



October 2014

COMPOUNDED DRUGS

Payment Practices
Vary across Public
Programs and Private
Insurers, and
Medicare Part B
Policy Should Be
Clarified

Why GAO Did This Study

Drug compounding is a process whereby a pharmacist mixes or alters ingredients to create a drug tailored to the medical needs of an individual patient. Compounded drugs make up 1 to 3 percent of the \$300 billion domestic prescription drug market. Compounded drugs and some of their ingredients are not approved by FDA. Members of Congress have questioned whether federal health care programs' payment practices create incentives for providers to prescribe these drugs.

GAO was asked to examine public programs' and private health insurers' payment practices for compounded drugs. GAO examined (1) Medicare's, Medicaid's, and private health insurers' payment practices for compounded drugs and (2) the extent to which these payment practices for compounded drugs affect their use. GAO reviewed the payment policies of CMS, the five largest state Medicaid programs, five of the largest insurers that offer both Medicare and Medicaid managed care plans as well as private plans, and the two largest Medicare Part D-only sponsors. GAO also interviewed officials from these entities and from provider associations.

What GAO Recommends

GAO recommends that CMS clarify its Medicare Part B payment policy to either allow or restrict payment for compounded drugs containing bulk drug substances and align payment practices with this policy. HHS disagreed with this recommendation, stating that the Part B payment policy does not depend on drug ingredients. GAO maintains that the policy needs clarification.

View [GAO-15-85](#). For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov.

COMPOUNDED DRUGS

Payment Practices Vary across Public Programs and Private Insurers, and Medicare Part B Policy Should Be Clarified

What GAO Found

Medicare, Medicaid, and private health insurers have varying payment practices for compounded drugs, depending upon whether compounded drugs and their ingredients can be identified on health insurance claims, and Medicare's Part B payment policy for these drugs is unclear.

- For drugs dispensed in pharmacy settings, claims contain sufficient information for public programs and private insurers to identify compounded drugs and their ingredients. These programs and plans use claims information to determine whether compounded drug ingredients are products approved by the Food and Drug Administration (FDA) or are bulk drug substances—usually raw powders—that are generally not approved by FDA. Two of the five insurers and one of the two Medicare Part D-only sponsors we spoke with generally do not pay for these substances in their Medicare Part D plans. Four of the five state Medicaid programs and three of the five insurers offering private health plans we spoke with generally do not pay for ingredients that are bulk drug substances in their respective plans.
- For drugs administered in outpatient physician office settings, claims lack information to identify compounded drugs because there are no specific billing codes for most of these drugs. Therefore, Medicare, most state Medicaid programs, and most private health insurers pay for these compounded drugs. Some public programs and private health insurers conduct further claims reviews for compounded drugs billed under nonspecific codes, including obtaining information that can be used to determine FDA-approval status of compounded drug ingredients, and make payment decisions based on this information.
- Additionally, the Centers for Medicare & Medicaid Services (CMS)—the agency within the Department of Health and Human Services (HHS) responsible for administering the Medicare program—has a national payment policy for compounded drugs under Medicare Part B, but this policy is unclear. The policy generally states that drugs must be FDA-approved to be paid for under Medicare. Payment may be available for compounded drugs, but the policy does not stipulate whether payment is available for ingredients that are bulk drug substances, which are generally not FDA-approved. CMS contractors who process Part B claims do not collect information on the FDA-approval status of drug ingredients and, therefore, may be paying for ingredients that are not FDA-approved products. Thus, it is uncertain whether Medicare payments are inconsistent with Part B policy.

Payment practices of public programs and private health insurers may affect the use of compounded drugs when specific payment exclusions exist, such as those for bulk drug substances; however, other factors also affect the use of compounded drugs. For example, insurers that restrict payment for compounded drugs dispensed in pharmacy settings in their private health plans to only ingredients that are FDA-approved products saw significant decreases in both the number of claims and the amount of payments for these drugs after they implemented these restrictions. Individual patient need, such as the need for custom dosages, and drug shortages also affect the use of compounded drugs.

Contents

Letter		1
	Background	6
	Medicare, Medicaid, and Private Health Insurers Have Varying Payment Practices for Compounded Drugs, and Medicare Part B Payment Policy Is Unclear	13
	Payment Practices, among Other Factors, May Affect the Use of Compounded Drugs	24
	Conclusions	26
	Recommendation for Executive Action	27
	Agency Comments and Our Evaluation	27
Appendix I	Comments from the Department of Health and Human Services	31
Appendix II	GAO Contact and Staff Acknowledgments	34
Related GAO Products		35
Figure		
	Figure 1: Number of New National Drug Codes for Bulk Drug Substances Added to First Databank's Database, 2009 through 2013	8

Abbreviations

AWP	average wholesale price
CMS	Centers for Medicare & Medicaid Services
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
NCPDP	National Council for Prescription Drug Programs
NDC	national drug code
PBM	pharmacy benefit manager
OIG	Office of Inspector General
USP	U.S. Pharmacopeial Convention

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October 10, 2014

Congressional Requesters

Traditionally, drug compounding is the process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a customized drug tailored to the medical needs of an individual patient upon receipt of a prescription. 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.¹ 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 States. Compounded drugs may contain ingredients that are FDA-approved products. These drugs may also contain bulk drug substances—typically raw powders—that are generally not FDA approved.² 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

¹Drug 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 of the scope of our report.

²FDA 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).

compounded drugs without prescriptions for individual patients and selling those drugs to facilities in multiple states with no assurance of their having met the safety and legal requirements with which drug manufacturers must comply.³ 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.⁴

Questions have also been raised about the cost of compounded drugs. The International Academy of Compounding Pharmacists estimates that the compounding industry makes up 1 to 3 percent of the \$300 billion retail prescription drug market in the United States in 2014.⁵ Pharmacy benefit managers (PBM)—companies that contract with health insurers to manage prescription drug benefits and process and pay claims—have expressed concerns that, while these drugs make up a small percentage of prescription drug claims, costs for compounded drugs, particularly those made with bulk drug substances, are increasing.⁶ For example, one PBM reports that the number of claims it received for compounded prescription drugs from retail pharmacies in one of its health insurer's plans increased 35 percent over a 12-month period between 2012 and 2013.⁷ Additionally, members of Congress have raised questions about potential financial incentives for providers to prescribe or dispense these drugs that may be inadvertently created by the coverage and

³In 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.

⁴See [GAO-13-702](#), *Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight*, (Washington, D.C.: July 31, 2013).

⁵In 2012, the International Academy of Compounding Pharmacists estimated that, of the more than 56,000 community-based retail pharmacies in the United States, approximately 7,500 of these specialize in compounding services.

⁶In addition to processing and paying prescription drug claims, PBMs are also responsible for developing and maintaining health plan formularies—lists of medications that health care providers are encouraged to prescribe—contracting with retail pharmacies, and negotiating rebates with drug manufacturers and discounts with retail pharmacies.

