United States Government Accountability Office

GAO

Report to Congressional Requesters

September 2009

RYAN WHITE CARE ACT

Health Resources and Services Administration's Implementation of Certain Provisions Hampered by Lack of Timely and Accurate Information

GAO-09-1020

September 2009

RYAN WHITE CARE ACT

Health Resources and Services Administration's Implementation of Certain Provisions Hampered by Lack of Timely and Accurate Information

GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-09-1020, a report to congressional requesters

Why GAO Did This Study

Under the CARE Act, funds are made available to assist over 530,000 individuals affected by HIV/AIDS. Grantees directly provide services to individuals (clients) or arrange with service providers to do so. The Department of Health and Human Services's (HHS), Health Resources and Services Administration (HRSA), which administers CARE Act programs, is required to cancel balances of grants that are unobligated after one year and redistribute amounts to grantees in need. HRSA began to collect client-level data in 2009. Under the CARE Act, states and territories receive grants for AIDS Drug Assistance Programs (ADAP), which provide HIV/AIDS drugs. GAO was asked to examine elements of the CARE Act. In this report, we review: (1) HRSA's implementation of the unobligated balance provisions, (2) HRSA's actions to collect client-level data, and (3) the status of ADAP waiting lists. GAO reviewed reports and agency documents and interviewed federal officials, officials from 13 state and 5 local health departments chosen based on location and number of cases, and other individuals knowledgeable about HIV/AIDS.

What GAO Recommends

GAO recommends that HRSA take action to ensure it obtains timely and accurate information on grantees' unobligated balances. HHS reviewed a draft of the report, but did not comment on the recommendations.

View GAO-09-1020 or key components.
For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

The lack of timely and accurate information reporting by grantees has delayed HRSA's distribution of certain grants and has placed at risk HRSA's ability to obligate these funds. The late submission of actual unobligated balances for the 2007 grant year delayed HRSA's ability to determine grantees' unobligated balances and redistribute these funds to other grantees. A number of grantees were late in their submissions. For example, 21 of the 56 metropolitan areas submitted their information beyond the date initially set by HRSA. Additionally, some grantees reported inaccurate unobligated balances, which required HRSA staff to correspond with grantees and request revised information, creating additional delays. HRSA is authorized to obligate fiscal year 2007 funds for a 3-year period and is at risk of losing the authority to make grants from these funds. HRSA officials said they have made changes to how they implement the unobligated provisions in an effort to avoid these issues in the future.

HRSA has taken actions to collect client-level data by implementing a new data collection and reporting system. However, some grantees and service providers did not submit the initial reports by HRSA's deadline. HRSA set a July 31, 2009, submission deadline for grantees' initial reports, but 100 of 638 grantees did not meet this deadline. Client-level data includes information such as the dates clients were served, the types of services provided, and the clients' health status. HRSA has implemented a system to collect data on the number of unique clients from grantees and service providers that will allow HRSA to determine the services each client received and the outcomes of these services. In order for HRSA to collect this information, grantees and service providers must first collect the data using their own systems, and HRSA has provided technical and financial assistance so that they can develop these systems. For example, under a project initiated in 2009, HRSA awarded approximately $4 million to CARE Act grantees for the development of their own client-level data collection systems.

The number of ADAPs with waiting lists and the number of individuals on those lists is increasing. In the first quarter of grant year 2008 (April 1, 2008, through June 30, 2008), 2 ADAPs had waiting lists with a total of 55 people on those lists; this grew to 3 ADAPs and a total of 112 people in the fourth quarter of the year, and increased to 4 ADAPs and 136 individuals in August 2009. Kentucky, Montana, Nebraska, and Wyoming were each maintaining a waiting list for ADAP services in August 2009; Nebraska had the largest number of individuals (71), and Wyoming had the smallest number (5). ADAP officials expressed concern that they will have to establish or expand waiting lists or implement other cost-control measures, such as limiting the number of drugs they make available.

Contents

Abbreviations

ADAP	AIDS Drug Assistance Program
AIDS	acquired immunodeficiency syndrome
CARE Act	Ryan White Comprehensive AIDS Resources Emergency Act of 1990
CDC	Centers for Disease Control and Prevention
DGMO	Division of Grants Management Operations
EMA	eligible metropolitan area
FSR	Financial Status Report
HAB	HIV/AIDS Bureau
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
NASTAD	National Alliance of State and Territorial AIDS Directors
RDR	Ryan White HIV/AIDS Program Data Report
RSR	Ryan White HIV/AIDS Program Services Report
RWTMA	Ryan White HIV/AIDS Treatment Modernization Act of 2006
SPNS	Special Projects of National Significance
TGA	transitional grant area

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

September 29, 2009

The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Richard Burr
United States Senate

The Honorable Tom A. Coburn
United States Senate

The Honorable Lisa Murkowski
United States Senate

It has been more than 28 years since the first cases of acquired immunodeficiency syndrome (AIDS) in the United States were reported in June 1981. Since that time, approximately 1.7 million Americans have been infected with human immunodeficiency virus (HIV), including more than 580,000 who have died.[1] The Centers for Disease Control and Prevention (CDC) estimates that approximately 1.1 million people were living with HIV infection in the United States at the end of 2006, and that there were 56,300 new HIV infections in that year.[2]

The Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act), administered by the Department of Health and Human Services's (HHS) Health Resources and Services Administration (HRSA), was enacted to address the needs of jurisdictions, health care providers, and people with HIV/AIDS and their family members.[3] Each year CARE Act programs provide assistance to over 530,000 mostly low-income,

[1]HIV is the virus that causes AIDS. In this report, we use the common term HIV/AIDS to refer to HIV disease, inclusive of cases that have progressed to AIDS. When we use these terms alone, HIV refers to the disease without the presence of AIDS, and AIDS refers exclusively to HIV disease that has progressed to AIDS.

[2]These were the most recent estimates available at the time of this report.

[3]Pub. L. No. 101-381, 104 Stat. 576 (codified as amended at 42 U.S.C. §§ 300ff through 300ff-121). The 1990 CARE Act added title XXVI to the Public Health Service Act. Unless otherwise indicated, references to the CARE Act are to the current title XXVI.

underinsured, or uninsured individuals living with HIV/AIDS. Under the CARE Act, approximately $2.2 billion in grants were made to states, localities, and others in fiscal year 2009. CARE Act programs have been reauthorized three times (1996, 2000, and 2006) and are scheduled to be reauthorized again in 2009.[4] The Ryan White HIV/AIDS Treatment Modernization Act of 2006 (RWTMA) reauthorized CARE Act programs for fiscal year 2007 through fiscal year 2009.

