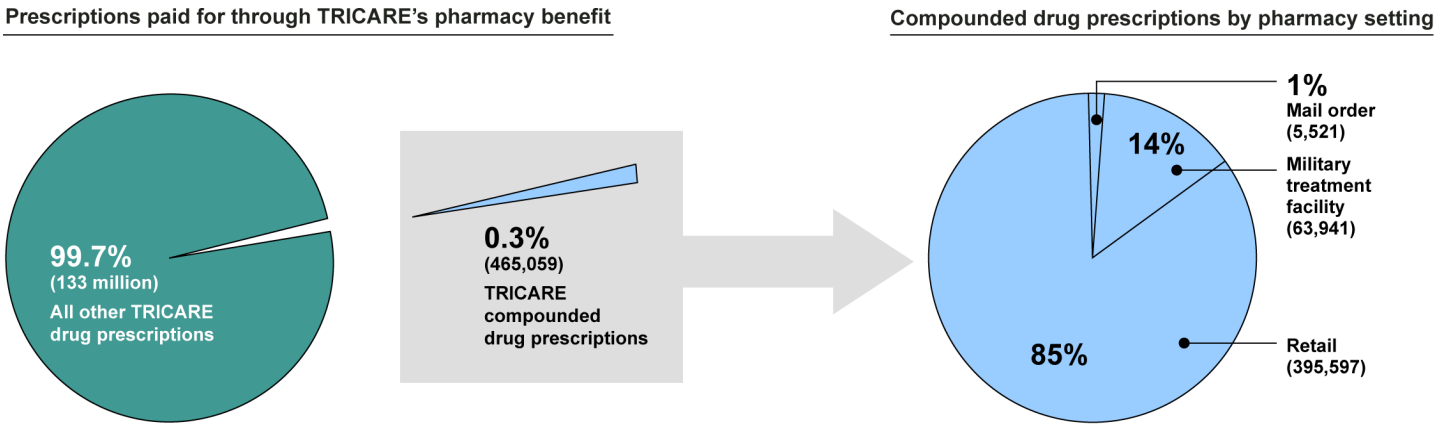
Through VA's pharmacy benefit, veterans may obtain prescription drugs through VA medical center (VAMC) pharmacies and VA's mail-order pharmacy. In certain cases, they may also obtain drugs from retail pharmacies. In addition, through VA's medical benefit, veterans may obtain drugs administered to patients in VAMCs and associated outpatient clinics. In certain cases, they may also obtain drugs from non-VA outpatient and inpatient providers in the non-VA care program, which provides payment for veterans' health care services in non-VA facilities in certain circumstances, such as in emergencies or if a VAMC is unable to provide health care services to the veteran.

TRICARE Paid for 465,000 Compounded Drug Prescriptions through Its Pharmacy Benefit in Fiscal Year 2013 Costing $259 Million, but Could Not Identify Such Prescriptions Paid for through Its Medical Benefit

TRICARE Paid for 465,000 Prescriptions for Compounded Drugs through its Pharmacy Benefit in Fiscal Year 2013, and They Were Mostly Dispensed in Retail Pharmacies and to Retirees and Dependents

In fiscal year 2013, TRICARE paid for about 465,000 compounded drug prescriptions through its pharmacy benefit, representing 0.3 percent of all prescription drugs paid for through its pharmacy benefit in that year. Over 395,000, or 85 percent, of these compounded drug prescriptions were dispensed in retail pharmacies. (See fig. 2.)

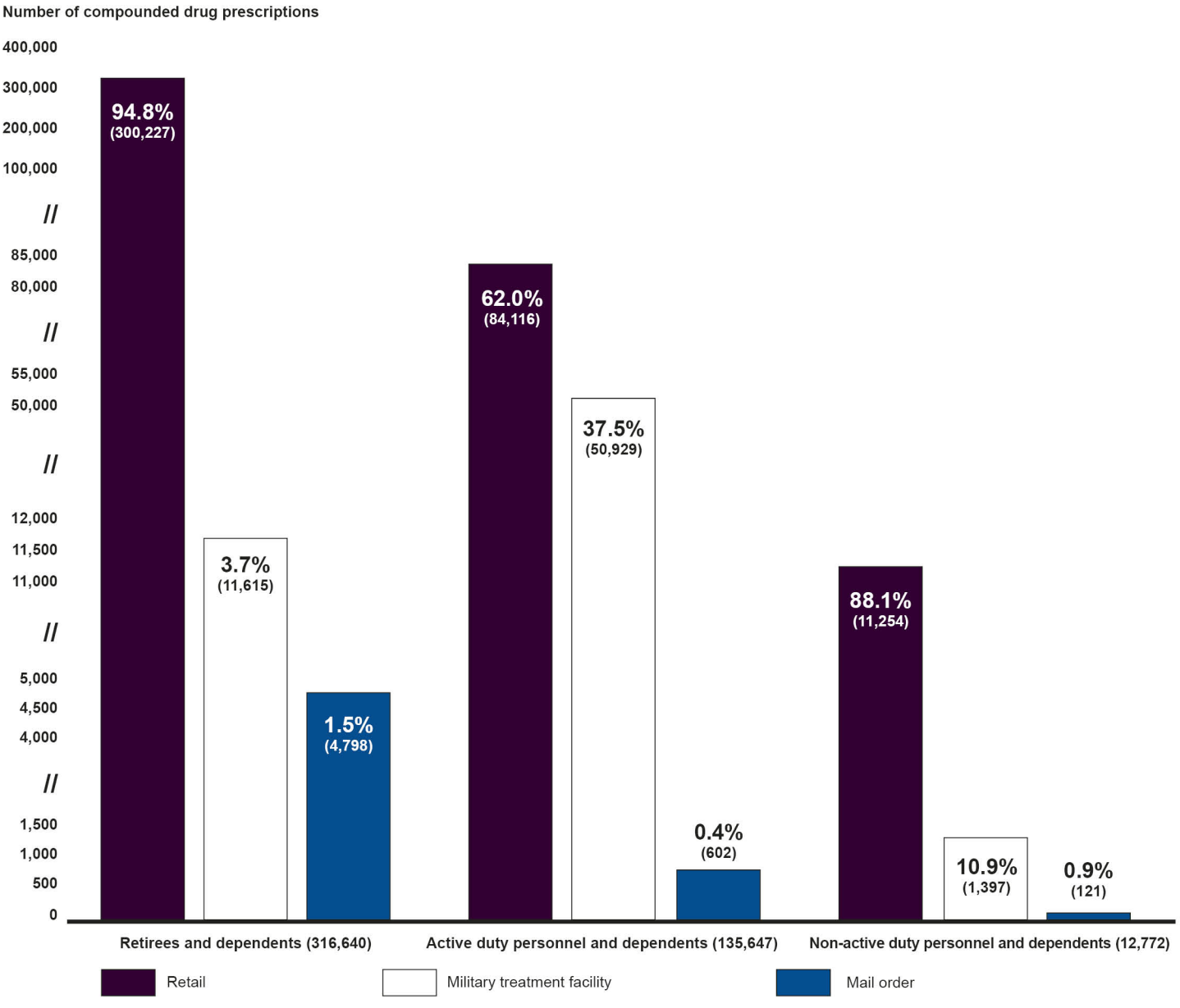
Figure 2: Total Prescriptions, Including Compounded Drug Prescriptions, Paid for through TRICARE's Pharmacy Benefit by Pharmacy Setting, Fiscal Year 2013