⁷OptumRx, *Compounding Pharmacies: A Costly Challenge*, April 24, 2014, accessed August 1, 2014, <http://www.optum.com/thought-leadership/compounding-pharmacies-costly-challenge.html>.

reimbursement practices of public health care programs, such as Medicare and Medicaid, and private health plans.⁸ For example, in 2004, one congressional committee attributed the growth of the compounded drug industry to payments for these drugs under Medicare Part B—the part of the Medicare program that covers certain physician, outpatient hospital, laboratory and other services, and medical equipment and supplies.⁹ In addition, this committee raised concerns that the coverage and payment practices of Medicare Part D sponsors—that is, those health insurers that administer the Medicare Part D prescription drug benefit¹⁰—might be interpreted the same way as Medicare Part B policies and lead to increased use of compounded drugs under the benefit. In 2006, another congressional committee raised similar concerns about Medicare Part B and Part D benefits.¹¹

You asked us to examine public programs' and private health insurers' payment practices for compounded drugs, as well as any possible financial incentives created by these practices. This report examines (1) Medicare's, Medicaid's, and private health insurers' payment practices for compounded drugs and (2) the extent to which these payment practices for compounded drugs may affect their use.¹²

⁸Medicare is the federal program that provides coverage of health services for people aged 65 and older and certain other individuals. Medicaid is the joint federal-state program that provides coverage of health services for certain low-income individuals. The Centers for Medicare & Medicaid Services (CMS) is the federal agency responsible for administering the Medicare and Medicaid programs.

⁹U.S. House of Representatives, Committee on Government Reform. *New Medicare Rules May Increase Risk from Unregulated Compounded Drug Copies* (Washington, D.C.: Sept. 28, 2004).

¹⁰Medicare Part D, established in 2006, provides a voluntary drug benefit for Medicare beneficiaries to obtain drugs through retail and mail-order pharmacies.

¹¹United States Senate, Committee on Finance. *Chairman Grassley Questions CMS, FDA about Substituted Inhalation Drugs* (Washington, D.C.: July 13, 2006).

¹²We examined payment practices for compounded drugs under TRICARE—the Department of Defense program that provides medical and prescription drug benefits to active duty personnel, military retirees, reservists and members of the National Guard, and their dependents—in a separate report. See GAO, *Compounded Drugs: TRICARE's Payment Practices Should Be More Consistent with Regulations*, [GAO-15-64](#) (Washington, D.C.: Oct. 2, 2014).

To examine Medicare's, Medicaid's, and private health insurers' payment practices for compounded drugs, we reviewed information and interviewed officials from the Centers for Medicare & Medicaid Services (CMS), the HHS agency responsible for administering the Medicare and Medicaid programs; state Medicaid programs; health insurers; and other stakeholders. To select the state Medicaid programs, we used publicly available CMS data as of February 2014 to identify the five state Medicaid programs with the highest number of enrollees and spoke with officials from these five states.¹³ To select private health insurers, we used CMS data and information from insurers' websites to select insurers that offer plans through Medicare Part C—that is Medicare managed care, known as Medicare Advantage—Medicare Part D, Medicaid managed care, and the commercial market.¹⁴ Specifically, we used publicly available CMS data as of February 2014 to identify the 10 insurers with the highest number of enrollees in Medicare Advantage and Part D plans and used information from insurers' websites to determine whether they also offer Medicaid managed care and private health plans in the commercial market.¹⁵ Of these 10 insurers, we spoke with officials from 4 national insurers and 1 state insurer, each of which offers Medicare Advantage plans with Part D benefits, Medicaid managed care plans, and private health plans in the commercial market; and officials from 2 insurers that offer Medicare Part D plans only, referred to as Part D-only sponsors.¹⁶ We interviewed officials from these entities to obtain information on public programs' and private health insurers' payment practices for compounded drugs in each market and how they calculate payment for these drugs.

¹³We used publicly available data from the Medicaid and CHIP Payment and Access Commission to identify state Medicaid programs by number of enrollees. The five state Medicaid programs are California, Florida, Illinois, New York, and Texas.

¹⁴CMS contracts with private health insurers that offer (1) medical benefits under Medicare through a managed care network, known as Medicare Advantage plans, (2) Medicare Advantage plans with Part D coverage, or (3) Medicare Part D prescription drug benefits only. State Medicaid programs also contract with health insurers to offer medical and prescription drug benefits through a managed care network.

¹⁵CMS's data includes enrollment in Medicare Advantage-only plans, Medicare Advantage plans with Part D benefits, and Medicare Part D-only plans.

¹⁶The four national insurers are Aetna, Humana, Kaiser Permanente, and WellPoint. The state insurer is Blue Cross Blue Shield of Michigan. The two Part D-only plan sponsors are CVS Caremark and Express Scripts. CVS Caremark and Express Scripts also serve as pharmacy benefit managers for other health insurers. These seven insurers and sponsors accounted for about 48 percent of all Medicare Advantage and Part D enrollees as of February 2014.

We analyzed available payment policies for compounded drugs and any related documents from CMS and each of the states, insurers, and sponsors we interviewed. In addition, we interviewed officials from three PBMs that process and pay prescription drug claims to obtain their perspectives on payment practices for compounded drugs in pharmacies, how claims for these drugs are processed, and how payments are calculated.¹⁷ We interviewed officials from two companies that publish national drug compendia for their perspectives on payments for compounded drugs.¹⁸ We also reviewed an April 2014 report from the HHS Office of Inspector General (OIG) on Medicare Part B payments for compounded drugs and interviewed officials from HHS OIG about their findings.¹⁹ We reviewed related documentation on how the CMS data are collected and determined that these data were sufficiently reliable for our purposes. However, the results of our analysis are intended to be illustrative; they are not generalizable to all state Medicaid programs; all private health insurers offering Medicare Advantage plans with Part D benefits, Medicaid managed care plans, and private health plans in the commercial market; or all Part D-only sponsors.

To determine the extent to which public programs' and private insurers' payment practices for compounded drugs may affect their use, we reviewed information and interviewed officials from the entities identified above, as well as officials from provider associations and other relevant organizations. Specifically, we analyzed payment policies and related documents of CMS, states, and insurers to identify any characteristics of these policies that may affect the use of compounded drugs. We interviewed officials from 11 national and international associations representing health care providers—including physicians and

¹⁷The three PBMs are CVS Caremark, Express Scripts, and OptumRx.

¹⁸These 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.

¹⁹Department of Health and Human Services, Office of Inspector General, *Compounded Drugs under Medicare Part B: Payment and Oversight*, OEI-03-13-00270 (Washington, D.C.: April 2014). We coordinated with HHS OIG officials to obtain information about and avoid overlap and duplication with their evaluation. In addition, while we report on some of HHS OIG's findings from its Medicare Part B assessment, we independently corroborated information in this report with CMS.

pharmacists—who administer or dispense compounded drugs in inpatient, outpatient, or pharmacy settings; 2 pharmaceutical standards-setting organizations; and 2 associations representing private health insurers and PBMs to obtain their perspectives on the extent to which payment practices affect the use of compounded drugs.²⁰

We conducted this performance audit from February 2014 through 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.²¹ The active ingredient or ingredients in a compounded drug

²⁰The 11 national and international associations representing health care providers are the American Academy of Dermatology, American Academy of Ophthalmology, American Hospital Association, American Pharmacists Association, American Society of Health-System Pharmacists, American Society of Parenteral and Enteral Nutrition, International Academy of Compounding Pharmacists, National Association of Chain Drug Stores, National Community Pharmacists Association, National Home Infusion Association, and Professional Compounding Centers of America. The 2 pharmaceutical standards-setting organizations are the National Council for Prescription Drug Programs and U.S. Pharmacopeial Convention (USP). The 2 associations representing private health insurers and PBMs are America's Health Insurance Plans and Pharmaceutical Care Management Association, respectively.