Part A of the CARE Act provides for grants to selected metropolitan areas—known as eligible metropolitan areas (EMA) and transitional grant areas (TGA)—that have been disproportionately affected by the HIV/AIDS epidemic.[5] Part B provides for grants to states, the District of Columbia, and territories and associated jurisdictions to improve quality, availability, and organization of HIV/AIDS services,[6] including grants specifically for AIDS Drug Assistance Programs (ADAP).[7] ADAPs provide medications for the treatment of HIV/AIDS. Program funds may also be used to purchase health insurance for eligible clients and for services that enhance access to, adherence to, and monitoring of drug treatments. ADAP grants accounted for about 37 percent of the total $2.2 billion in CARE Act grants awarded in fiscal year 2009. ADAPs and other programs funded through CARE Act grants serve as the payers of last resort for eligible individuals who have no other private or public sources available for the services they need. Some ADAPs have struggled to meet the demand for their services and have established waiting lists for eligible individuals who will be served when space in the program becomes available and have taken other measures that restrict access and control costs. For example, in the past

[4]CARE Act programs were previously reauthorized by the Ryan White CARE Act Amendments of 1996 (Pub. L. No. 104-146, 110 Stat. 1346), the Ryan White CARE Act Amendments of 2000 (Pub. L. No. 106-345, 114 Stat. 1319), and the Ryan White HIV/AIDS Treatment Modernization Act of 2006 (Pub. L. No. 109-415, 120 Stat. 2767).

[5]EMAs are areas that have a population of 50,000 persons or more and had a cumulative total of more than 2,000 new AIDS cases during the most recent 5-year period. TGAs are areas that have a population of 50,000 persons or more and had a cumulative total of 1,000 to 1,999 new AIDS cases during the most recent 5-year period. Prior to RWTMA, all metropolitan areas that received Part A funding were classified as EMAs. In fiscal year 2009, there were 24 EMAs and 32 TGAs according to HRSA.

[6]These territories and associated jurisdictions are American Samoa, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the Federated States of Micronesia, Guam, Palau, the Republic of the Marshall Islands, and the U.S. Virgin Islands.

[7]The ADAP in each state, the District of Columbia, territory, and associated jurisdiction is eligible for this funding.

ADAPs have required that individuals make a copayment in order to receive a drug and have placed caps on expenditures per enrollee.[8]

Most CARE Act funding is distributed to grantees either as base or supplemental grants. Base grants are distributed by formula, and HRSA uses a grantee's share of living HIV/AIDS cases to determine the amount of base grants. Supplemental grants are generally awarded through a competitive process based on the demonstration of severe need and other criteria. Grantees may deliver services directly to individuals (clients) or arrange with service providers to provide client services.[9]

RWTMA added provisions regarding the obligation of funds by Part A and Part B grantees. In the past, some CARE Act grantees did not obligate all of their funds in some years, while others obligated all of their funds.[10] RWTMA provided that base and supplemental grants were available for obligation by the grantee for a 1-year period beginning on the date awarded funds first became available to the grantee (i.e., the grant year). It also required HRSA to cancel any unobligated balances at the end of the grant year, recover funds that had been disbursed to grantees, and redistribute these funds to grantees in need as supplemental grants.[11] Under appropriations acts enacted since RWTMA, funds for these grants

[8]GAO, *Ryan White CARE Act: Improved Oversight Needed to Ensure AIDS Drug Assistance Programs Obtain Best Prices for Drugs*, GAO-06-646 (Washington, D.C.: Apr. 26, 2006), 16-17.

[9]A service provider is an agency that provides direct services to clients and their affected family members or provides support such as administrative or technical services to grantees. Service providers may be directly funded through one or more CARE Act parts; through agreements with one or more grantees; or through subcontracts with a grantee's fiscal intermediary (i.e., an administrative agent of the grantee).

[10]Grantees obligate funds when they commit them for a specific purpose that will require payment during the same period of time when the funds were committed or a future period of time. Funds that have not been so committed by grantees are unobligated.

[11]The unobligated balance provisions do not apply to Part A and Part B Minority AIDS Initiative grants. These grants are available to all Part A and B grantees as competitive, supplemental funding. For more information on Minority AIDS Initiative grants, see GAO, *Ryan White CARE Act: Implementation of the New Minority AIDS Initiative Provisions*, GAO-09-315 (Washington, D.C.: March 27, 2009).

are available for obligation by HRSA for a 3-year period. For example, fiscal year 2007 appropriations are available until September 30, 2009.[12]

In 2009, HRSA began requiring the collection of client-level data from grantees and service providers. Client-level data refers to information on each client receiving CARE Act-funded services, such as the dates services were received, the types of services provided, and current health status. Previously, grantees and service providers submitted only aggregate data to HRSA on those being served. To help ensure the accountability of CARE Act funds, HRSA has begun to collect client-level data. Implementing a client-level data collection and reporting system can allow HRSA to obtain accurate information on the medical and support services received by each unique client served with CARE Act funds. HRSA requires grantees and service providers to complete specified reports and transfer these reports electronically to HRSA.

As Congress prepares to reauthorize CARE Act programs, you asked us to examine various elements of CARE Act programs. In this report, we review (1) HRSA's first year implementation of the unobligated balance provisions; (2) the actions taken by HRSA to collect client-level data, and (3) the number and size of ADAP waiting lists.

To examine the first year implementation of the unobligated balance provisions, we reviewed all grant year 2007 Part A and Part B carryover requests that were provided to us by HRSA,[13] including those based on grantees' estimated unobligated balances and those based on grantees' actual unobligated balances. We also reviewed all grant year 2007 Part A and B financial status reports provided to us by HRSA. We reviewed HRSA documentation on grantees' carryover requests and financial status reports as well as HRSA documentation on grantees' unobligated balances at the end of grant year 2007. We interviewed HRSA officials and asked follow-up questions related to the calculation of unobligated balances, discrepancies in the carryover requests and financial status reports, grantee estimates of their unobligated balances that differed from their actual unobligated balances, and information provided by grantees that we found to be

[12]We also examined the unobligated balance provision in a previous report. See GAO, *Ryan White CARE Act: Effects of Certain Funding Provisions on Grant Awards*, GAO-09-894 (Washington, D.C.: Sept. 18, 2009).

