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MEDICAID AND SCHIP

Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns

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Abbreviations

CMS	Centers for Medicare and Medicaid Services
CBO	Congressional Budget Office
CRS	Congressional Research Service
EPIC	Elderly Pharmaceutical Insurance Coverage
EPSDT	Early and Periodic Screening, Diagnostic and Treatment
FMAP	Federal Medical Assistance Percentage
FOIA	Freedom of Information Act
FPL	federal poverty level
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HIFA	Health Insurance Flexibility and Accountability
OMB	Office of Management and Budget
PAAD	Pharmaceutical Assistance to the Aged and Disabled
SCHIP	State Children's Health Insurance Program
TANF	Temporary Assistance for Needy Families

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United States General Accounting Office
Washington, DC 20548

July 12, 2002

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

States provide health care coverage to about 40 million low-income uninsured adults and children largely through two federal-state programs—Medicaid and the State Children's Health Insurance Program (SCHIP). Medicaid generally covers low-income families and elderly and disabled individuals, while SCHIP provides health coverage to children in families whose incomes, while low, are above Medicaid's eligibility requirements. To receive federal funding, which covered on average about 57 percent of Medicaid expenditures and 72 percent of SCHIP expenditures in 2001, states must meet certain statutory requirements including providing a certain level of benefits to specified populations. Under section 1115 of the Social Security Act, the Secretary of Health and Human Services (HHS) can waive many of the statutory requirements in the case of experimental, pilot, or demonstration projects that are likely to promote program objectives. As part of their responsibility to protect the fiscal integrity of the programs, traditionally, HHS and the Office of Management and Budget (OMB) have had a policy that all approved waiver projects be "budget neutral" for the federal government—that is, the proposed project cannot result in federal expenditures that are higher than they would have been without the project.

Within the past year, HHS indicated that it would allow states greater latitude in using section 1115 waivers to modify the Medicaid and SCHIP programs and would expedite its consideration of state proposals. Specifically, the department announced two new section 1115 initiatives to expand health coverage to uninsured populations and to provide prescription drug coverage to low-income seniors using section 1115 waivers. One initiative, the Health Insurance Flexibility and Accountability Initiative (HIFA), focuses on proposals for covering more uninsured people while at the same time not raising program costs. Another initiative, called Pharmacy Plus, encourages states to expand access to prescription drug coverage to low-income seniors not eligible for Medicaid, again while not raising program costs.

The increased emphasis on using section 1115 waivers and these two new initiatives have raised concerns about whether HHS can both expedite its approval process and at the same time provide adequate review and oversight of waiver proposals that could change how, and to whom, program services are delivered. The expedited reviews have also raised concerns about the adequacy of the public's ability to review and comment on the proposed changes. At your request, we reviewed section 1115 waiver requests involving expanding coverage to the uninsured or providing seniors drug coverage that HHS has received since the first of these initiatives was put into effect in August 2001. Specifically, we examined three questions regarding the section 1115 waiver proposals submitted and approved in line with HHS's goals of expanding health coverage and providing prescription drug benefits to low-income elderly:

1. What types of waiver proposals have been submitted and approved?

2. Has HHS ensured that the approved waivers are consistent with the goals and fiscal integrity of Medicaid and SCHIP?

3. To what extent has there been opportunity for public input in the expedited process?

Our work is based on a review and analysis of section 1115 waiver proposals for new demonstration projects submitted since August 2001 and related to expanding insurance or providing pharmacy coverage in line with the two new initiatives. We analyzed HHS data on section 1115 waiver proposals for new programs submitted from August 2001 to May 2002, and documented the type, number, and outcome of these proposals. For the four approved waivers, we reviewed waiver proposals, HHS decision memorandums and approval letters, approved waiver applications, waiver terms and conditions, and operational protocols when available, and documentation of the states' public process and budget neutrality justifications. We also discussed these initiatives and waiver approvals with officials at HHS, the Centers for Medicare and Medicaid Services (CMS, the agency within HHS with the lead role in receiving and reviewing the applications),[1] OMB, and relevant state agencies. To obtain

[1]Although CMS has lead responsibility for administering Medicaid and SCHIP, throughout this report we refer to HHS as the primary program entity, because the section 1115 waiver authority resides with the Secretary and other HHS entities are also involved in the review and approval process. The CMS Administrator signed the approval letter on behalf of the Secretary for the four waivers we reviewed.

information on the opportunity for public input to the waiver-approval processes and any related research studies, we also contacted several health research and advocacy organizations including the Center for Budget and Policy Priorities, the National Health Law Program, and the Kaiser Commission on Medicaid and the Uninsured. We examined the statutory provisions governing the Medicaid and SCHIP programs and the section 1115 waiver authority, and obtained HHS's opinion on a legal question through written correspondence. Finally, we relied upon our past reports and testimonies on the approval of section 1115 waivers and other issues.[2] We conducted our work from December 2001 through June 2002 in accordance with generally accepted government auditing standards.

Results in Brief

Since August 2001, HHS has approved 4 of 13 waiver proposals from states to either expand health insurance to uninsured populations or extend pharmacy coverage to low-income seniors, consistent with the new initiatives' goals. Three of the approved waivers, from Arizona, California, and Utah, aim to reduce the number of uninsured, while Illinois's extends drug coverage to low-income seniors. Arizona's and California's HIFA waivers use unspent SCHIP funds to cover uninsured low-income adults not otherwise eligible for Medicaid. California's waiver allows the state to use SCHIP funds to cover the parents of children who are enrolled in Medicaid and SCHIP, while Arizona's waiver allows the state to cover previously uninsured low-income adults, including those with no children. Utah's waiver extends limited medical coverage, with an enrollment fee and cost sharing, to previously uninsured low-income adults by increasing cost-sharing requirements and reducing optional benefits to certain current Medicaid beneficiaries. Illinois's Pharmacy Plus waiver extends pharmacy benefits to many low-income seniors under the assumption that making this benefit available will avoid these individuals' spending down their resources and becoming eligible for Medicaid, thus reducing Medicaid's nursing home, hospital, and other medical costs. Of the nine proposals still under review, five seek to expand coverage to uninsured populations, while four would provide pharmacy benefits for low-income seniors.

We have both legal and policy concerns about the extent to which HHS has ensured that the approved waivers are consistent with the goals and fiscal integrity of Medicaid and SCHIP. The legal concern is that, under the

[2]See related GAO products at the end of this report.

Arizona waiver, HHS has allowed the state to use unspent SCHIP funding to cover adults without children, despite SCHIP's statutory objective of expanding health coverage to low-income children. In our view, HHS's approval of the waiver to cover childless adults is not consistent with this objective, and is not authorized. Allowing the expenditure of unspent SCHIP funds on childless adults could prevent the reallocation of these funds to states that have already exhausted their allocations, as required by the Congress. A related policy concern is that HHS used its waiver authority to allow Arizona and California to use SCHIP funds to cover parents of SCHIP- and Medicaid-eligible children without regard to cost effectiveness, when the statute provides that family coverage may be provided only if it is cost effective to do so—that is, with no additional costs beyond covering the child. For the Utah and Illinois waivers, we believe that HHS has not adequately ensured that approved demonstration projects will be budget neutral. In both cases, the projections of what the states would have spent without the waiver included certain costs that were either inappropriate or impermissible for assessing budget neutrality. For the Utah waiver, we estimate that if the project is fully implemented, the cost could be $59 million higher for the 5-year waiver than it would have been without the waiver. For Illinois, we estimate this amount to be at least $275 million. As a result, the federal government is at risk to spend more than it would have had the waivers not been approved.

Opportunity for the public to learn about and comment on pending waivers has not been consistently provided in accordance with policy adopted by HHS in 1994. At the federal level, HHS has not, since 1998, followed the process it established in 1994 to publish notification of new and pending section 1115 waiver applications in the *Federal Register* with a 30-day comment period. HHS officials indicated that they now consider the public notice and comment on waivers a state, rather than federal, responsibility and HHS's recent policy has been to refer interested parties to states for copies of waivers it is reviewing. But for one recently approved waiver, advocates were unable to get a copy of the application until after the waiver was approved, despite a Freedom of Information Act (FOIA) request. HHS's 1994 policy also directs states to ensure that public input is obtained before a waiver is submitted. For the four recent approvals, however, public input at the state level varied greatly, and some provider and advocacy groups we contacted raised concerns about access to information and various aspects of some of the approved waivers, such as the benefit reduction and increased cost sharing in the Utah waiver. In May, HHS reaffirmed that states need to follow the 1994 public process policy and also committed to publishing applications on its Web site, but

did not similarly affirm its commitment to follow the policy at the federal level, specifically the federal notice and comment period.

This report includes three matters for congressional consideration. The Congress should consider amending title XXI of the Social Security Act to (1) specify that SCHIP funds are not available to provide health insurance coverage for childless adults and (2) establish, for parents or guardians of SCHIP-eligible children, which statutory objectives should take precedence—those of title XXI to provide family coverage only if it is cost effective, or those of section 1115 that allows the Secretary to waive the cost effectiveness test. The Congress should also consider requiring the Secretary of HHS to improve the federal public notification and input process for state Medicaid and SCHIP section 1115 demonstration proposals under consideration.

This report also includes three recommendations to the Secretary of HHS. We are recommending that the Secretary (1) amend the approval of the Arizona waiver to prevent future use of SCHIP funds on childless adults, and deny any pending or future state proposals for this purpose, (2) better ensure that valid methods are used to demonstrate budget neutrality, and use these methodologies to adjust the federal obligation under the Utah and Illinois waivers as appropriate, and (3) provide for a federal public input process that includes, at a minimum, notice in the *Federal Register* and a 30-day comment period.

In commenting on a draft of this report, HHS disagreed with our recommendations. HHS stated that, in its view, (1) approving the use of SCHIP funds for childless adults in Arizona's waiver met the broad objectives of SCHIP in providing health insurance coverage to those who were previously uninsured, (2) its methods for assuring budget neutrality are appropriate, and (3) the opportunity for public comment is adequate. Because HHS did not provide additional evidence or information on its position beyond what we had earlier considered, we maintained these recommendations to the Secretary and elevated two of the issues for the Congress to consider, as indicated above—the appropriateness of spending SCHIP funds on childless adults and the need for a minimum federal public process.

We also provided a copy of a draft of this report to OMB and the states of Arizona, California, Illinois, and Utah. OMB and California declined to provide written comments. Arizona, Illinois, and Utah provided comments similar to HHS's on our findings related to their state waiver proposals.

Background

Medicaid and SCHIP are the nation's largest health-financing programs for low-income people, accounting for about $232 billion in federal and state expenditures in 2001 to cover about 40 million people. Medicaid was established in 1965 under title XIX of the Social Security Act to provide health care coverage to certain categories of low-income families and aged and disabled individuals. SCHIP was established in 1997 under title XXI of the Social Security Act to provide health care coverage to children living in low-income families whose incomes exceed the eligibility requirements for Medicaid. Both are federal-state programs whereby, within broad federal guidelines, states have considerable flexibility in whom and what they cover.

Medicaid establishes a framework that states must follow in order to receive federal funding, known as federal matching payments, for a share of a state's Medicaid program expenditures.[3] States are required to cover certain groups of individuals and offer a minimum set of services, such as physician, hospital, and nursing facility services, as well as early and periodic screening, diagnostic, and treatment (EPSDT) services for individuals under the age of 21.[4] States can also receive federal matching payments to cover additional optional groups of individuals. For example, while states are required to cover children under age 6 in families with incomes at or below 133 percent of the federal poverty level (FPL), children in families above this level may also be covered at a state's option. States may also choose to provide optional services—such as vision and dental services and prescription drugs—but if they do so, they must provide the same benefits to all covered beneficiaries. At present, nearly two-thirds of Medicaid expenditures are for optional populations and services, largely for long-term care services. Medicaid is an open-ended entitlement, meaning the federal government will pay its share of state expenditures for people covered under a state's approved Medicaid plan, and enrollment for those eligible cannot be limited.

[3]The federal share of a state's payments for Medicaid services is known as the federal medical assistance percentage (FMAP). FMAPs for each state are calculated annually based on a formula designed to provider a higher federal matching rate to states with lower per capita incomes. No state may have a Medicaid FMAP lower than 50 percent or higher than 83 percent.

[4]EPSDT services are required for all children up to age 18 with family incomes at or below 100 percent of the FPL and for other categorically needy children up to age 21. A state may also offer EPSDT services to children between the ages of 19 to 21 as an "optional" service; once it does, the service must be made available to all members of that group.

Like Medicaid, SCHIP is administered by states under broad federal guidelines to offer coverage to children in families with incomes up to 200 percent of the FPL who do not qualify for Medicaid.[5] The federal government pays a higher share of states' expenditures under SCHIP than under Medicaid. [6] SCHIP programs must provide a benefit package that meets certain standards.[7] In contrast to Medicaid, SCHIP is not an open-ended entitlement. The Congress in 1997 appropriated a fixed amount for the program—specifically, $40 billion in federal matching funds over 10 years (fiscal years 1998 through 2007) for SCHIP purposes. Annual allotments are made to states for use over a 3-year period and the Secretary is required to determine an appropriate procedure for redistributing the unused SCHIP funds to those states that have already spent their SCHIP allotments. In certain circumstances states may restrict enrollment if their allotment of federal funds has been expended,[8] but to date, SCHIP spending for most states has fallen well below allotment levels for a variety of reasons. According to the Congressional Research Service, despite the fact that 42 states began their SCHIP programs in late 1997 or 1998, new programs take time to get off the ground and the participation rates have been lower than expected.[9]

[5]Although SCHIP is generally targeted to families with incomes at or below 200 percent of the FPL, each state may set its own income eligibility limits, within certain guidelines. As of September 2001, states' upper income eligibility for SCHIP ranged from 100 to 350 percent of FPL.

[6]The SCHIP statute provides for an "enhanced" federal matching rate, based upon the state's Medicaid rate. Each state's SCHIP enhanced match is the lower of 70 percent of its Medicaid matching rate plus 30 percentage points, or 85 percent.

[7]States have three options in designing SCHIP: they may expand their Medicaid programs, develop a separate child health program that functions independently of the Medicaid program, or do a combination of both. A state's SCHIP Medicaid-expansion program must cover the same services as its Medicaid program, including any covered optional benefits, whereas a state's SCHIP separate child health program is not required to do so.

[8]While SCHIP programs created through a Medicaid expansion must continue to provide services to eligible children using Medicaid funds, states with separate SCHIP programs can establish waiting lists or stop enrollment when funds are exhausted.

[9]The Congressional Research Service reported that 19 states had spent less than 25 percent of their available allotments through September 2001. Of these 19 states, 5 had spent less than 10 percent of these funds. Another 22 states had used between one-fourth and one-half of their allotments. Only 10 states had expended more than 50 percent of their available funds. See Elicia J. Herz and Peter Kraut, *State Children's Health Insurance Program: A Brief Overview*, Congressional Research Service (Washington, D.C.: Jan. 9, 2002).

Section 1115 of the Social Security Act gives the Secretary of HHS broad authority to (1) allow states to provide services or cover individuals not normally eligible for Medicaid and SCHIP, and (2) provide federal funds for services and populations not otherwise eligible for a federal match. Title XIX governing Medicaid is one of several titles to which section 1115 specifically applies, and the Congress, in establishing SCHIP, extended section 1115 to SCHIP "in the same manner" as it applies to Medicaid. According to one report, in 2001 more than 20 percent of total federal Medicaid spending was governed by section 1115 demonstration terms and conditions rather than usual Medicaid rules.[10] Past demonstrations have significantly influenced the development of Medicaid policy, for example, by allowing states to restrict the enrollment of beneficiaries to managed care. The first statewide section 1115 waiver was approved for Arizona in 1982, requiring managed care for all beneficiaries and paying health plans a fixed amount per person to provide all covered services. Other examples of large-scale changes approved through waivers include programs begun in Oregon and Tennessee in the early 1990s. Recognizing its fiduciary obligations, HHS has since the early 1980s required that states justify that their section 1115 waiver demonstrations will not cost the federal government more money than the programs would have cost without the waivers. However, we have previously reported that section 1115 demonstration waivers approved for several states in the mid-1990s were not budget neutral.[11]

HHS's HIFA initiative, using the section 1115 authority, gives states flexibility to increase cost sharing and reduce benefits for some program beneficiaries in order to help fund coverage for uninsured populations within existing Medicaid and SCHIP program resources. HIFA allows states to provide different benefit packages to different groups of people covered under the waiver. To be considered, proposals must be statewide and seek to coordinate coverage with private health insurance options for low-income uninsured individuals. Responding to states' expressed concerns about HHS's prolonged review process for pending waivers, HHS has promised more expedited reviews and decisions. To facilitate this, as

[10]See Jeanne Lambrew, Kaiser Commission on Medicaid and the Uninsured, *Section 1115 Waivers in Medicaid and the State Children's Health Insurance Program: An Overview* (Washington, D.C.: July 20, 2001).