²¹Compounded 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).

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.

Active ingredients used to make a compounded drug—including bulk drug substances—are generally assigned national drug codes (NDC).²² FDA maintains a publicly available list of NDCs for FDA-approved products.²³ 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.²⁴ 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.²⁵ (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.)

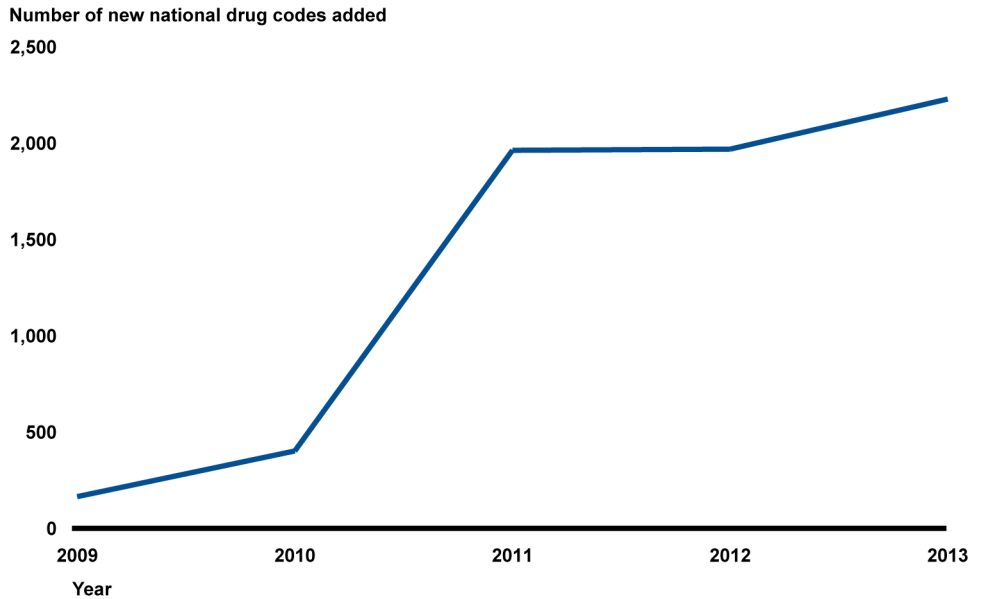
²²NDCs are three-segment numbers that are the universal product identifiers for drugs for human use. FDA assigns the first segment of the NDC, which identifies the labeler (i.e., the firm that manufactures, repackages, or distributes a drug). The labeler assigns the second and third segments. The second 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).

²³FDA’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.

²⁴Average 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.

²⁵According 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-15-85

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.²⁶ 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

²⁶Drug 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).²⁷ The Drug Quality and Security Act 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.²⁸ Outsourcing facilities, however, must comply with current good manufacturing practice requirements. In addition, the Drug Quality and Security Act 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.²⁹ 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

²⁷21 USC § 353a, as amended by Pub. L. No. 113-54, § 106, 127 Stat. 587, 598 (Nov. 27, 2013).

²⁸An 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 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 practices requirements.

²⁹FDA 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.

exemptions from certain requirements of the FDCA if they compound using bulk drug substances included on the lists.³⁰

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.³¹ 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 2013.³² 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

³⁰To 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).

³¹USP 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.

³²The 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.³³ These entities were required to be fully compliant with version D.0 by January 1, 2012.³⁴

Drug Benefits under Public Programs and Private Health Plans

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.³⁵ Medicare uses contractors to process and pay Part A and Part B claims.³⁶ Medicare Part C—Medicare's managed care benefit, also known 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 Medicare Part D. Medicare Part D provides a voluntary pharmacy benefit for Medicare beneficiaries. Beneficiaries may choose Medicare Part D plans from among those offered by private Part D-only sponsors. Part D beneficiaries may obtain drugs through retail and mail-order pharmacies.

³³74 Fed. Reg. 3296, 3302 (Jan. 16, 2009) (codified at 45 C.F.R. Part 162).

³⁴Prior to the implementation of the updated standard, providers typically submitted claims for compounded drugs based on the primary—and, typically, the most expensive—ingredient.

³⁵Medicare 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.

³⁶CMS 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).

Medicaid

States establish and administer their own Medicaid programs within broad federal guidelines. Medicaid programs vary from state to state, but all state Medicaid programs provide inpatient and outpatient medical benefits, which include benefits for drugs administered in inpatient hospital and outpatient physician office settings. In addition, all state Medicaid programs provide a prescription drug benefit under which they pay pharmacies for drugs dispensed to Medicaid beneficiaries.³⁷ States report these payments to CMS, which provides federal matching funds to states to cover a portion of these costs.³⁸ States may provide Medicaid benefits using a fee-for-service or managed care delivery system. In a managed care delivery system, states typically contract with managed care organizations to provide some or all Medicaid covered services to beneficiaries.

Private Health Plans

Private health plans in the commercial market provide medical benefits, which include benefits for drugs administered in inpatient hospital and outpatient physician office settings, and pharmacy benefits. Private health plans offered in the commercial market include individual and group market plans. Participants in the individual market purchase health insurance directly from an insurer, through a broker, or through a state health insurance exchange. Group market participants generally obtain health insurance through a group health plan, usually offered by an employer. These plans can include fee-for-service, preferred provider organization, and health maintenance organization options.³⁹

³⁷Prescription drug coverage is an optional Medicaid benefit; however, all state Medicaid programs have elected to include it in their Medicaid benefit packages.

³⁸The federal government matches state Medicaid expenditures for services according to a state's federal medical assistance percentage, which is based on a statutory formula under which the federal share of a state's Medicaid expenditures may range from 50 to 83 percent.

³⁹Health maintenance organizations and preferred provider organizations are insurance products that generally rely on providers to control service utilization, and they provide financial incentives to encourage patients to use network providers who have agreed to accept fee discounts.

Medicare, Medicaid, and Private Health Insurers Have Varying Payment Practices for Compounded Drugs, and Medicare Part B Payment Policy Is Unclear

For Compounded Drugs Dispensed in Pharmacy Settings, Medicare, Medicaid, and Private Health Insurers Have Varying Payment Practices

Medicare, Medicaid, and private health insurer payment practices for compounded drugs dispensed in pharmacy settings allow for the payment of FDA-approved products but vary in whether they allow payment for bulk drug substances in these compounds. As a result of version D.0 of NCPDP's standard for pharmacy transactions, officials from the states, insurers, and Part D-only sponsors we spoke with told us that claims for compounded drugs dispensed in pharmacy settings contain sufficient information to identify when a compounded drug is dispensed and the ingredients used to make the drug by NDC.⁴⁰ Therefore, these public programs and private health insurers are able to use NDC information from national drug compendia to determine whether the ingredients in the compounded drug are FDA-approved products or bulk drug substances.

