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FEDERAL GOVERNMENT PRESCRIPTION DRUG PRICING: STATUTORY, REGULATORY & CONTRACTUAL APPROACHES TO COST CONTAINMENT

By Jeffrey L. Handwerker, Michael J. Ruggiero, John T. Gould, and Walter F. Zenner

The enactment by Congress of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)[1] has spurred public debate about the most effective methods to contain the cost of prescription drugs purchased or paid for by the Federal Government. Through various programs—the Veterans Health Administration run by the Department of Veterans Affairs, the TRICARE program run by the Department of Defense, the Federal Employees Health Benefits Program (FEHBP) run by the Office of Personnel Management, Medicare run by the Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services, and state Medicaid programs that are partially federally funded and regulated—the Federal Government is already a significant presence in the market for prescription drugs. With the enactment of the MMA, the Government will soon expand its presence by making a wide variety of outpatient prescription drugs available to all 42 million of Medicare's beneficiaries. As a result, pharmaceutical manufacturers, pharmacy benefit managers (PBMs), insurance companies, and retail pharmacies alike can expect that the Federal Government will account for a significantly larger share of the prescription drug market.

IN BRIEF

Accordingly, it will be important for these companies to gain a better understanding of the Federal Government's involvement in this market and the unique statutory, regulatory, and contractual requirements that the Government imposes on them. These requirements vary from program to program, particularly in the ways in which they seek to control the

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prices that the Government pays for prescription drugs. At one end of the spectrum are programs that use direct Government price controls, such as statutory rebates and price ceilings. Medicaid, for instance, relies on both of these mechanisms. Similarly, the VA uses statutory price ceilings, augmented by various contractual means of regulating prices, such as bargaining with selected pharmaceutical manufacturers for reduced pricing in return for limiting the number and types of competing drugs available to veterans. Falling in the middle of the spectrum is the DOD TRICARE program for military service members and their families, which combines elements of the VA system with elements of free-market competition. At the other end of the spectrum is the FEHBP for civilian Government employees, which relies largely on competition among providers. Similarly, the new Medicare Part D drug benefit created by the MMA will rely on free-market competition among multiple prescription drug plans, with no direct involvement by the Government in negotiations concerning price or the number and types of drugs available.

After providing an overview of the size of the Government's presence in the market for prescription drugs, this BRIEFING PAPER describes the principal programs— Medicaid, the VA system, TRICARE, the FEHBP, and the Medicare Part D program— under which the Government provides or pays for prescription drugs, focusing on the various statutory, regulatory, and contractual methods by which the Government seeks to contain drug costs. Where relevant, the PAPER notes the resulting tradeoffs of these methods in terms of the ability of beneficiaries under the various programs to obtain the full range of prescription drugs available in the market. Finally, the PAPER offers practice pointers to pharmaceutical manufacturers, PBMs, insurance companies, and retail pharmacies that wish to participate in these programs to aid them in developing a better understanding of the Government's approaches to regulating drug prices.

Federal Prescription Drug Market

The Federal Government presently accounts for a large volume of the sales of prescription drugs in the United States, both in dollar terms and as a percentage of the entire market. For instance, federal Medicaid spending amounts to more than $14.2 billion annually, accounting for 10% of the market for retail prescription drugs.[2] The three FEHBP plans that cover over half of all enrollees in that program spent $3.3 billion for prescription drugs in 2001,[3] and the VA annually spends more than $3.4 billion dollars on pharmaceuticals.[4] Medicare, which already covers physician-administered drugs, spent approximately $6 billion on such drugs in 2001.[5] By greatly expanding coverage of outpatient drugs, the MMA will substantially increase that figure.

In the discussion below, it will be useful to keep in mind that the nature of the Government's participation in the prescription drug market through these programs is two-fold. Under some programs, the Government itself provides health care to beneficiaries. For example, this is true of the VA, which delivers drugs and health care services to its beneficiaries by means of phar-

BRIEFING PAPERS® (ISSN 0007-0025) is published monthly except January (two issues) and copyrighted © 2005 ■ Valerie L. Gross, Editor ■ Periodicals postage paid at St. Paul, MN ■ Published by Thomson/West / 610 Opperman Drive, P.O. Box 64526 / St. Paul, MN 55164-0526 ■ http://www.west.thomson.com ■ Customer Service: (800) 328-4880 ■ Postmaster: Send address changes to Briefing Papers / 610 Opperman Drive, PO Box 64526 / St. Paul, MN 55164-0526

macies and facilities that it owns and operates. Under other programs, the Government is only a third-party payor. This is true of Medicaid, the FEHBP, and Medicare, under which private entities provide health care to beneficiaries, and the Government only pays for that health care. Finally, under TRICARE, the Government is both a provider and a third-party payor. The distinction between care provider and third-party payor is significant here, because it determines whether the Government actually purchases prescription drugs or only pays for purchases made by others, and that in turn influences the methods available to the Government to contain costs.

With that background, we turn to an examination of the principal programs under which the Federal Government participates in the market for prescription drugs and its various approaches to regulating the cost of those drugs. We start at the direct Government price control end of the spectrum and proceed to programs that rely on free-market competition.