Source: GAO analysis of DOD data. | GAO-15-64

Retirees and their dependents were the most frequent users of compounded drugs, accounting for 68 percent, or about 317,000, of the compounded drug prescriptions paid for through the pharmacy benefit. These beneficiaries obtained about 95 percent of their compounded drug prescriptions from retail pharmacies. (See fig. 3.) Among retirees and their dependents, those beneficiaries under age 65 accounted for about 61 percent of compounded drug prescriptions. DHA officials attributed the higher use of compounded drugs by retirees and their dependents, among other reasons, to these individuals' tendencies to obtain care from civilian providers, whose prescribing practices DOD does not control.

Figure 3: Compounded Drug Prescriptions Paid for through TRICARE's Pharmacy Benefit by Beneficiary Category and Pharmacy Setting, Fiscal Year 2013



Source: GAO analysis of DOD data. | GAO-15-64

Note: Percentages may not total 100 due to rounding.

Compounded Drug Prescriptions Paid for through TRICARE's Pharmacy Benefit Cost $259 Million in Fiscal Year 2013, and Most Contained Bulk Drug Substances

Compounded drug prescriptions paid for through TRICARE's pharmacy benefit cost about $259 million in fiscal year 2013—representing about 3 percent of the total cost of prescription drugs paid for through its pharmacy benefit—up from about $5 million in fiscal year 2004.[34] Compounded drug prescriptions containing at least 1 bulk drug substance accounted for about 98 percent of the $259 million cost.[35] The average cost of a compounded drug that included at least 1 bulk drug substance was $557 per prescription compared to an average cost of $53 per prescription for a compounded drug that contained only FDA-approved products.[36] More specifically, DOD data on the top 25 highest-cost compounded drugs containing at least 1 bulk drug substance showed an average cost ranging from about $848 to $9,961 per prescription.[37] Each of these top 25 compounded drugs contained at least 1, and as many as 11, bulk drug substances. Baclofen, cyclobenzaprine hydrochloride, flurbiprofen, gabapentin, ketamine hydrochloride, and lidocaine hydrochloride powders were among the most common bulk substance included in these compounded drugs.[38] All 25 of these compounded drugs were topical medications (e.g., creams or gels), most of which were used to treat pain. See app. II for a list of the top 25 highest-cost compounded drugs containing at least one bulk drug substance dispensed in retail pharmacies in fiscal year 2013.

[34]In comparison, overall costs for drugs dispensed directly to TRICARE beneficiaries in pharmacies increased from about $5.01 billion in fiscal year 2004 to $9.74 billion in fiscal year 2013. These costs represent the cost to DOD and to TRICARE beneficiaries, including beneficiary copayments, and do not take into account any payments from beneficiaries' other health insurance or post-purchase refunds that manufacturers pay DOD for certain drugs. The total cost of a compounded drug prescription dispensed in a pharmacy setting consists of the cost of the individual drug ingredients, a dispensing fee, and an additional fee for the pharmacist's effort to compound the drug.

[35]In fiscal year 2013, about 343,000 of the 465,000 compounded drug prescriptions paid for by TRICARE through its pharmacy benefit contained at least one bulk drug substance.

[36]The average cost of all prescription drugs paid for through TRICARE's pharmacy benefit was $61 per prescription.

[37]We obtained and reviewed DOD data on the top 25 highest-cost compounded drugs, based on total cost, containing at least one bulk substance dispensed to TRICARE beneficiaries in retail pharmacies in fiscal year 2013. These 25 highest-cost compounded drugs represented about $44 million, or 17 percent, of the $259 million total cost of compounded drugs paid for through TRICARE's pharmacy benefit in fiscal year 2013.

[38]Cyclobenzaprine hydrochloride is a muscle relaxant, flurbiprofen is an anti-inflammatory drug, and ketamine and lidocaine are anesthetics.

DHA officials attributed the high cost of compounded drug prescriptions containing bulk drug substances to several factors, including the number of these substances used in each prescription, the aggressive marketing of compounded drugs containing these substances to providers, and the high AWP of these substances—which, according to DHA and Express Scripts officials, have been inflated by manufacturers of these substances. For example, according to Express Scripts, the AWP of bulk gabapentin increased by as much as 4,948 percent from 2011 to 2014, while the AWPs of bulk ketamine and bulk baclofen increased by as much as 1,313 percent and 1,102 percent, respectively, over the same period.

TRICARE Could Not Identify Compounded Drug Prescriptions Paid for through Its Medical Benefit

TRICARE could not identify compounded drug prescriptions paid for through its medical benefit because claims for drugs administered in outpatient and inpatient settings often lack specific billing codes for these drugs.[39] For drugs administered in civilian outpatient settings, TRICARE relies on specific codes for individual drugs in the Healthcare Common Procedure Coding System (HCPCS)—a standardized coding system that is used by public programs and private health insurance plans to help ensure medical claims are processed in a consistent manner—to indicate whether a beneficiary received a prescription drug, including a compounded drug, on outpatient claims. However, for the majority of compounded drugs administered in outpatient settings, no HCPCS codes exist.[40] Providers typically bill for compounded drugs using HCPCS codes for "not otherwise classified" drugs; these HCPCS codes are also used to bill for noncompounded drugs that lack specific HCPCS codes and, therefore, do not designate only compounded drugs or their ingredients. TRICARE's managed care support contractors and their subcontractor—who are responsible for processing outpatient and inpatient claims—told us that they expect providers to list all of the NDCs for each drug ingredient or provide information about the ingredients used in the drug administered to the beneficiary. However, according to DHA officials and a TRICARE managed care contractor and subcontractor, multiple NDCs

[39]Because TRICARE directly purchases drugs used in MTFs, DHA is able to determine whether a compounded drug prescription was provided to a beneficiary at an MTF. However, DHA officials told us that TRICARE is unable to determine whether the drug was administered by an MTF provider or dispensed directly to the beneficiary through an MTF pharmacy.