Officials from CMS, the five state Medicaid programs, four of the five insurers, and the two Part D-only sponsors provided us with information on their payment practices for compounded drugs, including those made with bulk drug substances. Of the five insurers we spoke with, one insurer owns and operates its pharmacies. Officials from this insurer told us that the insurer purchases drugs and drug ingredients, including some bulk drug substances used to make compounded drugs; therefore, the insurer's payment practices in pharmacy settings differ from the other four

⁴⁰The prior NCPDP standard, version 5.1, contained an indicator for compounded drugs but allowed for the inclusion of only the primary—and, typically, the most expensive—ingredient used to make the compounded drug on the claim.

insurers across the insurer's Medicare Part D, Medicaid, and private health plans.⁴¹

- Under Medicare Part D, federal payments are not available for non-FDA-approved products—including bulk drug substances—and inactive ingredients used to make a compounded drug.⁴² However, insurers that offer Medicare Part D benefits and Part D-only 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.⁴³ Officials from two insurers offering Medicare Advantage plans 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.⁴⁴ Officials from the remaining two insurers 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. However, in July 2014, the Part D-only

⁴¹Officials from this insurer told us that because it purchases drugs and drug ingredients directly from manufacturers for its pharmacies, it does not generally process pharmacy claims in any of its public or private plans. However, this insurer submits beneficiaries' prescription information to its PBM using the D.0 standard in order for the PBM to determine a beneficiary's share of the cost of the prescription.

⁴²In general, under Medicare Part D, federal payments are unavailable for drugs not approved by 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).

⁴³CMS's final rule for the Medicare Part D contract year 2012 notes that, while Part D sponsors may pay for non-Part D-covered 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). Of the five insurers and two Part D-only sponsors, only one insurer has specific written policies in place beyond what was stated in the CMS regulation.

⁴⁴Officials from one of the two insurers that do not pay for bulk drug substances told us that the insurer 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 insurer will reject claims with a bulk drug substance that is the primary ingredient. Officials from the other insurer told us that the insurer 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 insurer and the Part D-only 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.

sponsor that currently pays pharmacies for bulk drug substances announced its plans to discontinue payments for most of these substances by March 2015. This decision to cease paying for bulk drug substances was a result of the sponsor's internal analyses showing that pharmacies have been increasing their billed amounts for the ingredients not covered by Part D, including bulk drug substances, used to make compounded drugs; as a result, the sponsor's costs for these ingredients began to exceed its costs for the ingredients covered by Part D in compounded drug claims in early 2014.⁴⁵

- Under Medicaid, CMS provides federal matching dollars to states that opt to pay for compounded drugs under the prescription drug benefit, including those that contain bulk drug substances, and has issued a notice to the states informing them of this policy.⁴⁶ Officials from four of the five state Medicaid programs and two insurers that offer Medicaid managed care plans we spoke with told us that they generally do not pay for bulk drug substances used to make compounded drugs under the prescription drug benefit.⁴⁷ The fifth state Medicaid program and the remaining two insurers pay for only

⁴⁵The Part D-only sponsor will cease paying for hundreds of bulk drug substances typically used to prepare compounded topical medications; sponsor officials told us that these substances accounted for 95 percent of the sponsor's increased costs. In addition to discontinuing payment for most bulk drug substances in its Medicare Part D plans, this sponsor also plans to cease paying for over a thousand bulk drug substances in the plans for which the sponsor contracts with plan insurers as the PBM. According to sponsor officials, insurers will be able to opt out of this payment exclusion.

⁴⁶States that offer a prescription drug benefit are required to provide coverage for those drugs for which manufacturers pay rebates to state Medicaid agencies under the federal Medicaid drug rebate program. See 42 U.S.C. § 1396r-8. CMS has clarified that bulk drug substances are not subject to the drug rebate program's requirements and, therefore, states are not required to cover such compounded drugs under their prescription drug benefit. However, states may opt to do so. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program Notice, Release No. 158 (Baltimore, Md.: July 13, 2011).

⁴⁷Officials from two of these state Medicaid programs and the two insurers told us that they will pay for bulk drug substances in compounded drugs only after they have deemed a prescription to be medically necessary, which likely occurs in rare circumstances only. Of the four state Medicaid programs and two insurers that do not pay for bulk drug substances, only one insurer has specific written policies stating this payment exclusion.

those bulk drug substances that are listed on their formulary.⁴⁸

Officials from the fifth state Medicaid program told us that pharmacies may request to add a bulk drug substance to the state formulary, and the state will evaluate the request and the need to do so. However, these officials also told us that the state has received no such requests in at least the last 4 to 6 months.

- For private health plans offered in the commercial market, officials from three insurers we spoke with told us that they generally do not pay for bulk drug substances used to make compounded drugs and pay only for those ingredients in the compound that are FDA-approved products under their prescription drug benefit.⁴⁹ Officials from one of these three insurers told us that the insurer requires prior authorization for all compounded drug prescription claims;⁵⁰ officials from the other two insurers told us that they require beneficiaries to obtain prior authorization only for compounded drug claims over a certain dollar amount, regardless of whether the drug's ingredients are FDA-approved products or bulk drug substances.⁵¹ The fourth insurer pays for bulk drug substances as well as FDA-approved products, provided that the bulk drug substance is not listed as the primary ingredient on the claim.

Once states, insurers, and sponsors determine which ingredients they will pay for in compounded drugs dispensed in pharmacy settings, they typically calculate the amount of the payment based on common drug

⁴⁸A formulary is a list of medications, grouped by therapeutic class, that a health care system's providers are encouraged to use when prescribing medications. A therapeutic class describes a group of drugs that are similar in chemical structure, pharmacological effect, or clinical use.

⁴⁹Of the three insurers that do not pay for bulk drug substances, two insurers have specific written policies stating this payment exclusion.

⁵⁰According to officials from this insurer, this insurer may pay for bulk drug substances used to make compounded drugs in rare circumstances and only after the insurer has deemed a prescription to be medically necessary.