[13]Carryover requests are also referred to as waivers of the cancellation of unobligated balances.

incorrect. We determined that the information provided to us by HRSA was sufficiently reliable for our purposes.

To examine the actions taken by HRSA to collect client-level data, we reviewed statements, manuals, and other materials on the implementation of client-level data collection by HRSA, grantees, and service providers. We focused on 2009, the first year grantees and service providers were required by HRSA to submit client-level data, including deadlines for data submission. In addition, we interviewed officials at HRSA as well as officials from 12 state and 5 local health departments who are knowledgeable about the CARE Act and the client-level data that grantees and service providers must collect.[14] We also interviewed officials from the Henry J. Kaiser Family Foundation, the National Alliance of State and Territorial AIDS Directors (NASTAD), and other organizations knowledgeable about client-level data.

To examine the number and size of ADAP waiting lists, we obtained and reviewed the ADAP Quarterly Data Reports submitted to HRSA by ADAP grantees covering the first quarter of grant year 2008 (April 1, 2008, through June 30, 2008) and the fourth quarter of grant year 2008 (January 1, 2009, through March 31, 2009).[15] These reports contain information on waiting lists. We reviewed the ADAP Quarterly Data Reports and asked HRSA officials follow-up questions about the accuracy of the data, and determined that the data were sufficiently reliable for our purposes. We also obtained updated data from HRSA on ADAP waiting lists as of August 10, 2009, and determined that the data were sufficiently reliable for our purposes after discussing the data with HRSA officials. We

[14]We interviewed officials from 12 state health departments and 5 local health departments. We interviewed the following state health departments: California, Delaware, Florida, Hawaii, Indiana, Missouri, Nebraska, North Carolina, Ohio, Pennsylvania, Rhode Island, and Washington. We interviewed the following local health departments: Harris County, Tex.; Maricopa County, Ariz.; Memphis, Tenn.; New York, N.Y.; Sacramento County, Calif. We selected health departments to achieve a range in geographic locations and the number of HIV cases among jurisdictions.

[15]We reviewed and analyzed ADAP Quarterly Data Reports if the grantee submitted reports for both the first and fourth quarters of the 2008 grant year. Consequently, we reviewed the reports of 52 of the 59 grantees. Louisiana did not submit an ADAP quarterly report for the first quarter of grant year 2008 and the U.S. Virgin Islands did not submit a report for the fourth quarter of grant year 2008. American Samoa, the Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, and the Republic of the Marshall Islands did not submit reports for either the fist or fourth quarters of grant year 2008. Palau also did not submit a report for either quarter, but it also did not receive any ADAP funding in grant year 2008.

reviewed published information on ADAPs. We interviewed HRSA officials knowledgeable about ADAPs and interviewed officials from 13 states, which we chose based on their geographic location, size, and number of HIV/AIDS cases, about their ADAPs.[16] In addition, we interviewed officials from the Henry J. Kaiser Family Foundation, NASTAD, and other organizations knowledgeable about ADAPs.

We conducted this performance audit from April 2009 through September 2009 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

RWTMA includes provisions related to unobligated balances, client-level data, and ADAPs.

Unobligated Balance Provisions and Impact on Funding

RWTMA includes provisions to encourage grantees to obligate their grant funds in the year in which they were awarded. RWTMA provides that Part A and Part B grant funds are available for obligation for a one-year period beginning on the date funds first become available (referred to as the grant year for the award).[17] RWTMA requires HRSA to cancel the unobligated balance of grant awards at the end of a grant year and to require grantees to return any amounts from such balances that have been disbursed to them. However, in the case of base grants, a grantee may submit a request to carry over the unobligated balance prior to the end of the grant year. If HRSA approves the request, the unobligated balance that is approved for carryover (carryover funds) is available to the grantee for

[16]We interviewed officials from the following ADAPs: Arizona, California, Delaware, Florida, Hawaii, Indiana, Missouri, Nebraska, North Carolina, Ohio, Pennsylvania, Rhode Island, and Washington.

[17]Provisions establishing a one-year period for the obligation of funds apply to Part A base and supplemental grants to metropolitan areas, and all Part B grants to states and territories and associated jurisdictions—that is, Part B and ADAP base grants, Part B and ADAP supplemental grants, and supplemental grants for emerging communities. (Emerging communities are those metropolitan areas that do not qualify as EMAs or TGAs, but have 500-999 cumulative reported AIDS cases during the most recent 5-year period. Emerging community grants are distributed to states, which then pass them through to emerging communities.)

expenditure for a one-year period beginning upon the expiration of the grant year (referred to as a carryover year). Under the RWTMA unobligated balance provisions, HRSA is required to cancel any unexpended balance of carryover funds at the end of the carryover year. HRSA must make the canceled balances from the grant awards (that is, funds that were not eligible or approved for carryover and carryover funds that remain after the carryover year) available as supplemental grants for the first fiscal year beginning after the fiscal year in which HRSA obtains the information necessary for determining the balance available. Part A grantees with greater than 2 percent of their base grant awards unobligated at the end of the grant year and Part B grantees with greater than 2 percent of their Part B and ADAP base awards unobligated at the end of the grant year incur a penalty. RWTMA requires HRSA to reduce the amount of those grants by the same amount as the unobligated balance for the first fiscal year beginning after the fiscal year in which HRSA obtains the information necessary for determining the unobligated balance. The grant funds that become available as a result of these reductions are also to be made available as supplemental grants.[18]

RWTMA's authorization of appropriations for base and supplemental grants under Parts A and B provided that amounts appropriated for a fiscal year would be available for obligation until the end of the second succeeding fiscal year. Further, under appropriations acts enacted since RWTMA, funds for grants under Parts A and B, to which the unobligated balance provisions apply, are available for obligation for a 3-year period.[19] In fiscal year 2007, for example, funds were made available for obligation until September 30, 2009—the end of the 2009 federal fiscal year. Thus, as HRSA recognized in its guidance regarding the unobligated balance provisions, the initial obligation of funds, cancellation of unobligated balances, return of amounts disbursed to grantees, and the recompetition and redistribution of supplemental grants would need to occur within the 3-year window.

[18]The availability of funds for supplemental grants is subject to hold-harmless provisions that protect grantees' grant amounts at specified levels.