[11]See U.S. General Accounting Office, *Medicaid Section 1115 Waivers: Flexible Approach to Approving Demonstrations Could Increase Federal Costs*, GAO/HEHS-96-44 (Washington, D.C.: Nov. 8, 1995).

part of its HIFA initiative HHS has developed a standard template for states to use in applying for the waivers.

Like HIFA, the Pharmacy Plus initiative uses section 1115 waiver authority. The Secretary introduced the Pharmacy Plus initiative in January 2002 to encourage states to provide pharmacy benefits to low-income elderly populations. While HHS has described the initiative in budget and other documents, it has not published an application template and policy guidelines.

HHS Has Approved Four Section 1115 Waivers to Expand Insurance or Drug Coverage

Since HHS announced the HIFA initiative in August 2001, states submitted 13 proposals for section 1115 demonstration waivers designed to respond to HHS's goals of covering more low-income uninsured individuals and expanding pharmacy benefits as of May 1, 2002.[12] Eight of these 13 are designed to expand coverage for the uninsured, including 6 HIFA applications and 2 expansions that were not submitted in HIFA format, that is, using the HIFA template and following all of the HIFA principles. Five waivers proposed to expand pharmacy benefits, as envisioned by the Pharmacy Plus initiative. As of May 1, HHS had approved 4 of the proposals: 2 HIFA waivers for Arizona and California; an expansion offering primary and preventive care for the uninsured in Utah; and a pharmacy benefit waiver in Illinois. The remaining proposals were still under review as of early June 2002.

Four Waivers Have Been Approved Quickly to Expand Coverage

HHS has approved four section 1115 demonstration waivers to expand coverage for the uninsured and pharmacy benefits since August 2001. Formal review times for three of these four waivers, which averaged just 3-½ months (109 days), ranged from 60 days for the Utah application to

[12]Although the Illinois pharmacy proposal was received July 31, 2001, we include it in this group because it was one of the four demonstrations approved under HHS's flexibility initiatives. We do not include the Tennessee TennCare II Medicaid waiver, submitted February 12, 2002, and approved May 30, 2002, because it was initially reported to be under review as a 1-year extension to the existing TennCare demonstration before being approved, according to HHS, as a new 5-year demonstration program. Similarly, we did not include the Wisconsin pharmacy waiver in our analysis of approved waivers. HHS announced this approval on July 1, 2002. This approval came too late for us to include it in our analysis. Likewise, HIFA applications submitted in mid-May or later, including those from Colorado, Delaware, Minnesota, and Oregon, were not included in our analysis of pending proposals.

182 days for the Illinois pharmacy demonstration.[13] These review times compare with roughly 10 months' review, on average, for approved section 1115 waivers submitted in 2000 or earlier. These average review times do not include preliminary discussions and reviews of draft proposals and concept papers that state and federal officials indicated occurred for varying lengths of time before formal application, depending on the particular waiver.

The HIFA demonstrations approved for California and Arizona both allow expansions using unspent SCHIP funds, but the two differ in the populations to be added. The California waiver will add coverage for uninsured low-income parents, caretaker relatives, and legal guardians of children who are enrolled in Medicaid and SCHIP, testing whether covering these individuals will increase enrollment of eligible children and improve their continuity of care. The approved Arizona waiver will use unspent SCHIP funds to cover childless adults as well as parents of Medicaid and SCHIP children. HHS's terms and conditions for the approved Arizona waiver specify that SCHIP children are the first priority for coverage, then parents of SCHIP- and Medicaid-enrolled children, and last priority, childless adults.[14] Arizona was, however, allowed to retroactively cover childless adults effective November 2001, and parental coverage is not required until October 2002. In response to an objective of the HIFA initiative, both the Arizona and California waiver approvals include feasibility studies of whether and how an employer-sponsored insurance component might be incorporated into the demonstrations.

[13]The California waiver, once it was submitted in the HIFA template, was approved in only 10 days; however, that application was based on a section 1115 waiver proposal that had been under review since December 2000.

[14]Specifically, HHS's letter approving the Arizona HIFA waiver and the attached terms and conditions establish priorities for the use of SCHIP funds, as follows: "Title XXI [SCHIP] funding will be used to provide coverage in the following priority order: first to individuals eligible under the title XXI State plan [i.e., children], then to parents of Medicaid and SCHIP children between 100 and 200 percent of the FPL, and finally to single adults and childless couples up to 100 percent of the FPL. For this last group, title XIX [Medicaid] Federal matching funds will be used if title XXI funding is exhausted. Subject to legislative approval and the Governor's signature, the expansion to parents of Medicaid and SCHIP children will be implemented on or before October 1, 2002. If this expansion is not implemented, Arizona will no longer receive title XXI funding for childless adults." In addition, the terms and conditions require that "The State will not close enrollment, institute waiting lists, or decrease eligibility standards with respect to the children covered under its title XXI State plan while the HIFA amendment is in effect." Arizona expects that SCHIP funding for childless adults will only be used for 2 years.

The Utah waiver will expand coverage to some formerly uninsured adults for primary care and preventive services, but exclude other services, such as inpatient hospital and specialist care. In addition to enrollment fees and cost sharing for services used by this expansion population, the waiver will be funded by increased cost sharing and limits on some optional services for certain groups of currently eligible adults, including some with mandatory eligibility. Among the optional services being limited are mental health services, vision screening, and physical therapy. [15]

Illinois received approval for the first Pharmacy Plus waiver. The Illinois Senior Care program will expand pharmacy coverage to low-income seniors, most of whom participate in an existing state-funded pharmacy benefits program. The premise as to how the waiver program can be implemented without committing additional federal resources is that expanded access to medically necessary drugs will help keep seniors healthier and avoid medical expenses, including hospitalization and nursing home placement, that would reduce their incomes to the level of Medicaid eligibility.

Table 1 presents highlights about the section 1115 waivers approved for Arizona, California, Utah, and Illinois. (See app. I for further details about these four waiver programs.)

[15]The limits on optional services that apply to some adults with mandatory eligibility, as well as medically needy adults with optional eligibility, do not affect children, pregnant women, or aged, blind, or disabled Medicaid beneficiaries. However, because the demonstration defines adults as age 19 and older, HHS granted Utah a waiver of the EPSDT requirement for those individuals aged 19 and 20 who are currently eligible for EPSDT. As adults, they will be affected by the limits on optional services.

Table 1: Highlights of Four Section 1115 Waivers Approved Under HHS's Flexibility Initiatives

State and waiver	Highlights
Arizona HIFA Demonstration Waiver	• **Waiver approval**: The first approved HIFA waiver was submitted on September 20, 2001, and approved in 84 days on December 12, 2001. • **Populations served**: Arizona will expand coverage to two groups: (1) an estimated 27,000 childless adults at or below 100 percent of FPL, effective retroactively November 1, 2001, and (2) an estimated 21,250 parents of Medicaid- and SCHIP-enrolled children with family incomes above 100 and at or below 200 percent of FPL, effective October 1, 2002. • **Cost**: Federal spending over 5 years for childless adults is estimated at $414 million ($126 million in unspent SCHIP funding plus $288 million in Medicaid funding). In addition, an estimated $144 million in unspent SCHIP funds would cover the expansion to parents.
California Parental Coverage Expansion HIFA Waiver	• **Waiver approval**: Using an application originally submitted in December 2000, California revised and resubmitted its proposal as a HIFA application on January 16, 2002, and it was approved in 10 days on January 25, 2002. • **Populations served**: California will expand coverage to an estimated 275,000 custodial parents, caretaker relatives, and legal guardians of Medicaid and SCHIP children, with family incomes at or below 200 percent of FPL. • **Cost**: Federal spending over 5 years is estimated at $1.6 billion (66 percent of the estimated total cost of $2.4 billion). Unspent SCHIP funds will be used to cover the expansion.
Utah Primary Care Network Waiver	• **Waiver approval**: The Utah demonstration was submitted December 11, 2001, and approved February 8, 2002, after 60 days' review. • **Populations served**: Utah will offer benefits limited to primary and preventive care to two adult expansion groups: (1) 16,000 parents with incomes under 150 percent of FPL and (2) 9,000 childless adults, many from a state-only program, with incomes under 150 percent of FPL. Individuals in the expansion groups will pay a $50 annual enrollment fee plus charges for the services they use, such as $5 per office visit and $30 for an emergency room visit. About 17,600 current mandatory eligible people and some optional medically needy eligible people will receive somewhat reduced benefits (e.g., there will be limits on vision, physical therapy, chiropractic, dental, and mental health services) with cost sharing increased to $3 per physician visit, $2 per prescription, and $220 for each hospital admission. • **Cost:** Federal spending over 5 years is estimated at

State and waiver	Highlights
	about $422 million in Medicaid funds (71 percent of the estimated total cost of $595 million). The state is expected to contribute at least the equivalent of its previous state-only program budget.
Illinois Senior Care Program Waiver	• **Waiver approval**: Submitted July 31, 2001, the first Pharmacy Plus waiver was approved in 182 days on January 28, 2002. • **Populations served**: Up to an estimated 256,500 individuals aged 65 and older with incomes at or below 200 percent of FPL will be covered for prescription drugs with primary care coordination. The program was implemented June 1, 2002, with about 140,000 participants primarily from the state-only pharmacy program. Depending on whether their incomes are above or below FPL, participants may pay $1 for generic or $4 per brand name prescription for benefits up to a cap of $1,750, after which they will pay 20 percent of each prescription plus a nominal copayment. • **Cost**: Federal spending over 5 years is capped at an estimated $7 billion, or 50 percent of the approximately $14 billion aggregate cap on spending for the total Medicaid population aged 65 and older. The state will contribute at least what was spent on its previous state-only program, plus savings from reduced nursing home and hospital expenditures for the estimated 7,500 seniors per year who will be diverted from Medicaid eligibility.

Source: HHS approval letters, approved waiver applications for each state, and other documents.

Nine Waiver Proposals Are Still under Review

As of June 3, 2002, 9 of the 13 section 1115 waiver proposals to expand coverage and pharmacy benefits were still under review by HHS (see app. II for highlights of these proposals). Most were submitted since January 2002. These proposals included pending HIFA applications from Illinois, Maine, Michigan, and New Mexico. Three of these proposals would use unspent federal SCHIP funds to expand coverage to various groups, including children, parents, and in some cases, childless adults. Most of the HIFA applications require increased cost sharing for the expansion groups, and one proposal would reduce benefits for an optional eligibility group. One additional proposal under review from Washington, which was

not submitted in HIFA format, would also expand coverage for uninsured individuals, including childless adults using unspent SCHIP funds.[16]

Four states—Connecticut, New Jersey, South Carolina, and Wisconsin—had pharmacy benefit waiver proposals under review that were consistent with the Pharmacy Plus concept. In all cases, pharmacy benefits would be expanded to low-income seniors who are not currently eligible for Medicaid, and the states would fold in participants from state-only funded pharmacy programs.[17]

HHS Has Not Always Ensured That Approved Waivers Are Consistent With the Goals and Fiscal Integrity of Medicaid and SCHIP

HHS has not, with its recent approvals of waivers under the new flexibility initiatives, consistently ensured that waivers are in line with program goals and are budget neutral. Under the first approved HIFA waivers, HHS is allowing the use of unspent federal SCHIP funding to cover adults, including adults who have no dependent children. When the Congress established SCHIP, it required the Secretary to redistribute unspent funds to states that had exhausted their allotments to use for the program purposes of covering children. These waivers raise legal and policy concerns in light of SCHIP's stated purpose of expanding health coverage to low-income children. Similarly, HHS did not adequately ensure that the waivers will be budget neutral. Our review of the documents supporting the traditional budget neutrality test used in the two states subject to this requirement—Utah and Illinois—found that HHS's review process did not adequately ensure that the costs to the federal government for the Medicaid program would be no higher under the waivers than they would

[16]HHS responded to Washington's proposal by asking for more specific information regarding the planned approach and suggesting that the proposal could be more responsive to HIFA guidelines. The initial proposal asked for broad authority to reduce benefits, impose cost sharing, and cap enrollment.

[17]Connecticut, New Jersey, and South Carolina have existing state-funded pharmacy assistance programs for seniors that will be folded in or coordinated with their proposed pharmacy waiver programs. The Wisconsin legislature authorized such a program to be implemented by September 1, 2002, with funding through June 30, 2003, and the requirement that the state seek a Medicaid waiver to continue the program. HHS announced approval of the Wisconsin pharmacy waiver application on July 1, 2002, too late to be included in our review.

have been without the waivers.[18] The approval of the Illinois waiver also raises questions about the potential financial risk for the state and implications for covered elderly beneficiaries, and the extent to which HHS is ensuring that waivers are fiscally sound.

Allowing SCHIP Funding for Adults Raises Legal and Policy Concerns

SCHIP is a program created specifically for low-income children. The program is designed to enable states to initiate and expand health assistance to low-income, uninsured children in an effective, efficient, and coordinated manner. In establishing SCHIP, the Congress directed that funds made available under the program be used only for program purposes. Further signaling the importance of spending SCHIP funds on uninsured children, the Congress also provided for the Secretary to redistribute states' annual allotments remaining unspent after a 3-year period of availability to states that have exhausted their SCHIP allotments. In April 2002, CMS announced that 18 states and territories would receive $1.6 billion in reallocated funds because they had exhausted their own allotments.[19] Given the statutory objective of reducing the number of uninsured children, however, HHS's approvals of waivers that allow states to use unspent SCHIP funds on adults raise certain legal and policy questions about appropriate uses of the SCHIP allotments.

In our view, HHS has not established that its approval of SCHIP funding for childless adults in Arizona was reasonable and, therefore, authorized. Arizona plans to use $126 million in unspent federal SCHIP funds for childless adults. In approving the Arizona waiver, HHS stated that the Arizona project would demonstrate whether covering single adults and childless couples will improve the overall health of the community and reduce overall rates of uninsurance, and asserted that this result would "promote the objectives of the Act." However, HHS did not assert that insuring these childless adults would improve the provision of health assistance to low-income children. We are not aware of any basis for suggesting that the use of SCHIP funds to cover childless adults would promote the objectives of SCHIP.

[18]We reviewed the cost-neutrality justifications for the four waivers approved since August 2001. In Utah and Illinois, the applicable test for these Medicaid waivers was budget neutrality. In California and Arizona, the analysis or test of cost neutrality took the form of SCHIP allotment neutrality, which requires that combined spending in the state's SCHIP program and any waiver spending not exceed the state's available SCHIP allotment. These two states met the SCHIP allotment-neutrality test.

[19]See 67 *Fed. Reg.* 20794 (2002).

In response to our concern that the HIFA policy and Arizona approval are inconsistent with statutory objectives, HHS's Office of General Counsel stated that section 1115 provides considerable legal flexibility to authorize the use of program funds for items, services, or activities that would not normally be paid under the program. In a letter to us (reprinted in app. III), HHS also wrote:

"the language of section 1115 permits approval of demonstration projects based on the overall purposes of all of the listed Social Security Act programs (rather than segregating each program). In other words, in approving a Medicaid or SCHIP demonstration, the Secretary may consider the likelihood of promoting the objectives of the programs authorized under any of the titles of the Social Security Act listed in section 1115."[20]

The structure and language of section 1115 do not support HHS's interpretation of its authority. Section 1115 identifies the titles of the Social Security Act for which demonstration projects may be authorized. It also lists the statutory provisions within each title containing the requirements or expenditure limitations that may be waived[21] and clearly indicates that waiver of requirements or expenditure limitations are to

[20]Section 1115 lists title I (Old-Age Assistance), title X (Aid to the Blind), title XIV (Aid to the Permanently and Totally Disabled), title XVI (Supplemental Security Income for the Aged, Blind and Disabled), or title XIX (Medicaid), or part A (Temporary Assistance for Needy Families) or D (Child Support and Enforcement of Paternity) of title IV.