Medicaid

Medicaid is a health insurance program for low-income people. It is administered by the states, each of which runs its own program, subject to limited federal oversight. As long as a state's program meets various federal requirements (such as covering certain basic services), it receives federal matching funds. Currently, all states (and the District of Columbia) have chosen to cover outpatient prescription drugs—that is, drugs delivered to beneficiaries via retail pharmacies or, in some states, mail order pharmacies. To contain costs, Medicaid programs rely principally on *statutory rebates* and *price ceilings*.

■ Statutory Rebates

In 1990, Congress responded to rising Medicaid drug costs by enacting the Omnibus Budget Reconciliation Act of 1990 (OBRA 90),[6] which, among other things, created the Medicaid drug rebate program. OBRA 90 limits the availability of federal matching funds for prescription drug benefits to drugs made by manufacturers that agree to provide rebates.[7] These rebates equal a per drug "unit rebate amount" multiplied by the number of the units of that drug dispensed to Medicaid beneficiaries. The unit rebate amount depends on whether the drug is a brand-name drug or a generic drug. For brand-name drugs, the unit rebate amounts equal 15.1% of the average manufacturer price (AMP) or, if it is more, the difference between the AMP and the manufacturer's "best price" for the drug. Brand-name drugs are also subject to an "additional rebate" that depends upon inflation. For generic drugs, the unit rebate amount equals 11% of the AMP.[8]

AMP is defined as the average price paid by U.S. wholesalers for "drugs distributed to the retail pharmacy class of trade."[9] As originally contemplated, best price was defined as the lowest price offered to virtually any purchaser, including Federal Government purchasers. Today, for reasons explained below, best price is generally the lowest price offered to U.S. wholesalers, retailers, providers, health maintenance organizations (HMOs), nonprofits, or to government entities *other than* the VA, the DOD, and certain other federal purchasers.[10]

To help enforce compliance with these requirements, rebate agreements require manufacturers to calculate and report the AMP and best price (the latter for brand-name drugs only) to the CMS each calendar quarter.[11] These reports are subject to the False Claims Act (FCA),[12] which imposes civil penalties on anyone who knowingly presents or causes to be presented a false or fraudulent claim for payment or approval by the Government. (Thus, the False Claims Act applies to manufacturers' submissions of pricing data under not only the Medicaid program but also all of the other programs discussed in this PAPER.) Additionally, the Medicaid rebate statute provides its own penalties for false (or untimely) reports.[13]

■ Statutory Price Ceilings

The Federal Government has also attempted to contain Medicaid drug costs by taking steps to cap the payments that states make to pharmacies dispensing drugs to Medicaid benefi-

ciaries. In general, such payments can be no greater than the lowest of (1) the estimated acquisition cost, plus a reasonable dispensing fee, (2) the providers' usual and customary charges to the public for the drug, or (3) a federal upper limit amount (FUL), where applicable.[14] The FUL is applicable only to drugs with multiple brand or generic versions; it equals 150% of the published price of the least costly version, plus a reasonable dispensing fee.[15] The prices used to calculate the FUL are those published in standard reference books on prescribing and pricing drugs (such as the First Data Bank Blue Book, Red Book, or Medi-Span).

Because the Government has not defined the term "estimated acquisition cost," the foregoing formula gives the states broad discretion to determine the prices that they will pay pharmacies under Medicaid. In many instances, states have developed their own varying definitions for "estimated acquisition cost," often based on what is known as average wholesale price (AWP). This, too, is a term with no single formal definition, but it is generally understood to be the price at which a manufacturer recommends that a wholesaler sell a particular type of drug to subsequent purchasers.[16] AWP data can be found in the standard reference books mentioned above.

■ Other Cost Containment Measures

In addition to federally mandated rebates and price ceilings, states have implemented their own Medicaid cost containment measures.[17] For example, some states have required pharmacies to substitute less expensive generic drugs for brand-name drugs. Additionally, some states have leveraged formularies—lists of preferred drugs that beneficiaries can receive without preauthorization review—to negotiate lower drug prices or supplemental rebates. Because including its drugs on a formulary (or having its competitors' drugs excluded) will typically increase a manufacturer's sales, manufacturers often accept lower prices in exchange for preferred formulary treatment. As discussed below, the Federal Government uses similar methods in other programs.

VA System

The VA provides health care benefits to military veterans who served on active duty and meet certain other eligibility criteria. To apply for these benefits, most veterans must enroll with the VA, which gives priority access to veterans with service-connected disabilities or limited financial means.[18] As of October 2003, almost 7.2 million veterans were enrolled with the VA, making them eligible for prescription drug benefits.[19] The VA makes drugs available to its beneficiaries at pharmacies located in VA hospitals and through its mail order pharmacy, known as the Centralized Mail Order Pharmacy (CMOP).

To regulate its purchases of prescription drugs, the VA currently uses a combination of statutory price ceilings, contracting regulations, formulary restrictions, and volume-based discounts.