[40]Specific HCPCS codes exist for some compounded drugs used with durable medical equipment, such as nebulizers used to administer inhalational drugs.

on a claim could indicate more than one noncompounded drug administered to a beneficiary and would not necessarily indicate individual ingredients used to make a compounded drug.[41] Therefore, DHA officials told us that they would be unable to identify whether a compounded drug was administered to a beneficiary based on individual NDCs or track this information in any way.

Similarly, compounded drugs administered in inpatient settings, such as hospitals, cannot be identified through DOD's available data because prescription drugs are not billed separately from the rest of the services that a TRICARE beneficiary receives; rather, they are bundled together as part of the overall charge for the hospital stay or inpatient admission.[42] As a result, DHA officials told us that they cannot determine whether a beneficiary received a compounded drug in an inpatient setting, and thus, cannot determine the total number and cost of compounded drugs TRICARE paid for in this setting.

[41]There is a HCPCS code for pharmacy compounding and dispensing services but, according to TRICARE officials and contractors and subcontractor responsible for processing TRICARE claims for outpatient and inpatient services rendered at civilian health care facilities, this HCPCS code is primarily used for compounded drugs for infusion therapy and would not apply to other compounded drugs administered to patients. Infusion therapy is the administration of medication through a needle or catheter, such as intravenously.

[42]Costs for drugs provided in inpatient settings are typically accounted for in the diagnosis-related group–a system that classifies inpatient stays according to both patients' clinical conditions (the primary diagnosis along with any secondary illnesses and complications developed during the stay) and the procedures patients receive.

TRICARE's Payment Practices for Compounded Drugs Provided through Its Pharmacy and Medical Benefit Are Inconsistent with Regulations and Generally More Generous than Those of Medicare and VA

TRICARE's Payment Practices for Compounded Drugs Provided through Its Pharmacy Benefit Are Inconsistent with Regulations and More Generous than Those of Medicare and VA

TRICARE pays for all ingredients that make up a compounded drug—both FDA-approved products and bulk drug substances—inconsistent with its regulations, which stipulate that TRICARE is to pay for FDA-approved drugs only.[43] In fiscal year 2013, 74 percent of the compounded drug prescriptions paid for by TRICARE through its pharmacy benefit contained at least one bulk drug substance.[44] DHA officials told us that, neither TRICARE nor Express Scripts was able to determine whether TRICARE was paying for bulk drug substances in compounded drug prescriptions dispensed at retail pharmacies prior to Express Scripts' July 2012 implementation of the updated NCPDP standard for electronic transmission of prescription drug claims that enables pharmacies to identify compounded drug prescriptions and ingredients used to make

[43]32 C.F.R. §§ 199.2, 199.4(g)(15) (2013).

[44]Over 97 percent of the compounded drug prescriptions containing at least one bulk drug substance were dispensed at retail pharmacies. About 1 percent of these drug prescriptions was dispensed at TRICARE's mail-order pharmacy and about 1 percent was dispensed at MTF pharmacies. While MTF pharmacies dispense compounded drugs, including some that contain bulk drug substances, MTF providers are instructed to use drugs on TRICARE's formulary to the greatest extent consistent with the clinical needs of their patients.

them by NDC.[45] However, we found that, prior to implementation of the updated standard, TRICARE was able to identify bulk drug substances that comprised the primary ingredient—defined as the most expensive ingredient in a compounded drug prescription—based on claims information and was paying for these bulk drug substances. DHA officials told us that they were unaware that TRICARE was paying for compounded drug prescriptions for which the primary ingredient was a bulk drug substance until Express Scripts brought it to their attention after the implementation of the updated standard. In addition, according to DHA officials, since July 2012, TRICARE has continued to pay for compounded drug prescriptions containing bulk drug substances, including ones for which the primary ingredient is a bulk drug substance. As a result, TRICARE incurred additional costs reimbursing pharmacies for these compounded drug prescriptions.

DHA officials told us that they are considering denying payment for certain compounded drug prescriptions that include bulk drug substances, and are waiting to review the lists of bulk drug substances that may be used to make compounded drugs—and the lists of drugs that may not be compounded because they present demonstrable difficulties for compounding—that FDA is required to develop under the DQSA. However, DHA officials were not able to tell us when they planned to make any policy decisions because they are unsure of FDA's time frames for compiling and publishing these lists; in the meantime, TRICARE plans to continue paying for compounded drug prescriptions that include bulk drug substances. FDA officials told us that they do not expect to publish these lists until 2015. These officials also told us that the inclusion of a bulk drug substance on a list of substances that may be used for compounding does not signify that the bulk drug substance is FDA-approved.

In contrast to TRICARE, Part D's payment practices for compounded drugs are more restrictive. As required by statute, under Part D, federal payments are not available for non-FDA-approved products—including bulk drug substances—and inactive ingredients used to make a

[45]Express Scripts relies on First Databank to identify bulk drug substances. According to First Databank officials, First Databank determines whether a drug ingredient is a bulk drug substance based on self-reported data from manufacturers and information from FDA.

compounded drug.[46] For example, Part D would not pay for bulk ketamine or flurbiprofen used to make a compounded topical pain medication, whereas TRICARE currently does. Medicare Advantage organizations that offer Part D benefits and Part D plan sponsors may choose to pay for bulk substances but may not submit these payments as part of the Part D transaction data CMS uses to determine federal payments to Part D plans.[47] Officials from two Medicare Advantage organizations that include Part D drug benefits and one Part D-only sponsor we spoke with told us that they generally pay pharmacies for each ingredient in the compounded drug that is an FDA-approved product and is otherwise eligible for payment under Part D and, thus, do not pay for bulk drug substances.[48] Officials from the remaining two Medicare Advantage organizations and one Part D-only sponsor we spoke with told us that they pay pharmacies for bulk drug substances but do not include these payments as part of the Part D transaction data they submit to CMS. Officials from the remaining three Medicare Advantage organizations and one Part D plan sponsor—including one organization that purchases drug ingredients, including some bulk drug substances used to make compounded drugs, for its pharmacies, which it owns and operates—told us that they pay pharmacies for bulk drug substances, but do not include

[46]In general, federal Part D drug payments exclude drugs not approved by the FDA, drugs not available by prescription for purchase in the United States, and drugs for which payment would be available under Parts A or B of Medicare. 42 U.S.C. § 1395w-102(e).