[21]Section 1115 of the Social Security Act provides in pertinent part:

(a) In the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of title I, X, XIV, XVI, XIX, or part A or D of title IV, in a State or States——

> (1) the Secretary may waive compliance with any of the requirements of section 2, 402, 454, 1002, 1402, 1602, or 1902, *as the case may be*, to the extent and for such period he finds necessary to enable such State or States to carry out such project, and
>
> (2)(A) costs of such project which would not otherwise be included as expenditures under section 3, 455, 1003, 1403, 1603, or 1903, *as the case may be*, and which are not included as part of the cost of projects under section 1110, shall, to the extent and for the period prescribed by the Secretary, be regarded as expenditures under the State plan or plans approved under such title, or for administration of such State plan or plans, as may be appropriate . . ." (emphasis added).

correspond to the associated titles of the Social Security Act.[22] As a result, we believe that section 1115 requires HHS to justify that a demonstration project will likely assist in promoting the objectives of the particular title of the Social Security Act in which the waived program requirements or expenditure limitations appear. [23] With respect to programmatic requirements or expenditure limitations applicable to SCHIP funds, section 1115 requires HHS to establish that a demonstration project would promote the objectives of title XXI, which established SCHIP. As stated above, HHS has not asserted that the use of SCHIP funds to cover childless adults would promote the statutory objectives of the program, although it contends that the Arizona waiver, considered in its entirety, does serve program objectives.

HHS's interpretation of section 1115 effectively eliminates the distinctions among the programs authorized under the identified titles of the Social Security Act and would allow the agency to waive requirements or authorize otherwise impermissible expenditures under one program to promote the objectives of any other program. If HHS were to take this interpretation to an extreme, it could bypass funding limitations and mechanisms established for individual programs by funding any of the programs authorized in the identified titles of the Social Security Act with funds made available for any other title. This interpretation of section 1115 is particularly problematic in the context of SCHIP, given the congressional direction that allocated funds not spent for program purposes be redistributed to states that have exhausted their allotment.

[22]In the section 1115 waiver provision, the phrase "as the case may be" establishes a link between the titles of the Social Security Act for which demonstration projects may be authorized and the statutory provisions containing the requirements or limitations that may be waived. We note that the Congress used a similar structure and the phrase "as the case may be" to suggest a program-by-program application of a provision in title XI of the Social Security Act concerning penalties for false and misleading statements. Prior to amendment in 2000, section 1129A(e) contained a reference to only one title of the Social Security Act and only one source of supplementary payments under the act. When the Congress added a second title of the Social Security Act and a corresponding source for such payments, it used the phrase "as the case may be" to distinguish payments made under one title from payments made under the other.

[23]While not directly addressing the issue, the court, in *Crane v. Mathews*, 417 F. Supp. 532 (N.D. Ga. 1976), suggested that section 1115 authorizes waivers on a program-by-program basis. Considering a Medicaid waiver, the court stated that "[t] he only limitation upon the Secretary's authority under section 1115 is that he must judge the project to be one which is likely to assist in promoting *the applicable title* of the act" (emphasis added). *Id.* at 539.

Arizona's use of SCHIP funds for childless adults raises two additional concerns. First, Arizona had already received approval from HHS to use Medicaid funds to expand coverage to certain childless adults. As a result of the waiver, the federal government will now pay about 77 percent of the costs under the SCHIP matching rate, instead of about 66 percent if this same population was covered under Medicaid.[24] Second, if Arizona expends all of its federal SCHIP allotment, it arguably could qualify for reallocated unspent federal SCHIP funds from other states. It could then apply these reallocated funds to childless adults.[25]

HHS's approval of Arizona's and California's use of unspent federal SCHIP funds to cover parents illustrates the changing policy with regard to the use of waiver authority to allow states to cover adults. In creating SCHIP, the Congress authorized states to cover the entire family—both the parents or custodians and their children—if it was cost effective to do so. The cost-effectiveness test for family coverage specifies that the expense of covering both adults and children in a family must not exceed the cost of covering the children. Under these circumstances, achieving cost-effectiveness appears possible only when the cost to SCHIP of covering a family is subsidized by employer contributions or other state funds. This stringent cost-effectiveness test clearly showed congressional priority for covering children over their parents. However, we reported in 1999 that some states and advocacy groups were seeking increased flexibility to tailor their SCHIP programs to cover uninsured parents through the use of section 1115 waiver authority.[26] CMS, then called the Health Care Financing Administration, had questioned requests for section 1115 waivers to cover parents during the first year of SCHIP's implementation, expressing a concern that the SCHIP goal of providing insurance to low-income children should not be circumvented by the waiver process. The agency had indicated to states that the purpose of section 1115 waivers was to test innovative approaches and not to waive statutory provisions that the states found objectionable. In our first report on SCHIP

[24]These percentages represent an average of each of the federal Medicaid and SCHIP matching rates for 2002 and 2003.

[25]The waiver allows the state in future years to cover more childless adults than initially planned, if the state does not through its SCHIP program cover as many children as anticipated and the state has unanticipated unspent SCHIP funds.

[26]See U.S. General Accounting Office, *Children's Health Insurance Program: State Implementation Approaches are Evolving*, GAO/HEHS-99-65 (Washington, D.C.: May 14, 1999).

implementation in 1999, we noted that, as of April 1, 1999, only two states had been able to demonstrate cost-effectiveness and had received approval to use SCHIP funds to cover adults in families with children.[27]

Since our earlier report, HHS has changed its policy and no longer requires that states demonstrate the cost-effectiveness of family coverage in section 1115 waiver proposals. On July 31, 2000, HHS announced to states that it would consider section 1115 waivers to use unspent federal SCHIP funds to cover parents of SCHIP- and Medicaid-eligible children, but was silent on the application of the cost-effectiveness test. Since this announcement, four states, in addition to Arizona and California, have requested and obtained approval for these types of waivers.[28] In our view, this change raises broad policy questions about the use of section 1115 authority to waive those statutory requirements that states have found objectionable but that the Congress put in place clearly to demonstrate the priority of SCHIP to fund insurance coverage for children. It further raises the issue of which statutory objectives should take precedence—the Congress's direction to allow family coverage only if states could demonstrate its cost-effectiveness, or the Secretary's authority under section 1115 to allow states to spend money on individuals other than children.

Budget Neutrality Not Ensured in Utah and Illinois Waivers

Our review of the supporting documentation for the Utah and Illinois waiver approvals found inadequate justification that the waivers would be budget neutral—that is, the initiatives would result in no more cost to the federal government than under the existing program. To establish that a waiver is budget neutral, HHS requires the state to compare estimated program costs under two scenarios: (1) costs if the existing program was continued ("without-waiver" costs)[29] and (2) costs with the new waiver program ("with-waiver" costs). We found that the states' estimates of without-waiver costs included inappropriate costs in Utah and

[27]GAO/HEHS-99-65.

[28]Minnesota, New Jersey, Rhode Island, and Wisconsin have received SCHIP section 1115 waiver approvals to cover parents of children eligible for SCHIP or Medicaid.

[29]Estimating without-waiver costs involves several key steps. First, a recent 12-month period prior to waiver approval is identified as a base year. Second, Medicaid costs and the number of Medicaid individuals covered are estimated for the base year. Third, trend rates are developed to estimate the changes in costs and people served over the life of the waiver.

impermissible costs in Illinois. Including these amounts inflated each state's estimate and inappropriately increased the amount the federal government could pay in the absence of the proposed waiver.

- Utah's without-waiver estimate was inflated because it included the estimated cost of services for a new group of people who were not being covered under the existing Medicaid program. By including these costs, the state in effect inflated the without-waiver costs by about $59 million—10 percent—over the 5-year life of the waiver. Without this amount, Utah's waiver would not be budget neutral. The costs for this group were included based on the "hypothetical population" concept, under which HHS has previously allowed states to include the costs of populations that they could have hypothetically covered under Medicaid as an optional group, but did not actually cover. In 1995, we reported that states were using this hypothetical argument to justify higher without-waiver costs, making budget neutrality easier to achieve. We concluded that, because state officials indicated that cost containment was a primary consideration in seeking section 1115 waivers, it was questionable that these states would have added optional eligibility groups to their Medicaid programs without the waiver.[30] For Utah, however, the use of this methodology goes beyond our earlier concern because the group in question does not meet the criteria for designation as a hypothetical population. The group could not have been covered without a waiver, because it will receive a limited primary-care-only benefit package that would not be allowed under Medicaid's rules for comprehensive coverage. During the review process, some officials within HHS voiced concerns about allowing the use of this methodology; however, the waiver was still approved by HHS as a matter of policy.
- Illinois's without-waiver estimate was inflated for a different reason: it failed to account for mandatory reductions in program costs planned for the 5-year course of the waiver. These reductions pertain to the state's use of upper payment limit (UPL) arrangements.[31] We and the HHS Inspector General have reported numerous times about state funding arrangements

[30]HHS and OMB disagreed with our conclusions that certain states' approved waivers were not budget neutral, including our position that the hypothetical population method unduly inflates baseline estimates. HHS and we continue to disagree on this point. OMB declined to comment on our current report. See GAO/HEHS-96-44.

[31]To control federal expenditures, HHS established a set of UPLs on the amount it would agree to pay states for certain categories of services. The limits establish an aggregate ceiling for payments in service categories, including inpatient hospital services, outpatient hospital services, nursing facility services, and intermediate care services for the mentally retarded, at both the state and the local government levels.

that inappropriately generated excessive federal matching funds, including UPL abuses.[32] The Congress and HHS subsequently revised the upper payment limits and required states to reduce their claims for these excessive payments over the next several years.[33] Over the course of its 5-year waiver, Illinois will have to reduce its claims by $1.4 billion in accordance with these requirements.[34] Over this time period, the state's total payments to the facilities involved in the UPL arrangements will decline by 39 percent.[35] Based on this decrease, we estimate that at least

[32]We found that states used intergovernmental transfers that exploited UPL and other arrangements to inappropriately maximize federal Medicaid funds, which ultimately are not used to pay for Medicaid services for Medicaid-eligible individuals. See U.S. General Accounting Office, *Medicaid: State Financing Schemes Again Drive Up Federal Payments*, GAO/T-HEHS-00-193 (Washington, D.C.: Sept. 6, 2000*);* U.S. General Accounting Office, *Medicaid: HCFA Reversed Its Position and Approved Additional State Financing Schemes*, GAO-02-147 (Washington, D.C.: Oct. 30, 2001*);* and U.S. General Accounting Office, *Medicaid: States Use Illusory Approaches to Shift Program Costs to Federal Government*, GAO/HEHS-94-133 (Washington, D.C.: Aug. 1, 1994). In a 2001 review of Illinois's UPL arrangements, the HHS Inspector General found that from 1992 through 2000, Illinois generated at least $1.6 billion in excessive federal matching funds that were not used for services for the Medicaid individuals on whose behalf they were claimed. The report found that in 1999 total payments to the county involved in the UPL arrangement exceeded the total operating expenses of the facilities involved in the funding arrangement by $244 million. See Office of Inspector General, Department of Health and Human Services, *Review of Illinois' Use of Intergovernmental Transfers to Finance Enhanced Medicaid Payments to Cook County for Hospital Services*, A-05-00-00056 (Washington, D.C.: Mar. 22, 2001*)*.

[33]The final UPL rule that we are referencing was published January 12, 2001, and became effective March 13, 2001. The rule gives states a transition period to gradually reduce their excessive payments and comply with the new limits. It also increased the UPL for nonstate-government-owned hospitals from 100 percent of what Medicare would pay for comparable services to 150 percent of what Medicare would pay. On January 18, 2002, HHS published another final rule that lowered the UPL for nonstate-government-owned hospitals to 100 percent of what Medicare would pay. The 2002 UPL went into effect May 14, 2002, but it did not change the transition period or the rate of reduction in excess UPL payments required by the 2001 UPL rule that went into effect March 13, 2001.

[34]Under the UPL transition rules, states are required to identify excess UPL payments and reduce their claims for payment by a specified amount in accordance with a transition schedule set forth in the regulation. Illinois estimated that in 2000, $906 million, which was 78 percent of its total Medicaid payments to certain hospitals, would be over the new limit. Under the phase-out methodology the $906 million over the new limit is frozen and can be claimed until 2003, but from 2004 through the end of 2009, it is gradually eliminated. During this time, the total reduction is $2.9 billion of which $1.4 billion will occur over the 5-year course of the waiver.

[35]Under the new limits, Illinois will still be allowed some UPL-related expenses, which can increase over the life of the waiver. Combining the reduction in the excessive UPL expenses with the increase in the allowed UPL expenses results in a 39-percent net decrease in the amount of total payments allowed during the waiver.

$275 million in impermissible UPL expenses are included in the estimate.[36] This occurred because Illinois's calculations of without-waiver costs did not reflect the required reduction in UPL expenses. Rather, the Illinois without-waiver cost estimate projected increases in UPL payments by 51 percent over the 5-year life of the waiver.[37] It appears that, in reviewing Illinois's budget neutrality justification, HHS did not consider the extent to which any UPL-related impermissible funds were included. The Secretary has the authority, however, to revisit this decision and to require the state to recalculate its estimated without-waiver costs to appropriately account for the reduction in the amount of UPL expenses.

We have previously reported similar concerns with the approval of demonstration waivers that were not budget neutral and that could increase federal Medicaid expenditures. In our 1995 report, we found that, contrary to the administration's assertion, the approved spending limits for demonstration waivers in Oregon, Hawaii, and Florida were not budget neutral. At that time, we warned that the granting of additional section 1115 waivers merited close scrutiny in part because of the potential budgetary impact.[38]

[36]We believe that our estimate is conservative because the UPL-related expenses that are in excess of the new limits are reduced at a lower rate than they will be under the actual transition methodology required by regulations. This methodology separates the excess UPL expenses and the allowed UPL expenses to estimate total allowed payments during the UPL transition.

[37]This increase stemmed from attributing a certain percentage of the total UPL payments to the aged waiver population for a year prior to the waiver, and then applying the expected increases based on projections of how program costs would grow over the life of the waiver. In commenting on a draft of this report, Illinois officials stated that any impermissible UPL funds would likely be offset by additional spending authority provided under the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA). We did not consider this additional spending authority because the state and HHS did not include it in Illinois's submitted or approved budget neutrality justifications, and because it is unclear whether HHS will allow such spending authority for estimating without-waiver costs.

[38]See GAO/HEHS-96-44.

Illinois Waiver Approval Raises Questions about the Extent That HHS Is Ensuring That Waivers Are Fiscally Sound

Another concern related to HHS's approval of the Illinois waiver is the extent to which the agency's oversight ensures that approved waivers are fiscally sound, in particular related to their likelihood of achieving projected savings. This concern is separate from budget neutrality; it centers instead on whether the waiver project is placing the Medicaid or SCHIP programs in a vulnerable position. The waiver may put Illinois at financial risk even if federal budget neutrality is maintained. A major premise behind this initiative is that the prescription drug benefit will pay for itself by preventing low-income elderly individuals from becoming Medicaid eligible because of high health care costs, such as those for hospital and nursing home care. The Congressional Budget Office (CBO), OMB, and CMS's own actuary, however, have not accepted this premise, in assessing the cost of a Medicare prescription drug benefit. There are many reasons for this caution. According to a preliminary assessment by CBO, Medicare beneficiaries without any drug coverage already consume a large number of prescription drugs, and any additional or more expensive drugs beneficiaries might receive in gaining coverage would probably provide less-dramatic improvements in health than the drugs they are already taking. CBO's assessment stated that greater use of drugs, especially in an older population, would increase the chances of side effects, allergic reactions, medication errors, and other adverse drug events, which could increase the use of hospitals, emergency rooms, and other health care services. CBO found that research indicating there might be some savings in providing a Medicare prescription drug benefit have been difficult to interpret, and concluded that the magnitude of any savings would probably be quite small. CBO stated that recent evidence has suggested that the net effect of providing coverage may be to lower the cost of other services, but that the studies are difficult to interpret, especially in the context of a Medicare drug benefit, and that more evidence is expected from evaluations of state-level drug programs for low-income elderly people.[39]

While Illinois's approved waiver is intended to evaluate the extent to which a drug benefit may be able to generate cost savings, it makes several risky assumptions with regard to the extent of savings, potentially setting a precedent for other states' Pharmacy Plus proposals. In Illinois, many of the people who would gain drug coverage under the waiver are already

[39]See Dan Crippen, Director, CBO Letter to the Honorable Michael Bilirakis, Chairman, Subcommittee on Health, Committee on Energy and Commerce (Washington, D.C.: Aug. 10, 2001). www.cbo.gov/showdoc.cfm?index=2989&sequence=0&from=1, downloaded March 5, 2002.

receiving some drug coverage benefits under an existing, more limited, state-funded program. Despite this, the success of the Illinois waiver relies on assumptions that (1) providing the expanded prescription drug benefit under the waiver will divert 7,500 people by keeping them from becoming Medicaid-eligible, when an estimated 20,000 elderly individuals normally enter Medicaid in a given year, (2) this high diversion rate will occur immediately, the first year that the drug benefit is provided under the waiver, and (3) once diverted, aged individuals would stay out of Medicaid for at least 5 years. The waiver's underlying assumptions offer little margin of error. For example, if only half of the projected number of seniors are diverted in the first year of the waiver, we estimate that the cost of the waiver could increase by $339 million. The implications for elderly Medicaid beneficiaries of not achieving the high rate of savings could be significant. HHS limited total federal risk for this waiver by establishing an aggregate "cap" for payments to the state for all services to the elderly, including the drug benefit. However, this cap also means that once the state has spent up to this limit then it cannot receive additional federal matching funding for Medicaid services for the elderly. One assessment of the Illinois financing approach noted that, for any number of reasons, Illinois could find the costs of operating its new drug program or of serving elderly Medicaid beneficiaries to be higher than expected. If the state is unable to achieve savings from diverting people from Medicaid, then as Illinois officials acknowledge, it may need to choose other options. Such options could include cutting spending on elderly Medicaid beneficiaries, cutting spending on its prescription drug program, or paying for any unanticipated program costs entirely with state funds. The state could also roll back eligibility for optional elderly beneficiaries, increase cost sharing, reduce provider reimbursement rates, reduce the size of the waiver benefit, or eliminate the waiver altogether.[40]

HHS officials stated that this approval represents a true demonstration or policy experiment, in that the waiver will test whether it is possible to provide a drug benefit without increasing costs. Officials also pointed out that the federal risk was limited by the aggregate cap approach. As indicated earlier, four states have pending waiver proposals similar to Illinois's Pharmacy Plus waiver.