■ Statutory Price Ceilings

The VA's current approach to prescription drug acquisition grows out of its recent history. Up until 1990, the VA was able to purchase drugs at prices that were among the lowest that manufacturers charged to anyone in the United States.[20] The VA was able to obtain these prices because its facilities trained a large number of medical residents and students, which led pharmaceutical companies to offer the VA low prices in the hopes of influencing the long-term prescribing practices of these residents and students. This practice had little financial impact on manufacturers because the VA accounted for only about 1.5% of the national market for prescription drugs.[21]

This situation changed in 1990, however, when Congress passed OBRA 90 and thereby created the Medicaid rebate program discussed above. As noted, under that program, manufacturers are required to pay rebates that go up as their best prices go down. As OBRA 90 defined the term, a manufacturer's best price was the price it charged the VA, if that was the lowest price it charged to anyone.[22] For many manufacturers, the prices they charged the VA were in fact

their lowest prices and, therefore, they became their best prices for purposes of the Medicaid rebate program. While the manufacturers were willing to offer steep discounts to the VA, they apparently were not willing to pay equivalent rebates to Medicaid, which represented 15% of the market. This led many manufacturers to increase the prices that they charged the VA. The ripple effect of this phenomenon on the VA and on the veterans it served was pronounced. Because the VA was operating on a fixed budget, it was forced to institute rationing practices that reduced the quality of care provided to veterans. Congress had not anticipated this result and found it unacceptable.[23]

To remedy this problem, Congress enacted the Veterans Health Care Act of 1992 (VHCA).[24] The VHCA exempted certain prices charged to the Federal Government, including those charged to the VA, from Medicaid best price calculations.[25] Additionally, the VHCA conditioned federal payment for brand-name drugs (which the VHCA refers to as "covered drugs") on manufacturers meeting two important requirements.[26]

First, the VHCA required manufacturers that wished to sell covered drugs to the Federal Government to enter into Federal Supply Schedule (FSS) contracts for those drugs.[27] FSS contracts are open-ended agreements that aggregate the Government's purchasing power by permitting multiple Government agencies (and certain other approved buyers) to purchase commonly used commercial products and services at predetermined prices, typically incorporating volume-based discounts. Companies with FSS contracts list their products and services in a "schedule" from which agencies may order, much as one orders from a catalog.[28]

Second, the VHCA required manufacturers to enter into "master agreements" and "pharmaceutical pricing agreements" with the VA for each of their covered drugs. These agreements obligate manufacturers to charge the VA, the DOD, the Public Health Service (which includes the Indian Health Service), and the Coast Guard—collectively known as the Big Four—no more than the federal ceiling price (FCP) for drugs procured by the Government under FSS contracts or other bulk purchasing and distribution arrangements known as "depot contracting systems."[29] Before explaining what the FCP is, it will be useful to describe "depot contracting systems," particularly since the definition of this term will be relevant in connection with the TRICARE Retail Pharmacy Program discussed below.

A "depot" is a centralized commodity warehouse system through which covered drugs procured by the Government are received, stored, and delivered through (a) a federally owned and operated warehouse system or (b) a commercial entity operating under contract with a federal agency.[30] Alternatively, a depot contracting system can take the form of an arrangement in which a federal agency procures covered drugs from a commercial source that delivers them directly to the entity needing the drugs.[31] Historically, depot systems were Government-owned-and-operated warehouses in which products were stockpiled for Government use. Subsequently, the Government hired purchasing agents, known as prime vendors, to manage the Government's drug purchasing efforts. Because a prime vendor is "a commercial entity operating under contract" with the Government, this type of arrangement falls within the statutory definition of depot contracting system.[32]

The FCP for a given drug is derived from two separate discounts. The first is a 24% discount from the manufacturer's average price for that drug to wholesalers for the previous year (known as the nonfederal average manufacturer's price (non-FAMP")).[33] The second is an additional discount that is calculated based on the annual change in the commercial price of a covered drug and the Consumer Price Index for all urban consumers.[34] (Multiyear contracts are subject to a further price limitation—contract prices cannot increase faster than the Consumer Price Index for all urban consumers.[35]) The manufacturer's average price, or non-FAMP, consists of the average of drug prices paid by U.S. wholesalers for drugs destined for retail pharmacies, hospitals, and other nonfederal end users.[36] This method for determining non-FAMP is notable in that it takes into account a broader base of transactions than

the method for determining Medicaid's AMP, which is the average only of purchases for the retail pharmacy class of trade.[37]

The VHCA imposes significant penalties on manufacturers that fail to comply with its requirements: The Government may refuse to pay for covered drugs purchased by the Big Four, by entities that receive funds under the Public Health Service Act, and, most importantly, by state Medicaid programs and Medicare Part B.[38] To facilitate the Government's ability to monitor and enforce compliance with these requirements, including adherence to the FCP, the VHCA requires manufacturers to disclose pricing-related information to the Government.[39]

In addition to these requirements, the VHCA established the so-called "340B Program."[40] As a condition for covering their drugs under Medicaid, the 340B Program requires pharmaceutical manufacturers to enter into agreements with HHS obligating them to sell their drug products to "covered entities" at or below statutorily defined "ceiling prices.[41] For a brand-name drug, the ceiling price is the difference between its AMP and its unit rebate amount, where the unit rebate amount is either 15.1% of the AMP or, if it would be more, the difference between the AMP and the product's best price.[42] "Covered entities" can include federally qualified health center look-a-likes, disproportionate share hospitals, family planning clinics, sexually transmitted disease clinics, tuberculosis clinics, AIDS clinics, black lung clinics, and health centers servicing migrant workers, Native Americans, or Native Hawaiians.[43] Manufacturers must make their 340B ceiling (or sub-ceiling) prices available to these entities or to wholesalers that distribute drugs to these entities.[44]

■ Contractual Bargaining

In addition to the price constraints required by law, the VA also employs a variety of contractual approaches to further minimize its drug expenditures.

