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United States Government Accountability Office
Washington, DC 20548

April 30, 2009

The Honorable Edward M. Kennedy
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate

Subject: *Federal Employees Health Benefits Program: Enrollee Cost Sharing for Selected Specialty Prescription Drugs*

Dear Mr. Chairman:

Recent increases in prescription drug costs have been fueled in part by the high and rising cost of specialty prescription drugs.[1] Specialty prescription drugs are typically used to treat chronic or life-threatening conditions, such as multiple sclerosis and cancer, for which few other treatment options exist. The drugs typically have few competitors or generic alternatives and may require frequent dosage adjustment, special storage, patient education, or special methods of administration, such as by injection. Costs for specialty prescription drugs are usually high, typically ranging from $1,200 to $40,000 for a 30-day supply. Health plans—including those participating in the Federal Employees Health Benefits Program (FEHBP), which covers nearly 8 million federal employees, dependents, and retirees—provide coverage for many specialty drugs. Enrollees may be required to pay a portion of specialty drug costs through a copayment—a flat dollar amount—or coinsurance—a percentage share of the drug's actual costs.[2] To manage the high and rising costs of these drugs, some health plans have begun to require enrollees to contribute a greater share of their costs, such as by increasing the use of coinsurance. You asked us to examine the costs that FEHBP enrollees may incur for specialty prescription drugs. In this report we describe cost-sharing requirements and limits for specialty drugs covered by FEHBP plans.

[1]Drug costs have increased about 3 to 6 percent a year from 2004 to 2008, while specialty prescription drug costs increased 18 to 20 percent a year over the same period. Specialty drugs represented about 20 percent of total drug spending in 2008. The Health Industry Forum, *Managing Specialty Pharmaceuticals: Balancing Access and Affordability, Conference Report* (Washington, D.C.: 2008).

[2]For this report, "enrollees" refers to all individuals covered under FEHBP plans: federal employees, dependents, and retirees.

To obtain this information, we reviewed literature and consulted experts[3] to identify commonly used specialty prescription drugs in key therapeutic classes,[4] without lower cost alternatives. We identified 18 such drugs—3 drugs in each of 6 therapeutic classes.[5] We analyzed information from 184 FEHBP plans[6] regarding the cost sharing for a 30-day supply of these drugs through the plans' prescription drug benefit for the 2009 benefit year.[7] In particular, plans reported coinsurance or copayments for the specialty drugs; other out-of-pocket costs, such as deductibles; and limits on cost sharing, such as annual out-of-pocket maximums and per prescription dollar maximums, which limit an enrollee's cost for each prescription. To determine the number of enrollees in each plan, we used 2008 FEHBP enrollment data obtained from the Office of Personnel Management (OPM), the agency that administers FEHBP. Enrollment in these plans totaled nearly 7.8 million or 99.5 percent of total FEHBP enrollment in 2008.[8] To estimate the potential annual cost to enrollees for certain specialty drugs reviewed based on various cost-sharing arrangements, we used drug cost data obtained from the Web site of a large national FEHBP plan.

We relied on the data as reported by the plans and did not independently verify the data. However, we did review all plan responses for reasonableness and consistency, and we clarified apparent irregularities by reviewing plan benefit brochures and contacting plan representatives. Based on these activities, we determined the data were sufficiently reliable for the purpose of our report. We conducted our work from November 2008 to April 2009 in accordance with all sections of GAO's Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for any findings and conclusions.

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[3]We contacted three researchers—two with doctorate degrees in pharmacy and one with a doctorate in economics—who published studies within the last 3 years relating to specialty drug issues, including cost and health plan benefit designs. The researchers work at a university, a research institute, and in the private pharmaceutical industry.

[4]A therapeutic class is a group of drugs that are similar in chemical structure, pharmacological effect, or clinical use.