[40]See Jocelyn Guyer, Kaiser Commission on Medicaid and the Uninsured, *The Financing of Illinois' Prescription Drug Demonstration Project* (Washington, D.C.: April 2002).

HHS Policy to Ensure Public Input to Waivers Has Not Been Consistently Followed

HHS has not consistently followed its stated policy to ensure that people who may be affected by waivers have the opportunity to learn about and comment on waiver proposals. Recognizing that people who may be affected by a demonstration project "have a legitimate interest in learning about proposed projects and having input into the decision-making process," [41] HHS established policies and procedures in a 1994 *Federal Register* notice for both a federal- and state-level public notice and comment process.[42] HHS has not provided a federal level notice and comment period in line with the policy since 1998, and instead has relied on states to have a public process. The extent of public input varied greatly among the four states with recently approved waivers. Although HHS recently affirmed the public input requirements for states, its new streamlined review process under HIFA may not be sufficient to guarantee effective public involvement at the federal level.

HHS Has Not Followed Its Stated Federal Process For Public Input Since 1998

The 1994 notice specifies HHS's intent to publish regular notices of all proposals for section 1115 waivers it receives and to allow a 30-day period to receive and review written comments before taking official action. The notice describes the policies and procedures HHS will be guided by when reviewing section 1115 applications, but is not legally binding. We found that the last *Federal Register* notice of a section 1115 application submission and 30-day comment period was published in 1998. According to an HHS official, the current agency policy does not include publication of notices with a 30-day comment period while applications are under review at HHS because the states are considered to be a more appropriate forum for public input. Our discussions with HHS officials during the spring of 2002 indicated that current agency policy was not to release copies of pending waiver applications to interested parties, but to refer them to states. In May, the Secretary stated that the agency would publish waiver applications and background information on its Web site as soon as possible after receipt; HHS officials subsequently clarified to us that this includes applications that have been formally submitted but not yet approved. We were able to find copies of all but one of the pending HIFA

[41] See 59 *Fed. Reg.* 49249, September 27, 1994.

[42] This notice was HHS's response to concerns raised in the early 1990s about the rapid approval of some controversial statewide section 1115 waivers. For example, concerns were raised about the rapid approval and implementation of a waiver submitted by Tennessee and that state's acknowledged failure to consult with all affected stakeholders. See GAO/T-HEHS-95-115.

proposals on CMS's Web site, along with CMS contact names and phone numbers for each proposal. However, copies of any Pharmacy Plus or other section 1115 proposals that were not in the HIFA format were not yet available on the CMS Web site.

One problem with HHS's decision to defer to the states is that states have not always released copies of pending waivers when requested by interested parties. Advocates reported such difficulty obtaining a copy of Arizona's waiver application that one organization requested a copy from HHS under the Freedom of Information Act (FOIA) after the application had been submitted for review.[43] The FOIA request was made on November 15, 2001, and the agency responded in January 2002 stating that it was responding to requests in order of receipt and would notify the requester "as soon as possible" about the availability of the documents. Meanwhile, the waiver had already been approved in December 2001. The approved waiver is now posted on the agency's Web site, but was not available to the public during the time it was under review.

State Compliance with the 1994 Policy Varied Widely in Recently Approved Waivers

The 1994 policy contains provisions for state-level public participation, including a list of one or more approaches states are expected to follow. These include

- public meetings with copies of the proposal and opportunities to comment;
- using a commission where meetings are open to the public;
- legislation containing the outline of the waiver proposal;[44]
- formal notice and comment through the state's administrative procedures act with notice given at least 30 days prior to submission of the waiver;
- publication of notice in a newspaper of general circulation including information on how to obtain a copy and submit comments, with a comment period of at least 30 days; or
- any similar process providing an opportunity for interested parties to learn about and comment on the proposal.[45]

[43]FOIA, 5 U.S.C. §552 (2002), provides for public access to agency records that do not fall within specified exceptions.

[44]Specifically, the notice states that a process that results from enactment of a proposal by the state legislature prior to submission of the demonstration proposal, where the outline of the proposal is contained in the legislative enactment, can satisfy the 1994 policy.

Such state-level activities allow the public to be informed of and comment on proposed demonstration programs, but do not necessarily guarantee consensus on a state's planned waiver. We found wide variation in the approaches and level of effort states made to seek and incorporate public comment on written copies or descriptions of the waiver proposals, as well as the degree of controversy concerning the state proposals, as illustrated in the following examples.

- California had an extensive public process as well as a statute providing authorization to seek a waiver.[46] In addition, California conducted extensive outreach activities, including mailing hundreds of copies of the waiver application and soliciting comments, holding public hearings, and presenting the approach at a special legislative hearing.
- Illinois, like California, had a statute authorizing the state to seek a waiver for the pharmacy program expansion, which allowed the state to claim federal financial participation.[47] The interest groups we contacted did not raise concerns about the adequacy of the public process.
- Utah provided opportunity for groups to discuss the proposed waiver through meetings that state officials held with provider groups and committees involved with improving health coverage in the state. Despite these meetings, advocates and others indicated that in their view the public process was inadequate given the significance of the state's proposal and planned tradeoffs. Participants in some of these meetings indicated they had little or no opportunity to formally comment on and influence the waiver proposal.[48] Among other issues, advocates and providers expressed concern about reduced optional benefits and increased cost sharing for current beneficiaries, the planned enrollment fee and co-payments, and lack of specialty services and inpatient hospital

[45]HHS has also established a policy to ensure that there are effective, ongoing consultations between states and federally-recognized tribal governments during the decision-making process for Medicaid and SCHIP matters.

[46]*Section 12693.755* of the California Insurance Code provided for expanded eligibility for SCHIP coverage for uninsured parents of children enrolled in SCHIP and Medi-Cal (California's Medicaid program) whose income does not exceed 250 percent of the FPL if authorized by a waiver approved by CMS.

[47]*305 ILCS 5/5-5. 12a* authorized the Illinois Department of Public Aid to seek a Medicaid waiver to claim federal financial participation for a pharmacy assistance program for persons age 65 and over with income levels at or less than 250 percent of the federal poverty level.

[48]HHS's terms and conditions for the Utah waiver required, among other things, that the state comply with the 1994 public notice policy and submit documentation of its consultation with tribal representatives prior to implementing the waiver. This condition was applied after the waiver was approved.

coverage for the waiver expansion population. Specialty physicians and hospitals would be expected to contribute their services on a volunteer basis, and community health centers would receive lower payments for the expansion group.[49] After the waiver was approved, state officials indicated that inpatient hospital specialty physician services would be reimbursed, with state-only funds, under certain circumstances.

- Arizona did not release copies of its proposal until after it was approved. Officials indicated that this was because they were negotiating the waiver with HHS and did not want to release a document that was changing. Arizona's HIFA waiver application stemmed from a proposition approved by state voters in 2000 to extend Medicaid coverage to low-income childless adults, and a state law enacted in spring 2001 to provide coverage to parents of SCHIP- and Medicaid-eligible children. Although the HHS policy lists legislation as an acceptable way to fulfill the public process requirement, there was a significant change in Arizona's waiver application request from what was originally authorized. The section of the HIFA waiver covering childless adults with SCHIP funding was not included in the state statute or otherwise made public before the waiver was approved.

Streamlined Review Process Raises Additional Concerns

HHS's new initiatives further reduce the information states must provide on the extent of their public process. Prior to HIFA, states were required to indicate in their section 1115 applications specifically how they complied with HHS's policy for a public process. The 1994 policy directed states to include a narrative description of their public process with their applications, which became part of the administrative record for the waiver's approval. Such documentation provided a basis for HHS to determine whether the state provided an effective notice and comment process. Consistent with the agency's commitment to streamlining the waiver approval process, the HIFA waiver application template allows states to simply check a box indicating that they followed a public process that allowed beneficiaries and other interested stakeholders to comment on the proposal. No description of the state's public process is required.

HHS has recently emphasized to states that a public process is a priority, but has not similarly committed to a federal-level process. On May 3, 2002,

[49]The Utah approval includes a waiver of the requirement that states reimburse federally qualified health centers through a prospective payment system. This only applies to the expansion population. State officials estimate that this will result in payments about 10 percent lower than they would be under the prospective payment system.

CMS sent a letter to all state Medicaid directors encouraging the use of a public participation process, and stating that the agency would continue to review section 1115 waiver applications to ensure adherence to the 1994 policy. The letter did not, however, indicate that HHS intended to address public input at the federal level in line with its stated policy. The extent to which HHS's notice to states will ensure a process that provides for appropriate public input and consideration of comments remains to be seen. Concerns about the lack of an appropriate public process have been voiced in other states with pending HIFA waivers.

Conclusions

In providing section 1115 program demonstration authority under the Social Security Act, the Congress has indicated its willingness to allow states to experiment with innovative approaches in certain public programs to enhance their reach and effectiveness, including coverage of populations that might otherwise be ineligible for those programs. Over the years, many uninsured people in various states have benefited from such experimentation, receiving health insurance coverage otherwise unavailable to them. Using this same authority, HHS has recently committed to work with states to provide additional flexibility and more expedited approvals, including developing specific initiatives, such as HIFA and Pharmacy Plus. While only a handful of demonstrations have been approved to date, several other states have similar waivers under consideration that will likely be influenced by prior decisions and precedents.

Our review of recently approved waivers, however, raises certain legal and policy concerns that indicate the need to clearly establish purposes and populations for which SCHIP funds may be spent. While section 1115 authority provides the Secretary with broad discretion in approving demonstrations that further the program's objectives, it also creates the opportunity for HHS to approve state-operated programs that may not be consistent with program objectives established by the Congress. In exercising the section 1115 authority available for the SCHIP program, recent HHS approvals have allowed SCHIP funds to be spent on individuals other than the statute's stated target population: uninsured low-income children. At issue is the appropriateness of covering two distinct groups of adults: childless adults and parents or other custodians of SCHIP- and Medicaid-eligible children. With respect to childless adults, we believe that HHS has not presented a reasonable basis for authorizing states to cover childless adults under SCHIP. Furthermore, allowing states to cover parents with SCHIP funds without demonstrating its cost effectiveness allows limited program funds to be spent on individuals not

targeted in the statute. In this regard, it is not clear which statutory objectives should take precedence—those of the SCHIP statute, which allows for family coverage only to the extent that it does not exceed the cost of insuring eligible children, or section 1115 authority, which allows certain statutory provisions—such as cost-effectiveness tests—to be set aside.

Flexibility and program experimentation must be accompanied by accountability, as the HIFA name implies. Fiscal accountability is an important aspect of the Medicaid and SCHIP federal-state partnerships to ensure, among other things, that both the federal and state governments pay their fair share of program costs. We found, however, that HHS's review did not adequately ensure that two newly approved waivers were budget neutral, as required as a condition of section 1115 waiver approvals, because their ceilings included inappropriate or impermissible costs. Consequently, these waivers have put the federal government at increased financial risk. HHS approval of waivers that were based on use of inappropriate methods for demonstrating their budget neutrality is not a new problem, as we have earlier reported. However, as more states pursue additional flexibility in their Medicaid and SCHIP programs, HHS has an opportunity—if not an obligation—to develop more specific and consistent criteria on acceptable methodologies to predict permissible future costs and to ensure greater accountability in guarding against inappropriate federal financial risk.

Accountability should also entail a process of public input that is adequate to allow for the expression of issues and concerns that affected parties may have. Expediting the waiver review and approval process is an important goal. But it is also important to allow for public input into new and pending program proposals to help assure that proposals are consistent with overall program goals and that the benefits of waiving certain provisions justify forgoing their original purposes. Doing so at the state level facilitates informing those potentially most affected by new program approaches. However, a federal-level notice and comment opportunity is also important because approved waivers represent federal policy that may have influence beyond a single state. It also provides for a more visible and transparent process for all affected and interested parties, including the Congress—something that may be better accomplished at the federal level. For these reasons, we believe there is a need to adhere to some minimal federal input process for waiver proposals, such as the HHS policy established in 1994—in response to earlier concerns about the lack of an open process—that provided for notification in the *Federal Register* and a 30-day comment period.

Matters for Congressional Consideration

We believe the Congress should address three issues we identified in the course of our work. Two issues pertain to the availability of SCHIP funding to provide health insurance coverage to two distinct groups of adults: childless adults and parents or guardians of SCHIP-eligible children. The third pertains to the need for an improved federal-level process for public notification and input for state applications for Medicaid and SCHIP section 1115 demonstration projects.

In our view, HHS's use of section 1115 authority to allow states to use SCHIP funds to cover childless adults is not consistent with the program's statutory objectives to expand health coverage to uninsured, low-income children. Therefore, SCHIP funds should not be available for this purpose. Further, states' use of SCHIP funds to cover childless adults decreases the amount of unspent SCHIP funds available for redistribution in future years to states with unmet SCHIP needs. HHS disagrees with our view, asserting that the objectives of the Arizona HIFA waiver must be viewed as a comprehensive approach in providing health insurance coverage to those who were previously uninsured, including childless adults and parents. Because of the difference in our positions on whether SCHIP funds are available to cover childless adults, we are raising this to the attention of Congress for resolution. Resolving this issue is important not only for the Arizona waiver but also because of the precedent it sets for additional pending section 1115 demonstration applications currently under consideration and for the future availability of SCHIP funds for uninsured, low-income children.

Therefore, the Congress should consider amending title XXI of the Social Security Act to specify that SCHIP funds are not available to provide health insurance coverage for childless adults. In addition, the Congress should establish, for parents or guardians of SCHIP-eligible children, which statutory objectives should take precedence—those of title XXI, which allow for family coverage only to the extent it does not exceed the cost of insuring eligible children, or section 1115 authority, which allows certain statutory provisions—such as cost-effectiveness tests—to be set aside.

The Congress should also consider requiring the Secretary of HHS to improve the public notification and input process at the federal level to ensure that beneficiaries and groups affected by Medicaid and SCHIP section 1115 demonstration waiver proposals receive opportunity to review and comment on proposals before they are approved.

Recommendations for Executive Action

To ensure that SCHIP funds are spent only for authorized purposes, we recommend that the Secretary of HHS

- amend the approval of Arizona's HIFA waiver to prevent future use of SCHIP funds on childless adults, and
- deny any pending or future state proposals to spend SCHIP funds for this purpose.