First, the VA seeks additional price concessions (beyond the FCP) for drugs acquired under FSS contracts. Each FSS contract contains a "Price Reductions" clause.[45] Under that clause, manufacturers are required to identify a "basis of award" (BOA) customer that will be used to establish the FSS price. Usually, the BOA customer is the commercial customer that receives the manufacturer's best price. Through this process of identifying a BOA customer (backed up by the Government's audit rights under FSS contracts[46]), the VA is able to obtain FSS prices that are as low as, or lower than, the best prices that manufacturers charge to any of their commercial customers for similar purchases.[47] Furthermore, if a manufacturer subsequently reduces its BOA price, it must offer a proportional price reduction to the Government.[48] To finance its administration of the FSS program, the VA charges the manufacturers a fee known as the "industrial funding fee" (IFF), which is based on a percentage of each manufacturer's sales under its FSS contracts.[49]

Of note, for their FSS contracts, manufacturers are permitted to offer "dual pricing"—that is, one price for the Big Four and another price for other agencies. Dual pricing is possible because the FCP caps what a manufacturer may charge the Big Four, but does not apply to the other Government agencies eligible to make purchases under FSS contracts.[50] Accordingly, the manufacturer may opt to charge the Big Four the FCP and charge the other agencies a higher price. Alternatively, the manufacturer may opt to offer the same price to all FSS purchasers, in which case the price must be at or below the FCP.

Second, the VA often seeks to obtain lower prices (that is, pricing lower than FSS prices and the FCP) by concentrating its purchases on a smaller number of drugs within a drug class. As some states do under Medicaid, the VA does this by restricting the number of drugs on its formularies. Although drugs that are not on the formulary can be prescribed by special request, formulary restrictions can increase the volume of sales of the drugs that are included on the formulary. The VA uses a number of contractual devices to capture these price concessions, such as "national contracts" under which the VA commits to satisfy all of its needs for a product from a given manufacturer. The sav-

ings attributable to these contracts can be substantial. As of February 2000, there were 308 drugs covered by both a national contract and an FSS contract. On average, the national contract prices for these drugs were approximately 33% lower than the FSS contract prices.[51] The tradeoff for these savings, of course, is that formulary restrictions limit the ability of VA physicians to prescribe drugs that are not on the formulary and thus limit patient access to needed medicines.

TRICARE

TRICARE is a health care benefits program under which the DOD provides managed health care benefits—including a prescription drug benefit—to more than 8 million active-duty and retired military personnel and their family members.[52] Within the last two years, TRICARE has undergone significant changes, including a congressionally mandated transition to a new prescription drug regime intended to be more integrated and cost-effective than the previous regime. This new prescription drug regime seeks to contain costs by means of a combination of periodic competition among benefit providers, the use of a uniform formulary throughout TRICARE, economic incentives for beneficiaries to use the most cost-effective drugs and means of obtaining them, and, potentially, a requirement for pharmaceutical manufacturers to provide refunds to the DOD.

Under the TRICARE program, the DOD provides health care benefits both directly through a system of military hospitals and clinics (known as military treatment facilities (MTFs)) and acts as a third-party payor by contracting with private health care providers and related entities that in turn deliver health benefits (a system formerly known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)). Within the DOD, the TRICARE Program is overseen by the Under Secretary of Defense for Health Affairs and administered by the TRICARE Management Activity (TMA).[53]

As noted, TRICARE includes a prescription drug benefit, termed the "Pharmacy Benefits Program."[54] Under this program, the TMA provides prescription drug benefits to its beneficiaries via three channels, or "points of service": (1) the MTFs themselves, (2) the TRICARE Mail Order Program (TMOP), and (3) the TRICARE Retail Pharmacy Program (TRRx). Each of these points of service has traditionally imposed differing levels of financial responsibility and incentives on beneficiaries, implemented via cost sharing. As detailed below, there have been recent changes to the third of these channels—the TRRx Program—and to the overall Pharmacy Benefits Program.

Previously, TRICARE implemented the TRRx Program through a system of regional managed-care contractors, which in turn subcontracted with PBMs to acquire, deliver, and distribute prescription drugs to TRICARE beneficiaries through networks of retail pharmacies located within their respective regions. In 2003, as part of a larger restructuring effort involving a consolidation of the TMA's regions and the award of a new generation of managed-care contracts within the newly formed regions, the TMA "carved out" certain specialized pieces of the previous generation of managed-care contracts for competition on a stand-alone, national basis.[55] Among these carve-outs was the TRRx Program. In late 2003, TMA awarded a nationwide TRRx prime contract to a single PBM.[56]

More broadly, at the direction of Congress, the TMA in 2004 announced significant changes to the overall Pharmacy Benefits Program. The principal change involves the establishment of a uniform formulary that will be generally applicable to the entire TRICARE program— that is, to all three TRICARE points of service. Previously, the availability to a TRICARE beneficiary of specific prescription drugs varied depending on the point of service providing the drugs to the beneficiary. Most significantly, the MTFs made use of a basic core formulary (as augmented by any additional drugs that a particular MTF decided to offer), while the retail pharmacy networks used "open" formularies. Believing that such an approach provided cost incentives not in keeping with current commercial practice, Congress enacted legislation in 1999 that directed the DOD to establish an "integrated" Phar-

macy Benefits Program, including, as its principal component, a uniform formulary for all three points of service. Congress instructed that, in establishing the formulary, the DOD take into account both clinical effectiveness and cost effectiveness. Congress also required the DOD to make nonformulary drugs available to TRICARE beneficiaries through at least one of the three points of service. Additionally, Congress authorized the DOD to create a "tiered" prescription co-payment structure.[57]