[47]CMS's final rule for the Part D contract year 2012 notes that, while Part D sponsors may pay for non-Part D ingredients without reporting these costs to CMS, Part D sponsors are prohibited from billing beneficiaries for the uncovered ingredients. 76 Fed. Reg. 21432, 21523 (Apr. 15, 2011).

[48]Officials from one of the two Medicare Advantage organizations that do not pay for bulk drug substances told us that the organization will process claims and pay only for any ingredients in the compounded drug that are FDA-approved, provided that the FDA-approved ingredient is the primary ingredient; otherwise, this organization will reject claims with a bulk drug substance that is the primary ingredient. Officials from the other Medicare Advantage organization told us that the organization will pay for bulk drug substances in compounded drugs in rare circumstances and only after it has deemed a prescription to be medically necessary. This Medicare Advantage organization and the Part D sponsor will process claims with a bulk drug substance that is the primary ingredient but pay only for the ingredients that are FDA-approved products.

these payments as part of the Part D transaction data they submit to CMS.[49]

VA provides and pays for compounded drug prescriptions dispensed to beneficiaries on a limited basis and, therefore, VA's payment practices for these drugs are more restrictive than TRICARE's. VAMC pharmacies dispense a compounded drug prescription only if the beneficiary has a specific medical need that cannot be met by a commercially available drug and an alternative drug from the VA formulary has been given full consideration. According to VA officials, VA may pay for compounded drug prescriptions dispensed to beneficiaries at retail pharmacies through the non-VA care program, but those payments are limited and require VA review and approval.[50]

Once the decision by TRICARE, Medicare, or VA to pay for compounded drugs is made, payment calculations for determining reimbursement amounts vary across the three programs but are generally based on common drug pricing benchmarks.

- TRICARE reimburses pharmacies for each ingredient submitted as part of the claim at AWP minus a negotiated discount for compounded drug prescriptions dispensed at retail pharmacies. In addition, according to DHA officials, TRICARE also pays pharmacies an additional fee for the pharmacist's efforts to make the drug, known as a level-of-effort fee.[51] MTF pharmacies and TRICARE's mail-order

[49]In July 2014, the Part D-only plan sponsor that currently pays for bulk drug substances used to make compounded drugs announced its plans to discontinue payment for most of these substances by March 2015 as a result of an internal analysis that showed that pharmacies had been increasing their billed amounts for non-Part D ingredients, including bulk drug substances.

[50]VA officials told us that in the non-VA care program, VA typically only pays for a 10-day supply of drugs obtained at retail pharmacies that are on the VA national formulary and that are urgently needed. If a beneficiary needs a drug that is not on the formulary, including a compounded drug, a non-VA provider may request payment from VA, which will review and approve requests on a case-by-case basis.

[51]TRICARE's level-of-effort professional services fee, as determined by Express Scripts, is a four-tiered fee based on the complexity and risk level of the compounding process. For example, Express Script pays a smaller fee per prescription for compounded drugs that comprise two or more commercially available drugs mixed into a cream or ointment, and pays a larger fee per prescription for compounded drugs that comprise sterile or nonsterile FDA-approved products or bulk drug substances mixed together to make a sterile compound.

pharmacy purchase drugs, including ingredients used to make compounded drugs, directly from manufacturers and, therefore, do not reimburse providers for the use of these drugs.[52]

- Under Part D, officials from four of the five Medicare Advantage organizations and both Part D plan sponsors we interviewed told us that they reimburse pharmacy providers for compounded drugs based on a negotiated price for each covered ingredient based on common drug pricing benchmarks including AWP, wholesale acquisition cost, or maximum allowable cost.[53] In addition, two of the Medicare Advantage and both Part D plan sponsors pay an additional level-of-effort fee or a higher dispensing fee based on the complexity of the compounding or the number of ingredients in the drug.[54]
- According to VA officials, VAMCs typically purchase drug ingredients used to make compounded drugs. Drug ingredient purchases are usually made under contract with a prime vendor that provides the drug ingredients at a fixed percentage discount off the lowest price otherwise available for each ingredient. For drugs that beneficiaries obtain from non-VAMC pharmacies, VA will either reimburse the beneficiary for any out-of-pocket costs or reimburse the pharmacy at AWP.

[52]DOD purchases a small number of bulk drug substances for MTF pharmacies for the purposes of compounding drugs. We did not evaluate MTFs' and TRICARE's mail-order pharmacy's drug purchasing practices.

[53]Wholesale acquisition cost is the manufacturer's list price for wholesalers before rebates and discounts and is published on a weekly basis. The maximum allowable cost is the maximum allowable payment established by each organization or Part D plan sponsor.

[54]Officials from the Medicare Advantage organization that owns and operates its health care facilities and purchases drugs and drug ingredients for these facilities pays the price set by the manufacturer.

TRICARE's Payment Practices for Compounded Drugs Provided through Its Medical Benefit May Be Inconsistent with Regulations and Are Similar to Medicare's but More Generous than VA's

Through its medical benefit, TRICARE generally pays for compounded drugs administered in outpatient and inpatient settings, and it may have paid for bulk drug substances used to make these drugs in a manner that is inconsistent with its regulations stipulating payment for FDA-approved drugs only.[55] TRICARE reimburses civilian outpatient providers based on the HCPCS codes for "not otherwise classified" drugs and the specific NDC for each drug ingredient. While officials from TRICARE's managed care support contractors and their subcontractor told us that they require providers to either list all of the NDCs for each drug ingredient or provide information about which ingredients were used in the drug provided to the beneficiary, they do not use the NDCs to determine whether each drug ingredient listed on a claim is an FDA-approved product.[56] As a result, TRICARE may have incurred additional costs if it reimbursed providers for bulk drug substances used to make compounded drugs administered in civilian outpatient settings, which is inconsistent with TRICARE regulations. TRICARE contractor and subcontractor officials told us that prescription drugs, including compounded drugs, administered in civilian inpatient settings are not billed separately from the rest of the services the beneficiary received but bundled together as part of the overall charge for the hospital stay or inpatient admission. Therefore, TRICARE cannot identify compounded drugs or their ingredients and instead reimburses civilian inpatient providers based on codes for these bundled services.