[5]The 18 specialty drugs by therapeutic class are (1) cancer: Gleevec, Lupron Depot, and Tarceva; (2) multiple sclerosis: Avonex, Betaseron, and Rebif; (3) rheumatoid arthritis, psoriasis, and inflammatory conditions: Enbrel, Humira, and Remicade; (4) anemia and blood cell deficiencies: Aranesp, Epogen, and Procrit; (5) hepatitis C: Infergen, Pegasys, and Peg-Intron; and (6) growth hormone deficiencies: Genotropin, Humatrope, and Norditropin/NordiFlex.

[6]When a FEHBP plan offered multiple benefit options, we counted each option as a separate plan, for a total of 269 plans. We contacted 189 of the 269 FEHBP plans. These 189 plans represented 99.5 percent of total FEHBP enrollment in 2008. We received information regarding specialty drug coverage from each plan we contacted, for a 100 percent response rate. We excluded from our analysis 5 plans that responded but did not have enrollment in 2008. We asked plans to provide cost-sharing information for the drugs obtained in the manner resulting in the lowest cost to enrollees—that is, through retail, mail order, or specialty drug pharmacies. We requested cost information based on a 30-day supply of each drug reviewed because some plans limit specialty drug prescriptions to this quantity. However, some plans noted that enrollees may obtain the drug in a 90-day supply and incur lower unit costs.

[7]Drugs covered through a plan's prescription drug benefit may also be available through the plan's medical benefit if obtained in a therapeutic setting, such as a doctor's office. Drugs covered under the medical benefit are subject to their own cost-sharing limits.

[8]The enrollment data were also used to calculate weighted averages.

In summary, enrollees in FEHBP plans are subject to varying cost-sharing requirements for the 18 specialty drugs. More than 6.6 million of the nearly 7.8 million enrollees in the plans we reviewed (86 percent) are generally subject to copayments that limit enrollee costs to about $55 on average for a 30-day supply of the drugs. Nearly 900,000 enrollees (11 percent) are subject to coinsurance for more than 1 of the 18 specialty drugs, which requires the enrollees to pay on average nearly 31 percent of the cost of the drugs. About 700,000 of the enrollees subject to coinsurance are in plans requiring it for all 18 of the drugs. Enrollees' coinsurance costs for specialty drugs are typically limited by per prescription dollar maximums or annual out-of-pocket limits. Depending on the plan, these varying requirements can result in a wide range of costs for enrollees for the same drug. For example, we estimate that an enrollee taking the multiple sclerosis drug Betaseron for a year could pay $420 if subject to a copayment, $2,400 if subject to a coinsurance with a per prescription dollar maximum, or $6,000 if subject to a coinsurance with an annual out-of-pocket maximum.

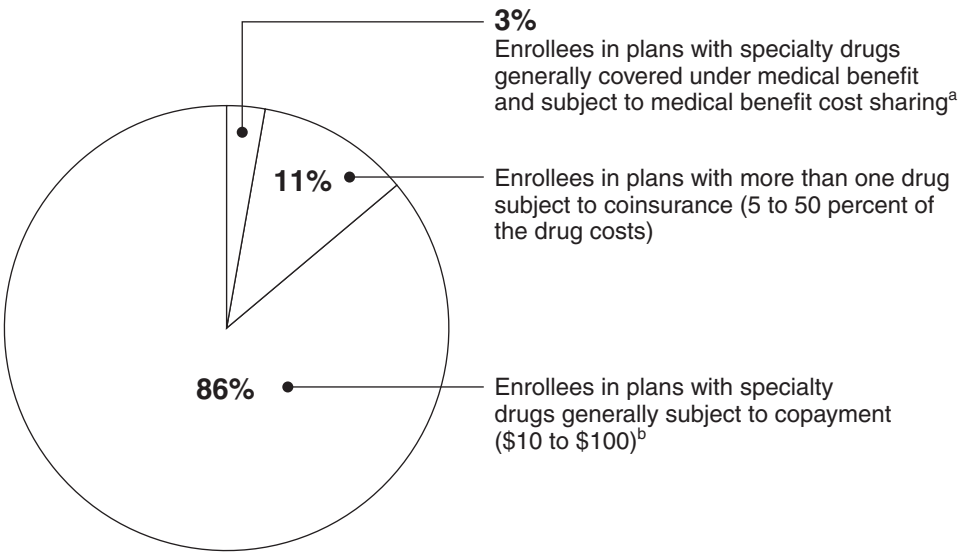
Cost Sharing for Selected Specialty Drugs