⁵¹Prior authorization requires the provider to obtain approval from a health plan before a prescription drug is administered or dispensed. The need for prior authorization for prescription drugs dispensed at retail pharmacies is typically determined at the point of sale. Insurers' claims processing systems have triggers built in to automatically request prior authorization for electronic claims submitted by pharmacists. Depending upon the insurer and the plan, either the pharmacist or the patient would request prior authorization from the prescribing clinician, including any forms or supporting documentation, and submit it with the claim.

pricing benchmarks.⁵² These pricing benchmarks apply to both FDA-approved products and bulk drug substances used to make compounded drugs. Officials from the states, insurers, and Part D-only sponsors we spoke with told us that they generally calculate payments to pharmacies based on a negotiated price for each ingredient, such as AWP, wholesale acquisition cost, or maximum allowable cost.⁵³ Some states, insurers, and one Part D-only sponsor calculate the price of each ingredient according to the pricing benchmarks and then pay pharmacies the lesser of the total calculated price for all included ingredients, the price submitted by the pharmacy, the usual and customary charge, or other payment calculations.⁵⁴

For Compounded Drugs Administered in Inpatient and Outpatient Settings, Medicare, Medicaid, and Private Health Insurers Generally Have Similar Payment Practices, Which Are Affected by Lack of Specific Billing Codes on Claims

Medicare, Medicaid, and private health insurers generally have similar payment practices for compounded drugs administered in outpatient settings, which are affected by the lack of specific billing codes for these drugs on claims. As a result, most of these public programs and private health insurers pay for compounded drugs, including both the FDA-approved products and bulk drug substances that comprise these drugs, because they may be unable to identify whether compounded drugs were administered and what individual ingredients were used to make the compounded drugs. For drugs administered in outpatient settings, public programs and private health insurers generally rely on specific codes for individual drugs in the Healthcare Common Procedure Coding System (HCPCS)—a standardized coding system used by public programs and private health insurers to help ensure medical claims are processed in a

⁵²The insurer that owns and operates its healthcare facilities pays the price set by the manufacturer for drugs and drug ingredients.

⁵³State Medicaid programs are generally required to pay pharmacies the lower of (a) the state's estimate of the drug's acquisition cost to the pharmacy, based on a state-determined formula, plus a dispensing fee, or (b) the pharmacy's usual and customary charge to the general public. See 42 C.F.R. 447.512 (2013). For certain multiple-source outpatient prescription drugs with three or more therapeutically and pharmaceutically equivalent versions, CMS will provide federal matching funds for reimbursements only up to a maximum amount—known as a federal upper limit. 42 U.S.C. § 1396r-8(e)(4). 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 insurer or Part D sponsor.

⁵⁴The usual and customary fee is the cost of the drug the beneficiary would pay without insurance. Other payment methodologies may include estimated acquisition cost, which is the estimated cost to purchase the drug.

consistent manner—to indicate whether a beneficiary received a prescription drug, including a compounded drug, on an insurance claim. However, for the majority of compounded drugs administered in outpatient settings, no specific HCPCS codes exist; rather, providers typically bill for compounded drugs administered in outpatient settings using HCPCS codes for “not otherwise classified” drugs.⁵⁵ Nonspecific HCPCS codes may also be used to bill for noncompounded drugs that lack specific HCPCS codes. Public programs and private health insurers may conduct further reviews of outpatient claims 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 decisions. Given the difficulty in identifying these drugs on insurance claims, the insurers we spoke with generally do not have specific written policies regarding payment allowances or limitations for any FDA- or non-FDA-approved ingredients used to make compounded drugs administered in outpatient settings. In addition, while CMS has a national policy for payment of compounded drugs under Medicare Part B, the agency does not have any policies regarding federal Medicaid payments for compounded drugs administered in outpatient settings and likely provides some federal matching dollars to states to pay for compounded drugs, including those that contain bulk drug substances.⁵⁶ State Medicaid programs may develop their own payment policies for these drugs.

CMS, the five state Medicaid programs, and four of the five insurers provided us with information on whether they review outpatient claims, including requesting and reviewing additional documentation, with drugs billed under the nonspecific code. Of the five insurers we spoke with, officials from one insurer told us that because the insurer 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 insurer is able to determine whether drugs administered to beneficiaries in outpatient settings are compounded drugs and what ingredients were used to make them. This

⁵⁵Specific HCPCS codes exist for some compounded drugs used with durable medical equipment, such as nebulizers used to administer inhalational drugs.

⁵⁶CMS contractors responsible for processing outpatient (Medicare Part B) claims develop their own policies in accordance with national Medicare policy. These contractors may be able to identify compounded drugs depending on what kind of information they require providers to submit on claims. We did not examine Medicare contractors' claims processing policies in our review.

insurer's payment practices for reimbursing its health care facilities differ from the other four insurers across the insurer's Medicare Advantage, Medicaid, and private health plans.

- Under Medicare Part B, CMS contractors manually review claims and any additional documentation, such as invoices for compounded drugs purchased by the provider. Most of the contractors do not require providers to submit NDCs for compounded drug ingredients to determine whether these ingredients are FDA-approved products or to obtain pricing information. Officials from two of the insurers we spoke with that offer Medicare Advantage plans told us that they review all claims with compounded drugs billed under the nonspecific code and request additional information. Officials from one of these insurers told us that the insurer 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 insurer determines that they are medically necessary. Officials from the other insurer told us that the insurer requires providers to submit supporting documentation, including invoices that list the name and amount of each ingredient in the compounded drug. A third insurer 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 insurer uses NDCs primarily to calculate payments, likely for all ingredients in the compounded drug.⁵⁷ The fourth insurer does not review claims with the nonspecific HCPCS code or collect additional information and pays for all ingredients in the compounded drug.
- Under Medicaid, officials from two state Medicaid programs told us that these states require providers to submit NDCs for each ingredient in compounded drugs billed under the nonspecific code and review the claims and the NDCs to determine medical necessity. However, neither state uses NDCs to determine which ingredients are FDA-approved products. Both states pay for compounded drugs, including those that contain bulk drug substances, if they determine the drugs are medically necessary. Officials from two other state Medicaid programs told us that the states require providers to submit NDCs for

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

every HCPCS drug code and not just the nonspecific code, and providers may not submit more than one NDC with the nonspecific code.⁵⁸ For one of these states, officials told us that providers may not bill compounded drugs as single line items on claims; rather, providers must bill each ingredient with the nonspecific code and the ingredient's NDC. This state uses the NDCs to determine which ingredients are FDA-approved products and does not pay for bulk drug substances. Officials from the other state told us that the state assigns a short list of NDCs for FDA-approved products to the nonspecific HCPCS code and updates it annually when CMS updates the HCPCS code database. Officials told us that the state's claims processing system will automatically reject those claims with the nonspecific code that are accompanied by an NDC that is not on the state's list. Two insurers offering Medicaid managed care plans process claims for compounded drugs billed under nonspecific HCPCS codes in a similar manner as they do for compounded drugs billed in their Medicare Advantage plans. One insurer that collects NDCs for drugs billed under nonspecific HCPCS codes for claims exceeding a certain dollar amount in its Medicare Advantage plans does not do so in its Medicaid managed care plans; rather, in its Medicaid managed care plans, this insurer collects information from the provider, either on the claim or in additional information submitted by the provider, about why a compounded drug is being administered.⁵⁹

- For private health plans offered in the commercial market, the four insurers require information about compounded drugs administered in outpatient settings and review claims in a similar manner as they do for compounded drugs billed in either their Medicare Advantage or their Medicaid managed care plans.

