

June 2004

MEDICAID WAIVERS

HHS Approvals of Pharmacy Plus Demonstrations Continue to Raise Cost and Oversight Concerns





Highlights of [GAO-04-480](#), a report to the Committee on Finance, U.S. Senate

Why GAO Did This Study

Under section 1115 of the Social Security Act, the Secretary of Health and Human Services may waive certain Medicaid requirements for states seeking to deliver services through demonstration projects. By policy, these demonstrations must not increase federal spending. GAO has previously reported concerns with HHS's approval process.

GAO was asked to provide information on a new Medicaid section 1115 demonstration initiative called Pharmacy Plus, intended to allow states to cover prescription drugs for seniors not otherwise eligible for Medicaid. GAO reviewed the (1) approval status of state proposals, (2) extent to which HHS ensured that demonstrations are budget neutral, (3) basis for savings assumptions, and (4) federal and state steps to evaluate and monitor the demonstrations.

What GAO Recommends

GAO recommends that the Secretary of HHS strengthen the processes for approving and overseeing Pharmacy Plus and other Medicaid section 1115 demonstrations. HHS concurred with several recommendations for strengthening demonstration approval and oversight but disagreed that review criteria should be clarified and applied to already-approved demonstrations. GAO maintains that the criteria for HHS's approvals should be clear and consistently applied.

www.gao.gov/cgi-bin/getrpt?GAO-04-480.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Kathryn G. Allen at (202) 512-7118.

MEDICAID WAIVERS

HHS Approvals of Pharmacy Plus Demonstrations Continue to Raise Cost and Oversight Concerns

What GAO Found

From January 2002 through May 2004, HHS reviewed Pharmacy Plus proposals from 15 states and approved four: Florida, Illinois, South Carolina, and Wisconsin. These demonstrations offer prescription drug coverage to low-income seniors not otherwise eligible for Medicaid. HHS denied proposals from Delaware and Hawaii as inconsistent with demonstration guidelines; most of the rest were not under active review because HHS had not determined how new Medicare prescription drug legislation will affect proposed or operating Pharmacy Plus demonstrations. Over 5 years, the four approved demonstrations will provide prescription drug coverage to half a million low-income people age 65 or older, at a projected cost of about \$3.6 billion, of which the federal share would be about \$2.1 billion.

HHS has not adequately ensured that the four approved demonstrations will be budget neutral, that is, that the federal government will not spend more with the demonstrations than without them. HHS approved the demonstrations' 5-year spending limits using projections of cost and beneficiary enrollment growth that exceeded benchmarks that HHS said it considered in assessing budget neutrality, specifically, states' recent average growth rates and projections for Medicaid program growth nationwide. Neither HHS's negotiations with the states nor its rationale for approving higher growth rates is documented. Using the benchmark growth rates, GAO estimates that none of the four demonstrations will be budget neutral and federal spending may increase significantly, for example, by more than \$1 billion in Illinois and \$416 million in Wisconsin over 5 years.

Unrealistic savings assumptions also contribute to demonstration spending limits that are not likely to be budget neutral. States assumed that keeping low-income seniors healthy—thus preventing them from spending down their financial resources on health services and “diverting” them from Medicaid eligibility—would generate sufficient savings to offset the increased costs of providing a new drug benefit. GAO found neither state experience nor other research to support such savings. Without state-specific evidence, HHS approved savings assumptions for the four states ranging from \$480 million to \$2 billion per state over 5 years. Had more conservative assumptions been used to estimate demonstration savings, the proposals likely could not have been approved as budget neutral.

Efforts by the states and HHS to evaluate and monitor the Pharmacy Plus demonstrations are in their early stages. The four states have taken few steps to put their own required evaluation plans into practice, and an independent evaluation contracted by HHS and started in October 2002 is scheduled to report in September 2005. In the interim, HHS has not ensured that all states meet requirements for progress reporting on the demonstrations. The information that states have submitted is often insufficient for determining whether the demonstrations are operating as intended, and this shortcoming will limit HHS's oversight capability.

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Abbreviations

CBO	Congressional Budget Office
CMS	Centers for Medicare & Medicaid Services
FPL	federal poverty level
HHS	Department of Health and Human Services
HIFA	Health Insurance Flexibility and Accountability
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
OMB	Office of Management and Budget
PACE	Pharmaceutical Assistance Contract for the Elderly
PACENET	Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier
SCHIP	State Children's Health Insurance Program
SSA	Social Security Act

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G A O

Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

June 30, 2004

The Honorable Charles Grassley
Chairman
The Honorable Max Baucus
Ranking Minority Member
Committee on Finance
United States Senate

Under section 1115 of the Social Security Act (SSA), the Secretary of Health and Human Services may waive certain statutory requirements for Medicaid—the joint federal and state program financing health care for low-income families, certain seniors, and disabled individuals—in connection with experimental, pilot, or demonstration projects that are likely to promote program objectives.¹ Because of the projects' experimental nature, the Department of Health and Human Services (HHS) requires demonstrations authorized under section 1115 to include measurable objectives and an evaluation component. In addition, since the early 1980s, HHS has required states to show that their proposals for section 1115 demonstrations are “budget neutral” for the federal government: that is, a proposed demonstration cannot raise federal expenditures beyond what they would be under a state’s existing program.

In January 2002, HHS announced the Medicaid Pharmacy Plus section 1115 demonstration initiative, offering states the opportunity to provide a prescription drug benefit to two groups—seniors (people age 65 or older) and disabled individuals—whose incomes, although low, exceed levels that would qualify them for full Medicaid eligibility. Under this initiative, HHS and the Centers for Medicare & Medicaid Services (CMS), the agency within HHS that has primary responsibility for reviewing the demonstration proposals, encourage states to test over 5 years whether extending a drug benefit to seniors who are not eligible for Medicaid

¹Section 1115 allows waivers of requirements in Medicaid, the State Children’s Health Insurance Program (SCHIP), and several other programs authorized under SSA. *See* section 1115 (codified at 42 U.S.C. § 1315 (2000)); *see also* section 2107(e) of SSA (codified at 42 U.S.C. § 1397gg(e)) (regarding the applicability of section 1115 to SCHIP).

would maintain these seniors' health and hold down overall Medicaid costs.²

Over the past decade, Congress and others have raised concerns about the extent to which HHS has ensured that approved section 1115 demonstration waivers promote the goals and fiscal integrity of both Medicaid and the State Children's Health Insurance Program (SCHIP). In particular, Congress has been concerned about HHS's waiver approval process and the federal costs associated with some of the demonstrations. Our past work has found, for example, that HHS's process for approving demonstrations is not always clear or open to public input and that the department has not always ensured the budget neutrality of approved demonstrations, thereby raising federal expenditures.³

You asked us for information on the Pharmacy Plus initiative. We focused our review on the following four questions:

1. How many states have applied for Pharmacy Plus demonstration waivers, and what is the status of their proposals?
2. To what extent has HHS ensured that the approved demonstrations are budget neutral to the federal government?
3. How well supported are states' assumptions about savings that may accrue to Medicaid from the Pharmacy Plus demonstration waivers?
4. What steps are states and HHS taking to evaluate approved demonstrations and to monitor if they are functioning as intended?

Our work is based on a review and analysis of Pharmacy Plus demonstration waiver proposals considered and approved by HHS from January 2002 through May 2004. Our analysis covers only demonstration proposals submitted in response to HHS's Pharmacy Plus initiative.⁴ To

²Although CMS is the agency within HHS that has primary responsibility for reviewing section 1115 demonstration waiver proposals, we refer to HHS throughout this report as the primary program entity because the authority to grant waivers for the demonstrations resides with the Secretary of HHS.

³A list of related GAO products appears at the end of this report.

⁴We do not include proposals to provide a prescription drug benefit to low-income seniors under an amendment to an existing section 1115 Medicaid managed care waiver, like those approved for Vermont and Maryland, because such proposals are reviewed under different guidelines.

determine the status of demonstrations under this initiative, we analyzed HHS data on all proposals it considered, including their number, outcomes, and characteristics. For approved demonstrations, we analyzed the applications as submitted by the states; HHS decision memorandums and approval letters; the applications as ultimately approved; HHS's terms and conditions for approved demonstrations; and, when available, the states' plans (called operational protocols) for how the demonstrations will operate. We also discussed the process of review and approval with officials of the reviewing agencies—HHS, CMS, and the Office of Management and Budget (OMB)—and we obtained information from officials representing the states with approved demonstrations. To assess budget neutrality, we obtained available budget justifications and documentation from state and federal officials and discussed with them the budget negotiations associated with each approved demonstration.⁵ To examine the assumptions behind the initiative and the likelihood of associated savings, we reviewed published literature and interviewed officials from the Kaiser Commission on Medicaid and the Uninsured and the Congressional Budget Office (CBO). We discussed plans for evaluating the approved demonstrations with HHS and state officials. During our review, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which adds a drug benefit to Medicare, the federal program providing health insurance for the majority of people age 65 or older regardless of income.⁶ We considered the limited information available as of May 2004 about the relationship between Pharmacy Plus and the act. We conducted our work from December 2002 through June 2004 in accordance with generally accepted government auditing standards.

Results in Brief

From January 2002 through May 2004, HHS reviewed Pharmacy Plus demonstration waiver proposals from 15 states. It approved four demonstrations (Florida, Illinois, South Carolina, and Wisconsin), denied two (Delaware and Hawaii), and considered nine other proposals. The four demonstrations, each approved for a 5-year period, cover most prescription drugs and incorporate cost sharing by beneficiaries. Together, the four demonstrations may enroll as many as half a million people age 65 or older whose incomes are higher than states' limits for Medicaid

⁵To verify the accuracy of data included in state demonstration applications, we discussed these data and their sources with state officials.

⁶Pub. L. No. 108-173, 117 Stat. 2066.

eligibility. Combined 5-year state and federal spending for the four approved demonstrations' new drug benefit is projected to total approximately \$3.6 billion, the federal share of which is estimated to be about \$2.1 billion. The two proposals that HHS denied were inconsistent with Pharmacy Plus guidelines. One state had an existing program that covered the same population proposed for the demonstration; the other wanted to expand coverage to people with incomes above the initiative's limit of 200 percent of the federal poverty level (FPL). As of May 2004, most of the remaining nine demonstration proposals were not under active review by HHS, primarily because the department had not determined how the new Medicare legislation would affect the Pharmacy Plus initiative and whether HHS would continue to review Pharmacy Plus demonstration proposals.

HHS has not adequately ensured that the four approved Pharmacy Plus demonstrations will be budget neutral, that is, that the federal government will spend no more with the demonstrations than without them. HHS has approved 5-year demonstration spending limits based on projections of cost and beneficiary enrollment growth that exceeded benchmarks that department officials said they considered in assessing states' proposals for budget neutrality. These cost and enrollment growth benchmarks incorporate the states' recent historical average growth rates and projections developed by CMS's Office of the Actuary for Medicaid program growth nationwide. HHS has not established written criteria for how it reviews or approves state-proposed cost or enrollment growth rates against these benchmarks. HHS's basis for approving state demonstrations' spending limits as budget neutral is not clear, particularly for Illinois and Wisconsin, for neither the department's negotiations with the states nor its rationale for approving higher-than-benchmark rates of estimated growth is documented. HHS's internal decision memorandums—which described the factors that HHS, CMS, OMB, and others considered in reviewing the demonstrations and which are not publicly available—did not provide the rationale for the approved spending limits, and neither did the publicly available demonstration approval letters. The approved 5-year spending limit for Illinois is more than \$2 billion higher than it would have been had benchmark growth rates been applied; Wisconsin's approved spending limit is \$713 million more than it would have been with benchmark rates. We estimate that over 5 years, with the approved demonstrations, the federal government could spend over \$1 billion more in Illinois, \$416 million more in Wisconsin, \$55 million more in Florida, and \$42 million more in South Carolina than without the demonstrations, thus not meeting the stated policy of budget neutrality.

States' assumptions about savings that may accrue to Medicaid from the Pharmacy Plus demonstrations are not well supported by state experience or research. The four states with approved demonstrations assumed that the cost of extending drug benefits to seniors now ineligible for Medicaid would be offset by savings accrued because demonstration beneficiaries would stay relatively healthy and therefore not deplete their income or assets to Medicaid eligibility levels. HHS approved the four states' savings assumptions—some projecting significant reductions in overall Medicaid senior enrollment and ranging from \$480 million to \$2 billion per state in combined federal and state spending over 5 years—without state-specific data supporting these assumptions. One state's estimate of savings, for example, was derived by determining how much the state needed to save in order to demonstrate that its proposal would be budget neutral, rather than how much the state could realistically expect to save. The limited research available indicates that health care savings due to improved access to prescription drugs are likely to be much less than what states assumed and HHS approved. Had more conservative savings assumptions been used to estimate the demonstrations' costs, the proposals likely could not have been approved as budget neutral. Because federal liability is capped by a 5-year spending limit for each demonstration, states will be at risk if anticipated savings do not accrue and if their demonstration spending reaches or exceeds the limits.

As of February 2004, efforts by the states and HHS to evaluate and monitor the Pharmacy Plus demonstrations—and particularly states' efforts to begin implementing their evaluation plans to address stated evaluation objectives—were in their early stages. The four states with approved demonstrations had taken few steps toward implementing the evaluation plans required as a condition of demonstration approval: Florida and South Carolina had not decided whether state officials or an outside entity would conduct their evaluations. Illinois and Wisconsin officials believed that participating in the independent evaluation contracted by HHS and started in October 2002 would take the place of their own evaluations. HHS officials, by contrast, told us that state evaluations were still required. This independent evaluation is scheduled to report by September 2005. But in the interim, HHS has not ensured that each state submits in its progress reports enough information for HHS to monitor that its demonstration is functioning as intended, that the information is in a form enabling comparisons across states, or that it is submitted in a timely manner. This lack of information limits the department's oversight capability. For example, Illinois did not submit required quarterly progress reports during the demonstration's first year of operation, and its annual report did not provide information that would allow HHS to assess

whether the new drug benefit was enabling seniors to avoid enrollment for full Medicaid benefits.

HHS's process for approving Medicaid demonstrations under the Pharmacy Plus initiative continues to raise some of the same cost and oversight concerns raised by other Medicaid section 1115 waiver approvals over the past decade, including a failure to adequately justify the basis for states' spending limits. We are recommending that the Secretary of HHS clarify criteria for reviewing and approving demonstration spending limits, consider applying these criteria to the four approved Pharmacy Plus demonstrations, and publicly document the basis for Medicaid section 1115 demonstration approvals to better ensure that approved demonstrations will not raise costs to the federal government. We are also recommending that the Secretary ensure that approved Pharmacy Plus and other Medicaid section 1115 demonstrations fulfill the objectives stated in their evaluation plans and more actively monitor approved Pharmacy Plus and other Medicaid section 1115 demonstrations.

In commenting on a draft of this report, HHS concurred with our recommendations related to evaluating and monitoring the section 1115 demonstrations and documenting the basis for demonstration approvals. HHS did not concur with our recommendations that it clarify criteria for reviewing and approving states' proposed demonstration spending limits and consider applying those criteria to its approval decisions for the four Pharmacy Plus demonstrations. HHS indicated that while review criteria are important, they cannot always be strictly applied because of variations in state Medicaid programs and demonstration proposals, and it also stated that the four approved demonstrations were based on well-supported budget estimates of future state spending. We have on several occasions raised concerns with HHS about the budget neutrality of particular Medicaid section 1115 demonstrations, and the Pharmacy Plus demonstrations are no exception. We acknowledge that variations in state demonstration proposals justify some review flexibility but believe that HHS has not clearly articulated or documented the rationale for its decisions in approving Pharmacy Plus demonstrations. Such lack of clarity raises questions about whether these demonstrations, involving billions of federal dollars, have been reviewed consistently.

We also provided a draft of this report to Florida, Illinois, South Carolina, and Wisconsin. Illinois and Wisconsin officials commented that we overstated the demonstrations' financial risk to the federal government in light of data showing that to date, the demonstrations were operating well within their spending limits. Both states asserted that their pharmacy

demonstrations were providing a valuable benefit to seniors and would be budget neutral. Although we do not dispute the health benefit to seniors of expanded access to prescription drugs, demonstrating savings to the Medicaid program as a result of this expanded access is a separate issue. Assumptions about such potential savings are not well supported by research or by data from the states, even though all the states except Wisconsin operated state-funded pharmacy assistance programs before applying for their demonstrations. Florida commented that the spending limit approved for its demonstration was less than 1 percent above the benchmark spending level. South Carolina and Wisconsin provided technical comments that were incorporated in the report as appropriate.

Background

Established in 1965 under title XIX of SSA, Medicaid is the nation's health care financing program for low-income families and certain people who are age 65 or older or disabled. The program accounted for about \$244 billion in federal and state expenditures in fiscal year 2002 and covered an estimated 53 million people.⁷ The states and the federal government share Medicaid spending according to a formula that provides a more generous federal match for states where per capita income is lower.⁸

Medicaid is an open-ended entitlement program, meaning that the federal government is obligated to pay its share of expenditures for all people and services covered under an HHS-approved state Medicaid plan. To qualify for federal matching payments, state Medicaid programs are required by law to cover certain categories of beneficiaries, including pregnant women and children with family incomes below specific limits, as well as individuals with limited income and assets who are age 65 or older or

⁷In fiscal year 2001, the latest year for which complete data are available, beneficiaries who were aged, blind, or disabled represented about 30 percent of those served by Medicaid but accounted for more than 65 percent (\$141 billion) of Medicaid's total \$216 billion in federal and state spending. Beneficiaries age 65 and older accounted for 26.5 percent of total Medicaid spending, or \$57 billion; blind or disabled individuals accounted for nearly 39 percent, or \$84 billion.