Medicare generally pays for compounded drugs administered in outpatient and inpatient settings in a manner similar to TRICARE. Like TRICARE, CMS and Medicare Advantage organizations generally rely on HCPCS codes, and for compounded drugs administered in outpatient settings, providers typically bill CMS and Medicare Advantage organizations using nonspecific HCPCS codes for "not otherwise classified" drugs. CMS contractors responsible for processing Part B claims and Medicare Advantage organizations may conduct further reviews of outpatient claims and supplemental information to determine whether the drug billed under a nonspecific HCPCS code is a compounded drug and to identify its ingredients in order to make payment

[55]According to DHA officials, MTF providers may compound drugs at their discretion as needed for individual patients.

[56]According to contractor officials, instead of listing the NDC for each drug ingredient, providers may instead provide a written description of the drug ingredients administered. In these cases, TRICARE managed care support contractors use these descriptions to look up NDCs for the purposes of calculating payment.

decisions. In Medicare Part B, Medicare contractors evaluate each claim containing the nonspecific HCPCS codes manually to make payment decisions, based on the responsible contractor's policy. Officials from two of the five Medicare Advantage organizations we spoke with told us that they review all claims with compounded drugs billed under the nonspecific code and request additional information. Officials from one of these two organizations told us that the organization requires providers to submit NDCs for each ingredient to determine which ingredients are FDA-approved products and does not pay for bulk drug substances, unless the organization determines that they are medically necessary. Officials from the second organization told us that the organization requires providers to submit supporting documentation, including invoices that list the name and amount of each ingredient in the compounded drug. A third organization reviews claims and requests additional documentation only when the amount for a drug billed under the nonspecific HCPCS code on a claim exceeds a certain dollar amount, but does not require NDCs to determine which ingredients are FDA-approved products. For these claims, the organization uses NDCs primarily to calculate payments, likely for all ingredients in the compounded drug.[57] The fourth organization does not review claims with the nonspecific HCPCS code or collect additional information and pays for all ingredients in the compounded drug. Officials from the fifth organization told us that, because the organization owns and operates its health care facilities and purchases drugs and drug ingredients—including some non-FDA-approved bulk drug substances used to make compounded drugs—the organization is able to determine whether a compounded drug was administered to a beneficiary in outpatient settings. As is the case for TRICARE, under Medicare Part A, both CMS and four of the five Medicare Advantage organizations we interviewed told us that compounded drugs administered in inpatient settings are bundled together as part of the overall charge for the hospital stay or inpatient admission.[58]

VA provides and pays for compounded drugs administered in outpatient and inpatient settings on a limited basis and, therefore, VA's payment

[57]For claims below the specified dollar amount, this organization also likely pays for all ingredients in the compounded drug.

[58]Officials from the remaining Medicare Advantage organization told us that, because the organization purchases drugs and drug ingredients for its health care facilities directly from manufacturers, they are able to determine whether a compounded drug was administered to a beneficiary as part of the inpatient service.

practices for these drugs are more restrictive than TRICARE's. VA instructs VAMCs to determine the suitability of FDA-approved drugs for inpatient and outpatient use prior to compounding drugs onsite or purchasing them from a pharmacy for VAMC use. For VA beneficiaries seeking care from non-VA providers, VA requires beneficiaries to obtain prior authorization from VA, except in emergencies. Because of VA's process for approving care outside of VA medical centers, VA officials told us that the agency makes decisions on whether to pay for a given procedure or service, including a compounded drug, on a case-by-case basis.[59]

Once the decision by TRICARE, Medicare, or VA to pay for compounded drugs is made, payment calculations for determining reimbursement amounts vary for compounded drugs administered in outpatient settings and inpatient settings across the three programs.

- TRICARE reimburses providers for compounded drugs at either the lesser of the billed charges or 95 percent of AWP for each ingredient as determined by ingredients' NDCs for compounded drugs administered in civilian outpatient settings. MTFs purchase drugs and drug ingredients directly from manufacturers and, therefore, do not reimburse providers for the use of these drugs. Officials from TRICARE contractors and their subcontractors told us that, for compounded drugs administered in civilian inpatient settings, TRICARE pays a preset rate for the cost to deliver inpatient services, including any drugs administered as part of the service. The use of a compounded drug—including one that contains bulk drug substances—would not generally change the inpatient payment rate for a given service.
- CMS generally reimburses Medicare providers for compounded drugs administered in outpatient settings based on the invoice price from the pharmacy, which the contractors responsible for processing Part B payments obtain during manual reviews of claims with the nonspecific

[59]Usually, a VAMC provider refers a veteran to a non-VA provider—for example, when the VAMC cannot provide the services needed by the veteran. The veteran is then evaluated by the non-VA provider, who submits a treatment plan to VA. A VA clinician is to review this treatment plan and approve it prior to services being rendered.

HCPCS codes.[60] Four of the five Medicare Advantage organizations we interviewed calculate payments based on either the provider-submitted price for the drug, which may include payment for non-FDA-approved bulk drug substances, or common drug pricing benchmarks, such as wholesale acquisition cost. The fifth Medicare Advantage organization owns and operates its healthcare facilities and pays the price set by the manufacturer for drugs and drug ingredients. For drugs administered in inpatient settings, CMS and these organizations pay a preset rate for the cost to deliver inpatient services, including any drugs administered as part of the service, and the payment rate would not change if the claim included a compounded drug.