Medicare Part B, the states, and the insurers vary in how they calculate payments for compounded drugs billed under nonspecific HCPCS codes on outpatient claims depending upon whether these entities review these claims. Medicare contractors calculate payments for compounded drugs

⁵⁸Officials from the fifth state Medicaid program did not provide us with information on whether it reviews outpatient claims to identify compounded drugs or its payment practices for these drugs.

⁵⁹Officials from the fourth insurer did not provide us with information on whether it reviews outpatient claims to identify compounded drugs billed under nonspecific HCPCS codes or its payment practices for these drugs.

based on the invoice price submitted by the provider, which may also include taxes and shipping fees. Officials from the state Medicaid program that requires NDCs for each ingredient and pays only for FDA-approved products told us that they calculate payment based on either the Medicare Part B rate or the pharmacy rate of reimbursement for each FDA-approved product.⁶⁰ The state that allows for the use of the nonspecific HCPCS code with only certain NDCs calculates payment based on the wholesale acquisition cost. Four insurers that offer Medicare Advantage, Medicaid managed care, and private health plans calculate payments based on either (1) the provider-submitted price for the drug, which may include payment for non-FDA-approved bulk drug substances; (2) common drug pricing benchmarks, such as wholesale acquisition cost, for the NDC of each FDA-approved product; or (3) the state Medicaid program's fee schedule. These insurers' payment calculations may depend on whether the plan is public or private and whether the insurer reviews claims and additional information. The insurer that owns and operates its healthcare facilities pays the price set by the manufacturer for drugs and drug ingredients.

In inpatient hospital settings, drugs, including compounded drugs, are generally not billed separately from the rest of the services the beneficiary received but are bundled together as part of the overall charge for the hospital stay or inpatient admission.⁶¹ Because these drugs are bundled, officials from CMS, all five states, and all but one of the insurers we spoke with told us that they cannot determine whether a beneficiary received a compounded drug. Medicare Part A, Medicaid, and private health insurers

⁶⁰The current Medicare Part B rate of reimbursement is the average sales price of a drug plus 6 percent. The pharmacy rate of reimbursement, when the Part B rate is not available, is defined in this state at the time this report was published as the lower of (1) AWP minus a negotiated percentage, (2) the federal upper limit, or (3) the maximum allowable ingredient cost. The federal upper limit is the maximum amount of matching federal funds that CMS will provide to states for certain multiple-source prescription drugs—that is, those drugs with three or more versions that either produce the same clinical effect and have the same safety profile or that contain the same active ingredient(s) in the same dosage form and meet strength and other applicable standards. 42 U.S.C. § 1396r-8(e)(4). The maximum allowable cost is the maximum allowable payment established by the state Medicaid program.

⁶¹Costs for drugs provided in inpatient settings are typically accounted for in the rate set for the overall charge for the hospital stay, such as under a per diem charge or a diagnosis-related group—a system that classifies inpatient stays according to both beneficiaries' clinical conditions (the primary diagnosis along with any secondary illnesses and complications developed during the stay) and the procedures beneficiaries receive.

generally pay a preset rate for the cost to deliver inpatient services, including any compounded drugs administered as part of the services;⁶² the use of a particular drug—including a compounded drug—would not generally change the inpatient payment rate for a given service.

Medicare's Payment Policy for Compounded Drugs under Part B Is Unclear

Medicare's Part B national payment policy for compounded drugs is unclear. The policy notes that federal law requires that drugs be reasonable and necessary in order to be covered under Medicare Part B and indicates the agency's view that, to be considered reasonable and necessary, FDA must have approved the drug for marketing.⁶³

Accordingly, the policy instructs Medicare contractors and insurers that offer Medicare Advantage plans to deny payments for drugs that have not received final marketing approval by FDA. The policy also indicates that payment is available for compounded drugs; however, it does not stipulate whether payment is available for ingredients in compounded drugs that are FDA-approved products only or whether it is also available for those ingredients that are bulk drug substances that have not been approved by FDA.⁶⁴ As noted above, most of the Part B contractors do not require providers to submit NDCs for compounded drug ingredients to determine whether these ingredients are FDA-approved products or bulk drug substances and, therefore, may be paying for ingredients that are not FDA-approved. Because Medicare Part B policy for compounded drugs is unclear, it is uncertain whether payment for such ingredients is consistent with that policy.

⁶²Officials from the remaining insurer told us that because the insurer purchases drugs and drug ingredients for its health care facilities directly from manufacturers, it is able to determine whether a compounded drug was administered to a beneficiary as part of the inpatient service.

⁶³Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual*, Chapter 15 – Covered Medical and Other Health Services (Baltimore, Md.: May 10, 2013).

⁶⁴Medicare's Part B payment policy may not apply to certain compounded drugs, such as infusion drugs administered through implantable pumps, because these drugs can be paid for under the Part B durable medical equipment benefit or under Part D. Infusion therapy is the administration of medication through a needle or catheter, such as intravenously. Infusion drugs may need to be compounded because commercially available drugs may not be available in necessary doses for infusion therapy. We previously examined Medicare's and private insurers' policies for home infusion drugs. See GAO, *Home Infusion Therapy: Differences between Medicare and Private Insurers' Coverage*, [GAO-10-425](#) (Washington, D.C.: June 7, 2010).

In addition to having unclear policies, CMS does not know how much it has paid for compounded drugs under Part B, the number of compounded drug claims it paid, or whether compounded drugs paid for under Part B were made using bulk drug substances. Having access to such information may help ensure that payment for such drugs is consistent with CMS policy. CMS lacks this information because the agency does not collect any information that the contractors responsible for processing Medicare Part B claims obtain during their review of claims with the nonspecific HCPCS code, including amounts paid to providers for compounded drugs based on the invoice price, which CMS officials attributed to limitations in claims processing systems. In April 2014, HHS OIG reported on payments for compounded drugs in Medicare Part B and found that neither CMS nor its contractors track compounded drug claims and confirmed what CMS officials told us about neither the agency nor the contractors being able to determine the total number of these claims, or CMS's payments, for compounded drugs. HHS OIG recommended that CMS establish a method specifically to identify compounded drugs on those Part B claims that contain the nonspecific HCPCS code in order to track compounded drug claims, as these claims undergo manual review because of the code and not because they are for compounded drugs. HHS OIG also found that, while most Medicare contractors require providers to list the individual ingredients that made up a compounded drug billed under the nonspecific HCPCS code in a text field on a claim, they do not require NDCs for these ingredients. NDCs could be used to (a) identify whether an ingredient is an FDA-approved product or a bulk drug substance and (b) help determine ingredient price for the purposes of calculating payment.⁶⁵ In August 2014, CMS officials told us that the agency was working to implement HHS OIG's recommendation regarding a compounded drug indicator for Part B claims. Without specific information indicating whether a beneficiary received a compounded drug in an outpatient setting or what ingredients made up the compounded