⁸In fiscal year 2003, the federal share of individual states' Medicaid expenditures ranged from 50 to 77 percent. Federal Medicaid matching rates were increased temporarily by 2.95 percentage points from April 1, 2003, through June 30, 2004, pursuant to title IV of the Jobs and Growth Tax Relief Reconciliation Act of 2003. *See* Pub. L. No. 108-27, § 401(a)(3), 117 Stat. 752, 764-765 (to be codified at 42 U.S.C. § 1396d note).

disabled.⁹ State programs are also required to cover certain services, including physician and hospital services and nursing home care. As long as states meet federal requirements and obtain HHS approval for their state Medicaid plans, they have considerable flexibility in designing and operating their programs. For example, states may choose to expand coverage to seniors whose incomes are above statutory limits, and all states have opted to provide prescription drug coverage. In addition, section 1115 of SSA permits the Secretary of HHS to waive certain statutory requirements applicable to Medicaid to allow states to provide services or cover individuals not otherwise eligible for Medicaid and to provide federal funding for services and populations not usually eligible for federal matching payments.¹⁰

The Pharmacy Plus initiative allows states to provide a prescription drug benefit to certain Medicare beneficiaries, specifically seniors and disabled people, with incomes at or below 200 percent of FPL.¹¹ Typically, Medicaid eligibility under an approved state plan provides access to all state Medicaid-covered services, but eligibility under a Pharmacy Plus demonstration covers only a prescription drug benefit.¹² The premise behind the initiative is that expanded access to medically necessary drugs will help keep low-income seniors healthy enough to avoid medical expenses that could cause them to “spend down” their resources to the

⁹Medicaid eligibility is determined by several factors, including individual or family income, age, and eligibility for certain other federal benefits. For example, although state Medicaid programs vary, most people who are age 65 or older, or are disabled, qualify automatically for Medicaid if their incomes and assets qualify them for cash assistance under the federal Supplemental Security Income program.

¹⁰In fiscal year 2001, more than 20 percent of total federal Medicaid spending was governed by the terms and conditions of section 1115 waivers rather than by standard Medicaid program requirements. See Jeanne Lambrew, *Section 1115 Waivers in Medicaid and the State Children's Health Insurance Program: An Overview* (Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured, 2001).

¹¹In 2003, the annual income that represented 200 percent of FPL was \$17,960 for an individual, \$24,240 for a family of two.

¹²States are also required to ensure that beneficiaries receiving only the prescription drug benefit have access to primary care services to assist with medical management related to pharmacy products, although they are not required to pay for these services. Most Pharmacy Plus beneficiaries are seniors covered by Medicare, which generally covers hospital and physician services.

point of Medicaid eligibility.¹³ The initiative assumes that budget neutrality for pharmacy-only coverage can be achieved by savings to Medicaid from fewer seniors' enrolling for full benefits, as well as from improved access to prescription drugs, improved service delivery or medication management, and better management of drug benefit costs.

Unlike some other section 1115 demonstration waivers, the Pharmacy Plus initiative requires a participating state to accept a fixed spending limit as part of its budget neutrality agreement with HHS. This spending limit—sometimes called an aggregate spending limit or global budget cap—applies not only to services and beneficiaries in the state's demonstration drug program, but also to all services for all Medicaid seniors in the state. The Pharmacy Plus budget neutrality approach limits the amount the federal government will match for a demonstration according to expected growth in both service costs and enrollment (see app. I). Once a state has reached its Pharmacy Plus spending limit, it cannot receive additional federal matching dollars for any Medicaid services for seniors in the state, nor can the state restrict enrollment of seniors who qualify for full Medicaid benefits.¹⁴ Under the Pharmacy Plus scenario, a state accepts the financial risks inherent in a fixed budget cap for unanticipated changes in both cost and enrollment growth. For some other section 1115 demonstrations, budget neutrality is based on a projected per capita cost for each demonstration beneficiary. This other scenario sets a limit on spending per person, but because federal matching funds are available for all people who enroll, a state does not have to accept financial risk for unexpected growth in enrollment.

¹³To be eligible for Medicaid, seniors must meet income and asset limits specified by each state, within federal requirements. Some individuals with income and assets too high to be immediately eligible may qualify for coverage on a monthly basis if they incur such high medical costs that they “spend down” to a qualifying income and asset level. Such spending down often happens when people enter nursing homes and quickly deplete their resources.

¹⁴According to the terms of approval for Pharmacy Plus demonstrations, to maintain budget neutrality, states may not alter eligibility or benefits for seniors who qualify for full Medicaid. States may pursue a variety of cost-control measures for the drug-only expansion, including limiting enrollment and increasing cost sharing for Pharmacy Plus beneficiaries.

HHS Has Reviewed 15 Pharmacy Plus Proposals and Approved 4

As of May 2004, HHS had approved four states' Pharmacy Plus demonstration proposals, denied two, and considered proposals from nine other states. All four approved demonstrations—Florida, Illinois, South Carolina, and Wisconsin—are to operate for 5 years, during which time they might enroll a total of half a million low-income individuals age 65 or older for the new prescription drug coverage. HHS denied two demonstration proposals, from Delaware and Hawaii, because they were not consistent with Pharmacy Plus guidelines. Of the remaining nine proposals, one was withdrawn by the state and others have been on hold since fall 2003, when Congress was considering Medicare prescription drug legislation. At the time we completed our work, legislation providing a new drug benefit through Medicare had been enacted, but HHS had not determined how the new drug program would affect the Pharmacy Plus initiative.

HHS Approved Four Pharmacy Plus Demonstrations

HHS has approved Pharmacy Plus demonstrations for low-income seniors in four states: Florida, Illinois, South Carolina, and Wisconsin.¹⁵ As of May 2004, all four demonstrations had been implemented and under way for at least 17 months: Illinois', Florida's, and Wisconsin's demonstrations were implemented in 2002, South Carolina's in 2003 (see table 1). Together, the four approved demonstrations are projected to enroll as many as 527,800 individuals for Medicaid prescription drug benefits only; as of April 2004, they reported combined enrollment of nearly 372,200 people. Illinois' demonstration is the largest, with expected enrollment for the drug benefit of more than 250,000 seniors over 5 years. As of April 2004, more than 192,600 people were enrolled in Illinois' demonstration, the majority of them moved into the Medicaid program from an existing state-funded pharmacy assistance program.¹⁶

¹⁵HHS approved a fifth demonstration proposal, from Indiana, in April 2003, but the state declined to accept the terms of HHS's approval, primarily because of the state's concerns about the spending limit for all Medicaid seniors. Instead, Indiana proposed a different budget approach that would not require the state to project and commit to a spending limit covering all Medicaid seniors. Indiana's alternative proposal, submitted May 2003, was one of the nine proposals under consideration by HHS as of March 2004.

¹⁶Illinois' state-funded program covered seniors and people with disabilities with incomes up to 250 percent of FPL. Participants who were 65 or older with incomes at or below 200 percent of FPL were automatically enrolled in the demonstration on June 1, 2002. Eligible seniors with incomes from 201 to 250 percent of FPL and people with disabilities continue to be covered by the state-funded program.

Table 1: Highlights of Pharmacy Plus Demonstrations Approved as of May 2004

State and demonstration status (in order of approval)	Description
<p>Illinois Approved January 2002 Implemented June 2002 Request for amendment submitted March 2003</p>	<p>Projected enrollment: As many as 256,500 seniors with incomes at or below 200 percent of FPL; 192,600 participants enrolled as of April 2004. Seniors with incomes at or below 200 percent of FPL who were participating in Illinois' previous state-funded program were automatically enrolled in the demonstration.</p> <p>Spending limit for all Medicaid seniors: \$14.0 billion in federal and state Medicaid funding over 5 years; prescription drug benefit represents \$1.4 billion.</p> <p>Benefits and cost sharing: Covers most prescription and some over-the-counter drugs recommended by physicians. Seniors with private insurance may choose to enroll for a \$25 monthly rebate program. No cost sharing for participants with incomes below 100 percent of FPL; participants at or above 100 percent of FPL pay \$1 for generic and \$4 for brand-name drugs. All participants pay 20 percent coinsurance after their annual drug benefits under the program exceed \$1,750.</p> <p>State program: Before the demonstration, Illinois' state-funded pharmacy assistance program enrolled about 170,000 participants. The state continues to operate a state-funded program covering prescription drugs for specified conditions for seniors with incomes from 201 to 250 percent of FPL and for people with disabilities and incomes up to 250 percent of FPL. Amendment sought to expand coverage to eligible seniors with incomes at or below 250 percent of FPL; amendment was pending as of March 2004.</p>
<p>Florida Approved July 2002 Implemented August 2002 Request for amendment submitted September 2003</p>	<p>Projected enrollment: As many as 58,500 seniors with incomes from 88 to 120 percent of FPL; 54,400 participants enrolled as of April 2004.</p> <p>Spending limit for all Medicaid seniors: \$16.7 billion in federal and state Medicaid funding over 5 years; prescription drug benefit represents \$477 million.</p> <p>Benefits and cost sharing: Covers all prescription drugs up to a monthly benefit limit of \$160 per participant. Except for some classes of drugs, such as mental health and HIV antiviral therapies, brand-name drugs are limited to four per month, although physicians are allowed to request exceptions. Participants pay \$2 for generic drugs, \$5 for drugs on the state's preferred drug list, and \$15 for other brand-name drugs.</p> <p>State program: Before the demonstration, Florida's state-funded pharmacy assistance program enrolled about 9,000 participants. Replaced by the demonstration, the state-funded program had the same income eligibility criteria as the demonstration but a lower benefit limit: \$80 per participant per month. Amendment sought to expand eligibility to seniors with incomes at or below 200 percent of FPL and to add a prescription drug discount program; amendment was pending as of March 2004.</p>

**State and demonstration status
(in order of approval)**

Description

Wisconsin

Approved July 2002
Implemented September 2002

Projected enrollment: As many as 146,800 seniors with incomes at or below 200 percent of FPL; 70,300 participants enrolled as of April 2004.

Spending limit for all Medicaid seniors: \$8.4 billion in federal and state Medicaid funding over 5 years; prescription drug benefit represents \$919 million.

Benefits and cost sharing: Covers prescription drugs, including insulin. Participants pay an annual enrollment fee of \$30 and those with incomes above 160 percent of FPL pay an annual deductible of \$500. Participants pay \$5 for generic and \$15 for brand-name drugs (those with incomes from 160 to 200 percent of FPL begin co-payments after meeting the required deductible).

State program: Wisconsin did not have a state-funded pharmacy assistance program for seniors before this demonstration. When the state implemented the demonstration, it also began offering state-funded pharmacy benefits to seniors with incomes from 201 to 240 percent of FPL.

South Carolina

Approved July 2002
Implemented January 2003

Projected enrollment: As many as 66,000 seniors with incomes up to 200 percent of FPL; 54,900 enrolled as of April 2004.

Spending limit for all Medicaid seniors: \$5.0 billion in federal and state Medicaid funding over 5 years; prescription drug benefit represents \$764.7 million.

Benefits and cost sharing: Covers generic and, when no generic is available, brand-name prescription drugs, over-the-counter drugs prescribed by physicians, insulin and other self-injected drugs, and syringes. Except for medications for specified conditions, including behavioral health disorders, cardiac disease, cancer, HIV/AIDS, and terminal or life-threatening diseases, coverage limited to four prescriptions or refills per month. Participants pay an annual deductible of \$500, plus \$10 for generic drugs; \$15 for brand-name drugs; and \$21 for drugs requiring prior authorization.

State program: Before the demonstration, South Carolina's state-funded pharmacy assistance program enrolled about 41,000 participants. Demonstration replaces that program and expands eligibility to seniors with incomes from 175 up to 200 percent of FPL.

Source: GAO analysis of state and HHS documents.

All the demonstrations except Florida's are approved to enroll seniors with incomes at or below 200 percent of FPL, the maximum eligible income established in HHS's Pharmacy Plus guidance.¹⁷ As approved, Florida's demonstration covers seniors with incomes from 88 to 120 percent of FPL, but in September 2003, the state submitted an amendment to expand income eligibility to 200 percent of FPL. Illinois also applied in March 2003 to amend its approved demonstration to expand eligibility, in its case to include seniors with incomes at or below 250 percent of FPL. The terms of Illinois' demonstration approval

¹⁷Although HHS has identified the initiative's target population as seniors and people with disabilities who have incomes at or below 200 percent of FPL, none of the states with approved pharmacy demonstrations have chosen to include people with disabilities.

specifically permit the state to seek this amendment, as long as the state submits data supporting its ability to cover this expansion population at no additional cost to the federal government. As of March 2004, HHS was reviewing both amendments.

Projected 5-year costs vary among the four approved demonstrations. For Florida, Illinois, South Carolina, and Wisconsin, total combined federal and state Medicaid spending on the new drug benefit alone is expected to be more than \$3.6 billion over 5 years, of which the federal share would be approximately \$2.1 billion. The combined federal and state Medicaid spending limits for the four demonstrations—for services to all Medicaid seniors in the four states—would total \$44 billion over 5 years, with a federal share of at least \$25 billion. The estimated 5-year costs solely for the drug benefit range from \$477 million in Florida to \$1.4 billion in Illinois, and combined 5-year federal and state spending limits (based on projected costs for services to all Medicaid seniors) range from \$5.0 billion in South Carolina to \$16.7 billion in Florida.

When they applied, three of the four states with approved demonstrations already operated state-funded pharmacy assistance programs for seniors. Most beneficiaries eligible for these programs are also eligible for Pharmacy Plus coverage. HHS allows the states to subsume all or a portion of an existing program under a demonstration, as long as the states' demonstrations propose to expand either the number of beneficiaries or the scope of drug coverage.¹⁸ In other words, the state may not simply secure federal matching dollars for the costs of an existing state-funded drug program with no expansion. To meet this condition, states with approved demonstrations either raised income eligibility thresholds or expanded the scope of drug coverage beyond that of their existing state programs. For example, Florida doubled its maximum monthly benefit from \$80 to \$160 per person, and South Carolina expanded eligibility to include seniors with incomes from 175 through 200 percent of FPL. Illinois' demonstration offered a more comprehensive

¹⁸The Pharmacy Plus application form and standard terms and conditions for three of the four approved demonstrations do not include a specific maintenance-of-effort requirement. Only Illinois, the first Pharmacy Plus demonstration approved, has such a maintenance-of-effort requirement. HHS officials told us that the department's policy regarding state maintenance of effort has been evolving. Since the Illinois approval, the officials told us that they have asked states to demonstrate that they are expanding their programs.

drug benefit than its state-funded program did.¹⁹ Wisconsin did not previously have a state-funded pharmacy assistance program for seniors.²⁰

HHS Denied Two Demonstration Proposals

In 2003, HHS denied Pharmacy Plus demonstration proposals from two states, Delaware and Hawaii. (See app. II for descriptions of denied, withdrawn, and pending proposals.) Delaware's proposal was denied primarily because HHS required that the state expand beyond the existing state-funded program and limit coverage to seniors with incomes at or below 200 percent of FPL. Delaware's state-funded pharmacy assistance program already covered seniors and disabled adults with incomes up to 200 percent of FPL or whose prescription drug costs exceeded 40 percent of their annual incomes. For this reason, the state could not expand either eligibility or coverage and stay within Pharmacy Plus guidelines. Although Delaware proposed adding a pharmacy benefit management component to monitor appropriate prescription use and to control costs, HHS found this proposed change to the existing program insufficient.²¹

Hawaii proposed to make prescription drugs available at the discounted Medicaid rate to state residents of all ages with family incomes at or below 300 percent of FPL. This benefit was to be funded through participant cost sharing, manufacturer rebates, and a fixed state contribution of \$1 per prescription. HHS's denial was based primarily on the request to cover individuals with incomes up to 300 percent instead of 200 percent of FPL. Other reasons for the denial included the proposed coverage for all state residents, instead of targeting seniors and people with disabilities, and the

¹⁹Illinois' state-funded program began in 1985 to cover prescriptions for cardiovascular disease and has expanded over the years to include drugs for several conditions, including arthritis, diabetes, Alzheimer's disease, cancer, glaucoma, lung disease, and Parkinson's disease.

²⁰Wisconsin began offering state-funded drug benefits to seniors with incomes from 200 up to and including 240 percent of FPL at the same time that it implemented its demonstration.

²¹A Delaware Medicaid official expressed concern that HHS's denial was inconsistent with its guidelines, which, as set forth in the application form, indicate that states may be allowed to provide enhanced pharmacy benefit management services as one option for expanding state-funded programs under the demonstration. HHS officials told us that the denial of Delaware's proposal would not be reconsidered because the proposed expansion was not large enough, and approving it would simply make the state-funded program eligible for federal matching payments.

minimal state financial participation of \$1 per prescription in the first year of the demonstration.²²

HHS Has Considered Nine Other Demonstration Proposals

From January 2002 through May 2004, HHS considered Pharmacy Plus demonstration proposals from nine other states: Arkansas, Connecticut, Indiana, Maine, Massachusetts, Michigan, New Jersey, North Carolina, and Rhode Island. As of May 2004, eight were still pending; one proposal, from Massachusetts, had been withdrawn. Most proposals would cover seniors with incomes at or below 200 percent of FPL; several would also cover adults with disabilities. The drug benefits would generally be comprehensive and require participant cost sharing, which in some cases would include an annual enrollment fee and 20 percent co-payment for each prescription. All but one of the states with pending proposals have state-funded pharmacy assistance programs that they propose to include in whole or in part in their demonstrations. (App. II describes these demonstration proposals.)

As of May 2004, most of the pending proposals were not under active review by HHS primarily because the department had not determined the effect of the Medicare prescription drug legislation on the Pharmacy Plus demonstration proposals. HHS officials told us in October 2003 that Arkansas, Rhode Island, and Indiana officials had asked that review of their states' proposals be put on hold until after Congress had completed consideration of the Medicare legislation. At that time HHS was still reviewing a proposal from North Carolina but regarded proposals from four other states as inactive because longtime negotiations with those states had reached an impasse. Connecticut and New Jersey, for example, already had broad state-funded drug coverage for seniors with incomes up to 200 percent of FPL. In such cases, HHS has been unwilling to approve federal financing for existing state-funded programs.