[19]Revised Continuing Appropriations Resolution, 2007, Pub. L. No. 110-5, § 2, 121 Stat. 8, 31; Consolidated Appropriations Act, 2008, Pub. L. No. 110-161, div. G, title II, 121 Stat. 1844, 2170; Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, div. F, title II, 123 Stat. 524, 763-64.

In order to implement the RWTMA unobligated balance provisions, HRSA created a multistep process for grantees and issued a policy notice to grantees explaining this process.[20] HRSA's process for implementing the unobligated balance provisions in grant year 2007 included five steps. First, a grantee wishing to carry over funds was required to submit a carryover request to HRSA with an estimated unobligated balance of base grant funds 60 days prior to the end of the grant year. In addition to the estimated unobligated balance, the initial carryover request also had to contain a viable plan and detailed budget for the use of the funds, and a description of the grantee's capacity to utilize the funds within one-grant year. Part A grantees had to submit their initial carryover request to HRSA by January 1, 2008. Part B grantees had to submit their initial carryover request to HRSA by February 1, 2008.

The second step of the 2007 grant year process was the evaluation of the initial carryover requests. HRSA authorized grantees that obtained approval before the end of the 2007 grant year to carryover 50 percent of the amount they requested in this initial carryover request. To authorize the use of the carryover funds, HRSA issued these grantees a notice of grant award that explained to the grantees that HRSA had effectively transferred the carryover funds from their grant year 2007 account into their grant year 2008 account, though balances remained, in effect, available to the grantees for obligation until the end of grant year 2007.[21] HRSA officials explained that they did not authorize the full amount of the initial carryover request because they believed it was possible that the grantees that requested waivers would incur obligations greater than anticipated in the 60-day estimate. HRSA officials stated that they wanted to authorize the carryover of a portion of the unobligated balance so that grantees with approved carryover requests would have a longer period of time to obligate the carried over funds.

[20]Department of Health and Human Services, Health Resources and Services Administration. HIV/AIDS Bureau. *Policy Notice 07-09: The Unobligated Balances Provision* (2007). http://hab.hrsa.gov/law/0709.htm

[21]HRSA accomplished this by deobligating funds from the grantees' 2007 grant year accounts and reobligating the funds to their 2008 grant year accounts. For grantees that incurred 2007 grant year obligations for which the use of CARE Act funds was appropriate, HRSA adjusted the accounts through a similar process at the end of the grant year, effectively transferring funds back to the grant year 2007 accounts.

For step three of HRSA's 2007 grant year unobligated balance process, grantees were required by HRSA to submit a Financial Status Report (FSR) 90 days after the end of the grant year. The FSR contains, among other things, a grantee's actual unobligated balance. For Part A grantees, FSRs were due on June 1, 2008. For Part B grantees, FSRs were due on June 30, 2008. HRSA can extend the deadlines for grantees for submission of their FSRs and granted extensions for 30 to 180 days.

For step four of the process, although not required by HRSA for grant year 2007, grantees could submit a final carryover request based on their actual unobligated balances. Those grantees that had their initial carryover requests approved and had been authorized by HRSA to carry over 50 percent of their unobligated balances at that time, could apply for the remaining funds (the difference between the 50 percent they had already been authorized to carry over by HRSA and their actual unobligated balance). HRSA then authorized the use of the additional amount of carryover funds by issuing a notice of grant award.

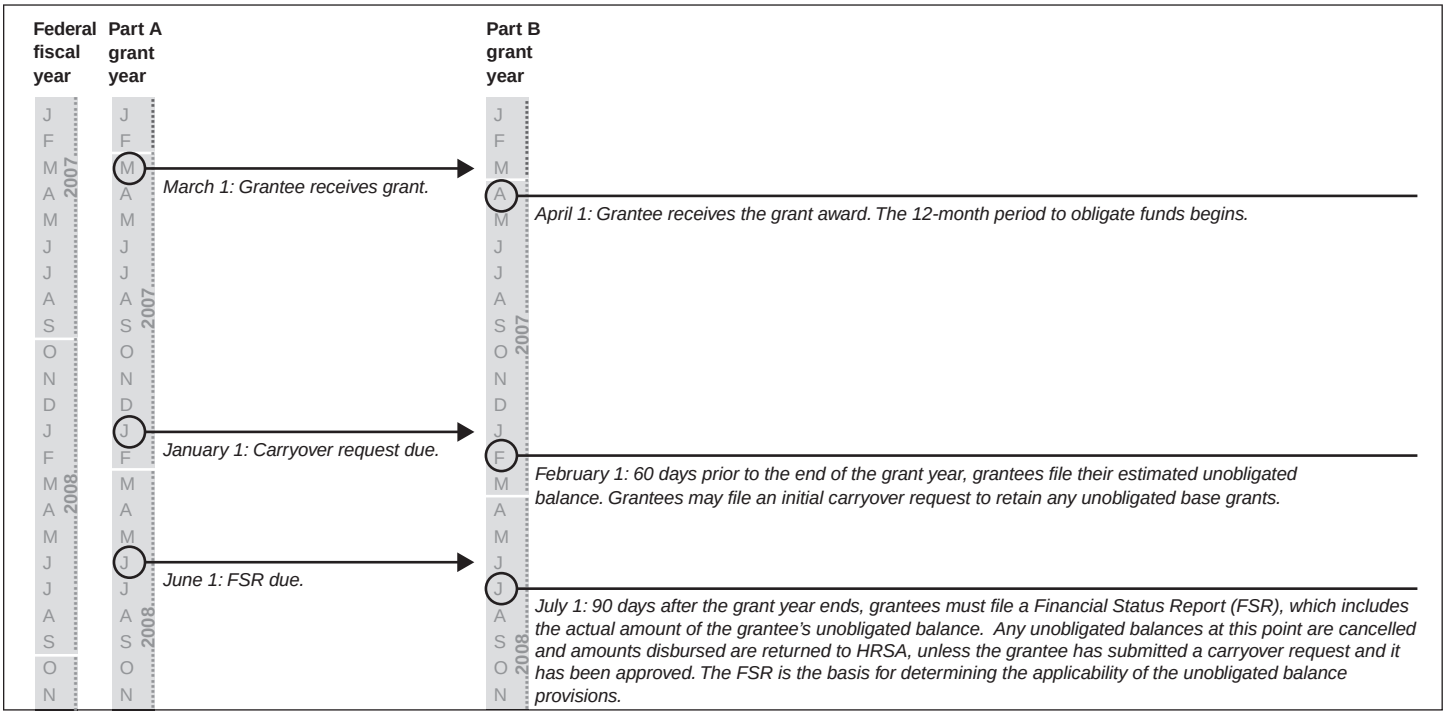
For step five of this process, grantees with unobligated balances of greater than 2 percent of their grant year 2007 Part A, Part B, and ADAP base grants were assessed a penalty. This penalty was a corresponding reduction in grant year 2009 funds.[22] In addition, Part A and B grantees with unobligated balances of greater than 2 percent for grant year 2007 were ineligible to receive supplemental grants in grant year 2009. For Part A grantees this meant that they were not eligible to receive grant year 2009 Part A supplemental grants. For Part B base grantees this resulted in ineligibility to receive grant year 2009 Part B supplemental grants. For Part B ADAP grantees, an unobligated balance of greater than 2 percent does not result in ineligibility for ADAP supplemental grants. Instead, ineligibility for the ADAP supplemental grant occurs when a grantee has