To meet its fiduciary responsibility of ensuring that section 1115 waivers are budget neutral, we recommend that the Secretary of HHS

- better ensure that valid methods are used to demonstrate budget neutrality, by developing and implementing consistent criteria for consideration of section 1115 demonstration waiver proposals, and
- reconsider Utah and Illinois's budget neutrality justifications, in light of our conclusions that certain costs were inappropriate or impermissible and, to the extent appropriate, adjust the limit on the federal government's financial obligation for these waivers.

To improve the opportunity for public input into HHS consideration of state Medicaid and SCHIP program proposals that waive statutory requirements, we recommend that the Secretary of HHS provide for a federal public input process that includes, at a minimum, notice of pending section 1115 waiver proposals in the *Federal Register* and a 30-day comment period in line with HHS's 1994 policy.

Agency and State Comments and Our Evaluation

We provided a draft of this report for comment to HHS, OMB, Arizona, California, Illinois, and Utah. OMB and California declined to provide written comments. In its general comments, HHS emphasized that increasing access to health insurance and providing prescription drugs to senior citizens are among its top priorities, and that given the current state of the economy, its actions to increase coverage through waivers are appropriate if not imperative. HHS also highlighted its history of using section 1115 waivers in the Medicaid program to expand health insurance coverage for individuals who would not otherwise be eligible for the program. HHS also commented that, since January 2001, the agency has approved nearly 1,800 Medicaid and SCHIP state plan amendments, managed care waivers, home- and community-based waivers, and section 1115 waivers and amendments, but noted that, because of the scope of our study, our report focused on only 4 of them. We reviewed new section 1115 demonstration waivers in line with the goals of HHS's new HIFA and Pharmacy Plus initiatives—initiatives of particular interest because of the

significance of their goals and HHS's plans to grant states new flexibility to achieve them—and only 4 had been approved at the time we conducted our work. We also considered, in addressing certain issues such as budget neutrality, earlier HHS actions and our own prior work.

HHS disagreed with each of our three recommendations for executive action. Arizona, Illinois, and Utah also disagreed with various aspects of our findings leading to these recommendations. A summary of their concerns and our evaluation follows. HHS's and states' comments are included in appendixes IV through VII.

SCHIP Funding for Adults

With regard to our recommendation that the Secretary amend the approval of Arizona's HIFA waiver to prevent future use of SCHIP funds on childless adults, and deny any pending or future state proposals for this purpose, HHS commented that our analysis was extremely narrow and did not recognize that the approval of the Arizona HIFA waiver promotes the objectives of SCHIP by providing health insurance coverage to those who were previously uninsured. HHS and Arizona both commented that the approved section 1115 SCHIP demonstration waiver prioritizes spending SCHIP (title XXI) funds for children. States are not permitted to limit or cap children's enrollment, and are required to ensure the availability of funds for children over funding adult expansion populations. We revised the report to better clarify these priorities and requirements for the Arizona waiver. HHS also noted that there were no states that were entitled to redistributed SCHIP funds that did not receive such funds as a result of expenditures on section 1115 demonstrations.

We acknowledge that covering the uninsured is an important public policy goal and that HHS has established coverage of children as a priority for use of SCHIP funds in the Arizona waiver terms and conditions. We also acknowledge that states that received redistributed funds in 2002 were not affected by HHS's approval of the Arizona waiver. However, any unspent SCHIP funds available for redistribution to states in future years to cover uninsured low-income children would be reduced because of the Arizona approval, and any similar approved state proposals.

We continue to believe that neither HHS nor Arizona has adequately explained how the objectives of the SCHIP statute—to provide health assistance to uninsured low-income children—is promoted by insuring childless adults. In its comments, HHS introduced a new rationale for this approval: that these adults could become parents or caretaker relatives in the future. This statement does not clarify how SCHIP funds used for this

purpose would likely support the program's objectives. To the contrary, HHS's assertion that it may use SCHIP funds for childless adults suggests that it could approve virtually any demonstration project and, thus, effectively eliminates the requirement that section 1115 demonstration projects be likely to promote the objectives of the particular program for which they are authorized. Similarly, HHS's discussion of the broader community benefits of the Arizona HIFA waiver does not clarify how it would likely promote the provision of health assistance to low-income children. In its detailed comments (number 12), HHS indicated that our discussion of the scope of the Secretary's authority under section 1115 is unnecessary and overbroad in view of the HHS position that the Arizona HIFA waiver—in its entirety—will promote SCHIP objectives. As indicated, our discussion was included in response to HHS's position that the Secretary need not exercise the section 1115 waiver authority on a program-by-program basis. Because our positions differ on whether SCHIP funds are allowable for this purpose, we believe it is important for the Congress to address this issue. Resolving it is also important because the Arizona waiver approval sets precedent for future waiver approvals and funding commitments that could potentially impact on SCHIP funds available for redistribution to states with unmet SCHIP needs. As a result, we elevated this issue to a matter for congressional consideration.

Neither HHS nor the states commented on the draft report's matter for congressional consideration concerning the use of section 1115 authority to approve spending SCHIP funds on parents or guardians of SCHIP-eligible children without regard to the statutory cost-effectiveness test.

Budget Neutrality

HHS, Utah, and Illinois disagreed with our findings supporting the recommendation that the Secretary better assure that valid methods are used to demonstrate budget neutrality. For Utah's estimate, HHS and Utah stated that the methods used to assure budget neutrality were valid. They commented that including the costs of a hypothetical population in the without-waiver costs was appropriate because the state has "current law" flexibility to cover that population at its own option, that is, the state could have covered the expansion population through its Medicaid program and thus should be allowed to consider the associated costs of their coverage as without waiver costs. We continue to maintain—despite HHS's disagreement both currently and in response to our 1995 report—that states should not be allowed credit for the costs of covering certain hypothetical populations in their without-waiver cost estimates. Indeed, the Medicaid statute provides states wide latitude in terms of covered populations and services and payment rates for those services, and the

federal government will pay its share of covered expenditures in an open-ended manner when the states cover the services under their state Medicaid plan. If states choose, however, to pursue broader authority under section 1115, they are required to meet the budget neutrality test. In the case of Utah and other states we have examined in the past, states had previously chosen not to cover such optional populations. In our view, to allow the inclusion of hypothetical costs for hypothetical populations not previously covered—in an attempt to demonstrate budget neutrality of new section 1115 demonstration proposals—turns the test of budget neutrality into a rather hollow exercise.

Regarding our conclusion that HHS allowed Illinois to include impermissible UPL costs in its baseline, HHS and Illinois each raised a different concern. HHS indicated that the final regulation implementing the UPL reduction was not in place at the time of the Illinois waiver approval. We disagree. The final rule that set new UPLs for nonstate-governmental facilities, including a 150-percent UPL for nonstate-government-owned hospitals and a mandated phase-out of payments above this limit, was published in January 2001 and effective March 2001, well before the Illinois waiver was approved in January 2002. A second rule, to which HHS may have been referring, reduced the UPL for nonstate-government-owned hospitals from the 150-percent level to 100 percent of what Medicare would pay and was effective May 2002. We revised the report to clarify the effective dates of these two rules. HHS in its comments recognized that the UPL reduction may now apply, and indicated that it was reviewing the budget neutrality cap in light of the new rules.

Illinois disputed that its budget neutrality projections are inflated by impermissible costs. The state said that other spending authority found in the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA) could have been used by the state in its waiver projection which would have offset the impact of the inappropriately included UPL funds. Illinois officials indicated that these costs that could be incurred in future years should have been considered in our assessment of their without-waiver estimate. However, the budget neutrality justification that Illinois submitted to, and was approved by, HHS did not include these hypothetical costs in the ceiling. The state in its comments did not provide any evidence that it intended, in the absence of the waiver, to modify its program so that some of these hypothetical costs would be incurred by the population covered by the waiver. Illinois officials also indicated that, even if these BIPA-related costs were not considered, that several technical corrections should be made to our estimate of impermissible

costs. After the state provided additional documentation for its budget neutrality analysis, we adjusted our estimate of impermissible UPL costs accordingly, to $275 million from $356 million. We note, however, that our methodology and estimate are conservative. We reduced the amount of UPL payments included in the without-waiver estimate at a lower rate than what would actually occur, because the detailed data needed to determine the actual and higher rate of reduction were not available at the time of our review. We maintain that our estimate, which remains higher than the estimate that the state developed using its own calculation, is a reasonable approximation of the impermissible costs included in Illinois's justification, and that HHS should revisit the Illinois budget neutrality justification and source documentation in light of this finding as it has committed in its comments to do.

Illinois and HHS also disagreed with our conclusions about the fiscal soundness of the Illinois Pharmacy Plus demonstration, restating that the premise that the low-income elderly who are provided prescription drug coverage will be less likely to become eligible for the Medicaid program is valid. Illinois stated that our report fails to cite any of the studies that show drug coverage can reduce other medical costs. In the course of our work, we reviewed all of the supporting research that Illinois cited in its waiver application.[50] While the cited studies indicated that access to prescription drugs yielded positive health benefits for people in poor health, all of them focused on access for people already diagnosed with specific conditions, such as diabetes, heart disease, and human immunodeficiency virus (HIV). In our view, the cited research did not

[50]Illinois in its comments also cited a report not included in its initial waiver application addressing the New York Elderly Pharmaceutical Insurance Coverage (EPIC) Program for pharmaceutical assistance to the low-income elderly. We reviewed a copy of the report (EPIC Evaluation Report to the Governor and Legislature, "*Maintaining Health, Dignity and Independence—1987-1995*"), which found that improved access to drugs for this population had a positive impact on their health. The state estimated $48 million in savings associated with lower hospital and institutional care for participants, as compared to the $41 million cost of the drug benefit program in 1993. However, the bulk of these savings, $42 million, were for reduced hospital costs. Illinois cannot claim such savings for its waiver program since Medicare, not Medicaid, pays for these costs for the elderly population. Only $6 million of the $48 million in estimated savings was from the expected reduction in the rate of nursing home admissions—comparing 17.4 admissions per thousand for the state's senior population, with 16 admissions per thousand for the EPIC participants. New York also has reported major changes in average prescription price, utilization, participation, and overall spending for EPIC since the early 1990s, the time period covered by its analysis of the cost savings from the benefit. New York has not conducted a more recent study of the hospital and nursing home admission rates for EPIC participants.

sufficiently support Illinois's theory that a full pharmacy benefit for the general near-poor elderly population will yield the amount of savings that the state depends on for its budget neutrality commitment. Illinois also commented that we did not identify the full range of actions the state could take should its estimated savings not materialize, such as establishing an enrollment cap for the waiver population or increasing cost sharing. We modified our report to clarify this point.

We do not question that some savings from providing a prescription drug benefit to low-income elderly may be realized and agree that the premise may be appropriate for an evaluation. Our major observation remains—that HHS is allowing a high level of risk for the state and its elderly beneficiaries in the Illinois demonstration, given the specific assumptions the state has made regarding the substantial savings it expects to gain from offering a drug benefit to this elderly low-income population. The state assumes that a drug benefit can largely pay for itself by diverting thousands of people from becoming Medicaid-eligible and from entering nursing homes. The state assumes this high diversion rate even though the majority of the people expected to be covered under the waiver already receive some drug benefit, albeit a more limited one, under the state's existing drug program. A broader point, as we report, is that the diversion premise is being accepted and applied on a broad scale before its validity is tested. HHS has encouraged states to submit Pharmacy Plus waivers and several have done so.

Public Process

HHS disagreed with our recommendation that the Secretary of HHS should improve the federal public process, commenting that the current opportunity for public comment in the waiver process is more than adequate at both the federal and state levels. HHS stated that CMS currently posts some proposals on the CMS Web site, such as HIFA proposals, and intends to post all pending and approved proposals on the Internet in the future. However, HHS did not specify when in the future it would do so. When we checked CMS's Web site, we were able to find copies of all but one of the pending HIFA proposals, but none of the Pharmacy Plus proposals and none of the pending proposals requesting section 1115 waiver authority that were not presented in the HIFA standard format. Consequently, reliance on the Web site provides an incomplete source of public information and does not substitute for the widely accepted *Federal Register* notice process. Our broader point remains that because of the variation in the level of public process at the state level, and because a waiver approval in one state sets precedent for others, a more formal and consistent federal approach is needed to ensure

that people potentially affected by waivers are aware of the proposals and have a structured venue for providing input prior to their approval. It would also provide a centralized focus on issues of national public policy interest for the Medicaid and SCHIP programs that is otherwise absent when relying on individual states as the focal point for public dialogue. Because HHS disagreed with our recommendation to improve the public notification and input process at the federal level, we elevated this issue to a matter for congressional consideration.

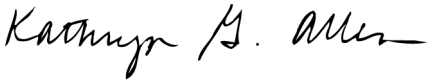
Utah suggested that we reconsider the discussion in the draft report of the state's public process and the concerns raised at the state level with its waiver. The state indicated that the concerns expressed about the waiver were apart from whether there was appropriate notice and opportunity for comment. We agree and have revised the report accordingly. We have retained, however, some discussion of the concerns with the waiver that groups we contacted felt were not adequately considered during the state's public process. We believe it helps demonstrate the importance of public input, particularly when proposed demonstration projects are viewed as controversial.

Other Comments

HHS and the states provided other comments that were not specific to our recommendations. Illinois and Utah expressed concerns that the report implied that HHS's expedited review was too fast to provide an adequate review. Utah, for example, indicated that much negotiation between the state and HHS took place before the waiver was formally submitted. It was not our intent to link the amount of time that applications were under consideration with the results of HHS's approval process for individual waivers. We revised the report to reflect that more time may be spent than indicated by formal approval times, because states and HHS may negotiate waiver proposals prior to their formal submission. We note, however, that beneficiary advocates raised concerns that these "behind-the-scenes" negotiations also result in less public awareness and scrutiny of the specific components of the proposals and that the expedited review times of the formal proposals may leave less time for public input and discussion of the written proposals. We believe that these concerns further support the need for a public process at the federal level once the state has submitted its proposal, to ensure adequate public notification of the proposals' specific components. Finally, HHS provided additional technical comments. We revised the report to address these comments 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 issuance 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 and Medicaid Services, the Director of the Office of Management and Budget, 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) 512-7119. Another contact and other major contributors are included in appendix VIII.



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Appendix I: Description of Four Recent Section 1115 Waiver Approvals

As of May 1, 2002, HHS had approved 4 of the 13 section 1115 new demonstration waivers submitted and under review since August 2001.[1] These include the first 2 HIFA waivers, for Arizona and California; the expansion of primary care for uninsured individuals in Utah; and the first Pharmacy Plus waiver for Illinois. The table below provides further specific details about these 4 approved waivers.

Table 2: Description of Section 1115 Waivers Approved for Arizona, California, Utah, and Illinois

	Arizona	California	Utah	Illinois
Name and type of waiver	**Arizona HIFA Demonstration**	**California Parental Coverage Expansion HIFA**	**Utah Primary Care Network**	**Illinois Senior Care Program**
Waiver goals	To expand coverage to uninsured low-income adults, including conducting a feasibility study of employer-sponsored insurance	To expand coverage to uninsured low-income parents in order to increase enrollment and continuity of care for SCHIP and Medicaid children, including conducting a feasibility study of employer-sponsored insurance	To expand primary care coverage to uninsured low-income adults[a]	To extend pharmacy benefits to low-income seniors
Sources of funding	Unspent SCHIP allotment and Medicaid (federal and state matching payments)	Unspent SCHIP allotment and tobacco settlement funds	Medicaid (federal and state matching payments)	Medicaid (federal and state matching payments)
Submission and approval dates	Sept. 20, 2001, and Dec. 12, 2001	Dec. 20, 2000 — original submission Jan. 16, 2002 – revised submission in HIFA format Jan 25, 2002 – HIFA approval date	Dec. 11, 2001, and Feb. 8, 2002	July 31, 2001, and Jan. 28, 2002
Review time[b]	84 days	10 days for HIFA application; 401 days from original submission date	60 days	182 days
Implementation date	Phase I: childless adults, Nov. 1, 2001 (retroactive implementation) Phase II: parents, Oct. 1, 2002	January 1, 2003 – possible start date, but under consideration by state legislature	July 1, 2002 –planned start date	June 1, 2002 – actual start date

[1]As noted elsewhere, HHS approved the Tennessee TennCare II waiver on May 31, 2002, and the Wisconsin pharmacy waiver on July 1, 2002, too late to be included in our analysis.