Medicare Prescription Drug Legislation May Affect Pharmacy Plus Initiative

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) will provide seniors access to a Medicare-covered prescription drug benefit and will likely affect how HHS and the states manage the Medicaid Pharmacy Plus initiative. This law gives Medicare

²²A Hawaii Medicaid official reported that the agency was unable to fundamentally change the nature of the proposal during HHS review because the proposal had been outlined in state law.

beneficiaries the opportunity to enroll for prescription drug coverage to begin on January 1, 2006, and, as an interim measure, the opportunity to enroll for Medicare-endorsed drug discount cards beginning in June 2004. It also directs HHS to establish effective coordination between Medicare plans and state Medicaid and pharmacy assistance programs and to establish a commission to address these and other transition issues.²³ In 2006, the Medicare drug benefit will replace Medicaid as the primary source of prescription drug coverage for low-income seniors who would have been eligible for both full benefits under Medicaid and drug benefits under Medicare plans.²⁴ Under MMA, individuals with limited assets and incomes below 150 percent of FPL will be eligible for federal subsidies to assist with the drug benefit's cost-sharing requirements.²⁵ But because Pharmacy Plus demonstrations in Illinois, South Carolina, and Wisconsin cover individuals with incomes above 150 percent and at or below 200 percent of FPL regardless of other assets, some current demonstration beneficiaries may not qualify for these subsidies. Pharmacy Plus beneficiaries are likewise ineligible for the Medicare drug discount cards.²⁶

²³Specifically, the law establishes a State Pharmaceutical Assistance Transition Commission to develop a proposal for addressing the transitional issues facing state-funded pharmacy assistance programs and their participants because of implementation of the new Medicare prescription drug benefit. Members of the commission are to include representatives of states operating pharmacy benefit programs, interested organizations, private insurers, and others. The commission is required to submit a detailed proposal, including specific legislative or administrative recommendations, to Congress and the President by January 1, 2005. *See* Pub. L. No. 108-173, § 101(a), 117 Stat. 2071, 2128-31 (adding sections 1860D-23 and 1860D-24 to SSA) (to be codified at 42 U.S.C. §§ 1395w-133 and 1395w-134); *see also* section 106, 117 Stat. 2168-9.

²⁴*See* Section 103(c), 117 Stat. 2158 (amending section 1935 of SSA) (to be codified at 42 U.S.C. § 1396n-5).

²⁵For example, individuals with incomes below 135 percent of FPL generally will be entitled to a full premium subsidy; individuals with incomes up to 150 percent of FPL will be entitled to an income-related premium subsidy determined on a sliding scale. In addition, after reaching an out-of-pocket threshold of \$3,600, individuals with incomes below 135 percent of FPL will have no co-payment for covered drugs, while those with incomes below 150 percent of FPL will pay either \$2 or \$5 for each drug. *See* Section 101(a), 117 Stat. 2107-9 (adding sections 1860D-14(a)(1) and (2) to SSA) (to be codified at 42 U.S.C. §§ 1395w-114(a)(1) and (2)); *see also* section 101(a), 117 Stat. 2077-9 (adding section 1860D-2(b)(4) to SSA) (to be codified at 42 U.S.C. § 1395w-102(b)(4)).

²⁶*See* Section 101(a), 117 Stat. 2132-3 (adding section 1860D-31(b) to SSA) (to be codified at 42 U.S.C. § 1395w-141(b)).

As of May 2004, HHS indicated it was considering how enactment of the new law would affect Pharmacy Plus demonstrations and proposals.²⁷ Officials from the four states with approved demonstrations told us in December 2003 that they were uncertain how the law would affect their demonstrations, but they had no plans to end the demonstrations early. After the Medicare prescription drug benefit begins in 2006, some demonstrations could be discontinued or modified. Early termination could have an impact on the demonstrations' budget neutrality, which often depends on savings in later years to offset higher start-up costs. Officials in Illinois and Florida indicated in December 2003 that their pharmacy demonstrations might be converted to state-funded programs in 2006.

HHS Has Not Ensured That Approved Demonstrations' Spending Limits Will Be Budget Neutral

HHS has not adequately ensured that the spending limits it has approved for Pharmacy Plus demonstrations will be budget neutral—in other words, that the federal government will spend no more under the demonstrations than without them. For all four demonstrations, HHS approved 5-year spending limits based on projections of cost and beneficiary enrollment growth that exceeded benchmarks that department officials told us they considered in assessing the reasonableness of states' demonstration proposals. These cost and enrollment growth benchmarks incorporate states' historical experience and expectations for Medicaid program growth nationwide. The discrepancies between the growth benchmarks and the approved growth rates were greatest for Illinois and Wisconsin. Neither HHS's negotiations with the states nor the department's rationale for approving higher-than-benchmark growth rates is well documented. Had HHS based the 5-year demonstration spending limits on the benchmark growth rates, the federal share of approved spending would be considerably lower, particularly for Illinois and Wisconsin: specifically,

²⁷In commenting on a draft of this report, HHS said that it expected less need for Pharmacy Plus demonstrations when Medicare coverage for prescription drugs is expanded under MMA and that states would need to decide if they want to continue their demonstrations.

\$1 billion lower in Illinois and \$416 million lower in Wisconsin.²⁸ For Florida and South Carolina, the federal share of approved spending would have been \$55 million and \$42 million lower, respectively.

HHS Approved Projected Growth Rates Exceeding Benchmarks

HHS based the Pharmacy Plus demonstration spending limits it approved on a range of estimated future growth rates for cost per beneficiary and for enrollment, which in some cases exceeded benchmarks²⁹ the department told us it considered in assessing the reasonableness of states' proposals. A standard Pharmacy Plus application form developed by HHS and a technical guidance document are the chief sources of criteria and formal guidance to states for developing demonstration proposals. But HHS has not established written criteria for how it reviews and approves the growth rates that states propose. These growth rates are key elements in the budget neutrality negotiations between states and the federal government because higher rates result in more generous spending limits, which represent the federal government's agreed-on maximum spending for all the states' Medicaid seniors during the demonstrations. An inappropriately high spending level can represent a higher federal liability than warranted.

The process used by HHS and the states to determine whether states' proposed Pharmacy Plus demonstrations will be budget neutral requires comparing two cost estimates: (1) projected 5-year costs of a state's existing Medicaid program for seniors ("without-demonstration costs") and (2) projected 5-year costs of the state's existing program plus the drug benefits and beneficiaries added by the demonstration ("with-demonstration costs"). These calculations factor in projected growth in

²⁸We have reported that by allowing Illinois to include impermissible costs in its projected spending under the Medicaid program without the demonstration, HHS approved a Pharmacy Plus demonstration in the state that was not budget neutral, inappropriately raising allowed costs for the project by \$275 million. We recommended to the Secretary of HHS that the agency ensure that valid methods are used to demonstrate budget neutrality and that it apply such methods to adjust the federal spending commitment under Illinois' demonstration. See U.S. General Accounting Office, *Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns*, GAO-02-817 (Washington, D.C.: July 12, 2002). As of March 2004, HHS had not adjusted the state's spending limit.

²⁹We use the term "benchmark" throughout this report to describe the cost and Medicaid enrollment growth rates HHS considered when making its approval decisions for Pharmacy Plus demonstrations. We use "benchmark" rather than "criterion" because, in contrast to its practice in approving some other section 1115 demonstrations, HHS did not have written cost or enrollment growth criteria for Pharmacy Plus.

costs and enrollment each year. As long as projected with-demonstration costs do not exceed projected without-demonstration costs, the demonstration can be approved as budget neutral. As a result, the projected costs of a state's existing, without-waiver Medicaid program for seniors effectively sets the spending limit for all services provided to all Medicaid seniors in the state for the 5-year demonstration term. Appendix I outlines the basic steps HHS follows in setting Pharmacy Plus demonstration spending limits.

To determine budget neutral spending limits for the pharmacy demonstrations, HHS officials told us they consider the following for estimating growth in costs and enrollment through the course of the demonstrations:

- For cost growth per beneficiary, similar to guidelines for other types of section 1115 demonstrations,³⁰ HHS seeks to approve a growth rate equal to the lower of either the state's historical average annual growth in per-beneficiary cost (that is, the average annual rate for the 5 years before the demonstration proposal) or the nationwide projected growth rate, developed by CMS's Office of the Actuary, for Medicaid cost per beneficiary age 65 or older.³¹
- For enrollment growth, HHS considers the state's historical average annual growth in enrollment as a starting point and, to a lesser extent, the CMS Actuary's nationwide rate, but it allows states to present a rationale for a higher rate that anticipates rising future enrollments.

HHS's approved growth rates in some cases exceeded these benchmarks (see table 2). For per-beneficiary cost growth rates in Florida, Illinois, and Wisconsin, HHS did not approve the lower of either the state's historical

³⁰The Health Insurance Flexibility and Accountability (HIFA) initiative, for example, another Medicaid section 1115 demonstration waiver initiative, specifies a similar benchmark for cost growth per beneficiary in its standard application form. The HIFA initiative provides two options for projecting cost growth per beneficiary: the Medical Care Consumer Price Index, developed by the Bureau of Labor Statistics, or a state-specific projection of what the program would have cost without the demonstration. For the second option, HHS policy is to apply the lower of state-specific experience—using 5 years of Medicaid data—or the CMS Actuary's Medicaid baseline for the eligible groups covered by the demonstration.

³¹The CMS Actuary's growth projections in effect during budget discussions for the four approved Pharmacy Plus demonstrations were a 6.3 percent annual increase in cost per beneficiary and a 1.8 percent annual increase in enrollment.

average rate or the CMS Actuary’s rate of 6.3 percent. Similarly, for beneficiary enrollment growth rates, HHS approved rates for Illinois and Wisconsin that exceeded both the states’ historical experience and the CMS Actuary’s 1.8 percent projected annual growth rate. In Illinois’ case, the approved rate for beneficiary enrollment growth—5 percent per year over the 5-year demonstration—was considerably higher than the state’s 5-year historical average enrollment growth of 1.6 percent per year.

Table 2: HHS-Approved, State Historical, and CMS Actuary Growth Rates

Annual growth rates in percent							
State	Cost growth rates			Enrollment growth rates			
	HHS- approved	State historical average	CMS Actuary	HHS- approved	State historical average	CMS Actuary	
Florida	6.5	6.5	6.3	1.4	1.4	1.8	
Illinois ^a	5.5	4.5	6.3	5.0	1.6	1.8	
South Carolina ^b	6.3	10.0	6.3	1.0	0.7	1.8	
Wisconsin	6.3	5.4	6.3	2.0	0.01 ^c	1.8	

Source: GAO analysis of HHS and state documents.

^aThe state historical average rates for Illinois (4.5 percent cost growth and 1.6 percent enrollment growth) reflect updated information provided by the state to HHS shortly before its approval decision on January 28, 2002. This information does not appear in the demonstration application that was submitted on July 31, 2001.

^bFor South Carolina, historical average rates reflect 3 years of data, rather than the generally required 5 years, because cost and enrollment data for Medicaid seniors were incomplete for 2 of the 5 years (data for certain long-term care waivers for seniors were not included).

^cThis figure is lower than the 0.12 percent enrollment growth rate Wisconsin proposed in its demonstration application. We included 5 years of data in calculating our average rate for the state, while the state itself averaged 3 years of data, excluding 2 years when enrollment declined slightly.

Basis for Approved Spending Limits Not Clear or Well Documented

HHS’s basis is unclear for approving growth rates higher than the benchmarks in some cases, particularly for approving higher enrollment growth rates for Illinois and Wisconsin. The department’s negotiation process with these two states, during which officials reached agreement on allowed growth rates, was not documented, nor was its rationale for approving rates that differed from the lower of state historical experience or the CMS Actuary’s projections. In particular, HHS’s internal decision memorandums—which described the factors that HHS, CMS, OMB, and others considered in reviewing the demonstrations and which are not publicly available—did not provide the rationale for the approved spending limits, and neither did the publicly available demonstration approval letters.

HHS and state officials told us that Illinois and Wisconsin used a variety of arguments to convince the department that their situations warranted higher enrollment growth rates. But the states provided little specific documentation to HHS or to us to support these arguments. For example:

- Illinois asserted that its projected annual enrollment growth rate for the demonstration years from 2002 through 2007 should be significantly higher than its 5-year average historical growth rate of 1.6 percent, because income eligibility levels for seniors in its Medicaid program increased from 41 to 100 percent of FPL from July 2000 through July 2002. As support, the state provided HHS with updated Medicaid enrollment data—which were more recent than those included in the original demonstration application and showed increased growth rates for seniors compared with earlier years—but these rates were still lower than the 5 percent HHS approved and did not raise the historical average to 5 percent.³² The state did not provide documents with actuarial projections of the estimated number of people expected to enroll in Medicaid because of the change in eligibility criteria. Illinois justified applying the 5 percent annual growth rate to all 5 years of the pharmacy demonstration by providing a chart showing that enrollment in a different state program, SCHIP, had grown more than 5 percent per year on average for 3 years after that program’s eligibility criteria were expanded. In our view, however, Illinois’ SCHIP enrollment experience with children does not provide a reasonable basis for predicting enrollment by seniors in the Pharmacy Plus demonstration.
- Wisconsin asserted that its projected annual enrollment growth rate for the demonstration years should be significantly higher than either its 5-year unadjusted historical growth rate of 0.01 percent or the 0.12 percent rate based on 3 years of historical data reported in its application because of the anticipated effects of a nationwide Social Security Administration mail outreach program to low-income Medicare beneficiaries. This outreach program informed seniors enrolled in Medicare about other benefits, including Medicaid assistance for Medicare cost-sharing

³²Illinois provided HHS with updated information on senior enrollment in the state’s Medicaid program, including growth of 1.3 percent between state fiscal years 1999 and 2000 and 4.2 percent between state fiscal years 2000 and 2001. These updated figures are incorporated in the 5-year historical average enrollment growth rate of 1.6 percent, covering state fiscal years 1997 through 2001.

requirements, for which they might qualify.³³ Wisconsin officials told us they proposed a 4 percent future annual enrollment growth rate for seniors in the expectation that this outreach program, along with factors including an aging population and the economic downturn, would increase Medicaid enrollment. According to HHS, Wisconsin did not document any projections of how many newly eligible Medicaid individuals could be prompted to enroll after the Social Security Administration outreach mailing. Instead, it submitted information based on a review of a similar outreach effort in Minnesota. According to Wisconsin state officials, during negotiations HHS proposed 1 percent as a more reasonable growth rate, and HHS and state officials agreed to an approved enrollment growth rate of 2 percent per year. Our related work suggests that Wisconsin may be justified in claiming some increase in Medicaid enrollment as a result of the outreach program, but the effect appears to be less than 1 percent. Notably, although the Social Security Administration mail outreach program was nationwide, HHS did not consider its effects when approving enrollment rates for other states.³⁴

Demonstration Spending Limits Would Be Lower if Based on Benchmark Rates

Application of benchmark rates for projected per-beneficiary cost and enrollment growth would have produced lower spending limits for all four approved Pharmacy Plus demonstrations (see table 3). Benchmark-based limits on combined federal and state spending would be approximately \$3 billion lower over 5 years than what HHS approved for the four demonstrations, and the federal share alone would come to about \$1.6 billion less. The higher-than-benchmark growth rates HHS approved for Illinois and Wisconsin accounted for most of these differences. Had the

³³The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 requires the Social Security Administration to notify Medicare beneficiaries nationwide about other benefits, including Medicaid, for which they could potentially be eligible. See Pub. L. No. 106-554, App. F, § 911(a), 114 Stat. 2763, 2763A-583 (adding section 1144 to SSA) (to be codified at 42 U.S.C. § 1320b-14). See U.S. General Accounting Office, *Medicare Savings Programs: Results of Social Security Administration's 2002 Outreach to Low-Income Beneficiaries*, GAO-04-363 (Washington, D.C.: Mar. 26, 2004).

³⁴See GAO-04-363. In 2002, the Social Security Administration outreach program sent letters to about 16.4 million low-income Medicare beneficiaries nationwide, yielding an estimated 74,000 additional individuals—a further increase in enrollment of 0.5 percent—enrolling in Medicaid programs that help low-income Medicare beneficiaries pay their Medicare premiums and, in some cases, their deductibles and coinsurance. On the basis of a sample, we estimated that Wisconsin experienced a statistically significant increase in additional Medicaid enrollment after the Social Security Administration mailing, although at 0.4 percent, the response was slightly less than the U.S. average. The Social Security Administration outreach program continued on a smaller scale in 2003 and thereafter.

spending limit for Illinois' demonstration, in particular, been based strictly on the benchmark rates, combined federal and state spending would have been almost \$2.2 billion, or 15 percent, lower, and the federal government's liability under the demonstration (at the state's 50 percent federal matching rate) lower by more than \$1 billion. The difference is less pronounced for Wisconsin, where the approved federal and state spending limit exceeds what it would have been had benchmark rates been applied by about \$713 million, translating into about \$416 million in additional federal spending.

Table 3: HHS-Approved and Benchmark 5-Year Spending Limits

Dollars in millions				
States	HHS-approved	Benchmark	Dollar difference (percentage difference) ^a	Federal share of difference ^b
Florida	\$16,669	\$16,575	\$94 (0.6)	\$55
Illinois	14,047	11,880	2,167 (15.4)	1,083
South Carolina	4,962	4,902	60 (1.2)	42
Wisconsin	8,378	7,666	713 (8.5)	416
Total^a	\$44,056	\$41,023	\$3,033 (6.9)	\$1,596

Source: GAO analysis of HHS and state documents.

Notes: Figures reflect total approved federal and state spending limits for all Medicaid services for seniors over the 5 years of each demonstration, including spending on new Pharmacy Plus prescription drug benefits. We calculated benchmark spending limits using, for cost growth per beneficiary, the lower of either the state's historical average cost growth rate or the CMS Actuary's projected rate, and for enrollment growth, the state's unadjusted 5-year historical average enrollment growth rate, except for South Carolina, where we used the average of 3 years' data.

^aDollar differences and totals are based on numbers before rounding.

^bFederal share calculated by applying fiscal year 2003 federal Medicaid matching rates for each state to the dollar difference for that state: Florida, 58.8 percent; Illinois, 50 percent; South Carolina, 69.8 percent; and Wisconsin, 58.4 percent.

The spending limits HHS approved for Illinois and Wisconsin exceed estimates based on consistent application of the benchmark growth rates by 15.4 percent and 8.5 percent, respectively.³⁵ The limits approved for

³⁵We calculated Wisconsin's benchmark spending limit based on the 0.01 percent average annual enrollment growth rate for 5 years of historical data, which included 2 years when enrollment declined slightly. Had the 0.12 percent average annual enrollment growth rate been used, based on 3 years of historical data as the state proposed in its demonstration application, Wisconsin's combined federal and state spending limit would have been \$7.9 billion, about 5.7 percent, or \$477 million, below what HHS approved.

Florida and South Carolina, while not budget neutral compared with the benchmark spending estimates, reflect relatively small differences. Florida's approved spending limit exceeds the benchmark estimate by less than 1 percent—\$94 million of a 5-year approved federal and state spending limit of nearly \$16.7 billion—and South Carolina's approved spending limit exceeds the benchmark by 1.2 percent, or \$60 million.