- According to VA officials, for drugs administered in both outpatient and inpatient settings, VAMCs purchase ingredients directly from a prime vendor or purchase compounded drugs from pharmacies. According to VA officials, each VAMC should develop its own policy for reimbursing non-VA providers for compounded drugs administered to beneficiaries in outpatient settings. For compounded drugs administered in inpatient settings, VA pays a preset rate for the cost to deliver inpatient services, including any drugs administered as part of the service

Conclusions

Although compounded drugs account for only a small percentage of the drugs dispensed to TRICARE beneficiaries in pharmacy settings, their costs have increased significantly over the past ten years, from $5 million in fiscal year 2004 to $259 million in fiscal year 2013, which is notably higher than TRICARE's overall increase in drug costs. The majority of these costs were for compounded drugs containing bulk drug substances, the payment for which is inconsistent with TRICARE regulations that authorize payment for FDA-approved drugs only. As a result, TRICARE incurred additional costs reimbursing pharmacies for these drugs. Moreover, because TRICARE does not track compounded drugs administered in outpatient settings and its contractors do not determine whether each drug ingredient listed on a claim is FDA-approved, TRICARE may have also paid for compounded drugs containing bulk drug substances in outpatient settings in a manner that is inconsistent

[60]For more information on how Medicare contractors process and pay compounded drug claims, see Department of Health and Human Services, Office of the Inspector General, *Compounded Drugs under Medicare Part B: Payment and Oversight,* OEI-03-13-00270 (Washington, D.C.: April 2014).

with its regulations, which may have also resulted in TRICARE incurring additional costs.

Recommendation for Executive Action

To help ensure TRICARE's payment practices for compounded drugs are consistent with its regulations, we recommend that the Secretary of Defense align TRICARE's payment practices for compounded drugs with applicable regulations governing the TRICARE program. This may include considering whether to amend TRICARE's regulations to explicitly allow payment for some or all bulk drug substances in compounded drugs.

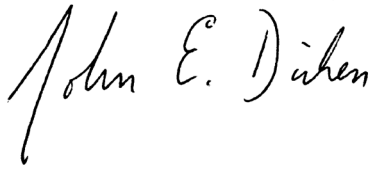
Agency Comments and Our Evaluation

We provided a draft of this report to DOD, HHS, and VA for review, and DOD and VA provided written comments, which are reprinted in appendixes III and IV, respectively. In its comments, DOD concurred with our recommendation that DOD align its payment practices for compounded drug prescriptions with applicable regulations governing the TRICARE program. DOD stated that it will monitor developments related to the changing statutory and regulatory environment on compounded drugs in order to inform its policy in the months ahead. Specifically, DOD stated that the DQSA, HHS's efforts to implement this act, and a provision in the Carl Levin National Defense Authorization Act for Fiscal Year 2015 to allow DOD to provide provisional coverage or authorization for coverage of certain health care products and services that have not been demonstrated to be safe or effective,[61] would help shape DOD's approach to payment practices for compounded drugs.

In its written comments, VA generally agreed with our conclusions. VA and HHS provided technical comments, which we incorporated as appropriate.

[61]S. 2410, 113th Cong. § 705 (2014) (as reported by the Senate Armed Services Committee on June 2, 2014).

We are sending copies of this report to appropriate congressional committees and the Secretaries of Defense, Health and Human Services, and Veterans Affairs. The report is also available at no charge on the GAO website at http://www.gao.gov. If you or your staff have any questions about this report, please contact me at (202) 512-7114 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs are on the last page of this report. GAO staff who made major contributions to this report are listed in appendix V.



John E. Dicken
Director, Health Care

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Appendix I: Pharmacy Accreditation Standards to Help Ensure the Safety of Compounded Drugs Provided by TRICARE

The Department of Defense (DOD) relies on accrediting organizations and its pharmacy benefit manager (PBM) to help ensure the safety of compounded drugs provided to TRICARE beneficiaries through military treatment facilities (MTF), TRICARE's mail-order pharmacy, and its network of retail pharmacies.

The Joint Commission, a not-for-profit organization, which accredits and certifies more than 20,000 health care organizations and programs in the United States, accredits MTFs, including MTF pharmacies, operated by the Army, Navy, and Air Force.[1] The Joint Commission establishes pharmacy standards that address all drugs—including those that are compounded—and assesses compliance with these standards during the accreditation process. The Joint Commission has standards related to an organization's critical medication management processes—those undertaken by the hospital or organization and those provided through contracted pharmacy services—that include planning, selection, storage, ordering, preparing and dispensing, administration, monitoring and evaluation. Furthermore, The Joint Commission's standards evaluate specific aspects of compounding such as verifying the credentials and assessing the competency of the staff, adherence to proper labeling of medication, manufacturer recommendations related to storage and end-use dates, following infection control processes and ensuring, when appropriate, a sterile environment. For example, to help ensure that compounded drugs are prepared safely, The Joint Commission standards specify that, in most circumstances, a pharmacist, or pharmacy staff under the supervision of a pharmacist, must prepare the compound or admixture for all sterile compounded drugs and that staff use clean or sterile techniques to avoid contamination. According to The Joint Commission officials, the MTFs that The Joint Commission accredits include small and large hospitals and ambulatory care clinics. Accreditation surveys are conducted for each facility on a regular basis.[2] In addition, the Army, Navy, and Air Force maintain written guidance on

[1]According to DOD officials, ambulatory care clinics operated by the Air Force are accredited by the Accreditation Association for Ambulatory Health Care, a not-for-profit organization that accredits more than 5,000 organizations in a wide variety of ambulatory health care settings. The Joint Commission and the Accreditation Association for Ambulatory Health Care also accredit civilian inpatient and outpatient health care facilities, including civilian hospitals and physician practices.

[2]In addition, The Joint Commission conducts "for cause" surveys if particular issues or potential deficiencies at a facility are brought to its attention.

drug compounding in MTFs. This guidance includes general instructions on the preparation of sterile and nonsterile compounded drugs, such as specifying that these drugs should be prepared in accordance with applicable U.S. Pharmacopeial Convention standards.

DOD requires TRICARE's PBM, Express Scripts, to ensure that pharmacies, which are part of its retail network, are fully licensed in accordance with applicable federal and state laws, credentialed according to Express Scripts' criteria, and have a current National Council for Prescription Drug Programs number. Accordingly, a pharmacy that provides compounded drugs to patients must adhere to individual state board of pharmacy laws and regulations governing the dispensing of compounded drugs.[3] Express Scripts requires pharmacies interested in joining its retail pharmacy network to complete a credentialing questionnaire, which asks, among other things, for the name and license number of all pharmacists and technicians employed by the pharmacy and whether the pharmacy or pharmacists, technicians, or other employees have previously been disciplined by a state board of pharmacy or other regulatory authority. Express Scripts has recently developed an additional questionnaire for compounding pharmacies, which includes a question on the source of the ingredients used to make compounded drugs. Officials from Express Scripts told us that they evaluate pharmacies' responses to these questions prior to admitting them to Express Script's retail pharmacy network.