[22]Grantees are not penalized in the year immediately following the year in which they have unobligated balances in excess of 2 percent. Because the grantee submits the actual unobligated balance on the FSR 90 days after the grant year ends, grants for the next year have already been made by the time HRSA has received the information necessary to determine which grantees have an unobligated balance greater than 2 percent. As a result, there is a one-year lag time between when the unobligated balance occurs and when the penalty is assessed. For example, if a grantee had an unobligated balance of three percent in grant year 2007, the grantee's FSR would have been filed in grant year 2008, and the dollar amount of the 2007 unobligated balance would have been deducted from the grantee's award in grant year 2009.

not obligated at least 75 percent of its ADAP grant award within 120 days of the award.[23]

Figure 1 shows a timeline for Part A and B grant distribution and the unobligated balance provisions.

Figure 1: Timeline for 2007 Part A and Part B Grants and Unobligated Balance Provisions



Source: GAO analysis of HRSA guidance.

HRSA cancelled and recovered $13,764,295 in combined grant year 2007 Part B base and supplemental unobligated balances from 16 Part B grantees with unobligated balances of greater than 2 percent. In addition, these 16 grantees' grant year 2009 awards were reduced by a total of $19,677,483 as a penalty for incurring an unobligated balance of greater

[23]Since its inception, the CARE Act has required Part B grantees to obligate 75 percent of their entire Part B grant within certain time frames and repay any unobligated balance to HRSA for reallocation to Part B grantees. States had 150 days to meet this requirement in the first year of the program and have had 120 days in subsequent years. HRSA requires Part B grantees to report this obligation within 150 days on an FSR. In addition, grantees that do not obligate this 75 percent are ineligible for ADAP supplemental grants.

than 2 percent in grant year 2007. Of this, $4,441,865 was from Part B base grants and $15,235,618 was from ADAP base grants.

Client-Level Data

Prior to RWTMA, HRSA used the Ryan White HIV/AIDS Program Data Report (RDR) to collect information on CARE Act services from grantees and their service providers. However, RDR was unable to collect client-level data with unique identifying information. Consequently, there was no way of knowing if the clients counted as being served by one provider were also included in the counts of those being served by other providers. Therefore, totaling the number of clients receiving services across providers could result in clients being counted more than once. Additionally, the lack of client-level data meant that HRSA was unable to assess the quality of care given to clients or sufficiently account for the use of CARE Act funds.

HRSA now collects client-level data to help ensure accountability of CARE Act funds. A client-level data collection and reporting system contains information unique to each client receiving CARE Act-funded services, such as their socio-demographic characteristics, the services provided, and each client's current health status. Because the system collects client-specific information rather than only aggregate-level data, HRSA can obtain a more accurate measure of the number of clients being served than was available using RDR.

ADAP Funding and Activities

Each ADAP is given broad authority under the CARE Act to design its own program. The scope of an ADAP's coverage—who and what is covered—is determined by each ADAP's program design, which includes criteria such as the number and types of drugs it will provide to its clients, and the income levels to qualify for services. However, RWTMA required that each grantee establish an ADAP formulary that covers all core classes of antiretroviral medications.[24]

[24]A formulary is a drug list that establishes the number of drugs available within a therapeutic class for purposes of drug purchasing, dispensing, and reimbursement. Antiretroviral medications are used to combat the reproduction of the HIV virus and to slow the progression of HIV-related disease. ADAPs must cover at least one drug from each of the six antiretroviral drug classes.

ADAP grants totaled approximately $821 million in fiscal year 2009. Of this amount, $780 million was provided to grantees as ADAP base grants, which are awarded by formula and are based on a grantee's share of living HIV/AIDS cases. The remaining $41 million was distributed to grantees as ADAP supplemental grants.[25] These grants are distributed to ADAPs that demonstrate a severe need to increase the availability of HIV/AIDS drugs.[26]

ADAPs must balance client need with available resources. In previous years, many ADAPs have had to institute waiting lists and other cost containment measures because of insufficient funds to provide services to all individuals who qualify. In our 2006 report, we found that in fiscal year 2004, 14 ADAPs had waiting lists of individuals they determined were eligible for assistance but they were unable to serve.[27] According to NASTAD and the Henry J. Kaiser Family Foundation, since 2002 a total of 20 different ADAPs have had waiting lists at some point. The largest number of individuals on waiting lists across all grantees at any time was 1,629 in May 2004. However, they reported that there were no individuals on waiting lists as of September 2007.[28] NASTAD, the Henry J. Kaiser Family Foundation, and others have cited several factors that contributed to the elimination of waiting lists as of September 2007. These reasons included HRSA's awarding $39.5 million in ADAP supplemental grants in September 2007, states' increasing their contributions to ADAPs,[29] and the continued implementation of Medicare Part D prescription drug coverage.[30]

[25]Annual appropriations acts specify the total amount of funding for ADAPs. Five percent of this funding is reserved for ADAP supplemental grants.

[26]Severe need is when a grantee is unable to provide medications consistent with Public Health Service guidelines.

[27]GAO-06-646, 28.

[28]National Alliance of State and Territorial AIDS Directors and the Henry J. Kaiser Family Foundation, *National ADAP Monitoring Project Annual Report* (Washington, D.C.: 2009) 10.

[29]In addition to federal funding, ADAPs can also receive funding from other sources such as state budgets.