CBO has similarly reported that Pharmacy Plus demonstrations are likely to increase federal Medicaid spending. Before passage of MMA, CBO estimated that the Pharmacy Plus demonstrations would add about \$18 billion to federal Medicaid spending over the 10 years from 2004 through 2013. According to CBO officials, the agency considered a range of scenarios for how the initiative might grow with new demonstration approvals and estimated the initiative's overall effect on Medicaid spending.³⁶ The officials told us that CBO did not include any of the demonstrations' projected savings in its analysis because it did not find the argument that savings would occur convincing.

Pharmacy Plus Savings Assumptions Not Well Supported

Neither data from state experience nor other research supports the savings assumptions necessary for budget neutrality in the Pharmacy Plus demonstrations. In developing their demonstration proposals, states assumed that keeping low-income seniors healthy—thus preventing them from spending down their financial resources on health services and “diverting” them from Medicaid eligibility—would generate savings to help offset the increased costs of providing a new drug benefit. Without state-specific evidence, HHS approved savings assumptions negotiated with the states, including significant projected reductions in Medicaid senior enrollment. But the limited research available suggests that potential health care savings due to improved access to prescription drugs are likely to be much less than the levels the states assumed and HHS approved. Had more conservative savings assumptions been used to estimate the demonstrations' costs, the proposals likely could not have been approved as budget neutral. Moreover, concerns have arisen about what actions states might take to control spending on behalf of seniors if estimated

³⁶According to CBO officials, the agency did not analyze the cost impact of individual Pharmacy Plus demonstrations but estimated potential impact on Medicaid spending overall under various growth scenarios. CBO estimated that roughly 1.2 million people would join the Medicaid rolls for the prescription drug benefit only. See U.S. Congressional Budget Office, *An Analysis of the President's Budgetary Proposals for Fiscal Year 2004: An Interim Report* (Washington, D.C.: March 2003).

savings do not accrue and states reach or exceed their spending limits under the demonstrations.

HHS-Approved Savings Assumptions Are Not Supported by State Experience

The approved Pharmacy Plus demonstrations count on expected savings based on reductions in the projected number of seniors who will enroll in states' Medicaid programs—ranging from a 3 percent reduction in Florida to a 25 percent reduction in South Carolina over the demonstrations' 5 years. The dollar amounts of combined federal and state savings projected under these assumptions in the demonstrations' budget neutrality calculations range from \$480 million in Florida to \$2 billion in Illinois (see table 4).

Table 4: States' Projections of Medicaid Senior Populations after 5 Years, with and without HHS-Approved Pharmacy Plus Demonstrations

Projections	Florida	Illinois	South Carolina	Wisconsin
Total projected Medicaid seniors, without demonstration, by year 5	210,200	186,683	90,006	70,412
Total projected Medicaid seniors, with demonstration, by year 5	204,300	145,240	67,946	57,297
Projected number of seniors diverted from Medicaid by year 5	5,900	41,442	22,060	13,115
Annual reduction in Medicaid seniors (percentage)	3	5	5	2.5–5
Cumulative 5-year reduction in Medicaid seniors (percentage)	3	22	25	19
Projected dollar savings due to diversion of seniors from Medicaid by year 5	\$480 million	\$2 billion	\$769 million	\$926 million

Source: GAO analysis.

Note: Analysis of state and HHS documents and of Jocelyn Guyer, *The Financing of Pharmacy Plus Waivers: Trade-offs between Expanding Rx Coverage and Global Caps in Medicaid* (Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured, 2003).

To project the extent to which Pharmacy Plus would reduce its new enrollment of Medicaid seniors, and thus its total senior enrollment, Florida made the relatively conservative assumption that the drug benefit would enable seniors to avoid Medicaid eligibility for 1 year; after 5 years, the state's total projected number of Medicaid seniors would be 5,900 (3 percent) lower with the demonstration than without it. The other states, in contrast, assumed that everyone diverted in each year of their demonstrations would remain out of Medicaid throughout the full demonstration period and would not, for example, enter a nursing home, which often results in Medicaid eligibility. As a result, Illinois, South Carolina, and Wisconsin projected reductions of nearly 20 percent or more in Medicaid senior enrollments at the end of 5 years. Had these states made more conservative assumptions—assuming, for example, as Florida chose to, that providing access to prescription drugs would delay seniors'

entry into Medicaid by only 1 year instead of 5—their projected with-demonstration costs would have exceeded projected without-demonstration costs and would not have been budget neutral.

Although states' demonstration proposals aim to achieve savings by expanding seniors' access to prescription drugs and improving their health, in practice it appears that some states' estimates of expected savings may have been derived in part by determining how much in savings was needed to demonstrate budget neutrality. In their proposals, none of the three states that previously had state-funded pharmacy assistance programs (Florida, Illinois, and South Carolina) provided data from those programs that specifically supported such high projected savings. Based on conversations with Wisconsin health care financing officials and a review of documents, we found that the state's demonstration savings estimates were a residual of the budget-negotiating process, derived from determining how much was needed in savings to demonstrate budget neutrality, rather than from research or data about what was realistic.

Premise behind Approved Demonstrations Not Well Supported by Research

The premise that Pharmacy Plus demonstrations will generate savings by keeping low-income seniors from becoming Medicaid-eligible is not supported by research. In a previous report, we reviewed the research studies cited in Illinois' demonstration proposal and found that they did not sufficiently support the state's theory that a full drug benefit for low-income seniors would yield the projected level of savings.³⁷ Although these studies indicated that access to prescription drugs benefited people in poor health, they all focused on people who already had specific diagnosed conditions, such as diabetes, heart disease, or HIV, rather than on a general population of seniors. An extensive 2003 review of research examining drug coverage for low-income seniors found relatively few studies about the effect on Medicaid spending of expanded access to a

³⁷ [GAO-02-817](#).

broad prescription drug benefit.³⁸ The one study this review considered most relevant, conducted in the mid-1980s, assessed Pennsylvania's state-funded program, Pharmaceutical Assistance Contract for the Elderly (PACE), and found that despite high enrollment, Medicaid entry among PACE participants was neither prevented nor delayed enough to have a discernible effect on the state's overall Medicaid budget.³⁹ Other studies of broad prescription drug benefits for low-income seniors, including one of New York's program, found some reductions in participants' health care costs but mainly for inpatient hospital care, which, for people age 65 or older, is covered by Medicare rather than Medicaid.⁴⁰ Still other studies in this review examined the more limited question of how access to appropriate drugs affects people already suffering from specific illnesses. Such research sheds little light on the cost-effectiveness of offering comprehensive drug benefits to a broad population of low-income seniors.

Some states that have not submitted Pharmacy Plus proposals examined the diversion and savings assumptions behind the demonstrations and found that they would not likely be realized. For example, in considering whether to apply for a demonstration, Minnesota found a substantial risk that seniors receiving only a drug benefit would eventually become Medicaid-eligible over a 5-year follow-up period. In its optimal model, the study estimated that to generate enough savings to offset the new drug costs, the risk of Medicaid entry would have to be reduced by 50 percent

³⁸Ellen O'Brien, "Will Prescription Drug Coverage for the Low-income Elderly Pay for Itself? A Review of the Literature," Georgetown University Health Policy Institute working paper, prepared for the Kaiser Commission on Medicaid and the Uninsured, May 2003, cited with permission. See www.hpi.georgetown.edu/pdfs/obrienrxcostoff.pdf, downloaded March 16, 2004. The author identified sources through a Medline search of the research literature and a manual search of citations in published papers. The analysis covered research literature on the effects of prescription drug coverage on low-income seniors, access limits in Medicaid and other insurance plans, studies of specific drugs or drug classes, and studies of the cost-effectiveness of recent prescription drugs.

³⁹Bruce Stuart and Daniel Lago, "Prescription Drug Coverage and Medical Indigence among the Elderly," *Journal of Aging and Health*, vol. 1, no. 4 (1989), 452-469.

⁴⁰In 2002 we reported that in assessing the cost of a Medicare prescription drug benefit at that time, CBO, OMB, and CMS's Actuary did not accept the premise that providing a prescription drug benefit to low-income seniors would pay for itself (GAO-02-817). CBO raised several reasons for caution, including that greater use of drugs among seniors could increase the risk of side effects and adverse drug reactions, which could in turn increase use of hospitals, emergency rooms, and other health care services. CBO concluded that Medicare beneficiaries without any drug coverage already consumed a large number of prescription drugs, and therefore any savings due to increased access would likely be small.

for non-nursing-home enrollees and by 30 percent for those who become eligible after entering a nursing home. Minnesota Medicaid officials concluded that this scenario was not realistic and dropped the state's Pharmacy Plus demonstration proposal.⁴¹

Pennsylvania also conducted a Pharmacy Plus demonstration feasibility study for PACE and the related Pharmaceutical Assistance Contract for the Elderly Needs Enhancement Tier (PACENET) programs, which together enrolled about 270,000 seniors in 2002.⁴² The study found that to offset drug benefit costs, the programs would need aggressive cost containment, through such approaches as increased co-payments, reduced provider reimbursements, and a preferred drug list. In addition, the study noted that in states with generous drug benefits, savings from expansion to more seniors are particularly difficult to realize because most beneficiaries who would have avoided expensive nursing home care have already done so. As of March 2004, Pennsylvania had not submitted a Pharmacy Plus demonstration proposal.

Concerns about Effects on States if Savings Do Not Accrue

Although it is early in demonstration implementation, we and others have raised concerns about how states may be affected if savings under Pharmacy Plus do not accrue and the states' spending reaches or exceeds HHS's approved spending limits. We noted in our July 2002 report that the Illinois Pharmacy Plus demonstration, as approved, makes several risky assumptions with regard to the extent of the expected savings.⁴³ In such cases the federal government would not be at financial risk, but the states would be, because the spending limits cover services for all the states' Medicaid seniors. Any expenditures for Medicaid seniors beyond the demonstration's federally matched spending limit would be entirely the state's responsibility. Officials in Florida and Wisconsin expressed concerns that their demonstration spending limits, based on fixed rates of growth projected over 5 years, could not be adjusted to reflect

⁴¹The results of this study by JEN Associates of Cambridge, Massachusetts, were reported in a memorandum to the Minnesota Department of Human Services, "Feasibility Analysis of PDP Expansion," dated March 7, 2002.

⁴²Pennsylvania's PACE program has operated since 1984 and PACENET has provided an expanded benefit to additional low-income seniors since 1996. See Mercer Government Human Services Consulting, *Pharmacy Plus 1115 Waiver Feasibility Study, Commonwealth of Pennsylvania* (Phoenix: October 2002).

⁴³See [GAO-02-817](#), 23-24.

unpredictable changes in costs and enrollment growth. One study has raised concerns about the potential effects on Medicaid seniors, noting that as state spending approaches the limit of what the federal government will match, states may feel pressed to reduce optional expansions of eligibility or optional benefits.⁴⁴ States could also try to control spending without reducing eligibility or services by lowering provider reimbursements—a step already taken in Illinois, although not in response to pharmacy demonstration enrollment or spending—or by implementing preferred drug lists.⁴⁵

States Have Taken Few Steps to Evaluate Demonstrations, and HHS Has Not Ensured Sufficient or Timely Progress Reporting

As of February 2004, efforts by the states and HHS to evaluate and monitor the four approved demonstrations, and to address some of the research questions the Pharmacy Plus initiative raises, were in their early stages. The four states with approved demonstrations had taken few steps toward implementing the evaluation plans required as a condition of approval, and an independent evaluation of two of the demonstrations, contracted by HHS and started in October 2002, was not scheduled to report until September 2005. In the interim, HHS has not ensured that the states' required progress reports contain sufficient information for monitoring whether the demonstrations are functioning as intended or that these reports are submitted in a timely manner.

States Have Taken Few Steps to Implement Evaluation Plans

As a condition of Pharmacy Plus approval, HHS requires states to design and carry out an evaluation and to report their results after the demonstration ends.⁴⁶ States are required to submit a plan for this evaluation in their proposals and in the operational protocols that HHS approves before states begin the demonstrations. Although the four states with approved Pharmacy Plus demonstrations submitted the required evaluation plans—containing research hypotheses, possible outcome

⁴⁴Jocelyn Guyer, *The Financing of Pharmacy Plus Waivers: Trade-offs between Expanding Rx Coverage and Global Caps in Medicaid* (Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured, May 2003).

⁴⁵According to an Illinois official, the reimbursement rate for all providers, including pharmacists, was cut by 6 percent in state fiscal year 2003, and that step helped the pharmacy demonstration operate well below its targeted first-year spending limit.

⁴⁶States are required to provide HHS with drafts of their final evaluation reports within 180 days of the end of the 5-year demonstrations; Pharmacy Plus terms and conditions do not require interim evaluation reports from the states. HHS also requires the states to cooperate with federal evaluators and contractors in the independent evaluation.

measures, and data needs—as of February 2004, they had taken few steps to put their evaluation plans into practice.

As HHS requires, the four states' initial proposals and operational protocols included plans for how they would evaluate whether their demonstrations were working as intended. With some variations, all the plans proposed to address the overall research question of how providing a pharmacy benefit to non-Medicaid-covered seniors would affect Medicaid costs, service use, and future eligibility trends, including whether savings achieved by diverting individuals from Medicaid eligibility would offset the benefit's cost. The first demonstration proposal, from Illinois, initially contained an extensive plan to assess demonstration outcomes; the plan later changed significantly. The initial plan proposed that the state collect data from sources such as Medicaid and Medicare claims systems, surveys of participants or case-study interviews, and demonstration-specific claims. In terms of outcome measures, Illinois' plan proposed comparing seniors who do have the drug benefit with seniors who do not on such measures as hospitalization rates, health care service costs, use of emergency room services, and rates and length of nursing home stays. A later version of Illinois' plan (as described in the state's operational protocol), however, calls for using existing Medicaid claims data for only one outcome measure, Medicaid spending for seniors.

Both South Carolina and Wisconsin adopted Illinois' relatively extensive initial evaluation plan in their demonstration proposals, and as of February 2004, neither South Carolina nor Wisconsin had changed its proposed plan. Florida, which did not submit an evaluation plan in its demonstration proposal, provided a two-paragraph discussion in its operational protocol. This discussion listed several hypotheses and indicators to be monitored, noted that data would be collected using the state's current Medicaid system, and gave no details about how or when the plan would be implemented.

As of February 2004, the states had taken few steps to implement their demonstration evaluation plans or to determine how they would collect or analyze data to support their evaluations. States' evaluation activities were generally limited to collecting and reporting to HHS data from their existing Medicaid data systems. Although plans for Illinois, South Carolina, and Wisconsin call for starting their evaluations at the start of their demonstrations to draw on data about services used before and

throughout beneficiaries' enrollment, these states and Florida indicated they were just beginning to collect and report data to implement their evaluation plans:

- Florida and South Carolina officials told us that they had not decided whether their evaluations would be designed and conducted by the state Medicaid agency or by an outside entity such as a university. Neither state had developed an evaluation implementation schedule.
- Illinois and Wisconsin reported providing extensive state data for HHS's independent evaluation of their demonstrations but, at the time of our review, had not begun their own evaluations. State officials told us they understood that participating in the independent evaluation would exempt them from conducting their own evaluations. But HHS officials told us that state evaluations were still required.

HHS Has Contracted for an Independent Pharmacy Plus Evaluation

HHS has contracted with independent university researchers for an extensive evaluation of the Pharmacy Plus demonstrations in Illinois and Wisconsin. The evaluation's goal is to document achievements and difficulties in implementing a Pharmacy Plus demonstration, as well as to identify impacts on entry into Medicaid and on costs to Medicare. According to HHS, the evaluation aims to address whether providing prescription drug benefits to non-Medicaid seniors will keep individuals relatively healthy, divert them from full Medicaid eligibility, and thus lower Medicaid and Medicare costs. To address these issues, the evaluation contract calls for four components of work, including (1) site visits to Illinois and Wisconsin to describe the demonstrations and their implementation; (2) telephone surveys of demonstration beneficiaries in those states about their health status, access to health care, and prior drug coverage; (3) analysis of Medicaid, Medicare, and demonstration claims data to assess patterns of drug use and effects on Medicaid and Medicare costs; and (4) an analysis of enrollment trends in each state's Medicaid program to determine if diversion assumptions are met. In addition, the evaluation aims to compare the experiences of demonstration beneficiaries with a similar population in another state that does not offer a prescription drug benefit.⁴⁷

⁴⁷The evaluators chose Ohio because of its proximity to both Illinois and Wisconsin; the characteristics of its senior population; and likely similarities in the attitudes of that state's policymakers, physicians, and public about the use of long-term care services.

Final results for all components of this planned 3-year evaluation, which began in October 2002, are scheduled to be reported to HHS by September 2005.⁴⁸ Specifically, a final report to HHS on the patterns of drug use is due in September 2004; final reports on the demonstrations' cost effects on Medicaid and Medicare are due in September 2005. The evaluation contract does not indicate when results from the work may be available to other researchers or the public.

According to the HHS evaluation project officer, the independent evaluators completed state site visits to Illinois and Wisconsin in July 2003 for the descriptive work component and submitted draft reports to HHS in December.⁴⁹ These reports were in review as of March 2004, and the project officer expected them to be approved and posted on HHS's Web site, although he did not know when posting would occur. A report containing results from the second evaluation component, the telephone surveys of beneficiaries, was expected later in 2004.⁵⁰

HHS Has Not Ensured That States Meet Progress-Reporting Requirements

HHS's monitoring and reporting requirements, which the states agree to carry out under HHS oversight, are set forth in the terms and conditions attached to each demonstration's approval letter. Although HHS and the states participated in required telephone conference calls to monitor the demonstrations' start-up, HHS has not ensured that all states submit the required quarterly and annual progress reports. The lack of sufficient and timely information from progress reports may impair the department's ability to monitor demonstration operations and accomplishments.

⁴⁸HHS selected Illinois and Wisconsin, the first two demonstrations to be implemented (in June and July 2002), for the independent evaluation. In March 2004, HHS's evaluation project officer indicated that the new Medicare prescription drug program and its potential effects on Pharmacy Plus demonstrations may lead the department to reassess plans and schedules for the independent evaluation.

⁴⁹The descriptions include such information as how each demonstration was established, demonstration features, each state's economic and political environment, obstacles encountered during program implementation, and the state's progress toward implementation and ensuring beneficiary access to prescription drugs.

⁵⁰The evaluators have also developed a database, including data provided from Illinois' and Wisconsin's Medicaid data systems, allowing them to track and analyze demonstration enrollment, costs, drug use, and demographics, along with HHS Medicare claims data for Pharmacy Plus beneficiaries from 1 year before enrollment in the demonstration through their first year.