[3]State laws and regulations governing drug compounding vary.

Appendix II: Top 25 Highest-Cost Compounded Drugs Containing Bulk Drug Substances Paid for by TRICARE

Department of Defense (DOD) officials identified the top 25 highest-cost compounded drugs, based on total cost, that included at least one bulk drug substance and were dispensed to TRICARE beneficiaries in retail pharmacies in fiscal year 2013.[1] Fifteen of the 25 highest-cost compounded drugs contained only bulk drug substances; the remaining 10 drugs contained a combination of bulk drug substances and inactive ingredients, such as sterile water. None of these drugs contained a product approved by the Food and Drug Administration (FDA). All 25 of these compounded drugs were topical medications (e.g., creams or gels), most of which were used to treat pain. The average cost per prescription for these drugs ranged from $848 to $9,961. See table 2 for information on each of these 25 compounded drugs, including the number of prescriptions dispensed, total cost, and average cost per prescription. DOD officials told us that there are alternate, FDA-approved drug treatment options for the medical conditions for which each of these drugs was prescribed.

[1]We obtained and reviewed DOD data on the top 25 highest-cost compounded drugs, based on total cost, containing at least one bulk substance dispensed to TRICARE beneficiaries in retail pharmacies in fiscal year 2013. These 25 highest-cost compounded drugs represented about $44 million, or 17 percent, of the $259 million total cost of compounded drugs paid for through TRICARE's pharmacy benefit in fiscal year 2013.

Table 1: Top 25 High-Cost Compounded Drugs Containing Bulk Drug Substances Dispensed to TRICARE Beneficiaries in Retail Pharmacies, Fiscal Year 2013

	Compounded drug ingredient combination[a]	Number of prescriptions	Total cost (dollars)	Average cost per prescription (dollars)
1	Amitriptyline HCL powder BHT granular[b] Gabapentin powder Ketamine HCL powder Lidocaine HCL powder Magnesium sulfate powder Nabumetone micronized powder PCCA custom lipo-max cream Prilocaine HCL powder Sodium metabisulfite granules Vitamin acetate liquid	721	5,252,363	7,285
2	BHT granular[b] Cyclobenzaprine HCL powder Flurbiprofen powder Gabapentinn powder Lidocaine HCL powder PCCA custom lipo-max cream Prilocaine HCL powder Sodium metabisulfite granules Vitamin E acetate liquid	864	4,964,082	5,745
3	Gabapentin powder Fluticasone propionate powder Levocetirizine dihydrochl powder Pentoxifylline powder Pracasil tm-plus gel Prilocaine HCL powder Propylene glycol liquid	259	2,579,822	9,961
4	BHT granular[b] Cyclobenzaprine HCL powder Flurbiprofen powder Gabapentin powder Lidocaine HCL powder PCCA custom lipo-max cream Prilocaine HCL powder Sodium metabisulfite granules Sterile water for irrigation[b]	565	2,560,298	4,532
5	Amitriptyline HCL powder BHT granular[b] Flurbiprofen powder Gabapentin powder Lidocaine HCL powder PCCA custom lipo-max cream Prilocaine HCL powder Sodium metabisulfite granules Sterile water for irrigation[b]	569	2,509,960	4,411

	Compounded drug ingredient combination[a]	Number of prescriptions	Total cost (dollars)	Average cost per prescription (dollars)
6	Baclofen powder Cyclobenzaprine HCL powder Flurbiprofen powder Gabapentin powder Lidocaine powder PCCA custom lipo-max cream	536	2,042,922	3,811
7	Clonidine HCL powder Flurbiprofen powder Gabapentin powder Ketamine HCL powder Lidocaine powder PCCA custom lipo-max cream	563	2,016,731	3,582
8	Fluticasone propionate powder Levocetirizine dihydrochl powder Base, PCCA pracamac oil Pracasil tm-plus gel base	233	2,006,594	8,612
9	Baclofen powder Cyclobenzaprine HCL powder Diclofenac sodium powder Ethoxy diglycol liquid Gabapentin powder Ketamine HCL powder Lidocaine powder Lipopen plus cream	717	1,834,285	2,558
10	Fluticasone propionate powder Gabapentin powder Levocetirizine dihydrochl powder Pentoxifylline powder Pracasil tm-plus gel Prilocaine HCL powder Propylene glycol liquid	228	1,801,542	7,902
11	Sterile water for irrigation[b] Tobramycin sulfate powder	806	1,758,878	2,182
12	Baclofen powder Bupivacaine HCL powder Cyclobenzaprine HCL powder Diethylen glycol m-ethyl ether Gabapentin powder Ketamine HCL powder Ketoprofen micronized powder PCCA custom lipo-max cream	321	1,471,395	4,584
13	BHT granular[b] Cyclobenzaprine HCL powder Flurbiprofen powder Gabapentin powder Lidocaine HCL powder PCCA custom lipo-max cream Prilocaine HCL powder Sodium metabisulfite granules	508	1,328,557	2,615

	Compounded drug ingredient combination[a]	Number of prescriptions	Total cost (dollars)	Average cost per prescription (dollars)
14	Baclofen powder Cyclobenzaprine HCL powder Ethoxy diglycol liquid Flurbiprofen powder Gabapentin powder Lidocaine powder PCCA lipoderm base	432	1,209,922	2,801
15	Amitriptyline HCL powder BHT granular[b] Flurbiprofen powder Gabapentin powder Lidocaine HCL powder PCCA custom lipo-max cream Prilocaine HCL powder Sodium metabisulfite granules Vitamin e acetate liquid	229	1,046,621	4,570
16	Baclofen powder Bupivacaine HCL powder Cyclobenzaprine HCL powder Diethylen glycol M-Ethyl Ether Gabapentin powder Ketamine HCL powder Ketoprofen micronized powder Menthol crystals PCCA custom lipo-max cream Tramadol HCL powder	178	1,036,868	5,825
17	BHT granular[b] Cyclobenzaprine HCL powder Flurbiprofen powder Gabapentin powder Lidocaine HCL powder PCCA custom lipo-max cream Prilocaine HCL powder Sodium metabisulfite granules Sterile water for injection[b]	248	1,025,785	4,136
18	Baclofen powder Bupivacaine HCL powder Cyclobenzaprine HCL powder Diethylen glycol m-ethyl ether Gabapentin powder Ketamine HCL powder Ketoprofen micronized powder Menthol crystals PCCA custom lipo-max cream Tramadol HCL powder	152	1,022,060	6,724