More than 6.6 million of the nearly 7.8 million FEHBP enrollees in plans we reviewed (86 percent) are generally subject to copayments that limit enrollee costs to about $55 on average for a 30-day supply of the drugs. About 11 percent of the enrollees are in plans that reported requiring coinsurance for more than one drug.[9] Reported coinsurance ranged from 5 to 50 percent and averaged nearly 31 percent of the drug cost. Just 3 percent of the enrollees are in plans that reported covering most of the specialty drugs only under the medical benefit of the plan, as opposed to the prescription drug benefit.[10] (See fig. 1.)

[9]One plan, with about half of all FEHBP enrollees, requires coinsurance for only one drug we reviewed—Epogen—when obtained from retail pharmacies. The coinsurance results in the lowest cost to enrollees; however, the drug is also available through a mail order pharmacy for a $65 copayment.

[10]Drugs covered under a plan's medical benefit are obtained in a therapeutic setting, such as a doctor's office. The cost to enrollees may include the cost sharing associated with an office visit, such as a copayment, and may require additional cost sharing associated with the drug.

Figure 1: FEHBP 2009 Cost-sharing Requirements for 18 Specialty Drugs by Enrollment



Source: GAO analysis of FEHBP plan-reported data.

Notes: Analysis was based on 2009 cost-sharing data and 2008 FEHBP enrollment for 179 plans, the most current data available at the time we conducted our analysis.

The 18 specialty drugs by therapeutic class are (1) cancer: Gleevec, Lupron Depot, and Tarceva; (2) multiple sclerosis: Avonex, Betaseron, and Rebif; (3) rheumatoid arthritis, psoriasis, and inflammatory conditions: Enbrel, Humira, and Remicade; (4) anemia and blood cell deficiencies: Aranesp, Epogen, and Procrit; (5) hepatitis C: Infergen, Pegasys, and Peg-Intron; and (6) growth hormone deficiencies: Genotropin, Humatrope, and Norditropin/NordiFlex.

Five plans, with approximately 0.1 percent of total enrollment, require no cost sharing for most of the specialty drugs we reviewed, and were thus excluded from this figure.

[a]Drugs covered under a plan's medical benefit are obtained in a therapeutic setting, such as a doctor's office. Medical benefit cost sharing may include the cost sharing associated with an office visit, such as a copayment, and may require additional cost sharing associated with the drug.

[b]Includes one plan with about 50 percent of total enrollment that requires a 30 percent coinsurance for one drug—Epogen—when obtained from retail pharmacies. The coinsurance results in the lowest cost to enrollees; however, the drug is also available through a mail order pharmacy for a $65 copayment.

Close to 900,000 enrollees are in 50 plans with coinsurance for more than 1 specialty drug we reviewed, and about 78 percent of those are in plans with coinsurance for all 18 drugs. (See table 1.) Of the 18 specialty drugs we reviewed, the 3 growth hormone deficiency drugs, the 3 hepatitis C drugs, and 2 rheumatoid arthritis drugs—Enbrel and Humira—were subject to coinsurance most often. The rheumatoid arthritis drug, Remicade, and the cancer drug, Lupron Depot, were least often subject to coinsurance.

Table 1: Enrollees in FEHBP Plans with Coinsurance for More than 1 of the 18 Specialty Drugs Reviewed

Number of drugs with coinsurance	Enrollees	Percentage of enrollees
18	692,677	77.7
17	16,225	1.8
15	43,933	4.9
14	22,503	2.5
13	18,146	2.0
11	18,871	2.1
10	49,033	5.5
9	3,037	0.3
3	27,549	3.1
Total	**891,973**	**100%**

Source: GAO analysis of FEHBP plan-reported data.