In response to this legislation, the DOD in April 2004 issued regulations implementing a revised TRICARE Pharmacy Benefits Program.[58] As directed by Congress, these regulations provided for the creation and maintenance of a uniform formulary generally applicable to all three TRICARE points of service. The regulations generally allow access to medically necessary prescription drugs, including those that may not be listed on the uniform formulary, through at least two of the three points of service. But the regulations also include provisions aimed at controlling the costs of providing prescription drugs, *first*, by mandating the substitution of generic drugs for brand-name drugs absent clinical necessity for the brand-name drug, and, *second*, by providing incentives for using formulary drugs.[59]

The regulations provide incentives to purchase formulary drugs by creating a tiered cost-sharing arrangement applicable to all TRICARE beneficiaries aside from those on active duty.[60] This cost-sharing arrangement consists of a structure that varies depending largely on two factors: (1) where the prescription is filled (that is, the point of service), and (2) the status of the drug prescribed (that is, whether it is classified as a generic drug, a formulary drug, or a nonformulary drug). [61]

While the details are complicated, the cost-share structure favors purchases at MTFs or through the mail order program over retail pharmacy purchases, and it favors purchases of generic and formulary drugs over nonformulary drugs. Thus, in terms of point of service, the beneficiary has no cost share for prescriptions filled at MTFs (which, as described below, have access to federal pricing for purchases of prescription drugs). There are cost shares, however, for prescriptions filled by mail or at retail pharmacies, and cost shares for the latter are higher, particularly for non-network pharmacies. In terms of drug status, generic drugs have the lowest cost shares, formulary drugs fall into the middle, and nonformulary drugs have the highest cost shares.[62]

In addition to these incentives, the uniform formulary regulations establish a formulary selection process that explicitly takes cost considerations into account in developing the formulary. The regulations establish a DOD Pharmacy and Therapeutics Committee (P&T Committee) charged with determining which drugs in each class will qualify for formulary status.[63] One of the factors that the P&T Committee must consider is the cost effectiveness of a drug, including the "[c]ost of the pharmaceutical agent to the Government" and the "[e]xistence of existing or proposed blanket purchase agreements, incentive price agreements, or contracts."[64] In December 2004, the DOD announced that the P&T Committee would use the FSS price to determine cost effectiveness with respect to the mail order and MTF points of service and the FCP to determine cost effectiveness for the retail pharmacy point of service. At the same time, the DOD strongly encouraged manufacturers to submit "uniform formulary blanket purchase agreements" offering deeper discounts.[65]

Despite the new formulary regulations, the DOD currently does not pay FCP or FSS prices for all prescription drugs dispensed to TRICARE beneficiaries. While the MTFs and the TMOP contractor have access to these prices (explaining in part the reason for structuring the cost-share incentives so as to encourage beneficiaries to fill prescriptions at MTFs or through the mail order program), retail pharmacies selling directly to TRICARE beneficiaries may pay pharmaceutical manufacturers commercial prices (directly or through a wholesaler). The DOD, the third-party payor with respect to this point of service, ultimately pays these commercial prices. Accordingly, TRICARE recently launched an initiative under which, beginning in March 2005, it intends to require manufacturers to pay it refunds on prescription drugs purchased by

TRICARE beneficiaries at TRICARE's approximately 53,000 retail network pharmacies. Through these refunds, TRICARE aims to achieve a final cost for each drug approximating its FCP.

The VA has supported the DOD's initiative. In October 2004, the VA sent manufacturers a letter asserting that the TRRx program qualifies as a "depot contracting system" under the VHCA and, as such, the DOD is entitled to pay no more than FCP for drugs beneficiaries receive from retail pharmacies.[66] Nonetheless, there are lingering questions, along with pending litigation, concerning the legal authority for the DOD's initiative. Additionally, the General Services Administration recently published a proposed rule that would affect drug pricing under the TRRx Program.[67] If adopted, the rule would insert in FSS contracts a clause that would treat retail pharmacy sales under the TRRx Program as sales to the DOD under the FSS contract. Consequently, the DOD could seek refunds from manufacturers based on FSS pricing for drugs sold through the TRRx program, and the VA could seek the IFF for those sales. The proposed rule raises a number of legal questions. Manufacturers and other organizations wishing to submit comments to the GSA must do so by June 13, 2005.