⁶⁵Department of Health and Human Services, Office of Inspector General, *Compounded Drugs under Medicare Part B: Payment and Oversight*. In addition, HHS OIG found that Medicare Part B contractors representing 10 of the 13 Part B regions paid providers based on invoice price of the drug or the purchase price set by the compounding pharmacy that made the drug, rather than according to common drug pricing benchmarks. To conduct its work, HHS OIG surveyed and asked for supplemental information from the nine contractors responsible for processing Medicare Part B claims in CMS's 13 regions as of December 2012; all nine contractors responded to HHS OIG's request for information.

drug, CMS may be may be paying for such drugs in a manner that is inconsistent with its policy.⁶⁶

Payment Practices, among Other Factors, May Affect the Use of Compounded Drugs

Officials from the public programs and private health insurers we spoke with generally agreed that payment practices for compounded drugs may affect the use of these drugs. Officials from CMS, one state Medicaid program, three of the five insurers, the two Part D-only sponsors, and the three PBMs with whom we spoke stated that payment practices for compounded drugs did affect their use, specifically when public programs and private health insurers excluded payments for bulk drug substances in retail pharmacy settings. In most cases, payment exclusions for bulk drug substances resulted in a decreased use of compounded drugs in these insurers' plans, particularly for compounded drugs dispensed in pharmacy settings. For example, according to CMS, a 2012 analysis of Part D data showed that compounded drugs comprised less than one percent of all Part D claims in that year, which is likely due at least in part to Part D drug rules that exclude payment for bulk drug substances. CMS officials told us that the small number of claims for compounded drugs is a result of the law limiting Medicare Part D payment to FDA-approved drugs. The Part D sponsor that pays for bulk drug substances in compounded drugs saw its costs for these bulk drug substances increase significantly between January 2012 and March 2014 and, as a result, will cease payments for these substances by March 2015. In contrast to this sponsor, officials from two insurers that do not pay for bulk drug substances in their Medicare Advantage plans that include Part D benefits told us that payments for compounded drugs have remained generally steady, with no significant increases or decreases. The experiences of the Part D sponsor and the two insurers suggest that Part D payment practices may affect the use of compounded drugs. Further, officials from one of the three insurers that pay for ingredients that are FDA-approved products only and do not pay for bulk drug substances in their private health plans in the commercial market told us that these practices have resulted in a decrease in compounded drug

⁶⁶Federal internal control standards call for agencies to have the information they need in a form that enables them to carry out internal control and other responsibilities and, on a day-to-day basis, to make operating decisions and allocate resources. GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00.21.3.1](#) (Washington, D.C.: November 1999). Internal control is synonymous with management control and comprises the plans, methods, and procedures used to meet missions, goals, and objectives.

claims and payments. For example, officials from one of the insurers told us that, in 2011, the insurer's payments for compounded drugs decreased by 205 percent in the quarter after it ceased paying for bulk drug substances.

Officials from one insurer that limits payment to only FDA-approved drugs in its private health plans in the commercial market and officials from one PBM expressed concern that manufacturers of bulk drug substances and outsourcing facilities are inflating the AWP of the bulk drug substances used to make compounded drugs. Further, these officials, as well as officials from two other PBMs, told us that outsourcing facilities are actively marketing their products to physicians, who may not know what ingredients these products contain or be sure of the compounded products' clinical benefits. Officials from one PBM said several of these outsourcing facilities are pushing certain compounded drugs onto the market through partnerships they have established with physicians who own shares in these facilities.

Officials from the majority of associations representing health care providers we spoke with cited factors other than payment practices that affect the use of compounded drugs—primarily individual patient need and drug shortages. Officials from CMS and some of the states and insurers we spoke with also told us that these factors affected the use of compounded drugs. For example, officials from CMS, 11 associations, 3 insurers, and 2 pharmaceutical standards-setting organizations told us that physicians primarily prescribe compounded drugs due to individual patient needs such as (1) the lack of a commercially available product for a patient's specific treatment needs; (2) a patient's allergy to an inactive ingredient, such as a dye or a filler, in an available FDA-approved drug; (3) a patient's need for a different delivery format for the drug, such as a patient who cannot swallow pills and needs a liquid formulation; or (4) a patient's need for custom dosage requirements, such as a pediatric patient who needs a lower dosage of a commercially available drug. In addition to individual patient need, officials from 7 of the 11 associations and 2 state Medicaid programs we spoke with also cited shortages of certain FDA-approved drugs as a significant factor contributing to the

need to prescribe and use compounded drugs.⁶⁷ For example, officials from one association told us that nutrition drugs that need to be administered intravenously are frequently in shortage. Patients who need these nutrition drugs sometimes require a combination of more than 20 drugs, all of which are FDA-approved. However, according to officials from this association, many of these FDA-approved nutrition drugs have been in shortage since 2010 and, therefore, clinicians have to use compounded intravenous nutrition drugs made with bulk drug substances instead.

Conclusions

Compounded drugs account for a small but likely growing percentage of all prescription drugs dispensed in retail pharmacies, but the number of these drugs administered in outpatient settings—as well as how much public programs and private health insurers are paying for them—is unknown. The lack of information about use and payments results from the fact that, unlike retail claims, outpatient health insurance claims, including Medicare Part B claims, may not contain information specific enough to identify whether a compounded drug was administered or what ingredients were used to make it. Medicare Part B policy for payment for compounded drugs is also unclear and instructs CMS contractors to deny payment for non-FDA-approved drugs but is silent with respect to whether payment is available for ingredients—namely, bulk drug substances—in a compounded drug that are not FDA-approved. In addition, CMS may be unable to appropriately apply Medicare payment policy because CMS's Medicare contractors do not collect information needed to determine whether each ingredient used to make a compounded drug administered in an outpatient setting is FDA-approved. As a result, CMS may have paid for compounded drugs containing bulk drug substances in outpatient settings inconsistently with its payment policy and incurred additional expenses in the process. In April 2014, HHS OIG recommended that CMS establish a method to identify Part B claims for compounded drugs, which could also help CMS to appropriately apply its payment policy.

⁶⁷We previously reported on drug shortages in February 2014 and found that shortages are primarily due to quality problems resulting in supply disruptions, coupled with constrained manufacturing capacity. See [GAO-14-194, Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability](#), (Washington, D.C.: Feb. 10, 2014).

Recommendation for Executive Action

To help ensure that Medicare Part B is able to appropriately apply its payment policy for compounded drugs, we recommend that the Secretary of Health and Human Services direct the Administrator of the Centers for Medicare & Medicaid Services to clarify the Medicare Part B payment policy for compounded drugs and, as necessary, align payment practices with the policy. For example, CMS should consider updating the Medicare Part B payment policy to either explicitly allow or restrict payment for compounded drugs containing bulk drug substances and, as appropriate, develop a mechanism to indicate on Medicare Part B claims both whether a beneficiary received a compounded drug and the drug's individual ingredients in order to properly apply this policy and determine payment.

Agency Comments and Our Evaluation

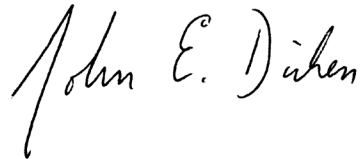
We provided a draft of this report to HHS for review, and its comments are reprinted in appendix I. In its comments, HHS disagreed with our recommendation that CMS clarify the Medicare Part B payment policy and align payment practices with the policy as necessary. HHS also provided technical comments, which we incorporated as appropriate.