Notes: Analysis was based on 2009 cost-sharing data and 2008 FEHBP enrollment in 50 plans, the most current data available at the time we conducted our analysis.

The 18 specialty drugs by therapeutic class are (1) cancer: Gleevec, Lupron Depot, and Tarceva; (2) multiple sclerosis: Avonex, Betaseron, and Rebif; (3) rheumatoid arthritis, psoriasis, and inflammatory conditions: Enbrel, Humira, and Remicade; (4) anemia and blood cell deficiencies: Aranesp, Epogen, and Procrit; (5) hepatitis C: Infergen, Pegasys, and Peg-Intron; and (6) growth hormone deficiencies: Genotropin, Humatrope, and Norditropin/NordiFlex.

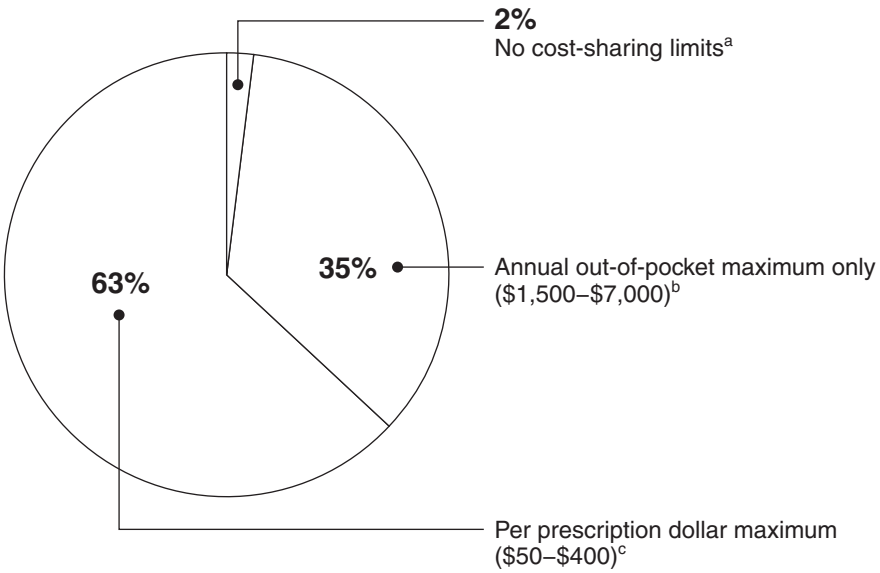
Cost-sharing Limits for Selected Specialty Drugs Subject to Coinsurance

Though coinsurance requires enrollees to pay a share of the high cost of selected specialty drugs, most plans limit these out-of-pocket costs. For example, of the nearly 900,000 enrollees subject to coinsurance for more than one specialty drug we reviewed, 63 percent are in plans that limit enrollees' costs with a per prescription dollar maximum for a 30-day supply of a drug. Some plans with per prescription dollar maximums also have an annual out-of-pocket maximum that applies to the specialty drugs reviewed, which would provide further limits to enrollees' out-of-pocket spending. Another 35 percent of enrollees are in plans that do not use per prescription dollar maximums but limit drug costs with annual out-of-pocket maximums. Per prescription dollar maximums reported by plans ranged from $50 to $400, averaging $143 for a 30-day supply. Annual out-of-pocket maximums ranged from $1,500 to $7,000, or $4,264 on average.[11] The remaining 2 percent of enrollees subject to a coinsurance for selected specialty drugs do not have any limits to their cost sharing for drugs covered under their plans' prescription drug benefit.[12] (See fig. 2.) The enclosure to this report categorizes FEHBP plans requiring coinsurance for selected specialty drugs by their methods for limiting enrollees' cost sharing.

[11]Annual out-of-pocket maximums can apply to enrollees' costs for drugs only or can also apply to other out-of-pocket costs, such as doctor's office copayments.