Monitoring and reporting requirements are not as clearly established for the Pharmacy Plus initiative as for the Health Insurance Flexibility and Accountability (HIFA) initiative:

- The HIFA and Pharmacy Plus initiatives both require states to participate with HHS in monthly telephone monitoring calls. For pharmacy demonstrations, however, monthly calls are required for 6 months after implementation and only as needed thereafter; for most approved HIFA demonstrations, monthly calls are unlimited.
- States with approved HIFA demonstrations are required to submit quarterly progress reports in a format agreed upon with HHS, and demonstration terms and conditions describe the required content of these reports. The terms and conditions for Pharmacy Plus demonstrations are less specific regarding progress report format and content.
- HIFA demonstrations are expected to submit separate annual reports that discuss progress in evaluating the demonstrations, including results of data collection and analysis to test research hypotheses. Pharmacy Plus annual reports, in contrast, may be combined with or include the fourth quarterly progress report, may follow the same broad content guidelines as quarterly reports, and are not required to report progress in evaluation.

As of March 2004, HHS and the four Pharmacy Plus states had participated in the initial monitoring phone calls and begun to gather data on how their demonstrations were working. HHS and the states confirmed participating in monthly telephone calls for the first 6 months and then agreeing to maintain contact as needed. An HHS official told us the department did not set agendas or document these informal contacts, which focused on demonstration operations as states tracked enrollment and began to gather information about drug use and expenditures for new beneficiaries. States reported taking some steps to develop the capacity to report on their demonstrations. Florida, Illinois, and Wisconsin, for example, reported having or developing data management systems containing state Medicaid and other data that are capable of generating demonstration-specific reports. South Carolina expected to rely on existing Medicaid data systems. None of the states, however, were tracking the number of demonstration enrollees who had become eligible for Medicaid, although officials in three states reported the ability to do so. Further, the states had not provided information to HHS to assess whether diversion savings were occurring.

The information that HHS requires states to report has been insufficient for determining whether the demonstrations are operating as intended. According to one HHS official, HHS has not prescribed a standard format for, or specific information to be provided in, either the quarterly or annual progress reports; rather, the department works with the states to obtain needed information. The Pharmacy Plus terms and conditions stipulate that written quarterly and annual progress reports contain, at minimum, (1) a discussion of events during the quarter, including “enrollment numbers, lessons learned, and a summary of expenditures”;⁵¹ (2) notable accomplishments; and (3) problems and questions that arose and how they were resolved. The same HHS official told us that in response to these general requirements, states’ progress reports did not always include all information considered useful for monitoring purposes. For example, HHS reported that officials were working with Illinois to obtain additional information to complete its draft annual progress report. Illinois’ six-page annual report, submitted in September 2003, reported only on new demonstration beneficiaries and did not include first-year starting or ending enrollment or cost information for the state’s Medicaid senior program as a whole—the services and population affected by the Pharmacy Plus spending limit. One HHS official told us that after review of Illinois’ report, these cost and enrollment data were specifically requested to assess whether the new drug benefit was keeping seniors from becoming eligible for full Medicaid benefits. As of February 2004, Illinois had not provided this information.

Finally, HHS has not insisted on timely submission of the required quarterly and annual reports. Although Pharmacy Plus terms and conditions specify that quarterly reports are due 60 days after the end of the quarter, and annual reports are due 60 days after the end of the fourth quarter, HHS has not ensured that states submit the reports on time. Again, the department’s policy is to work with the states toward compliance. As of January 2004, Florida and Wisconsin had submitted all required written quarterly reports, mostly on time, while South Carolina had submitted only one of three required progress reports.⁵² Illinois, whose

⁵¹Centers for Medicare & Medicaid Services, *Pharmacy Plus: A Demonstration Program under Section 1115: Model Special Terms and Conditions of Approval* (Washington, D.C.: U.S. Department of Health and Human Services, n.d.), 4, www.cms.hhs.gov/medicaid/1115/pharmplustemptc.pdf (downloaded Apr. 6, 2004).

⁵²According to an HHS official, quarterly reports for South Carolina’s demonstration were delayed because the state had difficulty generating data on demonstration expenses, requiring department officials to work with the state on the problem.

demonstration was the first to be implemented, did not submit any of the three required quarterly reports before submitting its combined fourth quarterly and first annual report early in September 2003.

Conclusions

HHS's approval and monitoring of state demonstrations under the Pharmacy Plus initiative raise cost and oversight concerns and, ultimately, program concerns. The department's approval of four states' demonstrations raises questions about HHS's basis for its decisions. Because HHS based the spending limits it approved on higher-than-justified growth rates, these spending limits do not, in our view, represent reasonable estimates of demonstration costs over the 5-year trial periods and are not budget neutral. It was difficult to assess the reasonableness of the spending limits themselves, given that they were decided upon through an undocumented negotiation process, and neither public nor HHS internal documents stated the rationale for approving higher growth rates. We found that if HHS's benchmarks had been used to establish the spending limits, the federal government's liability for the four demonstrations could have been \$1.6 billion lower over 5 years. Moreover, the approved demonstrations rely on highly questionable assumptions about the extent to which savings would accrue to Medicaid from improved health of people receiving the new pharmacy benefit, particularly since many of them already had pharmacy benefits through existing state-funded programs.

In addition, the Pharmacy Plus initiative raises important evaluation questions about how improved access to prescription drugs may affect seniors' health and Medicaid and Medicare costs. Although some of these questions will likely be addressed by the independent evaluation of two states' demonstrations, in the interim HHS does not appear to be ensuring that states provide sufficient, consistent, and timely information for demonstration monitoring or that states begin implementing their own evaluation plans. The limited available information on how these demonstrations are operating makes it difficult to assess whether they are operating as intended.

The concerns about HHS's approved Pharmacy Plus demonstrations parallel those we have raised about other section 1115 waiver demonstration approvals over the past decade. These include the extent to which the department is protecting the Medicaid program's fiscal integrity and the need for clear criteria and a public process when HHS reviews and approves demonstrations. Along with the authority to waive Medicaid requirements, and the flexibility given states to test new approaches for

delivering services more efficiently and effectively, comes the responsibility for making decisions based on clear criteria and for monitoring the demonstrations and learning from them. More can and should be done to fulfill this responsibility.

Recommendations for Executive Action

In light of our findings that the four HHS-approved Pharmacy Plus demonstrations are likely to substantially increase federal Medicaid spending, as previously approved Medicaid section 1115 demonstrations have done; that HHS's review process and basis for these approvals have not been clearly set forth; and that approved demonstrations are not all meeting evaluation and monitoring requirements, we are making seven recommendations to the Secretary of HHS related to the section 1115 demonstration process.

To improve HHS's process for reviewing and approving states' budget neutrality proposals for Pharmacy Plus and other Medicaid section 1115 demonstrations, we recommend that the Secretary take three actions:

- For future demonstrations, clarify criteria for reviewing and approving states' proposed spending limits.
- Consider applying these criteria to the four approved Pharmacy Plus demonstrations and reconsider the approval decisions, as appropriate.
- Document and make public the basis for any section 1115 demonstration approvals, including the basis for the cost and enrollment growth rates used to arrive at the spending limits.

To ensure that approved Pharmacy Plus and other Medicaid section 1115 demonstrations fulfill the objectives stated in their evaluation plans, we recommend that the Secretary take two actions:

- Ensure that states are taking appropriate steps to develop evaluation designs and to implement them by collecting and reporting the specific information needed for a full evaluation of the demonstration objectives.
- On acceptance, make public the interim and final results of HHS's independent Pharmacy Plus evaluation.

To ensure that the Secretary and other stakeholders have the information needed to monitor approved Pharmacy Plus and other Medicaid section 1115 demonstrations to determine if they are functioning as intended, we recommend that the Secretary take two actions:

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- Ensure that states provide sufficient information in their demonstration progress reports, in a consistent format, to facilitate the department’s monitoring.
 - Ensure that states submit required demonstration progress reports in a timely manner.

Agency and State Comments and Our Evaluation

We provided a draft of this report for comment to HHS and the states of Florida, Illinois, South Carolina, and Wisconsin. HHS and Florida, Illinois, and Wisconsin responded with written comments, which are reproduced in appendixes III through VI, respectively. South Carolina provided technical comments, which we incorporated in our report as appropriate.

HHS’s Comments and Our Evaluation

HHS concurred with five of our recommendations to strengthen the processes for approving and overseeing Pharmacy Plus and other Medicaid section 1115 waivers and disagreed with two. It concurred with our recommendations to make public the basis for section 1115 demonstration approvals and to ensure that Pharmacy Plus and other Medicaid section 1115 demonstrations fulfill the objectives of their evaluation plans by working with the states toward useful program evaluations and making results of the independent Pharmacy Plus evaluation publicly available. HHS also concurred with our recommendation to ensure that adequate information is available to monitor the demonstrations to determine if they are functioning as intended. In this regard, HHS stated that it has provided each state that has implemented a Pharmacy Plus demonstration with an example of an outline and content to be used as a guide for progress reports and that it will make concerted efforts to ensure that states submit the reports in a timely manner.

HHS did not concur with our recommendation that the Secretary of HHS clarify criteria for reviewing and approving states’ proposed demonstration spending limits, indicating that although the department recognizes the importance of using criteria for reviewing budget neutrality, strict criteria cannot be determined in advance because states’ circumstances differ. HHS also strongly disagreed with our recommendation that the Secretary consider applying clarified criteria to the four approved Pharmacy Plus demonstrations and reconsider the approval decisions as appropriate. HHS stated that it used criteria to review each of the approved, disapproved, and pending demonstration proposals; believes the four approved demonstrations were based on well-supported budget estimates of future state spending; and does not believe

it appropriate to reconsider approved demonstrations before the end of the approval periods.

We agree with HHS that some flexibility is appropriate in considering the unique Medicaid section 1115 demonstrations proposed by different states. Consistent with our analyses of other section 1115 demonstration waivers over the past decade, however, we believe HHS's review process and decision criteria should be clear, and the results—particularly when approved spending limits deviate significantly from limits developed using benchmarks that HHS said it uses as a starting point—should be publicly explained and documented in the demonstrations' approval letters and terms and conditions. Even though HHS has developed a standard application form for Pharmacy Plus demonstrations, that form and other guidance does not provide written criteria for how HHS reviews and approves the growth rates that states propose. HHS's rationale for significantly deviating from benchmarks for projecting future program growth in establishing different states' spending limits has not been documented or made clear to us or to others, including other states that may be seeking approval of demonstration proposals. Without such clarity, questions arise as to how consistently states have been or will be treated in applying for demonstrations. Further, in our view, Pharmacy Plus demonstration approvals were based on questionable savings assumptions. We believe that HHS should establish clear criteria on which to base the spending limits and should reconsider its spending limit decisions for the approved Pharmacy Plus demonstrations in light of such criteria.

HHS also commented that it was premature to evaluate the Pharmacy Plus demonstrations given the limited experience from 12 to 18 months of operation. HHS said that were the outcome predetermined, a demonstration would serve no purpose. The agency believes the Pharmacy Plus initiative provides states an opportunity to use a Medicaid demonstration to test if providing drug coverage will prevent the aged and disabled low-income population from becoming Medicaid eligible. HHS noted that the four approved demonstrations together are providing drug coverage to 346,000 seniors who would otherwise be without this important benefit.

We agree that it is too early to evaluate the outcomes of the 5-year demonstrations and that section 1115 demonstrations are intended to test new propositions. More needs to be done, however, to ensure that states' evaluations collect the information needed to determine whether those new propositions are functioning as intended. Four states have Pharmacy

Plus demonstrations in place to test such propositions, and substantial federal funding is involved, including costs that were previously paid for by the states themselves. For these reasons, HHS has a responsibility to (1) make fiscally prudent decisions in its approvals, (2) ensure that savings hypotheses have some grounding in experience or research, and (3) ensure that the evaluations are planned and conducted in a way that will produce adequate information regarding the demonstrations' research hypotheses.

We also agree that the demonstrations can provide a valuable benefit to low-income seniors and disabled individuals who might otherwise be without drug coverage. But three of the four states with approved demonstrations had state-funded drug coverage programs in place before implementing their Pharmacy Plus demonstrations, and these state-funded programs became eligible for federal matching funds when the demonstrations were approved. We therefore find HHS's statement that the demonstrations are providing drug coverage to seniors who would otherwise be without it to be an overstatement.

HHS also commented on how MMA may affect the operation of approved Pharmacy Plus demonstrations and the review of pending and new demonstration proposals. HHS stated that seniors covered by the four Pharmacy Plus demonstrations will be able to begin receiving drug coverage under the Medicare Part D program in January 2006, and states will be able to use their own funds to "wrap around" the Medicare benefit to assist other Medicare beneficiaries whose incomes exceed the level for low-income subsidies. At that time, HHS believes there will be less need for Pharmacy Plus demonstrations, given expanded Medicare coverage for prescription drugs, and states operating the demonstrations will need to decide if they want to continue doing so and if their demonstrations can continue to be budget neutral. We have reviewed and incorporated this new information as appropriate.

HHS's written comments appear in appendix III, along with our response to additional comments that HHS provided on the findings in our draft report. The department also provided technical comments, which we considered and incorporated as appropriate.

Illinois' and Wisconsin's Comments and Our Evaluation

Illinois and Wisconsin officials commented that our draft report overstated the demonstrations' financial risk to the federal government and was unnecessarily alarming in light of data showing that the demonstrations are operating well within their spending limits. In its comments, Illinois

said that it stood by the growth rates it used to develop the spending limit for its Pharmacy Plus demonstration; it further argued for the soundness of its demonstration's premise—that providing a drug benefit to seniors will keep them healthier than if they had no drug coverage. In its comments, Wisconsin said that the draft report failed to consider the significant benefits its demonstration offers to the federal government and to seniors.

We agree that providing a drug benefit to seniors could keep them healthier, and we do not dispute the benefit to seniors of the states' drug programs started or expanded through Pharmacy Plus demonstrations. The demonstrations were approved, however, on the presumption that the cost of each state's prescription drug program would be paid for in savings from keeping seniors with little or no previous drug coverage healthy enough that they would not become eligible for full Medicaid benefits. Illinois' demonstration was approved on this presumption even though most of the beneficiaries were already receiving some prescription drug coverage through the state's existing state-funded program. We remain concerned that HHS is not maintaining its policy to ensure demonstrations are budget neutral.

Illinois also commented that it had taken all necessary steps to conduct its own evaluation and that it had cooperated fully with federal evaluators and HHS officials. Illinois said that although it officially filed its quarterly reports late, it submitted all the detailed data contained in those reports to CMS monthly. We are principally concerned with the extent to which the information that Illinois provided could be used to monitor whether the demonstration was operating as intended. Its one- to two-page quarterly reports, filed late, tallied the number of beneficiaries enrolled in the demonstration and drug expenditures to date and provided a narrative paragraph on accomplishments, problems, or issues. The information itself, however, furnishes little insight as to whether the demonstration is operating as intended or whether the benefit is reducing Medicaid costs.

Wisconsin commented that the draft report failed to ascribe any value to the government of Wisconsin's agreement to cap its federal Medicaid funding for seniors as a condition of Pharmacy Plus demonstration approval. We believe the draft report accurately captured HHS's approach to limiting the federal liability for the Pharmacy Plus demonstrations by establishing a "cap," or spending limit, as a condition of approval. We remain neutral on the "value" of this cap for several reasons. Requiring states to abide by a spending limit is a departure from the open-ended entitlement nature of the Medicaid program. We also recognize that under

the Medicaid program, states have considerable discretion to alter spending by increasing—or decreasing—coverage for certain populations and services. In addition, we recognize that HHS's budget neutrality practices provide for flexibility in approach and that HHS has established such a limit on other section 1115 demonstrations before the Pharmacy Plus initiative.

Wisconsin also commented that the draft report failed to mention that the demonstrations were reviewed, determined reasonable, and approved by OMB. We recognize that OMB is involved in assessing budget neutrality and other aspects of Pharmacy Plus and mentioned that agency's role in our draft report. Nevertheless, as OMB officials told us, the authority for section 1115 waiver approval rests with the Secretary of HHS, and responsibility for final Pharmacy Plus approval decisions rests with the Secretary and his designees.

Wisconsin further commented that in criticizing CMS for not obtaining better evidence to support projected savings, our report fails to consider that the reason for demonstration projects is precisely to test such propositions. We maintain, however, that when HHS establishes a new initiative to encourage states to apply for Pharmacy Plus demonstrations, it is the agency's responsibility to ensure that each demonstration's evaluation objectives are reasonable, each demonstration's savings assumptions are realistic and grounded in some evidence, and the evaluations are well planned and data monitoring is established early enough to assure that the questions can be answered.

Other States' Comments and Our Evaluation

Florida commented that its demonstration was predicated upon savings to be achieved over the 5-year life of the program and that its proposed spending limit was close to—less than 1 percent above—the conservative benchmark spending level we calculated. We agree that Florida's spending limit was relatively close to a limit based on the benchmarks and included that information in the draft report.

South Carolina provided technical comments that we incorporated as appropriate.

As arranged with your offices, unless you release its contents earlier, we plan no further distribution of this report until 30 days after its date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Administrator of the Centers for Medicare & Medicaid Services, and others who are interested. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions, please contact me at (202) 512-7118. Another contact and other major contributors are listed in appendix VII.



Kathryn G. Allen
Director, Health Care—Medicaid
and Private Health Insurance Issues

Appendix I: Calculating a State's Pharmacy Plus Spending Limit for All Medicaid Seniors

To achieve budget neutrality, a state's projected 5-year spending with its Pharmacy Plus demonstration cannot exceed 5-year projected costs without the demonstration. As a result, the projected costs of a state's existing Medicaid program for seniors effectively sets the spending limit while the demonstration is under way. Calculating this without-demonstration limit (steps 1–5 in fig. 1) starts with a base year, generally the most recent full year for which data are available; calculations for each subsequent year are based on numbers from the previous year. The result limits a state's Medicaid spending for all services provided to all Medicaid seniors in the state.

Figure 1: Steps to Calculate Projected 5-Year Without-Demonstration Costs

Step 1

Estimate Medicaid costs per senior for each year

$$\text{Cost per senior} \times \text{Cost growth rate} = \text{Projected 1-year cost per senior}$$

Step 2

Estimate Medicaid senior enrollment for each year

$$\text{Enrollment} \times \text{Enrollment growth rate} = \text{Projected 1-year enrollment}$$

Step 3

Determine 1-year costs for Medicaid seniors

$$\text{Projected 1-year cost per senior} \times \text{Projected 1-year enrollment} = \text{Projected 1-year costs}$$

Step 4

Determine costs for each of 4 more years

Repeat steps 1–3 four times. Each time, cost per senior and enrollment figures come from preceding year's projection. Cost and enrollment growth rates remain constant.