[30]The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added a new prescription drug benefit, Part D, to the Medicare program. Some ADAP clients were eligible for Medicare Part D benefits and thus, ADAPs were able to reduce costs because they no longer had to pay all the prescription drug costs for these individuals.

Lack of Timely, Accurate Information Places at Risk Certain Funds, and HRSA Has Unsuccessfully Attempted to Obtain Needed Information

The lack of timely and accurate information has delayed HRSA's distribution of unobligated balances as supplemental grants and places at risk HRSA's ability to obligate these funds. HRSA has attempted to develop timely information on grantee obligations but was unsuccessful doing so for grant year 2007.

The Lack of Timely, Accurate Information Has Delayed HRSA's Redistribution of Funds and Places at Risk HRSA's Ability to Obligate Funds in the Required Time Frame

The lack of timely and accurate information in grantees' FSRs regarding grant year 2007 unobligated balances has delayed HRSA's distribution of Part B supplemental grants, and places at risk HRSA's ability to redistribute these funds by September 30, 2009, after which it will no longer have the authority to redistribute the funds. Because of late FSR submissions, as of September 14, 2009, HRSA had not yet redistributed funds that it canceled and recovered from grantees' 2007 unobligated balances. However, as HRSA recognized in its guidance regarding the unobligated balance provisions, the entire process for canceling and recovering grant funds and making the corresponding awards of supplemental grants must occur within the 3-year period of availability of those Part B funds.[31]

For HRSA's grant year 2007 process, Part A grantees were required to submit their FSRs by June 1, 2008, and Part B FSRs were to be submitted to HRSA by June 30, 2008. The FSR contains, among other information, a grantee's actual unobligated balance. HRSA uses the grantees' actual unobligated balances, as reported on their FSRs, to determine the total amount of unobligated balance funds that will be available for redistribution through supplemental grants. Without complete, accurate, and timely information from grantees about their unobligated balances,

[31]HRSA's entire unobligated balance process includes the initial obligation of funds, cancellation of unobligated balances, return of amounts disbursed to grantees, and the recompetition and redistribution of supplemental grants.

HRSA is unable to redistribute unobligated balance funding through the Part A and Part B supplemental grants.[32]

Many Part A and B grantees submitted their FSRs late, and some submitted their FSRs more than 120 days after the deadline. Of the 56 Part A grantees, 21 submitted FSRs after the June 1, 2008, deadline. Of the 59 Part B grantees, 24 submitted FSRs after the June 30, 2008, deadline. Table 1 shows the number of days after the deadline that Part A and Part B grantees submitted their FSRs.

Table 1: Number of Grantees Submitting Late FSRs by Amount of Time

	30 to 60 days after deadline	61 to 90 days after deadline	91 to 120 days after deadline	121 days or more after deadline	Total late final FSRs
Part A Grantees	3	5	3	10	21
Part B Grantees	3	7	10	4	24

Source: GAO analysis of HRSA data.

HRSA officials stated that grantees were often delayed in submitting their FSRs because of their end-of-the-year workload, which includes the need to submit grant applications and multiple reports for their formula and supplemental funding. HRSA officials stated that grantees normally request extensions for submitting their FSRs, and 60-day extensions are typically granted. HRSA officials stated that in grant year 2007, due to the new process HRSA implemented to address the unobligated balance provisions, grantees had to implement separate tracking of the expenditure of current grant year base grant and supplemental funds, and the expenditure of carryover funding from previous years. HRSA officials also stated that grantees had difficulty implementing the separate tracking of these funds. HRSA officials stated that due to grantees' difficulty tracking funds separately, some grantees' FSRs reported inaccurate unobligated balances, which required HRSA staff to correspond with grantees and request revised information, creating additional delays.

[32]The Part B supplemental grant program is a new program established by RWTMA. It provides for grants in fiscal years in which appropriations for Part B exceed a specified amount and serves as a mechanism for redistributing (1) carryover funds that are not expended by the end of the carryover year, (2) unobligated balances that grantees do not request to carryover, and (3) funds HRSA obtains through penalties assessed on grantees who exceed the 2 percent threshold for unobligated balances. No funds had been distributed as of September 14, 2009, under this program. Grant year 2009 is the first year funds will be available through this program.

According to HRSA officials, in addition to experiencing difficulty tracking funds, grantees were dealing with other factors including late receipt of final invoices from contractors, delays in receipt of ADAP rebates, and staff vacancies.[33]

While HRSA has typically approved grantees' requests for extensions in submitting their FSRs, the tardiness of grantees' FSR submissions and HRSA's need to correspond with grantees to address their inaccuracies has delayed HRSA's ability to determine the amount of unobligated balances available for redistribution to grantees through Part B supplemental grants. In April 2009, HRSA officials stated that they planned to distribute Part B supplemental grants in May 2009. However, as of September 14, 2009, HRSA had not distributed the 2009 Part B supplemental grants. As a consequence, HRSA had not yet fully implemented the unobligated balance provisions for the first time. HRSA officials stated that they plan to implement changes to improve the timeliness of their process. For example, HRSA officials also stated that beginning in grant year 2009 they will no longer approve grantees' requests for extensions for their FSR submissions. Additionally, beginning in grant year 2009, FSRs will be due 30 days after the end of the grant year instead of the grant year 2007 deadline of 90 days after the end of the grant year.

In Its 2007 Process, HRSA Attempted to Develop Timely Information on Grantees' Unobligated Balances but Was Unsuccessful

In its 2007 process, HRSA tried to develop timely information on grantees' unobligated balances, but these efforts were unsuccessful. For grant year 2007, in order to gain information on grantees' unobligated balances so that it could begin to determine how much funding would be available for distribution as supplemental grants and so that it could provide grantees with a full year to obligate carryover funds, HRSA requested that grantees submit estimates of their unobligated balances 60 days before the end of the 2007 grant year. Because unobligated balance funds that grantees decide not to carry over and unobligated balance funds from carryover requests that are not approved by HRSA are available for redistribution through supplemental grants, HRSA officials needed to complete processing of the carryover requests before they could determine the

[33]Twenty-seven Part B grantees purchase drugs exclusively through a federal drug discount program, under which they pay full price and receive a rebate at some point in the future. Federal regulations generally applicable to state and local government grantees require them to disburse these rebates before requesting additional cash payments. Thus, grantees receiving drug rebates must prioritize spending these funds and several grantees said that this makes it more difficult to obligate grant funds in the grant year. See GAO-09-894.

amount of funding that and could be made available as supplemental grants.