	Arizona	California	Utah	Illinois
Name and type of waiver	**Arizona HIFA Demonstration**	**California Parental Coverage Expansion HIFA**	**Utah Primary Care Network**	**Illinois Senior Care Program**
Target populations	Phase I: childless adults at or below 100% FPL Phase II: parents of children in Medicaid or SCHIP between 100% and 200% FPL	Custodial parents, caretaker relatives, and legal guardians of Medicaid and SCHIP children, at or below 200% FPL	Adults age 19 and older below 150% FPL, including childless adults from state-only program, and parents	Seniors age 65 and older, at or below 200% FPL, not otherwise eligible for Medicaid; many from state-only pharmacy benefit program
Number of people in waiver (5 years)	Phase I: 27,000 childless adults Phase II: 21,250 parents— both groups estimated, no enrollment caps[c]	275,000 adults— estimated, no enrollment cap[c]	9,000 childless adults, and 16,000 parents — both groups are enrollment caps	Up to 256,500 seniors — estimated, enrollment cap
Covered benefits	Childless adults and parents receive comprehensive benefits plan comparable to SCHIP for children	Parents receive comprehensive benefits plan similar to SCHIP children (comparable to state employees)	Expansion adults receive primary care and preventive services only, no hospital or specialty physician services;[d] about 17,600 current mandatory eligible adults and optional medically needy adults who are not aged, blind or disabled receive reduced benefits[e]	Seniors receive assistance in paying for prescription drugs, with primary care coordination; eligible beneficiaries have the option of premium and copayment assistance in paying for private insurance
Cost sharing	Phase I: childless adults have the same cost-sharing as Medicaid: copayments from $1 office visit to $5 nonemergency visit to emergency room Phase II: parents have the same cost sharing as SCHIP: family premiums not to exceed $25 per month, $5 nonemergency visit to emergency room, overall limit 5% annual family income	Parents will pay premiums based on income: $10 per parent per month for families at or below 150% FPL; $20 per parent per month for families above 150% FPL; plus copayments, for example, $5 for an office visit or emergency care, capped at $250 per household per year	Expansion adults pay $50 annual enrollment fee plus copayments, for example, $5 office visit, $30 emergency room visit Current mandatory eligible adults have no enrollment fee (optional medically needy adults have $50 enrollment fee), but have copayments, for example, $3 office visit, $6 nonemergency visit to emergency room, $220 for each hospital admission	Seniors with household incomes below the FPL pay no charge per prescription until reaching the benefit cap of $1,750 Seniors with household incomes at or above FPL pay $1 generic or $4 per brand name prescription, until reaching the $1,750 cap Above the cap, participant pays 20% of each prescription plus a nominal copayment

	Arizona	California	Utah	Illinois
Name and type of waiver	**Arizona HIFA Demonstration**	**California Parental Coverage Expansion HIFA**	**Utah Primary Care Network**	**Illinois Senior Care Program**
Research plans / evaluation	Outcome measure: reduce the rate of uninsurance by 1% overall Report on feasibility study of employer-sponsored insurance	Research question: will enrolling parents increase enrollment and continuity of care for children? Report on feasibility study of employer-sponsored insurance	Research plans being refined	Outcome measures: overall decrease in Medicaid hospital and long-term care stays; related cost savings to Medicare
Estimated 5-year waiver costs	Federal share: Phase I: childless adults SCHIP: $126 million Medicaid: $288 million total: $414 million Phase II: parents SCHIP: $144 million	Federal share: estimated $1.6 billion (66% of total $2.4 billion)	Federal share: Estimated $422 million (71% of the total $595 million)	Federal share: estimated $7 billion (50% of the total $14 billion)

[a]The Utah waiver approval also includes a separate demonstration population of high-risk pregnant women with assets exceeding the state maximum who will receive the full Medicaid benefits package.

[b]Review time is the elapsed time from date of submission to date of approval; It does not include any discussions HHS may have had with a state before a waiver was formally submitted for review.

[c]While Arizona and California do not have specific enrollment caps, enrollment is limited by the amount of unspent SCHIP funds available.

[d]Although the Utah waiver proposal, as approved, would provide no hospital or specialty physician services for individuals receiving primary care, state officials have since stated that they intend to cover limited inpatient physician specialty services, if pre-authorized, from state-only funds.

[e]The individuals with mandatory eligibility who will receive reduced benefits include adults age 19 and older who are eligible through section 1925 Transitional Medical Assistance or section 1931 Temporary Assistance for Needy Families (TANF), and adults age 19 through 64 who are medically needy and not aged, blind, or disabled. Benefit reductions for these groups affect optional services by placing some limitations on vision, physical therapy, chiropractic, dental, and mental health services. In addition, these recipients will pay $3 per physician visit (instead of $2) and $2 per prescription (instead of $1).

Sources: HHS approval letters and approved waiver applications for each state.

Appendix II: Section 1115 Waiver Applications under Review

Nine of the 13 section 1115 waiver applications submitted since August 2001 to expand coverage for the uninsured and pharmacy benefits were still under review by HHS as of June 3, 2002.[1] These proposals—including 4 HIFA applications, 1 uninsured expansion not in HIFA format, and 4 pharmacy proposals—are briefly described below.

Table 3: Section 1115 Waiver Applications Under Review by HHS, June 3, 2002

State and waiver	Highlights
Connecticut ConnPACE Pharmacy Program Waiver	• **Waiver submission**: March 6, 2002; under review for 90 days as of June 3. • **Populations served**: The waiver would expand eligibility for a comprehensive prescription drug benefit, by waiver year 5, to an estimated 104,000 individuals age 65 and older and the disabled age 18 and older with incomes up to 300 percent of the FPL. Drugs covered would be the same as those covered under the current state-only program. Participants would pay an annual registration fee of $25 and $12 to $20 per prescription. • **Cost**: The waiver would be financed by federal and state Medicaid payments, estimated to be $1.9 billion over 5 years, including savings from reduced use of Medicaid long-term care services and delayed spend-down to Medicaid eligibility. The state would also contribute about $76 million per year in state-only funds.
Illinois KidCare Parent Coverage HIFA Waiver	• **Waiver submission**: February 15, 2002; under review for 109 days as of June 3. • **Populations served**: The waiver would make health insurance coverage available to an estimated 318,200 individuals, the majority of whom would be parents of Medicaid and SCHIP children with incomes at or below 185 percent of FPL. Coverage would also be offered to low-income and uninsurable adults and children in several small state-funded programs, such as those for hemophilia, renal dialysis, and immigrant and other low-income children. Benefits would vary by group, ranging from the state's approved SCHIP plan (Medicaid benefits without home and community-based waiver services and abortion services) to limited types of services specifically for individuals with hemophilia or renal disease. Cost sharing will also vary by group. Newly eligible parents with incomes above 150 percent and at or below 185 percent of FPL, for example, would pay monthly premiums of from $15 (for one covered person) to $40 (five or more) plus copayments of $3 to $5 per prescription, $5 per medical visit, and $25 for each non-emergency visit to an emergency room. Current eligibles and several expansion groups would be offered the option of premium assistance for private insurance in lieu of state-administered coverage. • **Cost**: Federal spending over 5 years is estimated at $861 million (66 percent of the total estimated cost of $1.3 billion). Funding would come from Medicaid, SCHIP, and state general revenues.

[1]We do not include the TennCare II Medicaid waiver in this group because it was initially reported to be under review as an extension of the existing TennCare demonstration waiver. HIFA applications submitted in mid-May or later, including those from Colorado, Delaware, Minnesota, and Oregon, were not included in our analysis because they were submitted too late to be included. Note that this table is largely based on the states' waiver applications as submitted to HHS, and elements of the proposals may change during the review process.

State and waiver	Highlights
Maine Care for Childless Adults HIFA Waiver	• **Waiver submission**: February 22, 2002; under review for 102 days as of June 3. • **Populations served**: The waiver would expand Medicaid coverage to one population group: childless adults. In the first year, 11,480 individuals with incomes under 100 percent of FPL would be covered, and in later years the income limit could rise to 125 percent of FPL. New enrollees would receive the same benefits as other Medicaid beneficiaries with the same nominal cost-sharing. • **Cost**: Maine would finance the waiver, estimated to cost $236 million over 5 years, with federal and state Medicaid funds by relinquishing part of its Disproportionate Share Hospital allocation.
Michigan MIFamily Medicaid Expansion HIFA Waiver	• **Waiver submission**: March 1, 2002; under review for 95 days as of June 3. • **Populations served**: Michigan would expand coverage to an estimated 210,500 individuals in several groups that would receive different benefits. (1) About 70,000 parents of children in Medicaid with family incomes between 51 and 100 percent of FPL would receive a benefit plan including physician, lab, X-ray, inpatient hospital (coverage limited to a defined case rate payment per authorized admission), and many outpatient services. Copayments for this group would include $10 for each physician visit; $10 to $20 per prescription; and $25 for a nonemergency visit to the emergency room (based on the prudent layperson standard). (2) An estimated 62,000 childless adults with incomes up to 35 percent of FPL would receive a specified outpatient benefit plan, excluding any inpatient coverage. They would pay $3 for physician visits, up to $5 per prescription, and $25 for a nonemergency visit to the emergency room. (3) Up to 1,500 pregnant women with incomes between 186 and 200 percent of FPL would receive full existing Medicaid benefits. (4) Up to 75,000 childless adults with incomes between 35 and 100 percent of FPL could receive a specified outpatient benefit through county health plan programs supported by a federal, state, and county partnership that would be phased in across the state over 5 years. In addition, approximately 2,000 disabled Medicaid beneficiaries would be allowed to earn up to 350 percent of FPL and still receive Medicaid benefits. Waiver beneficiaries could receive premium assistance vouchers to purchase private employer-sponsored health insurance as an alternative to state programs. • **Cost**: Michigan proposes to fund its expansions, estimated to be $2.4 billion over 5 years, with unspent SCHIP funds, Medicaid savings from redefined benefits for the optional and expansion groups, redirecting a portion of the state's Disproportionate Share Hospital allocation, and new local funds from participating counties.
New Jersey Pharmaceutical Assistance to the Aged and Disabled (PAAD) Program Waiver	• **Waiver submission**: April 3, 2002; under review for 62 days as of June 3. • **Populations served**: The waiver would refinance the existing state-funded PAAD program for seniors age 65 and older and the disabled age 18 and older with incomes at or below 200 percent of FPL. State would continue funding its state-only Senior Gold pharmacy assistance program for eligible individuals with incomes up to 300 percent of FPL. These two programs currently serve about 199,000 and 26,000 individuals, respectively, and in 5 years would together serve an estimated 250,000 people. Both programs currently and under the waiver would provide the same drugs approved for the Medicaid formulary. There would be pharmacy benefit management, no enrollment fee, and $5 per prescription cost sharing. • **Cost**: Federal spending over 5 years is estimated at nearly $5 billion, half of the estimated total cost of $9.9 billion. The PAAD waiver program would be funded by federal and state Medicaid payments, while the Senior Gold program for higher income individuals would continue to be state-funded.
New Mexico State Coverage Initiative HIFA Waiver	• **Waiver submission**: April 3, 2002; under review for 62 days as of June 3. • **Populations served**: The waiver would expand coverage to up to 40,000 uninsured adults ages 19 to 64 with incomes at or below 200 percent of FPL in phase I. The expansion would be targeted to employed adults and parents of Medicaid and SCHIP children. No children are included in phase I. Benefits would be similar to basic commercial managed care packages in the state (including inpatient, physician, lab

State and waiver	Highlights
	and X-ray, pharmacy, and mental health and substance abuse services), with sliding scale cost sharing, for example, ranging from $5 per physician visit for individuals with incomes up to and including 100 percent of FPL, to $20 for those with incomes 151 through 200 percent of FPL. Similarly, hospital inpatient copayments would range from $25 to $150 per day, and nonemergency visits to the emergency room from $25 to $125. Coverage would be offered primarily through an employer-based system. The application states that an amendment to the demonstration would be submitted later for a phase II, which could reallocate existing Medicaid program resources to shift certain enrollees from Medicaid to the phase I benefits package, with the savings allowing coverage of an additional 40,000 uninsured adults. This proposal is not currently under review. • **Cost:** Federal spending over 5 years for the phase I program is estimated at $228 million from the state's SCHIP allotment, which is 82 percent of total program costs estimated at over $277 million. There would also be state and local funding and premium cost sharing by participants.
South Carolina Prescription Drug Benefit for Low-Income Seniors Program Waiver	• **Waiver submission**: January 8, 2002; under review for 147 days as of June 3. • **Populations served**: This waiver would provide comprehensive pharmacy benefits (the same as provided under the state's Medicaid plan) and medical case management for up to 50,000 seniors age 65 and older with incomes at or below 200 percent of FPL and no private drug coverage. An existing state-funded pharmacy program serving about 33,500 seniors with incomes at or below 175 percent of FPL would be folded into the waiver. Participants would pay a deductible of $500, then $10 to $21 per prescription with no ceiling or cost limit. • **Cost**: The program, estimated to cost $2.8 billion over 5 years (including expenditures for the Medicaid-aged population as well as the pharmacy benefit program itself), would be funded by federal and state Medicaid payments, savings from diverting people from Medicaid eligibility and reducing the rate of increase in use of Medicaid services, a drug rebate program, and participant copayments.
Washington Medicaid and SCHIP Reform Waiver	• **Waiver submission**: November 7, 2001; under review for 209 days as of June 3. On January 25, 2002, HHS requested the state to submit a more specific proposal outlining exactly what changes would be made to benefits and cost sharing, which eligibility groups would be affected, and what the timeframe would be. As of June 3 the original waiver was being revised and may be resubmitted as a HIFA. • **Populations served**: The Washington waiver as proposed in November of 2001 would cover about 32,000 parents of Medicaid and SCHIP children currently enrolled in the state-only Basic Health Plan, who would be transferred to the waiver, plus an estimated 20,000 additional parents (a figure that could include an unspecified number of childless adults). To do so, the November 2001 waiver proposal sought flexibility to adopt cost sharing, change benefits, or limit enrollment as needed in administering the state Medicaid program. For example, the application requested flexibility to design different benefit packages, with a benefit floor that would apply to both mandatory and optional eligibility groups. This benefit floor would be based on the state-funded Basic Health Plan—which offers inpatient and outpatient hospital services, ambulance, emergency room, physician services, maternity and well-baby care, and pharmacy—plus outpatient rehabilitation therapies. Cost sharing would be limited to 5 percent of family income, on average, from premiums paid by those with incomes above the FPL and from copayments on all nonpreventive services. • **Cost**: The state's November 2001 waiver proposal planned to use unspent SCHIP funds estimated at $486 million for the 5 years 2002-2006 to finance the expansion populations.

State and waiver	Highlights
Wisconsin SeniorCare Pharmacy Program Waiver	• **Waiver submission**: April 1, 2002; under review for 64 days as of June 3.[a] • **Populations served**: As proposed, the waiver would provide comprehensive Medicaid prescription drug coverage for an estimated 177,000 seniors age 65 and older with incomes below 240 percent of FPL who were not eligible for Medicaid. Participants would pay an annual enrollment fee of $20, $5 to $15 per prescription, and individuals with incomes between 160 and 240 percent of FPL would pay the first $500 as a deductible. State legislation in 2001 established a new state-funded pharmacy assistance program, SeniorCare, to be implemented September 1, 2002, and to be folded into this pharmacy waiver program once approved. • **Cost**: The program, with an estimated total cost of about $1 billion over 5 years, would be financed by federal and state Medicaid payments, including Medicaid savings from delaying or diverting seniors from spending down to eligibility.

[a]HHS announced approval of the Wisconsin pharmacy waiver application on July 1, 2002. Because it was approved after we completed our work, we did not assess the final approved waiver (which could potentially differ in scope from the initial proposal). Our assessment in this table references the initial plans included in the state's waiver proposal.

Sources: State section 1115 waiver applications.

Appendix III: HHS Office of the General Counsel Response to GAO Inquiry

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel
Centers for Medicare and
Medicaid Services Division

330 Independence Ave., S.W.
Room 5309 Wilbur J. Cohen Building
Washington, D.C. 20201

MAY 14 2002

Dayna K. Shah
Associate General Counsel
General Accounting Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Ms. Shah:

I am responding on behalf of General Counsel Alex M. Azar II to your inquiry concerning the approval of a demonstration project under section 1115 of the Social Security Act (Act) for the State of Arizona (approved pursuant to the Health Insurance Flexibility and Accountability (HIFA), process). Specifically, you asked about the "legal and policy justification" for allowing Arizona to use funds appropriated under title XXI of the Act for the State Children's Health Insurance Program (SCHIP) to provide insurance coverage to childless adults.