Step 5

Set Pharmacy Plus spending limit for all Medicaid seniors

$$\text{Add up projected costs for all 5 years} = \text{5-year Pharmacy Plus spending limit}$$

Source: GAO.

**Appendix I: Calculating a State's Pharmacy
Plus Spending Limit for All Medicaid Seniors**

Calculating projected 5-year with-demonstration costs follows the same steps but, in addition, factors in the estimated number of new beneficiaries receiving only the prescription drug benefit; the costs of providing them the benefit; and the expected savings, mainly from keeping these beneficiaries healthy enough to avoid eligibility for full Medicaid.

Appendix II: Denied, Withdrawn, and Pending Pharmacy Plus Demonstration Proposals as of May 2004

State and status	Description
Denied	
Hawaii Submitted January 2003 Denied April 2003	<p>Projected enrollment: Individuals with incomes at or below 300 percent of the federal poverty level (FPL).</p> <p>Coverage and cost sharing: Sought federal assistance only for administrative costs for a demonstration to make prescription drugs available at the discounted Medicaid rate plus a dispensing fee. State was to contribute \$1 toward the cost of each prescription in the first year, increasing to \$8 by the fifth year.</p> <p>Reasons for denial: Exceeded the Pharmacy Plus income limit at or below 200 percent of FPL, provided for only minimal state financial contributions to pharmacists, and did not include the necessary budget neutrality analysis.</p>
Delaware Submitted December 2002 Denied July 2003	<p>Projected enrollment: Seniors and adults with disabilities with incomes at or below 200 percent of FPL or, if income is above 200 percent of FPL, with prescription drug expenses exceeding 40 percent of their incomes.</p> <p>Coverage and cost sharing: All prescriptions covered by the Medicaid state plan, up to an annual benefit limit of \$2,500. Participants to pay co-payments of \$5 or 25 percent of the cost per prescription, whichever is greater.</p> <p>Reason for denial: State already provided drug benefits to the people to be covered under the demonstration.</p>
Withdrawn	
Massachusetts* Submitted July 2002 Withdrawn March 2003	<p>Projected enrollment: Seniors with incomes at or below 188 percent of FPL.</p> <p>Coverage and cost sharing: Same broad prescription drug coverage as state Medicaid plan. State proposed three levels of co-payments (exact amounts not specified): generic drugs, designated brand-name drugs, and all other brand-name drugs. Full cost of prescriptions to be covered after participants reached annual out-of-pocket spending limits: for example, a single person would pay the lesser of \$2,000 or 10 percent of gross annual income.</p> <p>Reason for withdrawal: State's existing pharmacy assistance program for seniors already covered the populations to be included in the demonstration, and without an expansion the state and the Department of Health and Human Services (HHS) could not reach agreement on budget neutrality.</p>
Pending	
Connecticut Submitted December 2001	<p>Projected enrollment: Seniors and adults with disabilities with incomes up to 300 percent of FPL.</p> <p>Coverage and cost sharing: All prescription drugs and insulin and syringes with specified exceptions, such as cosmetics and antihistamines. Annual registration fee of \$25 and co-payments of \$12 for those with incomes up to approximately 233 percent of FPL and \$20 for those above.</p> <p>State program: Covers low-income seniors and people with disabilities with incomes up to approximately 233 percent of FPL. Demonstration would expand eligibility up to 300 percent of FPL.</p>

**Appendix II: Denied, Withdrawn, and Pending
Pharmacy Plus Demonstration Proposals as of
May 2004**

State and status	Description
New Jersey Submitted March 2002	<p>Projected enrollment: Seniors and adults with disabilities with incomes at or below 200 percent of FPL.</p> <p>Coverage and cost sharing: All prescription drugs covered by state Medicaid plan, with \$5 co-payment for each prescription. For brand-name drug when generic is available, \$5 co-payment plus cost difference between the two.</p> <p>State program: Covers seniors and adults with disabilities with incomes up to 222 percent of FPL if single and 202 percent if married. Demonstration would cover individuals with incomes at or below 200 percent of FPL.</p>
Arkansas Submitted September 2002	<p>Projected enrollment: Qualified Medicare beneficiaries age 65 or older with incomes at or below 85 percent of FPL.</p> <p>Coverage and cost sharing: Would cover two prescriptions per beneficiary per month. Annual \$25 enrollment fee and co-payments of \$10 for each generic prescription and \$20 for each brand-name drug.</p> <p>State program: No state-funded pharmacy assistance program for seniors at the time of demonstration proposal submission.</p>
Indiana Submitted June 2002 Revised proposal submitted May 2003	<p>Projected enrollment: Seniors with incomes at or below 135 percent of FPL.</p> <p>Coverage and cost sharing: Same prescription drugs as the state's Medicaid program, plus insulin, up to annual benefit caps set on a sliding scale: \$1,000 for people with incomes up to 100 percent of FPL; \$750 for those with incomes up to 120 percent of FPL; and \$500 for those with incomes at or below 135 percent of FPL. Participants would pay 50 percent of the discounted program price, which is the same as the Medicaid price, for each prescription.</p> <p>State program: Existing state-funded pharmacy program for low-income seniors to be covered under the demonstration with no change in eligibility or drug coverage. State indicated that increased enrollment was expected in the demonstration following a change from a mail-in rebate system to a point-of-sale system using a discount card.</p>
Maine Submitted August 2002	<p>Projected enrollment: Seniors age 62 or older and adults with disabilities with incomes at or below 185 percent of FPL.</p> <p>Coverage and cost sharing: Prescription drugs for specified conditions with 20 percent co-payment for each prescription, or 10 percent if from mail-order sources. Broader range of drugs available for coverage with 20 percent co-payment after \$1,000 out-of-pocket expenses.</p> <p>State program: Demonstration would cover state-funded pharmacy program, expand conditions covered, and add voluntary mail-order purchase.</p>
Rhode Island Submitted October 2002	<p>Projected enrollment: Seniors and adults with disabilities or chronic illness, including chronic mental illness, with incomes at or below 200 percent of FPL.</p> <p>Coverage and cost sharing: All prescription drugs covered by state Medicaid plan. Annual \$25 enrollment fee (waived for first year of program) and co-payments that increase after participants have incurred \$1,800 of drug expenses per year under the program, from \$2 to \$4 for generics and from \$8 to \$12 for brand-name drugs with no generic equivalent; other brand-name drugs have a \$25 co-payment.</p> <p>State program: The demonstration would cover individuals with incomes at or below 200 percent of FPL from three state-funded pharmacy programs, while individuals in those programs with higher incomes would continue to be state funded. The scope of drugs covered by state programs would be expanded under the demonstration.</p>

**Appendix II: Denied, Withdrawn, and Pending
Pharmacy Plus Demonstration Proposals as of
May 2004**

State and status	Description
North Carolina Submitted January 2003	<p>Projected enrollment: Seniors with incomes at or below 200 percent of FPL.</p> <p>Coverage and cost sharing: All prescription drugs and insulin. Co-payments of \$5 for generic and \$15 for brand-name drugs; annual benefit limit of \$1,000 per participant.</p> <p>State program: Demonstration would cover and expand existing state-funded program by broadening prescription drugs covered from drugs for three specific conditions to those for all conditions, reducing cost sharing, and increasing annual benefit limit from \$600 to \$1,000.</p>
Michigan Submitted February 2003	<p>Projected enrollment: Seniors with incomes at or below 200 percent of FPL.</p> <p>Coverage and cost sharing: Most prescription drugs covered by state Medicaid plan, plus insulin and syringes. Annual \$25 enrollment fee and coinsurance of 20 percent of cost of each prescription up to a monthly cap on a sliding scale determined by household income. An additional co-payment would be charged for brand-name drugs with generic equivalents.</p> <p>State program: Demonstration would cover existing state-funded pharmacy assistance program with the same eligibility and coverage and expand enrollment.</p>

Source: GAO analysis of state and HHS documents.

Notes: These descriptions of states' Pharmacy Plus demonstration proposals are based on the proposals as submitted for HHS review. Changes to proposals that may be made during the review process and before approval are not available in documents.

³In March 2003, Massachusetts withdrew two separate section 1115 demonstration proposals from review: a Pharmacy Plus demonstration for seniors (the proposal described in this appendix) and a prescription drug benefit for individuals with disabilities as an amendment to the state's section 1115 Medicaid managed care demonstration. At the same time, Massachusetts submitted a new proposal—not a Pharmacy Plus proposal—to add a drug benefit for certain seniors and disabled individuals as an amendment to its existing managed care demonstration. In August 2003, that proposal was also withdrawn.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

JUN 8 2004

Ms. Kathryn G. Allen
Director, Health Care – Medicaid
And Private Health Insurance Issues
United States General Accounting Office
Washington, D.C. 20548

Dear Ms. Allen:

Enclosed are the Department's comments on your draft report entitled, "Medicaid Waivers: HHS Approvals of Pharmacy Plus Demonstrations Continue to Raise Cost and Oversight Concerns" (GAO-04-480). The comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

The Department provided several technical comments directly to your staff.

The Department appreciates the opportunity to comment on this draft report before its publication.

Sincerely,

A handwritten signature in black ink, appearing to read "D. Duquette".

Dennis J. Duquette
Deputy Inspector General of the
Office of Management and Policy

Enclosure

The Office of Inspector General (OIG) is transmitting the Department's response to this draft report in our capacity as the Department's designated focal point and coordinator for General Accounting Office reports. OIG has not conducted an independent assessment of these comments and therefore expresses no opinion on them.

COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT: "MEDICAID WAIVERS: HHS APPROVALS OF PHARMACY PLUS DEMONSTRATIONS CONTINUE TO RAISE COST AND OVERSIGHT CONCERNS" (GAO-04-480)

This report looks at the Administration's initiative to simplify and encourage States to consider demonstrations under section 1115 of the Social Security Act to expand coverage for prescription drugs under the Medicaid program to seniors and individuals with disabilities who have income exceeding that permitted for Medicaid eligibility but not exceeding 200 percent of the Federal poverty level.

As the report notes, HHS' Centers for Medicare & Medicaid Services (CMS) approved four States' applications for Pharmacy Plus waivers. These programs together are providing drug coverage to 346,000 seniors who would otherwise be without this important benefit. However, beginning in January 2006, these individuals will be able to begin receiving drug coverage under the Medicare Part D program. When Pharmacy Plus began, enactment of a drug benefit under Medicare was far from certain. With enactment of this historic legislation, Medicare beneficiaries will receive substantial coverage for drugs. Low-income beneficiaries will receive additional benefits, leaving them with minimal out-of-pocket costs. And, States will be able to use their own funds to wrap around the Medicare benefit to assist other Medicare beneficiaries with incomes that exceed the level for low-income subsidies.

When the Medicare Part D benefit is in place, we believe there will be less need for Pharmacy Plus waivers. States with waivers in effect will need to decide if they want to continue their waiver and if their waiver can continue to be budget neutral. Furthermore, the overlap of the Pharmacy Plus and Medicare Part D programs will make it difficult to fully evaluate the cost-effectiveness of Pharmacy Plus waivers. States generally projected that the break-even point for Pharmacy Plus would not occur until the fourth or fifth year of the demonstrations. In all of the Pharmacy Plus States, the Medicare drug benefit will begin *before* the time projected by the State for the savings generated by pharmacy coverage to exceed the cost of the benefit.

Based on the amount of time expected by the States and HHS for the Pharmacy Plus investment to pay off, our overall comment to GAO's findings and recommendations is that it is premature to evaluate the Pharmacy Plus waivers based on the limited experience available to date. It is important to note that the very nature of a demonstration project is to test new concepts and approaches in the Medicaid program. Were the outcome predetermined, a demonstration would serve no purpose. Each of the approved demonstration programs is scheduled to run for 5 years. As noted in the report, when this review was conducted, the four

programs reviewed had been in operation from 12 to 18 months—hardly sufficient time to determine the demonstrations’ outcomes.

The premise underlying the Pharmacy Plus demonstration program is straightforward. Prescription drugs are an increasingly important and a costly part of medical care. Medicare beneficiaries—the aged and disabled—who have income marginally in excess of that permitted for Medicaid eligibility, are at high risk of not adhering to their drug regimens if they lack insurance or other financial support to pay for prescription drugs. This is why 20 States established State-funded pharmacy assistance programs for their low-income citizens. Failure to take prescribed medications results in poorer health and increased health care costs. Pharmacy Plus provides the States an opportunity to use a Medicaid demonstration to test if providing drug coverage will prevent these populations from becoming Medicaid eligible and result in lower Medicaid costs.

GAO Recommendation

To improve HHS’ process for reviewing and approving States’ budget neutrality proposals for Pharmacy Plus and other Medicaid section 1115 demonstrations, we recommend that the Secretary take three actions first:

First, for future demonstrations, clarify criteria for reviewing and approving States’ proposed spending limits.

HHS Response

We nonconcur. We recognize the importance of using criteria for reviewing budget neutrality for Pharmacy Plus and other Medicaid section 1115 demonstrations; however, because State circumstances differ, strict criteria cannot be predetermined as our review is dependent on the specific proposal at issue. CMS, together with the Federal team of staff in other components of HHS and the Office of Management and Budget (OMB), works with the submitting States to understand the States’ proposals and budget estimates. This review process involves much back and forth conversation to clarify the submission, note omissions or needed changes, and discuss budget assumptions. It is unrealistic and impractical to document all of these discussions. However, we note that for Pharmacy Plus we developed a template for the State application. This provides guidance both on the program elements that HHS expects to be included in the application and State historical budget data that must be submitted. The program and budget templates guide States through the program elements that must be submitted in the application in order for HHS to review and approve the proposal. We believe that the template brings a considerable degree of standardization to the Pharmacy Plus application review process over that which would exist were no template available. In fact, of all the types of demonstrations, those with HHS-developed templates (such as Pharmacy Plus, Health Insurance Flexibility and

Accountability, and Independence Plus) provide the most clarity in the development and approval process.

GAO Recommendation

Second, consider applying these criteria to the four approved Pharmacy Plus waivers and reconsider the approval decisions, as appropriate.

HHS Response

We strongly concur. The Federal team has used the process and criteria stated above to review each of the approved, disapproved, and pending Pharmacy Plus demonstrations.

This process has resulted not only in the approval of four demonstrations, but two denials of demonstration applications, and nine pending demonstrations that have not been approved largely due to concerns about budget neutrality. HHS believes that the four projects approved were based on well-supported budget estimates of future State spending. We do not believe it is appropriate to reopen approved demonstrations before the end of the approval period.

GAO Recommendation

Third, document and make publicly available the basis for any section 1115 demonstration approvals, including the basis for the cost and enrollment growth rates used to arrive at the spending limits.

HHS Response

We concur. HHS makes available on our CMS web site the incoming applications (including the budget neutrality spreadsheets, which contain all growth trend rates and show the historical, without waiver, and with waiver trend rates), the approval or disapproval letters, terms and conditions, and final budget neutrality spreadsheets.

GAO Recommendation

To ensure that approved Pharmacy Plus and other Medicaid section 1115 demonstrations fulfill the objectives stated in their evaluation plans, we recommend that the Secretary take two actions:

First, ensure that States are taking appropriate steps to develop evaluation designs and to implement them by collecting and reporting the specific information needed for a full evaluation of the objectives.

HHS Response

We concur. HHS agrees that the evaluation component of demonstrations is important, which is why it is a requirement of approval. The application specifies that there must be an evaluation conducted by the State. States are required to submit an evaluation plan for their Pharmacy Plus demonstrations prior to implementation. We will continue to work with States toward a useful evaluation of their programs.

GAO Recommendation

Second, make the interim and final evaluation results of HHS' independent Pharmacy Plus evaluation public when approved by HHS.

HHS Response

We concur. HHS agrees with this recommendation and plans to make the results of this evaluation public by making it available on our CMS web site.

GAO Recommendation

To ensure that the Secretary and other stakeholders have information needed to monitor approved Pharmacy Plus and other Medicaid section 1115 demonstrations to determine if they are functioning as intended, we recommend that the Secretary take two actions:

First, ensure that States provide sufficient information in their demonstration progress reports, in a consistent format, to facilitate the Department's monitoring.

HHS Response

We concur. During implementation and the initial years of the demonstration, HHS' monitoring focus is to ensure that: a) individuals are not adversely affected by the demonstration, b) individuals are being served by the program, and c) that actual State and Federal spending does not exceed the budget neutrality projections. We think that receiving this information is sufficient to monitor the program as it develops. For every State that has implemented a Pharmacy Plus program, HHS has provided an example of an outline and content that is to be used as a guide for the progress reports.

We think that a consistent format is more important for evaluative purposes than it is for monitoring purposes. To evaluate the Pharmacy Plus initiative as a whole, it is helpful to have standard data collected to measure the effects of the program. As HHS continues to work with the Pharmacy Plus States toward an

evaluation of the program, we will seek to have States collect consistent data to help us best understand the effect of these demonstrations.

GAO Recommendation

Second, ensure that States submit required demonstration progress reports in a timely manner.

HHS Response

We concur. HHS agrees that States should submit their reports timely and will make concerted efforts to ensure that States do so.

The following are HHS' comments to the GAO Findings in the draft report:

GAO Finding: *Four HHS-Approved Pharmacy Plus Demonstrations are Likely to Substantially Increase Federal Medicaid Spending.*

GAO concludes that the four approved Pharmacy Plus demonstration projects will not prove to be budget neutral to the Medicaid program, resulting in increased costs to the program. HHS disagrees with this conclusion. We find the GAO analysis faulty and lacking in substance. We note that while we approved four applications, we disapproved two others, and reviewed but did not approve another nine. The reason we approved only four applications is that we take seriously our responsibility to ensure budget neutrality and will not approve applications until we are confident that the budget estimates are well supported.