[12]These individuals are enrolled in two plans: Anthem Blue Cross-HMO-high with 45 percent coinsurance and Amerihealth HMO-high with 50 percent coinsurance.

Figure 2: FEHBP 2009 Cost-sharing Limits for 18 Specialty Drugs Subject to Coinsurance, by Enrollment



Source: GAO analysis of FEHBP plan-reported data.

Notes: Analysis was based on 2009 cost-sharing data and 2008 FEHBP enrollment in 50 plans, the most current data available at the time we conducted our analysis.

The 18 specialty drugs by therapeutic class are (1) cancer: Gleevec, Lupron Depot, and Tarceva; (2) multiple sclerosis: Avonex, Betaseron, and Rebif; (3) rheumatoid arthritis, psoriasis, and inflammatory conditions: Enbrel, Humira, and Remicade; (4) anemia and blood cell deficiencies: Aranesp, Epogen, and Procrit; (5) hepatitis C: Infergen, Pegasys, and Peg-Intron; and (6) growth hormone deficiencies: Genotropin, Humatrope, and Norditropin/NordiFlex.

[a]One plan will limit cost sharing to a $30 copayment if the prescribing physician requires the prescription to be dispensed as written with no permitted substitutions.

[b]Annual out-of-pocket maximums can apply to drugs only or also to other out-of-pocket costs for medical services, such as doctor's office copayments.

[c]Some plans with per prescription dollar maximums also have an annual out-of-pocket maximum that applies to the specialty drugs reviewed, which could further limit enrollees' out-of-pocket spending.

Examples of Enrollees' Annual Out-of-pocket Costs for Certain Specialty Drugs

Depending on the cost-sharing requirements and limits imposed by a plan, enrollees could pay a significantly different amount for the same drug. While most enrollees have their costs limited by fixed copayments, those subject to coinsurance may be responsible for much higher costs. For example, under the scenarios described in table 2, below, based on an estimated total cost of $2,300 for a 30-day supply of Betaseron,[13] an enrollee's annual out-of-pocket costs for this drug could range from $420 with a $35 monthly copayment to $6,000 with an annual out-of-pocket limit of $6,000. Under these cost-sharing arrangements, enrollees would have the same range of out-of-pocket costs for a 30-day supply of Humira, based on an estimated total cost of $1,500.[14] (See table 2.)

[13]Drug cost data were obtained from the Web site of one FEHBP plan with high enrollment.

[14]Health plans may have different costs for the same drug depending on their prescription drug provider.

Table 2: Estimated Annual Cost in 2009 of Betaseron and Humira for FEHBP Enrollees under Four Cost-sharing Scenarios

				Estimated annual cost to enrollee	
Cost-sharing scenario	**Cost sharing**	**Per prescription dollar maximum**	**Annual out-of-pocket maximum**	**Betaseron**	**Humira**
Copayment only	$35 copayment	None	None	$420	$420
Per prescription dollar maximum	25% coinsurance	$200	None	$2,400	$2,400
Annual out-of-pocket maximum	50% coinsurance	None	$6,000	$6,000	$6,000
No cost-sharing limits	45% coinsurance	None	None	$12,420	$8,100

Source: GAO analysis of FEHBP plan-reported data.

Agency Comments

We provided a draft of this report to OPM for comment. OPM did not comment on GAO's analysis of the data provided by the FEHBP plans, but did provide technical comments to clarify the coverage of specialty drugs by certain plans. We contacted officials of these plans to confirm the information they had originally provided. In response to OPM's technical comments and our follow up with the plans, we made changes to the report as appropriate.

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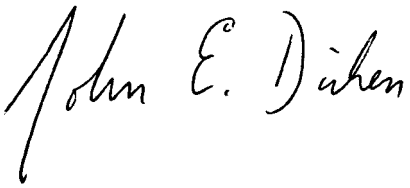
As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Director of OPM. The report will also be available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report were Randy DiRosa, Assistant Director; Daniel Lee; Sari B. Shuman; Timothy Walker; and Margaret J. Weber.