While the Office of the General Counsel advises on legal issues, we do not have ultimate responsibility for determining the justification for approving a demonstration project under section 1115 of the Act. Section 1115 accords the Secretary broad discretionary authority to approve any demonstration project "which, in the judgment of the Secretary, is likely to assist in promoting the objectives" of various titles of the Act (including title XIX and, by virtue of the reference in section 2107(e)(2)(A), title XXI). As I am certain you can appreciate, this standard involves a degree of policy discretion that only program officials can appropriately exercise.

The statutory language of section 1115 quoted above provides considerable legal flexibility to authorize the use of program funds for items, services or activities that would not normally be paid under the program. Section 1115 by its terms provides for federal participation in expenditures that are not "otherwise matchable." Furthermore, the language of section 1115 permits approval of demonstration projects based on the

overall purposes of all of the listed Social Security Act programs (rather than segregating each program). In other words, in approving a Medicaid or SCHIP demonstration, the Secretary may consider the likelihood of promoting the objectives of the programs authorized under any of the titles of the Social Security Act listed in section 1115.

I hope that this response has been helpful.

Sheree R. Kanner
Associate General Counsel

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Washington, D.C. 20201

JUN 27 2002

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 and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns." 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 appreciates the opportunity to comment on this draft report prior to its publication.

Sincerely,

Michael Mangano
for Janet Rehnquist
Inspector General

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. The 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 on the General Accounting Office's Draft Report, "Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns" (GAO-02-817)

General Comments

The Department of Health and Human Services (HHS) appreciates the opportunity to comment on this draft report on recent approvals of Medicaid and the State Children's Health Insurance Program (SCHIP) demonstrations. Since January 2001, Secretary Thompson has approved nearly 1,800 Medicaid and SCHIP state plan amendments (SPAs), managed care waivers, home and community-based care waivers, and 1115 waivers and amendments. As a result, over 1.8 million more low-income Americans have become eligible for Medicaid or SCHIP and 4.9 million individuals have become eligible for expanded benefits or services.

Staff from the Centers for Medicare & Medicaid Services (CMS) began meeting in November 2001 with your staff on the request from Senator Baucus and Senator Grassley to review the actions we have taken in Medicaid and SCHIP. Since then, the Department has provided GAO with access to all staff and materials you have requested. We understand that, because of the time constraints set by the requestors, the GAO study has a limited focus. We would like to note that GAO's conclusions and recommendations reflect an analysis of only 4 of the 1,800 SPAs, waivers, and amendments approved since January 2001.

Increasing access to health insurance and providing prescription drugs to senior citizens are among our top priorities Given the current state of the economy, we believe our actions to increase coverage through waivers are appropriate, if not imperative. We have responded at a time when this issue is so crucial to the health and well-being of so many low-income Americans, many of whom work - and pay taxes - but are still below the poverty level and do not have health insurance.

Under section 1115 of the Social Security Act, Congress authorized the Secretary the power to waive provisions of the Social Security Act and authorized the Secretary to use federal program funds to share in demonstration project costs that would otherwise not qualify for federal funding. Because of Medicaid's complex eligibility rules, an individual may be below the poverty level but still not eligible for Medicaid. We have used 1115 waivers in the Medicaid program to expand health insurance coverage for individuals who would not otherwise be eligible for the program. In 1997, Congress extended the power to grant 1115 waivers of provisions of Title XXI, SCHIP. We would note that many members of Congress have often indicated their support for a wide variety of 1115 waivers. Some of these waivers have been comprehensive such as those granted to California, Massachusetts, New York, Oregon, and Tennessee among others. Some 1115 waivers have been targeted to specific geographic areas such as Los Angeles County. Others are targeted to specific services or specific individuals.

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In general, non-disabled adults aged 21 to 64 are more likely to be uninsured than children or senior citizens. Approximately 40 percent of uninsured adults have no regular source of health care. The vast majority of uninsured low-income adults are in the work force and paying taxes. In the Medicaid program, of the four distinct population groups (aged, blind/disabled, children, and adults), adults have the shortest duration on Medicaid. For example, in Arizona, 77 percent of blind and disabled individuals were enrolled for the full 12 months in FY 2000. However, only 29 percent of non-disabled adults were covered by Medicaid for the full 12 months. In Utah, only 16 percent of non-disabled adults were covered by Medicaid for the full 12 months. Thus it is likely that the Arizona and Utah waivers will provide health insurance coverage for individuals who were formerly on Medicaid, but have lost eligibility.

The SCHIP enrollment is higher than ever. The number of children ever enrolled in SCHIP increased from 3.3 million in FY 2000 to 4.6 million in FY 2001, an increase of 38 percent. Arizona started its SCHIP program in 1998 and has set eligibility at 200 percent of the federal poverty level. Its increase in SCHIP enrollment between FY 2000 and FY 2001 was 43 percent, which is above the national average. Yet Arizona still had an allotment balance of approximately $373 million when it applied for a waiver to cover certain adults who have annual income of less than $8,860.

The Health Insurance Flexibility and Accountability (HIFA) initiative, announced in August of 2001, establishes new flexibility for States to cover the uninsured by pursuing coordinated waivers of Medicaid and SCHIP provisions. One important provision of this initiative is coordination between public and private health insurance coverage. We believe that it is appropriate to provide, wherever feasible, opportunities for low-income Americans to be covered through employer-sponsored plans. Because this is a cost-effective approach, it does enable States to increase coverage to additional uninsured individuals.

The following are our specific comments on the recommendations and findings of the report. We have divided our comments into two sections -- responses to specific recommendations, and additional comments.

GAO Recommendations for Executive Action

To ensure that SCHIP funds are spent only for authorized purposes, we recommend that the Secretary of HHS –

- *Amend the approval of Arizona's HIFA waiver to prevent future use of SCHIP funds on childless adults, and*
- *Deny any pending or future state proposals to spend SCHIP funds for this purpose.*

HHS Response

We want to be very clear that the coverage of uninsured low-income children remains the priority of SCHIP. States that have received Title XXI section 1115 demonstrations are

required through Special Terms and Conditions to prioritize spending Title XXI funds for children. States are not permitted to limit or cap children's enrollment and must ensure the availability of funding children over funding for adult expansion populations.

We strongly disagree with GAO's recommendation. The GAO's analysis of the objectives of SCHIP is extremely narrow and fails to recognize that the approval of Arizona's HIFA waiver does promote the objectives of the SCHIP program. The objectives of the Arizona HIFA waiver must be viewed as a comprehensive approach in providing health insurance coverage to those who were previously uninsured, including parents and childless adults, some of whom may indeed be former Medicaid recipients. The objectives of the Arizona HIFA waiver must be viewed as a comprehensive approach in providing health insurance coverage to those who were previously uninsured, including parents and childless adults. The waiver cannot be adequately viewed by its individual components. Overall we anticipate the demonstration will decrease the number of uninsured children by an additional 2 percent. In addition, demonstration waivers historically have been granted to provide health insurance coverage to individuals not otherwise eligible for a program. In the Arizona demonstration, as GAO noted, this includes childless adults. These adults could become parents or caretaker relatives in the future, and some of them may indeed be former Medicaid recipients. Moreover, extending coverage to these adults strengthens the health status and awareness of the low-income community in general, supports the development of "medical homes" to encourage preventive care, and widens the health delivery network available to the low-income community. Congress specifically extended the section 1115 waiver authority to the SCHIP program in 1997. Members of Congress have previously indicated their support for SCHIP waivers that include adults and Congress has long been aware of the Secretary's view that he possesses broad authority to authorize waivers.

Funds spent on adult populations through demonstrations have not impeded the ability of other states to provide SCHIP coverage to children in contrast to statements made in the report (pages 4 and 15). As GAO notes, in 2002, CMS redistributed unspent SCHIP funding to 18 states and territories in a manner that complied with the formula set forth by Congress in the Title XXI statute as modified by the Medicare, Medicaid, and SCHIP Benefit Improvement and Protection Act of 2000. In other words, there were no states that were entitled to redistributed funds that did not receive such funds, or received fewer funds than they were entitled to, as a result of expenditures on section 1115 demonstrations.

GAO Recommendation

To meet the fiduciary responsibility of ensuring that section 1115 waivers are budget neutral, we recommend that the Secretary of HHS:

- *Better ensure that valid methods are used to demonstrate budget neutrality, by developing and implementing consistent criteria for consideration of section 1115 demonstration proposals, and*

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- *Reconsider Utah's and Illinois's budget neutrality justifications, in light of our findings on the inappropriateness of certain costs and, to the extent appropriate, adjust the limit on the federal government's financial obligation for these waivers.*

HHS Response

We strongly disagree with both elements of this recommendation. Our methods of assuring budget neutrality are valid.

Additionally, we note that the scope of the GAO's report – four approved demonstrations - is too narrow to gain an accurate view of the section 1115 waiver review process and the methods used to determine budget neutrality and allotment neutrality. A review of all of the waivers approved over the past decade involving eligibility expansions would show that the methods used to determine budget neutrality were consistent with waivers approved by previous administrations. The unique feature in the Utah approval was the actual scope of the benefit package, not the fact that the expansion population is receiving a different benefit package compared to the state plan population. Our methodology of allowing Utah to include the projected costs of the proposed benefit package is consistent with other approvals where the benefit package differs from that offered to the state plan population.

The HIFA waiver guidance published in August 2001 is the first time that HHS has detailed precisely how budget neutrality is determined. We have been explicit in explaining its methodology and policies concerning the approval of waivers and have shed light on a process that previously was largely unclear to States. This guidance will only serve to reinforce our consistent application of budget neutrality principles.

We disagree with GAO's assertion that the Utah demonstration is not budget neutral because we include the costs of certain new eligibles in establishing a baseline for the purpose of assessing future budget neutrality. The GAO drew the same conclusion in a 1995 report that did not contain any recommendations; the GAO is now recommending that we re-consider the use of this methodology. As we did in 1995, we disagree with GAO's analysis. Additional comments appear at the end of this document.

We also disagree with GAO's conclusions regarding the Illinois Pharmacy Plus demonstration. GAO contends that the Illinois Pharmacy Plus waiver will not be budget neutral, and questions the Illinois budget neutrality premise that low-income elderly who are provided prescription drug coverage will be less likely to become eligible for the Medicaid program. As supportive evidence, the GAO points out that neither the Congressional Budget Office (CBO), the Office of Management and Budget (OMB), nor the CMS actuary scored savings for the Medicare program in estimating the costs and savings of a Medicare prescription drug benefit

Estimating the costs of legislative proposals is a substantially different exercise than estimating the costs of a proposed demonstration. The purpose of section 1115 is to permit the Secretary to approve state proposals to demonstrate program changes that

further the purposes of enumerated programs of the Social Security Act. The state hypothesizes that savings will accrue from providing a drug benefit to low-income seniors and has set out to demonstrate this in a real-world setting. The state believes that by extending a pharmacy benefit to a low-income, elderly population it can maintain the health and economic welfare of the newly eligible group, which will result in savings that will offset the cost of the benefits. We find this an exciting and promising demonstration that is consistent with the intent of the statutory waiver authority. Findings from this demonstration will provide evidence to support future legislative cost estimates. Indeed, the CBO states in its August 10, 2001, letter to Chairman Bilirakis that state pharmacy programs such as these will provide additional evidence on which to base future estimates.

The GAO further notes that the without-waiver estimates provided by the state include impermissible costs related to payments to facilities in excess of the upper payment limits (UPL). It estimates that more than $356 million in inappropriate UPL expenses are included in the without waiver estimate. We disagree that any costs were inappropriately included in the without-waiver estimate. Additional comments on this matter appear at the end of this response.

GAO Recommendation

To improve the opportunity for public input into HHS consideration of state Medicaid and SCHIP program proposals that waive statutory requirements, we recommend that the Secretary of HHS provide for a federal public input process that includes, at a minimum, notice in the Federal Register and a 30-day comment period.

HHS Response

We disagree on the need for this recommendation because opportunity for public comment is more than adequate. CMS and the States have ensured that there is ample opportunity for public comment at both the State and Federal levels. The May 3, 2002 State Medicaid Director letter re-affirms the guidance in the September 27, 1994 Federal Register notice. In addition, information about demonstrations is currently posted on the Internet, including fact sheets and information about key dates in the review process. The CMS currently posts some proposals on the CMS Website, such as HIFA proposals, and is working to post all pending and approved proposals on the Internet in the future.

Although CMS has not published notice of waiver proposals in the Federal Register since 1998, and does not have a formalized comment period on proposals, CMS accepts and responds to written comments on all demonstration proposals.

The CMS is proactively seeking public input through the addition of a Low Income Health Access Open Door group to its existing 11 Open Door Groups. This group will start in late June and will permit beneficiaries, providers and other stakeholders to discuss many issues relating to access to care for low-income populations, including waivers.

We disagree with GAO's implication that public notice requirements were not met in Arizona and Utah. While provider groups and committees in Utah indicated to GAO that they had little or no opportunity to formally comment on and influence the proposal, the State has indicated that there was a great deal of discussion with these groups. The public notice process is intended to allow states to receive and consider input from stakeholders in the community, not necessarily to modify the proposal in a way that would satisfy each commenter's concerns.

ADDITIONAL POINTS:

1. We continue to disagree with the GAO about the Utah demonstration because including the cost of new eligibles in the base does not violate the principle of budget neutrality. The GAO's assertion is based on the assumption that budget neutrality is only assured when the costs under the waiver are less than or equal to the costs without the waiver, assuming the State makes no changes to its program. This methodology does not take into account the flexibility States have, to increase eligibility in their programs. Budget neutrality is, and has been since the *Federal Register* guidance was published in 1994, based upon a comparison of with-waiver costs to without-waiver costs assuming current-law flexibility. That is, once a State decides to expand eligibility, we assume the State would have used current law to the extent possible to cover the new populations in the absence of the demonstration. The GAO's argument in support of its position that States' interest in cost containment would preclude expansions under current law is not persuasive; if States did not want to increase costs they would not fund expansions, whether under current law or under a demonstration.

Now on p. 2.

2. Although it is mentioned, we believe that the report does not adequately distinguish the difference between the budget neutrality requirements of Title XIX section 1115 demonstrations and the allotment neutrality requirements of Title XXI section 1115 demonstrations. We first note this on page 3 in the first partial sentence, and later on page 14 in the first paragraph under fiscal integrity, in which only the term "budget neutrality" is used. We would recommend that GAO refer to "budget and allotment neutrality justifications" – as these are separate and distinct measures of fiscal integrity applicable to Medicaid and SCHIP, respectively. More significantly, we believe it is important that the distinction is made in the body of the document. Page 14 in the last paragraph, discusses SCHIP followed by the statement, "Similarly, HHS did not consistently ensure that the waivers will be budget neutral". Although the report goes on to reference the Utah and Illinois demonstrations, it reads as though the Title XXI California and Arizona demonstrations are subject to budget neutrality and is confusing to the reader. It also suggests that the California and Arizona demonstrations are not allotment neutral, when the case is that they are allotment neutral. We would suggest that the information in footnote 15 be elaborated upon and highlighted more prominently in the document because it is an important distinction. Budget neutrality means that Medicaid costs under the waiver cannot exceed what would

be allowable in the State's Medicaid plan under current law, taking into consideration the populations, including expansion populations, included in the waiver. Allotment neutrality means that combined spending in the State's SCHIP program and any SCHIP demonstration spending cannot exceed the available allotment, including currently available redistributed funds. All waivers are required to meet one or both of these requirements, depending upon their funding source(s).

3. At the time that the Illinois waiver was approved, the final set of regulations on upper payment limits were not yet effective, which affects the amount of payments the state must phase out to come into compliance with Medicaid UPL regulations. As referenced in the report, we included a Term and Condition to the waiver approval that provides for the budget limit to be modified to reflect changes in laws, regulations, and policy statements that would have affected state spending in the absence of the demonstration. We are in the process of reviewing the budget neutrality cap in light of the new rules.

4. The CBO memorandum referenced in the report appears to address only Medicare savings. (Clearly, substantial Medicaid savings would accrue from a Medicare drug benefit by substituting Medicare as the payer of prescriptions for dually-eligible Medicare and Medicaid beneficiaries.) We believe that the impact of a prescription drug benefit for low-income seniors may be greater than that of the general population on Medicare. First, the demographic and health characteristics of the aged Medicaid population may differ in important ways from the group considered by CBO. They may be poorer, sicker, and less able to obtain prescription drugs. Therefore, the impact of a prescription drug benefit may be greater, resulting in more savings. Second, it is unclear if CBO considered the impact of reductions in long-term admissions to nursing homes. This is a substantial part of Medicaid costs, and diversions from or delays in nursing home admissions may yield substantial savings to Medicaid.