Many grantees' estimates of their unobligated balances in advance of the end of the grant year differed from their actual unobligated balances at the end of the grant year. In accordance with HRSA's requirements, many Part A and Part B grantees submitted estimates of their unobligated balances with requests to carryover these funds 60 days before the end of the grant year, but their estimates proved to be substantially different from the actual unobligated balances reported on their FSRs. Of the 29 Part A grantees that submitted initial carryover requests, compared to the actual unobligated balances they submitted on their FSRs, 25 overestimated their unobligated balances, two grantees underestimated their unobligated balances, and two grantees correctly estimated their unobligated balances. Among the grantees that overestimated their balances were nine grantees that were ultimately able to obligate all of their funding by the end of the grant year and therefore did not need to carry over any funds. Of the 24 Part B grantees that completed initial carryover requests, compared to the actual unobligated balances they submitted on their FSRs, 18 overestimated their unobligated balances. Two of these grantees, New York and New Jersey, overestimated their unobligated balances by more than the amount they received from HRSA based on their initial carryover requests and had to request that HRSA return the grant year 2007 carryover funds that the grantees had previously requested be transferred into their grant year 2008 accounts.[34] Six grantees underestimated their unobligated balances. Nine grantees that overestimated their balances were ultimately able to obligate all of their funds by the end of the grant year and did not need to carryover any unobligated balances.

[34]According to HRSA, New York submitted an initial carryover request for $2,491,742. HRSA approved its request for 50 percent of the funding, which was $1,245,871. New York then submitted its final FSR with an actual unobligated balance of $0 and requested that the carryover funds be deobligated from the grant year 2008 account and reobligated into the grant year 2007 account, because New York had been able to obligate the entire $2,491,742 for CARE Act purposes. Similarily, according to HRSA, New Jersey submitted an initial carryover request for $911,621. HRSA approved its request for 50 percent of the funding, which was $455,810. HRSA deobligated this amount from New Jersey's 2007 grant and reobligated these funds to New Jersey's 2008 grant. New Jersey then submitted its final FSR with an actual unobligated balance of $169,057 and requested that $286,574 in carryover funds be deobligated from grant year 2008 and reobligated to the grant year 2007, because New Jersey had been able to obligate all but $169,057.

The process of approving grantees' initial carryover requests sometimes extended into the 2008 grant year. As a result, grantees were not authorized to use carryover funds at the expiration of the 2007 grant year as provided for by RWTMA. HRSA officials stated that the implementation of procedures to process, approve, and authorize carryover funding required significant staff time from the HRSA project officer, grants management staff, and program managers. The HRSA process called for staff to review these initial carryover requests, approve them, and authorize carryover funding to be transferred from the grantees' 2007 accounts into their 2008 accounts. HRSA officials stated that the multiple grantee submissions, which often included revised proposals, resulted in processing delays and confusion for HRSA staff. On average, it took HRSA staff 3 months to complete processing of Part A grantees' initial unobligated balance carryover requests and 4 months for Part B grantees. Because grantees were only given until the end of grant year 2008 to expend carry over funds, grantees who received authorization to carryover funds after the start of the grant year did not have the entire grant year to expend these funds.

In light of HRSA's difficulty implementing procedures related to the submission of initial carryover requests and the differences between grantees' estimated and actual unobligated balances, HRSA has decided to discontinue its process of approving initial carryover waiver requests based on estimated unobligated balances.

HRSA Has Taken Actions to Collect Client-Level Data, but Some Grantees Did Not Submit Initial Reports by the Deadline

HRSA has taken actions to collect client-level data by implementing a new data collection and reporting system. It has also provided financial and technical assistance to grantees and service providers implementing their own client-level data and reporting systems. In addition, HRSA developed a timeline for the submission of reports covering the initial reporting period using client-level data, but some grantees did not submit the initial reports by the deadline.

HRSA Has Taken Actions to Collect Client-Level Data by Implementing a New Data Collection and Reporting System

HRSA has taken actions to collect client-level data from CARE Act grantees and service providers. Beginning in December 2007, after the initial design and development of a client-level data collection and reporting demonstration project, HRSA held meetings with CARE Act grantees, national organizations, and federal agencies to discuss collecting and reporting client-level data. Topics discussed included data collection and reporting barriers, data elements to be collected, how the data would be used, and the technical assistance that would be available from HRSA. Using information from these sessions, HRSA finalized the Ryan White HIV/AIDS Program Services Report (RSR), its client-level data collection and reporting system. RSR consists of three reports: the Grantee Report, the Service Provider Report, and the Client Report. RSR was submitted to the Office of Management and Budget for approval in November 2008, which granted approval for HRSA to collect data from grantees and service providers using RSR in March 2009.

HRSA stated that RSR will improve information on the clients served, the services provided to clients, and the outcomes of the services provided. RSR is designed to provide HRSA with a more accurate measure of the number of unique clients receiving CARE Act-funded services by assigning each individual an encrypted Unique Client Identifier thereby allowing the tracking of individuals who receive services from multiple providers.[35] Because RSR will contain client-specific data, HRSA will be able to determine the services each client received and the outcomes of these services.

RSR is part of a process through which HRSA plans to collect information, including client-level data, from grantees and service providers funded under CARE Act Parts A, B, C, D, and F.[36] First, the grantees and service providers collect data using their own data collection systems. Second, the

[35]HRSA has stated that there will still be some degree of duplication due to error, and has estimated the total error rate will be 8.8 percent. Duplication will occur when two different clients receive the same identifier because of a recording error, such as a mistake in recording a client's date of birth. An error may also occur when a client receives two different identifiers. For example, this might occur when a client changes his or her last name.

[36]Part C provides for grants to public and private nonprofit entities to provide early intervention services, such as HIV testing and ambulatory care. Part D provides for grants to public and private nonprofit entities for family-centered comprehensive care to children, youth, and women and their families. Part F provides for grants for demonstration and evaluation of innovative models of HIV/AIDS care delivery for hard-to-reach populations, training of health care providers, and for Minority AIDS Initiative grants.

grantees and service providers report the data to HRSA in specified reports using RSR.[37] HRSA has stated that it intends to use the data collected through RSR to generate reports on the use of CARE Act funds and the providers that receive them. HRSA reports are expected to provide client-level information on the characteristics of the clients served, the types of services they received from the provider, and their current health status. Additionally, HRSA has stated that it intends to conduct detailed analyses of national and regional information about clients and services.