Federal Employee Health Benefits Program

In 1959, Congress established the FEHBP, a high-quality health insurance benefit intended to enable the Government to compete with private-sector employers in attracting talented employees by offering commensurate health care benefits.[68] The OPM, which administers the FEHBP, is authorized to contract with a variety of health insurance plan types, including fee-for-service (FFS) plans, plans sponsored by federal employee and postal organizations, and health maintenance organizations (HMOs). Generally, the OPM contracts with all plans that satisfy the minimum standards set forth in regulations, thereby maximizing enrollee choice.[69] As of 2002, the FEHBP covered 8.3 million beneficiaries.[70]

To contain costs, the OPM relies principally on competition among the various health plans. This competition relates not so much to gaining approval to participate in the FEHBP in the first instance, as to enrolling sufficient numbers of employees after gaining approval. The impact of this competition is reflected in the process by which the OPM enters into agreements with plans. In April of each year, the OPM circulates a "call letter" inviting plans to submit proposals for the benefit packages they would offer to enrollees during the following calendar year, specifying premium rates, deductibles, and cost-sharing amounts. The plans typically submit proposals offering differing benefits and cost shares. The OPM reviews these proposals and negotiates with the various plans to finalize their aggregate benefits packages. The scope of those negotiations is relatively limited, however, because the OPM is charged only with ensuring that each plan's premium "reasonably and equitably" reflects the cost of the benefit package that it is offering.[71]

Consequently, the OPM generally does not demand that a particular plan make specific revisions to its proposal with respect to the benefits that are offered or the costs that are charged. For example, in the call letters that the OPM issued in 2001 and 2002, it urged plans to control the rising costs of prescription drugs by adopting formularies and multi-tiered benefits.[72] But the OPM did not condition its acceptance of any plan on the adoption of such measures. And once the OPM accepts a plan into the FEHBP, the plan's contract is presumptively renewable, even if it modifies its benefit package over time.[73] Thus, in contrast to the VA and TRICARE, the OPM does not negotiate directly with manufacturers or rely on price controls or rebates to regulate drug prices.

As noted, the real incentives for cost containment in the FEHBP system stem from competition among the various plans to enroll employees. Toward the end of the calendar year, federal employees enter an open enrollment period during which each employee may select his or her health plan for the coming year. Regardless of the plan selected, each employee is responsible for paying a portion of the premiums for the plan. Under the FEHBP statute, the Government generally pays 72% of

the weighted average premium of all FEHBP plans, but no more than 75% of any one plan's premium, while the employees pay the remainder.[74] The employee's portion of the premium can vary from plan to plan. Accordingly, to attract enrollees, plans have an incentive to maximize the benefits they offer and to minimize the premiums they charge. If a plan does not remain competitive, it risks losing enrollees and then potentially being dropped from the program, since the OPM can refuse to renew the contract of any plan that has failed to enroll at least 300 federal employees or retirees in each of the two preceding contract years.[75]

Medicare Part D Program

The MMA was signed into law in December 2003, becoming the most recent and significant expansion of the Federal Government's role in the market for prescription drugs. Among other things, the MMA established a new Medicare "Part D" outpatient prescription drug benefit, which is scheduled to begin operating in January 2006.[76] Once this Part D benefit begins, Medicare beneficiaries who choose to enroll in a Part D prescription drug plan will be entitled to receive greatly expanded outpatient prescription drug benefits,[77] subject to certain deductible and cost-sharing obligations.[78] In January 2005, the CMS issued a final rule implementing the Part D benefit.[79] At the same time, the CMS also issued solicitations for bids from plans wishing to participate in Part D.[80] The CMS expects that these solicitations will lead to contract awards by late 2005.

As discussed below, the Medicare Part D program design is similar to the FEHBP, but it differs fundamentally from most other federal health care programs in relying exclusively on commercial transactions between private entities—rather than on statutory price controls or other forms of Government intervention in the market—to regulate prescription drug costs.

■ Contract Award Process

As noted, the CMS has solicited the first bids for the new Part D prescription drug benefit. To be eligible for consideration, a bidder must be a private, risk-bearing plan licensed in the states in which it will offer the benefit.[81] Eligible plans include both stand-alone prescription drug plans (PDPs) and Medicare Advantage prescription drug plans (MA-PDPs), which are plans offering both Medicare Advantage benefits under existing Part C and prescription drug benefits under new Part D. Under the MMA, the CMS is required to divide the country into "PDP regions,"[82] and it has established 34 PDP regions for the Part D drug benefit.[83] The CMS must award contracts to at least two plans in each region, and it must award at least one of the two contracts in each region to a stand-alone PDP.[84]

The MMA specifies that these contracts will require the plans to bear significant financial risk. If the CMS is unable to contract with two plans in a given region, the CMS may award "limited risk" contracts or, as a last resort, nonriskbearing "fallback" contracts, under which the CMS would reimburse the plan's actual costs of providing Part D benefits.[85] An entity may not offer a fallback plan if it has submitted a bid for a risk-based Part D plan.[86] These fallback plans are akin to cost-reimbursement contracts, whereas risk-bearing plans have attributes of fixed-price contracts in the sense that the risk of cost overruns is borne by the contractor, subject to certain limitations. The statute provides for reinsurance and risk-adjusted subsidies to Part D plans that limit the plans' risk exposure.[87]

The MMA allows the CMS to enter into Part D contracts "without regard to such provisions of law or regulations relating to the making, performance, amendment or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose" of the statute.[88] Pursuant to this authority, the CMS has exempted contracts for risk-bearing, limited-risk, and fallback plans from the Federal Acquisition Regulation, including FAR Part 15, which governs the negotiation and award of most procurement contracts.[89] But the CMS does plan to use the "competitive procedures" of the FAR for fallback contracts.[90]

In their bids for Medicare Part D contracts, plans must address certain items. These include