As noted in the report, HHS requires that Medicaid demonstrations be budget neutral to the Medicaid program. Because the premise of Pharmacy Plus is that a drug benefit will "divert" low-income individuals from Medicaid, budget neutrality needs to encompass not only the expenditures for those covered by the demonstration, but also the entire affected population group. That is, we include expenditures for the regular Medicaid population from which costs are to be diverted, as well as the expansion benefit to Pharmacy Plus demonstration participants. States seeking Pharmacy Plus waivers are required to agree to a 5-year aggregate budget cap. This cap is an estimate of total Medicaid expenditures for the population group included in the waiver (e.g., aged), including the States' long-term care expenditures--the most costly category of care in Medicaid. Clearly, this cap puts the States at risk, making it critical that the cap be an accurate estimate of future Medicaid costs without the waiver. Likewise, it is important to HHS that the estimate be accurate because the Federal Government commits to matching State expenditures up to the cap. For each State, HHS worked closely with State and Federal staff to develop and agree to the best estimate of each State's expenditures over the 5-year life of the waiver. Clearly, there is no standard formula that can be used for this calculation.

The GAO report spends much time discussing deviations from “benchmark” numbers for expected program growth, going as far as to calculate the difference between the States’ agreed upon caps and what the caps would have been based on the benchmarks, and equating these to \$1.5 billion in excess Medicaid payments. We take strong exception to this analysis and its conclusions, and find the arguments made by GAO invalid. HHS policy has never been to hold States to benchmark levels of growth. Rather, we used two benchmarks as a starting point in our discussions with States. The starting point for evaluating budget neutrality is the lower of the State’s historical rates of growth, based on the most recent 5 years, for costs and enrollment, or the national growth rate estimated by the Office of the Actuary in CMS and used in the President’s Budget.

We are concerned that GAO has missed the fundamental purpose of budget neutrality. It is not to hold the State to a formula-driven cap. Rather, the goal is to estimate the amount the State would have spent in the absence of the demonstration. The estimation process is necessarily an individualized one, and must take into account the particular demographic, economic, and program characteristics of the State at issue. For this reason, we regard the growth measure described above not as a “benchmark” but as a “starting point” for the estimation process.

This starting point is viewed as the low-end estimate for the State. Both estimates have limitations that would make it unreasonable of us to use either one as the sole standard in setting an aggregate budget cap for future spending. We know that State historical growth rates may not be predictive of future growth rates and that growth rarely occurs at a steady pace. Regarding the President’s budget estimates, these are estimated on a national basis: clearly growth for individual States is expected to vary both up and down from these estimates. Estimating future expenditures for an individual State’s Medicaid program is a process that takes into account many different factors. State Medicaid programs are dynamic. Change is routine, not the exception. We acknowledge that this makes estimating future expenditures on an aggregate basis very difficult. This is why budget neutrality for section 1115 demonstration programs is generally constructed on a per capita basis. But the nature of the hypothesis underlying Pharmacy Plus requires an aggregate cap. We work closely with States to define that cap because of the risk the States are accepting. We believe that each State best knows its Medicaid program, population, cost drivers, and effects of exogenous factors. HHS tries to balance State historical growth, HHS’ own national estimates, and the State’s individual best estimates. From there, budget neutrality estimates are negotiated and agreed to by all parties. This is consistent with the approach taken with other demonstrations. Demonstrations approved in the past, such as State Health Reform demonstrations, have included future program growth estimated by States, including increases due to planned program expansions.

GAO focuses inappropriately on two “benchmarks” for growth in State costs and enrollment. It argues that the aggregate budget caps are not budget neutral

Now pages 19 and 20.

because HHS approved caps based on higher growth assumptions. As GAO acknowledges (pages 25 and 26), HHS allows States to present a rationale for higher growth rates. GAO's conclusion that we violated our own approval criteria in allowing higher growth rates is wrong.

The report also gives the impression that we grossly exceeded the benchmarks (the starting point for us); in fact only two (for Illinois and Wisconsin) of the eight estimates (cost and enrollment growth for each of the four States) did we approve a growth rate that exceeded both the State average and the President's budget estimate.¹ In these cases we were convinced, by data presented by the State, that changed circumstances in the State would result in higher enrollment growth. In three instances, we used the lower of the State historical growth and the President's budget estimate. In one instance the number agreed was between the two benchmarks. In the remaining two instances, we used the greater of the two benchmarks.

It is also worth taking a closer look at instances where the estimate used exceeded the two benchmarks. For those instances that involve enrollment growth, it is generally more volatile than cost growth, as a variety of factors can result in abrupt and significant caseload growth. Liberalizing program eligibility clearly causes enrollment to grow. Other factors, such as program exposure, outreach, and the creation of an easier enrollment process, have the same effect. It is important to remember that enrollment growth by State varies more widely from the national President's Budget estimates than does cost growth.

Illinois' growth was largely the result of an expansion in eligibility scheduled to take effect shortly after the start of the Pharmacy Plus demonstration. The Federal team reviewed the estimates used by the State in its budget. These estimates were not developed to support the State's Pharmacy Plus application. They were used to request funds needed to implement a legislated program expansion. We found these numbers to be credible.

In Wisconsin, the State's estimates were based on several factors including enrollment/education initiatives launched by the Social Security Administration and several State initiatives designed to increase enrollment by removing application and renewal barriers to Medicaid eligibility. Wisconsin estimated annual enrollment increases of 4 percent. The enrollment growth rate approved was 2 percent. HHS neither violated its own benchmarks, as GAO describes them, nor approved unreasonable, unfounded cost increases to the Medicaid program.

¹ We note an error in the GAO chart on page 26 of the report. Our records show South Carolina's historical average for enrollment growth to be 1.0, not 0.7 as indicated by GAO. Our records show Wisconsin's 3-year growth rate to be 6.6 percent (5.4 percent if using 5 years as was used by GAO). CMS used the 3-year estimate; therefore, the approved percentage was the lower benchmark.

GAO Finding: *HHS' Review Process and Basis for These Approvals Have Not Been Clearly Set Forth.*

The Federal review process for Pharmacy Plus demonstrations is similar to that for other Medicaid Section 1115 demonstration applications and does not differ greatly from other types of program requests that HHS processes. HHS considers many other types of State program requests that require us to evaluate future costs in order to avoid incurring new expenditures in the Medicaid program. These programs with costs tests, such as section 1915(b) waivers, section 1915(c) waivers, and section 1115 demonstrations, are all reviewed similarly in HHS. CMS, other HHS components, and, at times, OMB work with the State to reach agreement on best estimates for future spending using historical costs trends. The Federal team takes into consideration the information provided by the State as well as its own estimates.

The process for all these program reviews, including Pharmacy Plus, is very interactive. Numerous teleconferences take place within the Federal team and between Federal and State staff. The HHS staff also regularly report progress to senior management and receive guidance on how to proceed. A prime focus of this interaction is to develop the best estimate of future State spending to use in the budget neutrality calculation. We see no reason to establish a different review process for Pharmacy Plus demonstration applications.

GAO Finding: *Approved Demonstrations Are Not All Meeting Evaluation and Monitoring Requirements.*

A standard Term and Condition of approvals of Medicaid 1115 demonstration projects is a requirement for the State to evaluate the program. At times, HHS also undertakes its own evaluation. As noted in the GAO report, HHS has a contract with Brandeis University to evaluate the Illinois and Wisconsin Pharmacy Plus demonstrations. Ideally, a State would develop its evaluation plan prior to program implementation. In practice, HHS has found that, even when States present an evaluation design prior to the start of the demonstration, it frequently changes as States gain experience implementing the program, gathering initial data, and discovering new questions to address. HHS is also aware that States have limited resources to fund independent evaluations and usually rely on in-house staff. States frequently do not have staff with the skills needed to develop or carry out a sophisticated evaluation design, nor the funds for a costly evaluation. For these reasons, HHS works with State staff to assist them in developing a reasonable evaluation plan that addresses the key questions of benefit coverage and costs in the demonstration program.

In monitoring the demonstration programs, HHS is primarily concerned with tracking Medicaid enrollment and expenditures. As we noted during implementation and the initial years of the demonstration, HHS' focus is to ensure that: a) individuals are not adversely affected by the demonstration; b)

individuals are being served by the program, and c) that actual State and Federal spending does not exceed the budget neutrality projections. The monthly calls held between HHS and the State, and the quarterly progress reports are designed to help HHS monitor program activity. HHS monitors actual spending by reviewing financial reports submitted through the CMS 64 system. HHS is monitoring the Pharmacy Plus demonstrations through these means.

HHS provided examples of progress reports to all States and specified those items that HHS wanted to be reported on a quarterly basis. While Illinois has not been timely on some of its quarterly progress reports (but did provide them), the State has been sending HHS enrollment data, utilization data, and data about program enrollees.

This information, together with the financial expenditure reports and the monthly phone calls, provide us adequate information to monitor their program. HHS also asked Illinois to revise its originally submitted annual report to include more information. South Carolina, likewise, has not been timely in submitting its formal progress reports. However, the State and HHS continue to have monthly progress calls that involve discussions about program enrollment and operation. Florida and Wisconsin have been timely on their report submissions. As noted above in our response to a GAO recommendation, HHS plans to make concerted efforts to ensure timely submission of these reports in the future.

GAO's Response to the Department of Health and Human Services' Specific Comments on GAO's Findings

In addition to indicating whether it concurred with our seven recommendations, HHS commented on the report draft's findings in three areas.

Effect of HHS-Approved Pharmacy Plus Demonstrations on Federal Medicaid Spending

HHS disagreed with our conclusion that the four approved Pharmacy Plus demonstrations will not prove to be budget neutral to the Medicaid program and will possibly result in increased federal Medicaid spending. HHS stated that the department takes seriously its responsibility to ensure budget neutrality in the Medicaid demonstrations it approves, noting that it approved four Pharmacy Plus demonstrations while denying two and reviewing but not approving nine other proposals whose budget estimates were not well supported.

HHS was concerned that we missed the fundamental purpose of budget neutrality, which HHS says is not to hold states to a formula-driven cap but to estimate the amount of future Medicaid spending. HHS believes that the four approved demonstrations' spending limits were based on well-supported budget estimates of future state spending,¹ and said its policy has never been to hold states to benchmark levels of growth. Those benchmarks are, in HHS's view, a starting point in projecting how the program will grow, because HHS typically permits states to present rationales for higher growth rates.

We agree that there may be state-specific circumstances that justify departures from benchmarks HHS considers as starting points. Nevertheless, we believe that, given the potential impact on federal Medicaid spending, HHS and states should justify and document any significant departures from those starting points. In conducting our assessment, we interviewed HHS officials and Illinois and Wisconsin state

¹HHS also stated that the 0.7 percent per year state historical average enrollment growth rate we cite for South Carolina (table 2) is in error, because its records showed that South Carolina's historical average for enrollment growth was 1.0 percent. In verifying the state's historical enrollment rate, we noted that the rate had been "rounded up" to the next full percentage from the 0.7 percent actual historical rate. For consistency with other rates in the table, we did not round it.

officials and requested all documents that were considered in their budget neutrality negotiations. Those interviews and documents, which we discussed in the draft report, did not fully support the higher growth rates that were approved. We note that enrollment growth rates, in particular, can have a significant multiplier effect on future spending estimates. Further, we note that HHS allowed at least one state to argue for a higher growth rate using broad justifications—such as the effect of the Social Security Administration’s nationwide outreach program for low-income Medicare beneficiaries—that other states could also have used but did not, raising questions of clarity and consistency in both the process and the final decisions.

Documentation of HHS’s approval decisions and the basis for approved spending limits could provide a rationale for higher cost and enrollment growth rates and offer guidance and assurance of consistent treatment to other states applying for Pharmacy Plus demonstrations. Absent such documentation, neither HHS nor the states have adequately justified the departures from states’ historical growth rates or the CMS Actuary’s growth projections in establishing states’ spending limits.

HHS’s Review Process and Basis for Approvals

In its comments, HHS stated that the federal review process for Pharmacy Plus demonstration proposals is similar to the review process for other Medicaid section 1115 demonstrations, indicating that the process is necessarily interactive and involves numerous meetings within the federal team and with states. We acknowledge that the review process for Medicaid section 1115 demonstration proposals benefits from being inclusive and interactive, and we are not suggesting that HHS should establish a new or different review process specifically for the Pharmacy Plus demonstrations. Our concern is that the basis for its decisions and any agreed-upon spending limit be clear and justified, not only for Pharmacy Plus demonstrations but for all section 1115 approvals. As noted in the draft report, the concerns raised by HHS’s approved Pharmacy Plus demonstrations parallel those we have raised about other section 1115 waiver demonstration approvals over the past decade, including concerns about the extent to which the department is protecting the Medicaid program’s fiscal integrity and the need for clear criteria and a public process in reviewing and approving demonstrations.

Approved Demonstrations’ Evaluation and Monitoring Requirements

HHS commented that the department plans to continue working with states toward developing useful program evaluations based on consistent data collection as well as sufficient, consistent, and timely monitoring information. HHS also plans to make results of the independent Pharmacy

Plus evaluation available on the CMS Web site. With regard to states' own evaluations, HHS emphasized practical limitations, such as constraints on state financial and staff resources, indicating that while states ideally would develop evaluation plans before implementing demonstrations, in practice such plans often change. HHS commented that it obtains sufficient information for monitoring the demonstrations through telephone contacts and progress reports that respond to an example outline the department provided to each demonstration state.

We recognize that state resources are limited, demonstration implementation tends to be a higher priority than evaluation, and the independent contractor evaluation of Pharmacy Plus will provide substantial information. Nonetheless, the lack of action to monitor key information—such as whether demonstration enrollees are being diverted from Medicaid—to plan how their evaluations will be conducted, or to collect data needed for such evaluations suggests a low priority for ensuring that evaluations can and will be done. HHS needs to ensure that states provide sufficient, consistent, and timely information for both demonstration monitoring and for determining whether the demonstrations are functioning as intended and to ensure that evaluation plans are put into place.

Appendix IV: Comments from the State of Florida



JEB BUSH, GOVERNOR

MARY PAT MOORE, INTERIM SECRETARY

May 14, 2004

Katherine Iritani
Assistant Director
U.S. General Accounting Office
Washington, D.C. 20548

Dear Ms. Iritani:

This letter responds to your request for written comments concerning draft report GAO-04-480 "Medicaid Waivers – HHS Approval of Pharmacy Plus Demonstrations Continue to Raise Cost and Oversight Concerns". The report raises concerns with both state and federal methodologies used to substantiate budget neutrality for Medicaid Pharmacy Plus demonstration waivers.

We would note that the Florida waiver application was based in part upon assumptions provided to Florida Medicaid by CMS, and that Florida's proposed limits were less than 1% above the conservative benchmark spending levels in the GAO reports.

Florida's Pharmacy Plus waiver was predicated upon savings to be achieved over the five-year life of the program. Larger savings were expected to accrue in the last two years of the program, based upon avoiding nursing home admissions and hospital based care as a result of improved prescription drug therapies available during the early years of the program. While the program may be terminated early due to the implementation of the Medicare prescription drug benefit, Florida's calculations continue to reflect budget neutrality at a minimum, and possible incremental savings.

Sincerely,

Steven A. Grigas
Acting Deputy Secretary
Florida Medicaid



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Tallahassee, FL 32308

Visit AHCA online at
www.fdhc.state.fl.us

Appendix V: Comments from the State of Illinois



Rod R. Blagojevich, Governor
Barry S. Maram, Director

Illinois Department of Public Aid

201 South Grand Avenue East
Springfield, Illinois 62763-0002

Telephone: (217) 782-1200
TTY: (800) 526-5812

May 14, 2004

Ms. Kathryn G. Allen, Director
Health Care – Medicaid and
Private Health Insurance Issues
United States General Accounting Office
Washington, D.C. 20548

Dear Ms. Allen:

Illinois provides the following comments on the GAO draft Report to the Committee on Finance, U.S. Senate, “Medicaid Waivers: HHS Approvals of Pharmacy Plus Demonstrations Continue to Raise Cost and Oversight Concerns (GAO-04-480).” These comments should be included in the final report as Illinois’ comments.

Illinois stands by the growth rates used to develop the cost neutrality cap for its pharmacy plus waiver. They are supported by the data and other information submitted with the state’s waiver application. Illinois also believes that the basic premise of the demonstration—that providing a drug benefit to an aged population without comprehensive drug coverage will keep that population healthier—is a sound premise. In fact, it is self-evident. Some states may have determined that a drug benefit for seniors would not produce sufficient diversion from Medicaid to make a pharmacy plus waiver cost neutral. However, every state’s Medicaid program is different with respect to benefits and population. Illinois is confident that due to its particular program structure and population, particularly with respect to spend down and long term care, there will be sufficient diversion to make the demonstration budget neutral. In fact, preliminary data already shows a drop in nursing facility admissions.

Concerns expressed about reduction in services to the aged population are unfounded and unnecessarily alarming in light of the fact that cost data shows Illinois’ demonstration operating within the cost neutrality cap.

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Appendix V: Comments from the State of Illinois

Illinois has taken all necessary steps to conduct its own evaluation in addition to supplying extensive data and participating in numerous lengthy interviews for the federal evaluation. Every data element necessary for the evaluation is being collected.

Although Illinois' first three quarterly reports were officially filed late, all of the detailed data contained in those quarterly reports had previously been submitted to CMS on a monthly basis. All issues discussed in the narrative portion had been discussed with CMS during the monitoring phone calls and on-site visit. Official reporting for Demonstration Program purposes of the cost data for the Medicaid aged population has not and will not occur until the data set is complete. Medicaid law allows one year to submit a claim. Therefore, complete data for the first year will not be available until after July 1, 2004. Nevertheless, preliminary budget neutrality cost data is submitted quarterly to CMS on the CMS-64.

Sincerely,



Anne Marie Murphy, Ph.D.
Administrator
Division of Medical Programs

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Appendix VI: Comments from the State of Wisconsin



Jim Doyle
Governor

Helene Nelson
Secretary

State of Wisconsin

Department of Health and Family Services

DIVISION OF HEALTH CARE FINANCING

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May 14, 2004

Kathryn G. Allen, Director
Health Care – Medicaid and Private Health Insurance Issues
General Accounting Office
Washington, DC 20548

Dear Ms. Allen:

Thank you for the opportunity to provide comments to the draft report "Medicaid Waivers: Health and Human Service Approvals of Pharmacy Plus Demonstrations Continue to Raise Cost and Oversight Concerns" (GAO-04-480). The attached addresses substantive comments, corrections, clarifications and omissions that we believe should be incorporated in the General Accounting Office (GAO) final report.

We believe the GAO audit vastly overstates the financial risk to the federal government of Wisconsin's Pharmacy Plus waiver and fails to consider the significant benefits to the federal government of the terms and conditions of the SeniorCare waiver. Under the terms of the approved Pharmacy Plus waiver, in the current state fiscal year SeniorCare will reduce drug costs for 90,000 Wisconsin seniors by over \$112 million, of which the federal government will pay approximately \$39 million (34.8 percent).