5. On page 3, under Results in Brief, and on page 10 in the second paragraph, in the description of the Arizona and California approvals, we recommend that GAO clarify that the coverage of adult populations is for those that meet the articulated eligibility criteria and are ineligible for Medicaid. These states cannot enroll or claim Title XXI funds for adults that could be enrolled in Medicaid.

Now on pp. 40-41.

6. On page 35, in the appendices, for the Arizona and California waivers – the chart describes it as having no enrollment cap. It is important to note that while there is no explicit enrollment cap, i.e., 25,000 people – enrollment in both states is limited based upon the availability of Title XXI funding and based upon the assumption that Title XXI funding goes first to pay for state plan children. As written, it makes it sound as if our liability is unlimited and that is not the case.

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7. On page 3 under Results in Brief, in the description of the Arizona proposal, we recommend that GAO refer to these individuals as just "uninsured low-income…" and delete the word "previously".

8. On page 8, middle paragraph, second sentence, we recommend that it be rewritten to indicate: "To be considered, proposals must be statewide and seek to coordinate coverage with private health insurance options for low-income uninsured." The reference to employer-sponsored insurance options is too limiting and refers to only one type of coordination with private health insurance that we would find acceptable.

9. On page 8 there is a statement that in 1995 the GAO "reported" that demonstrations are not budget neutral. The term "reported" suggests that the GAO was reporting a fact; rather, the GAO asserted based on its own methodology (which openly differs from our methodology) that demonstrations were not budget neutral. The text should be changed accordingly.

10. On page 12, under Arizona populations served, the word "estimated" should be inserted for the numbers of both populations to be enrolled in the demonstration. Otherwise, it appears that this is a set number for enrollment, which is not the case.

11. The chart on page 13 shows an enrollment fee for the Illinois SeniorCare program. The state is not charging an enrollment fee.

Now on pp. 15-17.

12. On pages 16-17, the discussion of the scope of the Secretary's 1115 authority is unnecessary and overbroad in light of CMS' position that the Arizona HIFA demonstration project will promote the objectives of Title XXI of the Social Security Act.

Now on pp. 23-24.

13. On page 23 the statement is made that many people in Illinois are already receiving some drug coverage under an existing state funded program. While this is correct, we note that the implication is that the benefit expansion is not extensive. In fact, the demonstration covers three times as many drugs as the state-only program and opens eligibility to many additional seniors.

Now on p. 24.

14. Also on page 23, the statement is made that Illinois is assuming diversion of "7,500 of the estimated 20,000 elderly individuals who would normally enter Medicaid. . . ." Not all of the diversions will be from new enrollees – Illinois also assumes that some current medically needy Medicaid enrollees will no longer be eligible for Medicaid once they begin receiving a comprehensive drug benefit.

Now on p. 40.

15. On page 36, cost-sharing requirements for Phases I and II are respectively identical to the state's (or Arizona's) Medicaid and SCHIP programs, not merely "comparable."

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Now on p. 42.

16. On page 36, Arizona's goal is to reduce the overall rate of uninsurance by 1 percent, not 2 percent.

Now on p. 42.

17. On page 37 in footnotes "b" and "c", we recommend GAO use the term "separate child health program" instead of "separate from Medicaid child health program" and "separate program".

Now on p. 44.

18. On page 38, the description of the Michigan HIFA, the state would use SCHIP and Medicaid funds, rather than just SCHIP funds as the report indicates.

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Appendix V: Comments from the State of Arizona

AHCCCS

ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

Committed to excellence in health care

Jane Dee Hull
Governor

Phyllis Biedess
Director

June 20, 2002

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

Dear Ms. Allen:

Thank you for the opportunity to comment on the draft report entitled Medicaid and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns (GAO-02-817).

Arizona notes that the General Accounting Office (GAO) is concerned that "...HHS has allowed the state to use unspent SCHIP funding to cover adults, including those without children, despite SCHIP's fundamental goal of expanding health care coverage to low-income children." It is accurate that CMS did grant approval to use SCHIP funding for SCHIP parents and childless adults but not at the expense of curtailing coverage to SCHIP eligible children. Under the Terms and Conditions, the state agreed that it would not close enrollment, institute waiting lists or decrease eligibility for SCHIP children while the HIFA amendment is in place.

Children remain the state's first priority for Title XXI funds as documented in the approval letter from HHS. Not only have we added over 49,000 through our SCHIP program, the state has added another 99,000 children to Medicaid due to an SCHIP application.

Arizona is requesting that GAO add into the final report a discussion of the funding priorities that the state agreed to as a condition of the waiver. Any available SCHIP funds will first be used for SCHIP eligible children between 100 and 200% of FPL. The second priority for SCHIP funding will be parents of children between 100% and 200% of FPL. One of the compelling reasons to expand coverage for the parents was to use the lure of family coverage as an incentive to keep children enrolled in the SCHIP program. Only after the state pays for these children and parents will SCHIP funds be used for childless adults. In fact, the state fully expects that SCHIP funding for childless adults will only be used for two years based on the priorities we have set.

Arizona is very concerned that the draft report may leave an impression that Arizona is diverting SCHIP funding for children to fund parents and childless adults. This is not accurate. Arizona has more than sufficient SCHIP funding to cover the current population of 49,000 SCHIP children and the expected growth in this population at an

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income level of up to 200% of FPL. We responded to a HHS HIFA initiative and maintained coverage for SCHIP children at the maximum income level while adding over 21,250 parents in the midst of a budget-cutting year. As discussed above, we will only use SCHIP funding for the childless adults after children and parents are covered.

Thank you for the opportunity to comment on the Arizona specific contents of the draft report. The GAO had several other recommendations and observations in the draft report that impact Arizona but the state believes that it is more appropriate for HHS to respond to these issues that include: the ability of HHS to use the 1115 waiver authority contained in the SCHIP legislation; adequate review and oversight of waiver proposals by HHS; and a recommendation for a federal notice and comment period.

If you have any questions, please call Lynn Dunton at (602) 417-4447.

Sincerely

Branch McNeal
Deputy Director

c: Katherine Iritani
Assistant Director

Appendix VI: Comments from the State of Illinois

George H. Ryan, Governor
Jackie Garner, Director

Illinois Department of Public Aid

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June 26, 2002

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 and SCHIP: Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns." These comments should be included in the final report as Illinois' comments.

Waiver Process

Although not explicit, the report contains an implicit criticism of the speed with which HHS approved the Illinois and other waivers covered, implying that this speed led to the lack of cost neutrality. Illinois would point out that there is nothing in the report that links the speed of the review to the concerns raised about the approved waivers. In fact, the GAO report states that the GAO raised the exact same concerns about cost neutrality in 1995, prior to the expedited review process.

Illinois believes that the revised waiver parameters promote good management by clearly recognizing the importance that timely decisions are critical to the federal and state partnership, the states' abilities to meet established obligations, and the removal of months of indecision by expediting health care to beneficiaries.

Budget Neutrality

Illinois strongly disputes that its projected costs are inflated by impermissible costs included in its projection. The GAO asserts that Illinois' costs were inflated because its projection failed to account for certain reductions in UPL expenses required by section 705b of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act (BIPA). The GAO reaches its conclusion by focusing on the requirements of only one section of the act and ignoring the effect of two relevant sections of the same law. Sections 701c and 701d of the act mitigate the effect of section 705b and allow Illinois to increase total spending at the institutions involved in the UPL arrangements discussed in the GAO report, not reduce them. When the law as a whole is read and applied, the GAO is incorrect in asserting that Illinois' budget neutrality cap is inflated.

Even accepting the GAO's position that it is acceptable to issue its report asserting inflated costs by considering only one section of BIPA, Illinois notes that the $356 million estimate in the draft report Illinois was allowed to review is miscalculated due to several mistakes by the GAO auditors. The mistakes brought to GAO's attention include:

- Misapplying spending not paid to non-state government owned hospitals as going to such hospitals, thereby inflating the GAO baseline costs and more than doubling the number identified as excess spending by the GAO;
- Transposing a number in the calculation of the UPL;
- Using population figures higher than those used by CMS in setting the actual waiver cap.

Without considering GAO's not applying two relevant sections of federal law, correcting for these mistakes would reduce GAO's estimate of inflated costs to $165 million, approximately 1% of the budget neutrality cap.

Fiscal Integrity

Cost neutrality in the Illinois demonstration program is based on the premise that providing a drug benefit to low-income seniors will keep them healthy and therefore divert them from costly hospitalizations and institutionalization in nursing homes that allow them to spend down to Medicaid eligibility. The section of the Report headed "Illinois Waiver Approval Raises Questions About The Extent that HHS is Ensuring Waivers Are Fiscally Sound" questions the validity of this premise. Illinois believes that this section is totally unsupported by research, study, references or any citation to authority and therefore is misleading and unfair. Illinois would like to make three points with respect to this section.

First, the GAO report actually makes no attempt to refute this premise or make reference to any study or data that contradicts it. The only source cited by the report to buttress its conclusion that HHS failed to insure fiscal integrity by approving a waiver based on this premise is a one-page letter from the Director of the CBO expressing caution as to how much savings *to the Medicare program* a prescription drug benefit would generate. The report fails to cite any of the many studies that show drug coverage can reduce other medical costs, including those sources cited in Illinois' waiver application. There are many other studies in addition to those cited in Illinois' waiver application. Of particular relevance is the report of the New York state-funded Epic Program for pharmaceutical assistance to the low-income elderly.[1] Allowing states to test credible premises that, if successful, are of tremendous benefit to the fiscal resources of states and the federal government and to the health of low-income citizens is the reason Congress gave waiver authority to the Secretary of HHS in Section 1115.

Second, the fact that a prescription drug benefit for all Medicare recipients is not cost neutral to the Medicare program does not mean that such a benefit given to the target low-income population of the Illinois demonstration program is not cost neutral to the Illinois Medicaid program. The arguments set forth in the report against a Medicare drug benefit being cost neutral are not directly applicable to the Illinois waiver. Medicare is not a means-tested program. Therefore, many moderate- and high-income Medicare beneficiaries may have access to prescription drugs. Many studies indicate that low-income seniors do not have the same access. Therefore, the improved health outcomes and reduced medical costs associated with a prescription drug benefit will be most dramatic for the low-income population served by the waiver.

Further, even within the context of Medicaid, the unique characteristics of the Illinois Medicaid program and the health care system in Illinois will result in a low-income elderly drug benefit generating more Medicaid savings and diversion than would be the case in other states. It should be noted that Illinois has 42% more nursing home beds per 1,000 people than the national average.

Finally, the report also fails to mention cost containment measures available to Illinois in the demonstration program (e.g., cost sharing latitude and enrollment caps) to maintain cost neutrality. These options allow the state to avoid loss of FFP for its base Medicaid population should combined costs of the program with the waiver exceed projections.

Sincerely,

Jackie Garner
Director

cc: The Honorable Max Baucus, Chairman, Committee on Finance
The Honorable Charles Grassley, Ranking Minority Member, Committee on Finance
Bill Koetzle, Office of Congressman Hastert

[1] Epic Evaluation Report to the Governor and Legislature, "Maintaining Health, Dignity & Independence—1987-1995.

Appendix VII: Comments from the State of Utah

Utah Department of Health

DIVISION OF HEALTH CARE FINANCING

State of Utah

Michael O. Leavitt
Governor
Rod L. Betit
Executive Director
Michael J. Deily
Division Director

June 20, 2002

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Kathryn Allen, Director
Health Care
Medicaid and Private Health Insurance Issues
U.S. General Accounting Office
441 G St NW Room 5A14
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Dear Ms. Allen:

Thank you for the opportunity to review your draft report to the Committee on Finance, U.S. Senate, entitled "Recent HHS Approvals of Demonstration Waiver Projects Raise Concerns." We have a number of concerns with the conclusions reached as outlined below.

First, the report implies that the HHS approval of the Utah waiver in a 60-day time period was too fast to provide adequate review. However, GAO does not take into account the interactions between HHS and the State of Utah that began in early 2001 and continued up until the waiver was approved on February 9, 2002. Nearly a year of discussion and negotiation took place before the waiver was approved.

Following the recommendation of HHS, Utah started working closely with CMS staff approximately eight months prior to formally submitting its waiver application. There was frequent communication between the State and CMS during this eight-month period that provided the opportunity to outline the basic concepts of the waiver and address many of the issues and concerns surfaced by CMS prior to the formal application submittal. These pre-application communications saved a significant amount of time in the approval processes and differed substantially from our earlier 1995 experience in which negotiations with HCFA (now CMS) dragged on for well over a year after the waiver request was submitted, resulting in Utah losing the opportunity to implement an innovative demonstration proposal, which would have provided coverage to 56,000 uninsured people. GAO should encourage HHS to continue the practice of intensive pre-approval communication rather than intimate the approval process moves too fast.

Another area of concern with the draft report is the analysis of cost neutrality. In addressing its opposition to the inclusion of populations that could be covered under a State plan amendment, GAO returns to its 1995 hypothesis that "it was questionable that these states would have added optional eligibility groups to their Medicaid programs without the waiver." This hypothesis is based on the argument that "state officials indicated cost containment was a primary consideration in seeking section 1115 waiver....." Cost containment is not what the Utah waiver is trying to achieve in the sense GAO is suggesting. Utah has a solid history of trying to address the challenge of providing access to insurance coverage for the uninsured. There has been debate about the best approach to accomplish this for low income persons, some favoring a full blown Section 1931 expansion with a full benefit package, as noted in this same GAO report where it addresses public notice issues. While some in the community favor a 1931 expansion, others have serious concerns with crowd out related to this type of expansion (which would increase the cost to the federal government even more) and in our ability to capture the current

private and public dollars covering the costs of uncompensated care for the target waiver population. While we hold that the more limited approach is fiscally responsible, it is not clear on what basis the GAO can conclude what action the State would take in the absence of the 1115 application. The fact is that the expenditures will be significantly less than what the federal government would be legally obligated to pay if the State covered the same group through its State Plan option.

Finally, in its Utah example, the report appears to confuse notice requirements with whether there is consensus from all sectors of the community on the design of the demonstration. Rather than addressing the notice process, the bulk of the notice requirements section regarding Utah addresses some areas of concern with specific components of the Utah waiver. This is a demonstration program. Lack of consensus on different aspects of the demonstration should be expected, and criticism targeting different aspects of the program's design is no surprise. These areas of controversy, while important, do not demonstrate a problem with the structure of the public notice process. One point of notice requirements is to give those with differing opinions a chance to be heard. The GAO draft report does not demonstrate or suggest that adequate notice did not occur in Utah; it simply indicates that "some of the participants in these meetings.....indicated they had little or no opportunity to formally comment on or influence the waiver proposal." In fact, Utah put this proposal in front of a variety of public forums for comment and public inclusion in program development. There is also a formal rule making process which has been followed. This is not being questioned in the GAO report. While there is clearly on-going debate about several aspects of this demonstration, we believe that the purpose of a demonstration is to sort through some of the questions that have surfaced as a result of putting forward this proposal. The fact that there is on-going debate is solid evidence that there has been notice and open discussion about Utah's demonstration proposal, and we have certainly received comment. We suggest that the paragraph on page 27 of the draft report describing the Utah process be removed or that it more accurately address the notice and comment process rather than focus on areas of disagreement with specific components of the demonstration.

Again, thank you for the opportunity to comment. I have enclosed a background paper on the Utah demonstration project for your information and with the hope that you will better understand what we are trying to accomplish. I look forward to seeing your final report.

Sincerely,

Michael Deily, Director
Division of Health Care Financing

Enclosure

Appendix VIII: GAO Contact and Staff Acknowledgments

GAO Contact

Katherine Iritani, Assistant Director (206) 287-4820

Acknowledgments

In addition to those named above, Tim Bushfield, Helen Desaulniers, Behn Miller, Amy Murphy, Suzanne Rubins, Ellen M. Smith, and Stan Stenersen made key contributions to this report.

Related GAO Products

Medicaid: HCFA Reversed Its Position and Approved Additional State Financing Schemes. GAO-02-147. Washington, D.C.: October 30, 2001.

Medicaid: State Financing Schemes Again Drive Up Federal Payments. GAO/T-HEHS-00-193. Washington, D.C.: September 6, 2000.

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