In disagreeing with our recommendation to clarify the Medicare Part B payment policy, HHS stated that it did not believe that clarifying the policy to specifically address payments for bulk drug substances was necessary at this time. HHS commented that the Part B payment policy does not currently distinguish between compounded drugs that contain bulk drug substances and compounded drugs that contain FDA-approved products but, rather, recognizes differences between compounded drugs and FDA-approved manufactured drugs. According to HHS, the policy allows for payment for compounded drugs prepared in a manner that does not violate the FDCA and does not permit payment for drugs manufactured or otherwise prepared in a manner that is inconsistent with the FDCA. As we state in the report, the Part B policy indicates the agency's view that, to be eligible for Medicare coverage, FDA must have approved the drug for marketing, while at the same time indicating that payment is available for compounded drugs. We also note that neither bulk drug substances nor compounded drugs, regardless of their ingredients, are generally approved by FDA. Based on HHS's comments, CMS does not consider the FDA-approval status of compounded drug ingredients in making Part B payment determinations and focuses on whether the drug was prepared in a manner consistent with the FDCA. We appreciate HHS's explanation of this distinction; however, we maintain that the Part B policy should be clarified to explicitly contain this exception for compounded drugs.

With regard to HHS's comment that payment is not made for drugs manufactured or otherwise prepared in a manner that is inconsistent with the FDCA, including cases in which FDA has determined that a company is producing compounded drugs in violation of the FDCA—such as a company compounding drugs on a large scale that resembles manufacturing—the extent to which CMS ensures compliance with this policy is unclear. As noted by HHS OIG in its April 2014 report on Medicare Part B payments for compounded drugs, Medicare contractors generally review claims for compounded drugs to determine payment amounts and assign payments on the basis of the description of the drug given by the provider on the claim. The HHS OIG report was silent on whether the contractors also review these claims to determine who produced the compounded drug but noted that CMS contractors, whose specific policies and requirements for claims vary, do not necessarily require providers to submit this information. As we note in the report, and as the HHS OIG report confirmed, CMS does not collect information from the Medicare contractors on payments for compounded drugs, and neither CMS nor its contractors track claims or payment amounts for these drugs. Therefore, CMS does not know what compounded drugs the contractors paid for or whether the contractors were able to determine whether the company that produced the compounded drug had been found by FDA to be in violation of the FDCA for the purposes of denying payment in adherence with the Part B policy. In addition, it is unclear whether CMS contractors are collecting sufficient information to identify specific bulk drug substances used to make compounded drugs. This information will be necessary for the contractors to make payment determinations when FDA finalizes its lists of bulk drug substances that may or may not be used for compounding under the FDCA.

In addition, HHS commented on the limitations of the Part B claims systems that would prevent CMS from collecting detailed information, such as NDCs of drug ingredients, from claims. However, HHS noted that CMS concurred with the HHS OIG recommendation to develop a modifier or other mechanism to identify claims for compounded drugs, which is consistent with our recommendation. In light of CMS's inability to obtain detailed information about compounded drug ingredients collected by its contractors, we remain concerned that the agency is unable to ensure that payments are made in accordance with the Part B policy.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of Health and Human Services. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>. If you or your staffs 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 may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix II.



John Dicken
Director, Health Care

List of Congressional Requesters

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

The Honorable Jim McDermott
Ranking Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Appendix I: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 23 2014

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

Dear Mr. Dicken:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Compounded Drugs: Payment Practices Vary Across Public Programs and Private Insurers, and Medicare Part B Policy Should Be Clarified" (GAO-14-831).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: COMPOUNDED DRUGS: PAYMENT PRACTICES VARY ACROSS PUBLIC PROGRAMS AND PRIVATE INSURERS, AND MEDICARE PART B POLICY SHOULD BE CLARIFIED (GAO-14-831)

The Department appreciates the opportunity to review and comment on this draft report.

GAO Recommendation

We recommend the Secretary of Health and Human Services direct the Administrator of the Centers for Medicare & Medicaid Services (CMS) to clarify the Medicare Part B payment policy for compounded drugs and, as necessary, align payment practices with the policy. For example, CMS should consider updating the Medicare Part B payment policy to either explicitly allow or restrict payment for compounded drugs containing bulk substances; and as appropriate, develop a mechanism to indicate on Medicare Part B claims whether a beneficiary received a compounded drug and its individual ingredients in order to properly apply this policy and determine payment.

HHS Response

HHS non-concurs with GAO's recommendation. HHS does not agree that clarification about the use of bulk ingredients in compounded drugs is necessary at this time. In general, Part B policy does not prohibit the use of bulk substances in compounded drugs. As stated in Chapter 17, Section 20.1.2 of the Claims Processing Manual, Medicare Administrative Contractors (MAC) are responsible for pricing compounded drugs, and the MACs may establish additional limitations or restrictions on payments for these drugs.

A recent report by the Office of Inspector General (OIG) (OEI-03-13-00270), which is referenced in footnote 18 on page 5 of this GAO report, accurately summarized Medicare Part B payment policy for compounded drugs. Page 3 of the OIG report states that: "Generally, compounded drugs are eligible for coverage under Medicare Part B. However, when FDA determines that an entity is producing compounded drugs in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), Medicare does not pay for these drugs."

The Part B policy for compounded drugs generally does not distinguish between compounded drugs that contain bulk drug substances or those prepared from FDA-approved drug products. Instead, Medicare Part B policy recognizes differences between compounded drugs and FDA-approved manufactured drugs. Payment for compounded drugs is permissible provided that the compounded drugs are prepared in a manner that does not violate the FDCA. Payment is not made for drugs that are manufactured or otherwise prepared in a manner that is not consistent with the FDCA, including in those cases in which the FDA has determined that a company is producing compounded drugs in violation of the FDCA.

We would also like to note that in response to the above-referenced OIG report, CMS indicated concurrence with a recommendation to identify compounded Part B drug claims and described a possible approach for addressing this matter. However, because the Part B claims system uses Healthcare Common Procedure Coding System (HCPCS) billing codes and has limitations regarding additional information that can be included on a claim and then archived and retrieved, HHS would not be able to obtain detailed information such as ingredient NDCs on each claim. When making payment and medical necessity determinations on compounded drug claims, Part

B MACs collect and utilize additional data, such as drug ingredients. As reported by OIG on page 8 of the above-referenced report, MACs review all claims for compounded drugs.

We thank GAO for their efforts regarding this complicated issue.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

John 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; Jyoti Gupta; and Laurie Pachter made key contributions to this report.

Related GAO Products

Compounded Drugs: TRICARE's Payment Practices Should Be More Consistent with Regulations. [GAO-15-64](#). Washington, D.C.: October 2, 2014.

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

Medicaid Prescription Drugs: CMS Should Implement Revised Federal Upper Limits and Monitor Their Relationship to Retail Pharmacy Acquisition Costs. [GAO-14-68](#). Washington, D.C.: December 19, 2013.

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

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