Wisconsin data shows that our costs for SeniorCare are significantly below the benchmark, and that the risk to the federal government of higher federal spending is significantly less than anticipated. Even prior to adjusting SeniorCare for savings derived from individuals diverting from Medicaid and from reduced hospitalization and nursing home expenditures, the cost to the federal government would total \$250 million, not \$416 million based on more recent, actual data. The transmittal letter is not consistent with statements in the draft report. While the transmittal letter states unequivocally that the approved terms will cost the federal government an additional \$416 million, the report indicates that it might cost up to that amount. Since statements in the transmittal letter may unduly influence some, it is important that this false impression be corrected in the transmittal letter. The draft report also fails to note that the terms and conditions of Pharmacy Plus waivers for Wisconsin and the other states were independently reviewed, determined reasonable, and approved by the federal Office of Management and Budget (OMB).

The Pharmacy Plus program is a unique and valuable demonstration of the importance of providing a comprehensive drug benefit program to low-income seniors with significant drug costs. Under the Pharmacy Plus model, the Wisconsin SeniorCare program has proven to be an efficient and cost-effective program, currently providing full prescription drug benefits to 90,000 low-income Wisconsin seniors.

Wisconsin.gov

Appendix VI: Comments from the State of Wisconsin

Kathryn G. Allen
May 14, 2004
Page 2

Moreover, the draft report fails to ascribe any value to the federal government of Wisconsin's agreement to cap its federal Medicaid funding for seniors as a condition of Pharmacy Plus waiver approval. Wisconsin took considerable risk in agreeing to cap federal Medicaid matching funds for the elderly, and the federal government unquestionably realizes a benefit from capping its exposure. While reasonable people may differ on the exact value of that benefit, it cannot be assigned zero value. In addition, when criticizing CMS for not obtaining better evidence to support projected savings, the GAO report fails to consider that the reason for demonstration projects is precisely to test such propositions. In order to encourage sufficient participation to test questions in the real world, the risk parameters must be reasonable.

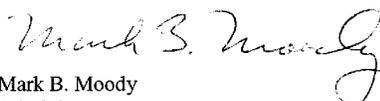
The Wisconsin SeniorCare waiver was approved prior to the recent federal enactment of Medicare drug coverage as an effort to address both state and federal interest in expanding assistance for low-income senior drug costs. At the time it was approved, the Wisconsin program provided the Centers for Medicare and Medicaid Services (CMS) a cost-effective way to make progress towards that goal. As such, the SeniorCare program has proven to be a bargain for taxpayers and beneficiaries. In the first 18 months of operation, SeniorCare has demonstrated successful and efficient delivery of a drug benefit that justifies continued strong support from the Federal government. We encourage Congress, CMS and GAO to carefully weigh the importance of SeniorCare to 90,000 low-income seniors in Wisconsin as a cost-effective model for prescription drug coverage.

In summary, Wisconsin's SeniorCare waiver will generate significant cost savings to the federal government through reduced Medicaid and Medicare payments for hospital and nursing home care. The waiver will ensure that low-income seniors have continued access to an easy application, to a simple, comprehensive prescription drug benefit, and to uncomplicated, reasonable cost sharing requirements when the Medicare Part D drug benefit is implemented.

Please find attached a list of complete comments and clarifications to the report. Again, thank you for the opportunity to respond to the draft. You may contact Russell Pederson, (608) 266-1720, with questions regarding this matter.

In closing, I would like to thank you and the GAO staff responsible for this report. The GAO has demonstrated a collaborative and collegial approach to learning more about the Wisconsin SeniorCare program in order to produce this report to Congress.

Sincerely,



Mark B. Moody
Administrator

MBM:my
HP05026
04-043005

Attachment

Wisconsin Department of Health and Family Services
Comments to GAO Draft Report

*Medicaid Waivers: Health and Human Service (HHS) Approvals of Pharmacy Plus
Demonstrations Continue to Raise Cost and Oversight Concerns (GAO-04-480)*

Submitted May 14, 2004

Comments

1. The General Accounting Office (GAO) uses a figure of \$416 million as the potential liability for the federal government because of “too liberal” benchmarks. However, the five-year costs of SeniorCare to the federal government will be significantly less than this amount. GAO’s use of this figure without any mention of the actual cost of SeniorCare exaggerates the federal fiscal effect. The current projection for the five-year cost of SeniorCare is \$250 million (FED). As such, even prior to adjusting SeniorCare for savings derived from individuals diverting from Medicaid, the cost to the federal government would total \$250 million - not \$416 million. Most importantly, the \$250 million of federal expenditures will provide Wisconsin seniors over \$641 million in prescription drug savings and will result in savings from reduced hospitalizations and nursing home care.
2. The draft states that the Centers for Medicare and Medicaid Services (CMS) should have applied a rule to use the lower of the state experience or the CMS standard in setting the budget neutrality parameters. We believe this is an unreasonable standard and rule to apply to Pharmacy Plus waivers. If historical experience provides sufficient justification to lower the accepted benchmark, it should also be permitted to expand the benchmark. In addition, the GAO report mentions several criteria that were discussed throughout the negotiations on the waiver, including the potential impact of the SSA outreach on Medicaid enrollment, the growth in the elderly population, and the cost trends and enrollment projections for the elderly in the President’s budget. The report, however, does not incorporate these factors into the benchmark factor analysis, and as noted earlier, the failure to do so is not reasonable given the requirement to place an aggregate cap on federal Medicaid matching funds for the elderly.
3. The report questions the savings from expanding drug coverage by noting that some of the savings (such as hospital care) will accrue to Medicare, rather than Medicaid. This argument is an unreasonably narrow interpretation considering the federal government pays 100 percent of Medicare and, in Wisconsin, about 60 percent of Medicaid. Although the benefit to the Medicare program is not considered in the CMS test of Medicaid savings, Medicare savings should be considered and are relevant to the GAO review of the overall federal fiscal effect of the waivers. In fact, the CMS independent evaluation of the Wisconsin Pharmacy Plus waiver expressly requires a component that will review the Medicare costs of SeniorCare participants. An estimate of savings could be developed using these data.

4. The GAO criticizes the CMS approval of a Wisconsin standard benchmark increase of 6.3 percent for the cost per eligible because Wisconsin's historical experience was lower. However, the historical trend was an increasing trend so that the five-year average may very well underestimate what will happen in the five years of the SeniorCare waiver. The higher cost per eligible figure (6.3 percent) is reasonable given the upward trend that Wisconsin was experiencing at the time the waiver was in negotiation. In particular, the historical trend in the last three years was 7.3 percent.
5. The GAO references the Social Security Administration outreach factor for the higher caseload growth factor. However, the draft does not mention other important factors, such as the expansion of Wisconsin FamilyCare and PACE/Partnership. Because FamilyCare and Pace/Partnership expand access to home and community-based waiver services, there is an expansion in the number of eligibles on Medicaid that will be enrolled as waiting lists for community-based care are eliminated.
6. The GAO suggests there is not firm evidence that expansion of drug coverage would produce savings in Medicaid by diverting or delaying Medicaid enrollment. We strongly object to this characterization of the Wisconsin waiver negotiation and intent of the Pharmacy Plus programs. The GAO criticism ignores the central purpose of demonstration waivers. In fact, Pharmacy Plus demonstrations are *intended to determine* if this important health care benefit can be delivered cost-effectively. In addition, research does suggest that coverage of prescription drugs is beneficial to seniors.
7. The draft also suggests Congress and others have raised concerns about whether 1115 demonstration waivers actually promote the goals of Medicaid. We strongly dispute the implication that the Wisconsin SeniorCare Pharmacy Plus waiver is not, in fact, providing critical prescription drugs to a vulnerable elderly, low-income, uninsured population. The report provides no information that is routinely reported by Wisconsin to CMS under the terms of the approved waiver (and shared with GAO) that demonstrates budget neutrality to date. It should be noted that the waiver was obtained to serve more low-income seniors under Medicaid and it did not limit benefits or services to current Medicaid recipients.

Contrary to the GAO draft summary, there is no evidence to date that the Wisconsin SeniorCare demonstration waiver will increase federal spending. SeniorCare is lauded by virtually every local, state and federal stakeholder, and participant audience as an exemplary, cost-effective, uncomplicated program that provides critical prescription drugs to low-income Wisconsin seniors.

8. The GAO mis-characterizes the benchmark standards for Wisconsin. Wisconsin was not allowed significant "extra room" in the trend rates given reasonable variation that is expected in any trend. In addition, the benchmarks must also address the risk to the state of capping all federal Medicaid matching funds for Medicaid benefits to the elderly.

9. The report states that a “lack of information” on how the demonstrations are operating “compromises any attempt to assess whether they are operating as intended.” We strongly object to this statement. The Wisconsin Division of Health Care Financing (DHCF) has developed sophisticated fiscal and program utilization monitoring systems and reports all of which are available and reported in aggregate on a quarterly basis to CMS. DHCF has met all requirements under the Terms and Conditions in providing timely, comprehensive program cost and utilization reports.
10. DHCF administers a data reporting system that allows staff to conduct ongoing reporting and monitoring of the state commitment to budget neutrality through evaluative analysis. As such, we strongly object to the draft statement, “the information states have submitted is insufficient for determining whether the demonstrations are operating as intended, which will limit HHS oversight capability.” Wisconsin has submitted detailed quarterly and annual reports that correspond directly to CMS operational protocols. The reports provide CMS, state staff, and the public with quantitative measures and analysis of the budget neutrality calculation, program costs, participant utilization and an array of program data. As such, we are confident the SeniorCare program is, in fact, functioning as intended and reported.
11. In addition, Wisconsin has agreed to a rigorous independent evaluation by a CMS contractor to ensure a complete and impartial analysis of Wisconsin SeniorCare and Medicaid data, as well as corresponding analysis of participant Medicare medical claims data. The independent evaluation is a comprehensive review of the program effectiveness, including state, federal and participant costs, drug utilization, and overall impact on low-income Wisconsin seniors. Wisconsin has provided the CMS contractor, Brandeis University, with extensive program information and data over the course of the past year, including direct program and participant cost information, detailed fiscal analyses and any information requested for the purpose of the evaluation.

The GAO draft omits any reference to the importance of the independent evaluation as an effective approach to review CMS assumptions relating to budget neutrality and program effectiveness. We believe Congress’ interest in the effectiveness of the approved Pharmacy Plus waivers is best addressed through the unbiased and independent evaluation. We also believe CMS has correctly exercised its authority under the SeniorCare Terms and Conditions to allow the independent evaluation as meeting the program evaluation requirement under the waiver.

GAO's Response to the State of Wisconsin's Specific Comments

In addition to overall comments on our draft report contained in its letter and discussed in the body of this report, Wisconsin provided 11 specific comments in an attachment to its letter, which is reproduced on pages 67 through 69. Our responses to Wisconsin's specific comments are numbered below to correspond with each of the state's numbered comments.

1. Wisconsin commented that our \$416 million figure (the estimated federal share of the difference between HHS-approved and benchmark 5-year spending limits in table 3) exaggerates the federal fiscal effect, because the actual costs of the demonstration's first years have come in under the projected costs. The state currently projects federal costs for the new drug benefit under the demonstration totaling \$250 million over 5 years instead of roughly \$537 million, which is the federal share of \$919 million approved for the new benefit (see table 1). Although we recognize that the actual costs of Wisconsin's demonstration to date are less than the costs projected at the time the waiver was approved, our analysis examined the extent to which HHS ensured that the demonstrations—in the form they were approved—maintained spending limits that were budget neutral to the federal government. Because Wisconsin's approved spending limit represents the total amount the state is authorized to spend over the demonstration's 5-year life-span, the federal government could be liable for as much as \$416 million more than what it would have been liable for had HHS held the state to a spending limit based on benchmark rates (see table 3).
2. Wisconsin commented that it is unreasonable to hold HHS to applying the lower of two benchmark growth rates in calculating budget neutrality: state experience or projections by the Centers for Medicare & Medicaid Services' (CMS) Actuary for Medicaid costs. The state also expressed concern that our analysis did not incorporate factors other than the benchmarks that affect program growth. We believe that it is reasonable to expect HHS to use objective benchmark growth rates in projecting the Medicaid costs on which it bases spending limits and to document its reasons for deviating from those benchmarks—even if the department regards them as starting points. Otherwise, the department's rationale for setting higher spending limits (based on higher growth rates) for some states than for others is not apparent to other states involved in waiver negotiations and reviews. As noted in the draft report, HHS responded to Wisconsin's request for higher growth rates but did not, in our view, adequately document the basis for approving higher rates. In our own analysis of the spending limits, we did not include the additional factors that Wisconsin asserted

should raise its spending limits because neither the state nor HHS provided adequate support to justify doing so.

3. Wisconsin stated that our interpretation was unreasonably narrow in not accounting for potential savings accruing to Medicare, as well as to Medicaid, from expanding prescription drug coverage for seniors. We considered savings to Medicaid alone because HHS allows states to include savings only to Medicaid, not Medicare, in determining whether their Medicaid demonstrations are budget neutral.
4. Wisconsin commented that because its historical cost growth rate has been rising, it was appropriate for HHS to calculate the state's spending limit using a rate higher than its historical 5-year average. We believe that whenever HHS allows growth rate projections that exceed its benchmarks, it should document the basis for this deviation.
5. Wisconsin mentioned two state programs that it believes will, like the Social Security Administration's outreach program for low-income Medicare beneficiaries, help increase senior enrollment in Wisconsin's Medicaid program because they are likely to identify individuals who qualify for full Medicaid benefits. But the state did not quantify or provide any data or other evidence to show the potential effects of these programs or of Social Security Administration outreach. We did not include these effects in our benchmark analysis for the same reason we did not include other factors that Wisconsin believed should raise its spending limit (see our response to comment 2).
6. Wisconsin noted that we found no firm evidence to support the idea that expanding drug coverage would produce significant savings in Medicaid by diverting or delaying Medicaid enrollment. The state asserts that this criticism ignores the central purpose of these demonstrations: to determine if an important health care benefit can be delivered cost effectively. We acknowledge the value of demonstrations to test health care alternatives, but we believe that the case for substantial savings to Medicaid due to expanded prescription drug coverage is not well supported. We also believe that HHS has not done enough to ensure that states develop and implement demonstration evaluation designs. Although we do not dispute Wisconsin's comment that research suggests coverage of prescription drugs benefits seniors, we believe that demonstrating the effects of drug coverage on avoiding Medicaid enrollment is a separate issue.
7. Wisconsin has interpreted our mention of congressional concern about the extent to which HHS has ensured that section 1115 demonstration waivers promote the goals of Medicaid as implying that the state's

demonstration is not providing critical prescription drugs to a vulnerable elderly, low-income, uninsured population. We did not intend to suggest that Wisconsin's demonstration is not a valuable benefit to these individuals. We were referring to our earlier work on section 1115 Medicaid and State Children's Health Insurance Program (SCHIP) demonstrations, which, in addition to raising concerns about HHS's use of section 1115 waiver authority to approve demonstration spending limits that were not budget neutral, also found that HHS was allowing states to use unspent SCHIP funding to cover childless adults, despite SCHIP's statutory objective of expanding health coverage to low-income children.¹

8. Wisconsin commented that we mischaracterized the growth rates approved by HHS for the state's demonstration as too high. See our response to comment 2.
9. Wisconsin objected to our conclusion that the lack of available information on how these demonstrations are operating compromises attempts to assess whether they are operating as intended. This statement does not apply to any one state alone but synthesizes our findings for the four approved demonstrations taken together. We acknowledge that Wisconsin has been responsive to HHS's requirements for informative and timely progress reports and have revised our report as appropriate.
10. Wisconsin stated that its data reporting system allows its staff to monitor that the demonstration is operating as intended. In the draft report, we noted that Wisconsin officials reported having the capability for monitoring. We have not assessed Wisconsin's monitoring system.
11. Wisconsin commented on the importance of, and Wisconsin's full participation in, CMS's contracted independent evaluation as an effective approach to reviewing the agency's assumptions relating to budget neutrality and program effectiveness. We believe the draft report captured the plans for this independent evaluation, as well as the apparent confusion over each state's responsibility for conducting

¹See [GAO-02-817](#) and U.S. General Accounting Office, *SCHIP: HHS Continues to Approve Waivers That Are Inconsistent with Program Goals*, [GAO-04-166R](#) (Washington, D.C.: Jan. 5, 2004).

its own evaluation. We have revised our report to reflect that Wisconsin officials believe the state is not required to conduct an evaluation, whereas HHS officials told us the state would be required to do so.

Appendix VII: GAO Contact and Staff Acknowledgments

GAO Contact

Katherine Iritani, (206) 287-4820

Acknowledgments

In addition, Tim Bushfield, Ellen W. Chu, Helen Desaulniers, Behn Kelly, Suzanne Rubins, Ellen M. Smith, and Stan Stenersen made key contributions to this report.

Related GAO Products

SCHIP: HHS Continues to Approve Waivers That Are Inconsistent with Program Goals. [GAO-04-166R](#). Washington, D.C.: January 5, 2004.

Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns. [GAO-02-817](#). Washington, D.C.: July 12, 2002.

Medicare and Medicaid: Implementing State Demonstrations for Dual Eligibles Has Proven Challenging. [GAO/HEHS-00-94](#). Washington, D.C.: August 18, 2000.

Medicaid Section 1115 Waivers: Flexible Approach to Approving Demonstrations Could Increase Federal Costs. [GAO/HEHS-96-44](#). Washington, D.C.: November 8, 1995.

Medicaid: State Flexibility in Implementing Managed Care Programs Requires Appropriate Oversight. [GAO/T-HEHS-95-206](#). Washington, D.C.: July 12, 1995.

Medicaid: Statewide Section 1115 Demonstrations' Impact on Eligibility, Service Delivery, and Program Cost. [GAO/T-HEHS-95-182](#). Washington, D.C.: June 21, 1995.

Medicaid: Spending Pressures Drive States toward Program Reinvention. [GAO/T-HEHS-95-129](#). Washington, D.C.: April 4, 1995.

Medicaid: Spending Pressures Drive States toward Program Reinvention. [GAO/HEHS-95-122](#). Washington, D.C.: April 4, 1995.

Medicaid: Experience with State Waivers to Promote Cost Control and Access to Care. [GAO/T-HEHS-95-115](#). Washington, D.C.: March 23, 1995.

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