Sincerely,



John E. Dicken
Director, Health Care

Enclosure

Table 3: Cost-sharing Limits in FEHBP Plans with Coinsurance for More than 1 of the 18 Specialty Drugs in 2009

Per prescription dollar maximum
American Postal Workers Union Health Plan—consumer driven health plan (CDHP)
American Postal Workers Union Health Plan—high
Association Benefit Plan—high
Capital District Physicians' Health Plan (Capital Region)—high[a]
Capital District Physicians' Health Plan (Capital Region)—standard[a]
Connecticare—basic
Connecticare—high
Dean Health Plan—high[a]
Foreign Service Benefit Plan—high
GEHA Benefit Plan—high[a]
Healthpartners Three for Free—standard[b]
Medica Health Plan—high[c]
Presbyterian Health Plan—high[d]
Presbyterian Health Plan—standard[d]
SAMBA Health Benefit Plan—standard[a]
Triple-S (Puerto Rico)—high[e]
Unicare Health Plans—high[a]
Unicare Health Plans—standard[a]
VISTA Healthplan of Southern Florida—high
Annual out-of-pocket maximum only
Altius Health Plans—high deductible health plan (HDHP)
Altius Health Plans—high
Amerihealth HMO—standard
Aultcare—HDHP
AV-MED Health Plan (Miami)—high
AV-MED Health Plan (Miami)—standard
Blue Preferred HMO—high
Firstcare (Central Texas)—high
Firstcare (West Texas)—high
GEHA Benefit Plan—HDHP
GEHA Benefit Plan—standard
Grand Valley Health Plan—high
Grand Valley Health Plan—standard
Health Alliance HMO—high
Health Alliance HMO—standard
Healthpartners Open Access Copay—high
Humana (Puerto Rico)—high
Humana Coveragefirst (Cincinnati)—CDHP
Humana Coveragefirst (Tampa)—CDHP

Humana Health Plan (Chicago)—high
Humana Health Plan (Chicago)—standard
Humana Health Plan of Texas (San Antonio)—high
Humana Health Plan of Texas (San Antonio)—standard
Humana Kansas City—high
Humana Kansas City—standard
Humana Medical Plan (South Florida)—high
Humana Medical Plan (South Florida)—standard
Mailhandlers Benefit Plan—value
Personalcare's HMO—high
No cost-sharing limits
Amerihealth HMO—high
Anthem Blue Cross-HMO—high[f]

Source: GAO analysis of FEHBP plan-reported data.

Notes: The 18 specialty drugs by therapeutic class are (1) cancer: Gleevec, Lupron Depot, and Tarceva; (2) multiple sclerosis: Avonex, Betaseron, and Rebif; (3) rheumatoid arthritis, psoriasis, and inflammatory conditions: Enbrel, Humira, and Remicade; (4) anemia and blood cell deficiencies: Aranesp, Epogen, and Procrit; (5) hepatitis C: Infergen, Pegasys, and Peg-Intron; and (6) growth hormone deficiencies: Genotropin, Humatrope, and Norditropin/NordiFlex.

[a]Plan also has an annual out-of-pocket maximum that could further limit costs to enrollees.

[b]Plan also has an annual out-of-pocket maximum that could further limit costs to enrollees for 12 of the 18 specialty drugs, and 3 drugs have only an annual out-of-pocket maximum.

[c]Plan also has an annual out-of-pocket maximum that could further limit costs to enrollees for 16 of the 18 specialty drugs, and 1 drug has only an annual out-of-pocket maximum.

[d]Plan also has an annual maximum on the out-of-pocket spending for each individual drug, which could further limit costs to enrollees.

[e]Plan also has an annual out-of-pocket maximum that could further limit costs to enrollees for 17 of the 18 specialty drugs, and 1 drug has only a per prescription dollar maximum.

[f]Plan will limit cost sharing to a $30 copayment if the prescribing physician requires the prescription to be dispensed as written with no permitted substitutions.

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