	Compounded drug ingredient combination[a]	Number of prescriptions	Total cost (dollars)	Average cost per prescription (dollars)
19	BHT granular[b] Cyclobenzaprine HCL powder Flurbiprofen powder Gabapentin powder Lidocaine HCL powder PCCA custom lipo-max cream Prilocaine HCL powder Simethicone liquid Sodium metabisulfite granules Vitamin e acetate liquid	252	1,020,496	4,050
20	Baclofen powder Bupivacaine HCL powder Custom base PCCA lipoderm cream Cyclobenzaprine HCL powder Diclofenac sodium powder Gabapentin powder	1,203	1,019,731	848
21	Baclofen powder Bupivacaine HCL powder Cyclobenzaprine HCL powder Diclofenac sodium powder Gabapentin powder Ibuprofen powder Ketamine HCL powder Krisgel 100 liquid PCCA custom lipo-max cream Pentoxifylline powder Trolamine liquid	385	984,559	2,557
22	Baclofen powder Cyclobenzaprine HCL powder Flurbiprofen powder PCCA custom lipo-max cream Tramadol HCL powder	286	983,528	3,439
23	Baclofen powder Cyclobenzaprine HCL powder Gabapentin powder Flurbiprofen powder Lidocaine powder PCCA lipoderm base	357	961,367	2,693
24	Amitriptyline HCL powder BHT granular[b] Gabapentin powder Ketamine HCL powder Lidocaine HCL powder Magnesium sulfate powder Nabumetone micronized powder PCCA custom lipo-max cream Prilocaine HCL powder Sodium metabisulfite granules Sterile water for irrigation[b]	183	959,379	5,243

	Compounded drug ingredient combination[a]	Number of prescriptions	Total cost (dollars)	Average cost per prescription (dollars)
25	Baclofen powder Clonidine HCL powder Diclofenac sodium powder Gabapentin powder Ketamine HCL powder Lidocaine powder Versapro cream base	262	934,598	3,567

Source: GAO analysis of DOD data. | GAO-15-64

[a]All ingredients in these 25 compounded drugs are bulk drug substances unless otherwise noted. A compounded drug is a customized drug tailored to the medical needs of an individual patient. Ingredients in a compounded drug may be one or more FDA-approved products or bulk drug substances, which are not generally approved by the FDA.

[b]BHT granular, which, according to a DOD official, is used primarily as a preservative with no therapeutic effects, and sterile water for irrigation are not bulk drug substances.

Appendix III: Comments from the Department of Defense

THE ASSISTANT SECRETARY OF DEFENSE
1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

SEP 19 2014

John E. Dicken
Director, Health Care
United States Government Accountability Office
441 G Street, N.W.
Washington, DC 20548

Dear Mr. Dicken:

This is the Department of Defense's (DoD) response to the Government Accountability Office (GAO) Draft Report titled "COMPOUNDED DRUGS: TRICARE's Payment Practices Should be More Consistent with Regulations" (GAO-14-805) dated August 15, 2014. Thank you for the opportunity to review and comment on the Draft Report. Overall, I concur with the GAO's recommendation for DoD to align its payment practices for compounded prescriptions with applicable regulations governing the TRICARE program. My specific response to the GAO's recommendation is below.

In light of the changing statutory and regulatory environment concerning compounds, e.g., the Drug Quality and Security Act and the Department of Health and Human Services' (HHS) efforts to implement that Act, DoD will continue to monitor developments in order to shape its policy and regulatory posture. Further, the Senate Armed Services Committee included in its proposed National Defense Authorization Act for Fiscal Year 2015 a provision that would allow DoD to provide provisional coverage of "health care products and services that have not been demonstrated to be safe and effective…but have been demonstrated to the satisfaction of the Secretary to be likely safe and effective health care products or services." This new authority, if enacted, may also shape DoD's approach to compounded drugs. Accordingly, the Department will determine its policy as HHS and Congress shape the overarching statutory and regulatory environment in the months ahead.

My points of contact on this matter are Dr. George Jones (Functional) and Mr. Gunther Zimmerman (Audit Liaison). Dr. Jones may be reached at (703) 681-2890, or George.E.Jones@dha.mil. Mr. Zimmerman may be reached at (703) 681-4360, or Gunther.Zimmerman@dha.mil.

Jonathan Woodson, M.D.

Appendix IV: Comments from the Department of Veterans Affairs

DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

September 18, 2014

Mr. John E. Dicken
Director
Health Care
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Dicken:

The Department of Veterans Affairs (VA) has reviewed the Government Accountability Office's (GAO) draft report, ***"COMPOUNDED DRUGS: TRICARE's Payment Practices Should Be More Consistent with Regulations"*** (GAO-14-805). VA generally agrees with GAO's conclusions.

The enclosure provides technical comments to the draft report. VA appreciates the opportunity to comment on your draft report.

Sincerely,

Jose D. Riojas
Chief of Staff

Enclosure

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

John E. Dicken, (202) 512-7114 or dickenj@gao.gov

Staff Acknowledgments

In addition to the contact named above, Rashmi Agarwal, Assistant Director; Shana R. Deitch; Sandra George; Laurie Pachter; Carmen Rivera-Lowitt; and Michael Zose made key contributions to this report.

Related GAO Products

Prescription Drugs: Comparison of DOD, Medicaid, and Medicare Part D Retail Reimbursement Prices. GAO-14-578. Washington, D.C.: June 30, 2014.

Defense Health Care: Evaluation of TRICARE Pharmacy Services Contract Structure Is Warranted. GAO-13-808. Washington, D.C.: September 30, 2013.

Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight. GAO-13-702. Washington, D.C.: July 31, 2013.

Prescription Drugs: Comparison of DOD and VA Direct Purchase Prices. GAO-13-358. Washington, D.C.: April 19, 2013.

DOD Pharmacy Benefits Program: Reduced Pharmacy Costs Resulting from the Uniform Formulary and Manufacturer Rebates. GAO-08-172R: Washington, D.C.: Oct 31, 2007.