(1) the PDP region for which the plan is bidding, (2) a description of its formulary and Part D benefits package, including the deductible and other costs payable by the beneficiaries, (3) a certified actuarial valuation of the benefits package, conducted in accordance with actuarial methodologies established by the CMS, (4) an estimate of the plan's average monthly revenue requirements to provide coverage for a Part D eligible individual with a national average risk profile, (5) a description of the costs for which the plan is responsible, and (6) the amount of the plan's administrative costs and return on investment and profit.[91]

The MMA permits the CMS to approve a plan only if it (a) is based on valid actuarial determinations, (b) meets the requirements for Part D coverage, and (c) does not discourage enrollment of particular classes of beneficiaries, such as those needing more expensive drugs.[92] As discussed in further detail below, the CMS has indicated it might seek to examine data concerning specific discounts and other price concessions that a plan obtains from drug manufacturers, and it might disapprove a bid if it determines that the underlying drug prices do not reflect "market rates."[93]

Plans seeking Medicare Part D contracts had to submit an application by March 23, 2005, and must electronically submit their proposed formularies to the CMS by April 18, 2005. The CMS will then negotiate formularies with applicant plans between May 2, 2005, and May 18, 2005, and allow resubmission of formularies between May 18, 2005, and May 31, 2005. To be compliant, a proposed formulary must include (1) a formulary notes file, providing explanations about the plan's exceptions processes, and if necessary, additional details about dosage form or strength restrictions, and (2) step-therapy-algorithm and prior-authorization-criteria files, to the extent plans intend to use such utilization management tools. The plans also must electronically submit bids to the CMS between May 20, 2005 and June 6, 2005.[94]

Plans can seek to protect any proprietary or confidential information under Exemption 4 of the Freedom of Information Act[95] by properly labeling such information in the bid submission and explaining why the exemption applies.[96] CMS has indicated plans must show that (a) disclosure will likely impair the Government's ability to obtain information in the future, (b) disclosure will likely cause substantial competitive harm to the submitter, and (c) the records are valuable commodities that will lose substantial market value upon disclosure.[97]

Plans must acknowledge in their bid submissions that they will implement a fraud-and-abuse compliance program, and they must describe their program in detail.[98] In addition, plans must certify that all of the information that they submit is accurate and complete and that it conforms to regulatory requirements.[99]

■ Statutory Mandate For Competition

Central to the Part D program is the MMA's "noninterference" provision, which expressly prohibits the CMS from (1) interfering with negotiations among drug manufacturers, PDPs, and pharmacies, (2) requiring PDPs to use a particular formulary, or (3) instituting a price structure for the reimbursement of drugs provided under Part D.[100] This provision is intended to stimulate competition[101] and will provide Medicare beneficiaries and the Medicare program the benefit of any discounts that the plans are able to obtain through private negotiations.[102]

The noninterference provision prominently distinguishes Medicare Part D from other federal health care programs. Rather than imposing discounts by law or contract (as Medicaid, VA and TRICARE do), Part D will seek to obtain discounts by encouraging competition among plans, manufacturers, and pharmacies. Furthermore, by prohibiting the CMS from requiring a particular formulary for Part D benefits,[103] the noninterference provision permits Part D plans to fashion their formularies in accordance with private market practices as long as other Part D requirements are met, such as those concerning actuarial equivalence, nondiscrimination, and the minimum number of drugs required in each formulary category and class.[104] Where only one drug exists for a particular therapeutic category class, only that drug need be included.[105]

■ CMS's Interpretation Of The Noninterference Provision

The CMS has stated that, while it interprets the MMA as prohibiting it from regulating the prices of particular drugs or imposing discounts in the aggregate (as the VA does), it does not interpret the MMA as prohibiting it from obtaining justification for "aggregate price levels for groups of drugs."[106] Thus, as the CMS stated in its final rule, where a plan's bid differs "significantly" from other bids, the CMS may request pertinent information from the plan. In particular, the CMS might request information about the specific rebates and discounts that the plan has negotiated with manufacturers or retail pharmacies—that is, "inquire as to the 'net cost' of drugs."[107] The CMS also might request an explanation of the plan's pricing structure and the nature of its arrangements with manufacturers.[108] According to the CMS, the purpose of such requests would be to enable it to make "apples to apples" comparisons of the drug prices of different PDPs, so that it can ensure robust negotiations between PDPs and manufacturers.[109] Where the CMS determines that bids are "unjustifiably high," it may attempt to negotiate the bids down to levels "in keeping" with bids from other sponsors, or disapprove a bid where it determines that the bid and its underlying drug prices do not reflect market rates.[110]

In the Part D final rule, the CMS responded to comments that such scrutiny of PDP negotiations with manufacturers could exceed its authority under the MMA. First, the CMS stated its view that while the MMA's noninterference provision prohibits the CMS from setting drug prices or requiring average discounts, the provision does not preclude it from "requir[ing] justification of aggregate price levels" or otherwise "negotiat[ing] the level of the overall bid,"[111] both of which the CMS believes would permit it to ask for specific plan pricing data. Second, the CMS pointed out that that the MMA provides that its negotiating authority under the MMA is "similar" to the OPM's authority with respect to the FEHBP.[112] According to the CMS, this MMA provision authorizes it to reserve negotiating authority to ensure "reasonable and equitable" bids.[113] Finally, the CMS cited its "general authority" to negotiate the terms and conditions of submitted bids and proposed plans.[114] The CMS went on to emphasize, however, that it will "rely on competition rather than negotiation" to the maximum extent feasible, and that it will sparingly use its limited authority to negotiate with plans.[115] The CMS also said that it does not intend to "universally" require detailed pricing information, and that requests for such information will be based on questions triggered by an initial bid submission.[116]

In the event that the CMS does request detailed pricing information, a plan should (as explained above) be sure to label the information as confidential and submit a written explanation of why the information is protected by FOIA Exemption 4. The CMS indicated in the final rule an intent that, under these circumstances, price and cost information marked as confidential will "generally" be protected by the Trade Secrets Act, [117] a criminal provision prohibiting Government employees from publicly disclosing trade secrets.[118] This position finds support in case law holding that specific pricing information, such as rebates and other contractual arrangements, may constitute trade secrets,[119] or, at a minimum, confidential information protected from disclosure under FOIA Exemption 4.[120]

■ Other MMA Contracting Reforms

Besides creating the Part D prescription drug benefit, the MMA significantly changed the rules governing the negotiation and award of contracts with insurers for the administration of Medicare Part A (hospital benefits) and Part B (physician and other services). Among other changes, the MMA makes the FAR applicable to these contracts, fosters competition by enabling more firms to bid for these contracts, and contemplates consolidating the distinct roles played by two different types of contractors, known as "carriers" and "intermediaries," into a single type of contractor known as a Medicare Administrative Contractor (MAC).[121] Medicare plans to award the first MAC contract by December 2005, and to have its contracting reforms fully in effect by 2011.[122]

★ GUIDELINES ★

These *Guidelines* are intended to assist potential suppliers of prescription drugs purchased or paid for by the Federal Government in understanding the basic policies, procedures, and rules applicable to those sales. They are not, however, a substitute for professional representation in any specific situation.

1. Recognize that pharmaceutical manufacturers, health insurance companies, PBMs, pharmacy chains, and others participating in federal prescription drug programs need to be aware of the different pricing and reporting rules that apply to each of the various programs.

2. Remember that manufacturers of both brand-name and generic drugs must pay rebates on drugs supplied to Medicaid beneficiaries, and they must report pricing information to permit the Government to verify the calculation of these rebates. To avoid penalties under fraud and abuse laws, manufacturers must ensure the accuracy of the drug pricing information that they submit to the Government, whether for Medicaid or any other program.

3. Be aware that if manufacturers selling covered prescription drugs to the Big Four agencies—the DOD, the VA, the PHS, and the Coast Guard—charge more than the statutorily mandated federal ceiling price, they risk losing significant federal business.

4. Keep in mind that the VA routinely seeks to negotiate prices below FCPs. In connection with the FSS program, the VA requires manufacturers to identify a basis-of-award customer, which is generally the customer or class of customers to whom a manufacturer offers its best prices. The VA then seeks equally favorable pricing. If a manufacturer fails to accurately identify its basis-of-award customer and accurately report the prices that it charges that customer, it is at risk of incurring penalties.

5. Be cognizant that the VA also uses formulary restrictions and special types of contracts, such as national contracts, to obtain further price concessions from selected manufacturers in exchange for agreeing to purchase certain minimum volumes from those manufacturers or to fill all of its requirements for a particular type of drug by means of those manufacturers' products. Such agreements may limit the choices available to VA beneficiaries.

6. Bear in mind that the DOD has recently restructured its TRICARE health care system to include a uniform formulary under which the same prescription drugs will be available through all three TRICARE points of service. The FCP serves as a cap on the prices that the DOD pays under this new system for drugs furnished through two of the three points of service, but not currently for those furnished through retail pharmacies. The DOD and the VA, however, are attempting to extend the FCP to retail pharmacy transactions. In any event, TRICARE's cost-sharing rules provide beneficiaries with economic incentives to use the two points of service that are subject to the FCP.

7. Remember that the Government first introduced a "competition" health care pricing model in 1959 through the FEHBP and that all plans that meet certain minimum requirements are eligible to participate in the FEHBP. The FEHBP promotes market-based competition among plans by permitting employees to switch to a different plan every year and by making employees responsible for paying a portion of the costs of the plans. Although the OPM has authority to negotiate with participating plans concerning the overall amount of their rates and the nature of the benefits offered, it has not participated directly in negotiations between participating plans and manufacturers, doctors, or pharmacies.

8. Consider that CMS's final rule implementing the Medicare Part D prescription drug program suggests that the CMS may attempt to influence negotiations to some extent between participating plans, manufacturers, and retail pharmacies.

9. Be aware that the CMS has solicited bids by health plans wishing to become PDPs or MA-PDPs. These procurements generally will not

be subject to the FAR, although the CMS does plan to follow FAR competition requirements with respect to "fallback" plans. The CMS plans to execute contracts with approved bidders in late 2005. The CMS will consider offering protection under FOIA and the Trade Secrets Act to bids that are marked with the appropriate legend.

10. Note that the MMA has changed the rules by which the CMS will negotiate and award contracts for the administration of Medicare Parts A and B, including a determination that such contracts will be governed by the FAR. Those insurers that have in the past decided not to bid on these contracts may want to reconsider in light of these changes.

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