HRSA Has Provided Financial and Technical Assistance to Grantees to Develop Their Own Client-Level Data Collection and Reporting Systems

HRSA provided financial assistance to CARE Act grantees to develop or adapt their client-level data collection and reporting systems so that they could submit the required information to RSR. There are grantees who must develop new systems while other grantees' systems require modification to enable them to generate data compatible with the requirements of RSR. HRSA administered a Special Projects of National Significance (SPNS) initiative in fiscal year 2008 and another in fiscal year 2009 to provide funds to support CARE Act grantees in developing client-level data systems that could be used to report information to RSR.[38] Under the fiscal year 2008 SPNS initiative, HRSA awarded 17 grants ranging from $87,000 to $200,000 to all 17 CARE Act Parts A and B grantees that applied for funding. Under the fiscal year 2009 SPNS initiative, HRSA awarded a total of approximately $4 million to all 57 Parts C and D grantees that applied for funding. Officials from 4 of the 17 health departments we interviewed stated that they received financial assistance from HRSA to develop and implement a client-level data collection and reporting system. Two of these health departments received $200,000 each. One of these health departments used the funding to help

[37]A grantee or service provider can use a customized client-level data collection system, a vendor-distributed client-level data collection system, or HRSA's CAREWare to collect client-level data. A customized client-level data collection system is created by a grantee or service provider to collect client-level data. A vendor-distributed client-level data collection system is created by a vendor. On its Web site, HRSA maintains a list of vendors whose data systems meet HRSA's reporting requirements or are progressing toward meeting these requirements. CAREWare is a free, comprehensive electronic health information system that is available to grantee and service providers through HRSA's Web site. CAREWare generates data for RDR and is also capable of collecting the needed client-level data for RSR.

[38]According to HRSA, the SPNS initiatives fund innovative models of care and support for HIV/AIDS care. RWTMA authorized SPNS funding to assist CARE Act grantees in developing their own standard electronic client-level information data systems so that they could report their client-level data to HRSA.

build its own new system while the other department used the funding to adapt its current system to be compatible with CAREWare, a free, data collection system available through HRSA's Web site. In addition to the SPNS funds, HRSA has made other funding available for infrastructure development. In 2008, HRSA provided a total of more than $1 million to 15 CARE Act Part C grantees that included funds for them to develop their client-level data systems. As of April 2009, HRSA was reviewing 72 applications for infrastructure development grants.

HRSA also provided technical assistance to CARE Act grantees and service providers to develop client-level data collection and reporting systems. HRSA established the Technical Assistance Resources, Guidance, Education & Training Web site to provide information and resources, such as help desk support. HRSA conducted training sessions and webcasts to provide information on issues relating to implementing a client-level data system. Additionally, HRSA established the RSR Triage Committee to monitor and address the technical assistance needs of grantees. The committee meets weekly to discuss technical assistance concerns of grantees and monitors contractors charged with addressing technical concerns on behalf of HRSA. Officials from 7 of the 17 health departments we interviewed told us that they received technical assistance from HRSA to develop and implement a client-level data collection and reporting system. For example, one state grantee told us that HRSA provided a 2-day training session on CAREWare in November 2008. The HRSA official returned in March 2009 to provide assistance in implementing the CAREWare system.[39]

The state and local health departments that we interviewed have taken steps to implement a client-level data collection and reporting system that can report client-level data to RSR. Officials from all 17 health departments we spoke with stated that they either already had a client-level data system or were implementing such a system. Officials from six health departments indicated that they either currently use or plan to use CAREWare. The other eleven said they will use or plan to use a customized or vendor-distributed client-level information data system. Officials from 8 of the 17 departments stated that they had a system to

[39]HRSA also consulted with vendors to make sure that their client-level data software was compatible with RSR.

collect client-level data before HRSA's requirement to implement such a system.[40]

Officials from 10 of the 17 health departments we interviewed had concerns or challenges with implementing a client-level data collection and reporting system and reporting client-level data to HRSA. For example, officials from three health departments stated they were concerned about how to train service providers and other partners to collect client-level data. An official from 1 of these 3 health departments mentioned that it had been a challenge for his state to train the 100 case managers in the state to report client-level data in a consistent manner. Additionally, officials from three departments stated that they were concerned with potential breaches in the confidentiality of client information when data are entered into the RSR system.

HRSA Developed a Timeline for Submitting the Initial Reports to RSR, but Some Grantees Did Not Submit Initial Reports by the Deadline

HRSA developed a timeline for grantees to submit their initial reports to RSR, but some grantees did not submit initial reports. The initial RSR reporting period covered January 1, 2009, through June 30, 2009; however, the deadlines varied for the different reports.[41] Table 2 provides a description of the reports to be submitted to RSR by grantees and service providers and the deadline for the initial reporting period for each report.

[40]While some grantees already had client-level data collection and reporting systems in place, HRSA officials told us that they still needed to assist these grantees in making the systems compatible with RSR.

[41]After the initial reporting period of January 1, 2009, through June 30, 2009, grantees and service providers must also submit reports for the entire 2009 calendar year. In subsequent years, grantees and service providers will only submit reports on an annual basis. HRSA officials said that they anticipate that grantees and service providers will continue to report aggregate data using RDR for calendar years 2009 and 2010 to allow HRSA to monitor the CARE Act services provided to clients while transitioning to RSR.

Table 2: Description of Data Submitted for Ryan White HIV/AIDS Program Services Reports

Report	Party responsible for completing the report[a]	Description of data collected	Deadline for initial reporting period[b]
Grantee report	CARE Act Part A, B, C, D, or F grantees[c]	Information about the grantee organization and the service providers that it funded	July 31, 2009
Service provider report	Service providers who provide CARE Act-funded services	Information about the service provider and the CARE Act services it delivers	September 15, 2009
Client report	Service providers that deliver and/or pay for direct client services with CARE Act funds	Information about each client that receives services funded by the CARE Act such as demographic data, HIV clinical information, and medical and support services received at the service provider	September 15, 2009

Source: GAO analysis of HRSA data

[a]For the initial reporting period of January 1, 2009, through June 30, 2009, and the first annual reporting period of January 1, 2009, through December 31, 2009, only service providers receiving CARE Act funds to provide outpatient/ambulatory medical care and/or case management services will be required to submit a Client Report. All service providers will eventually be required to submit Client Reports.

[b]The submission deadline for Grantee Reports is July 31, 2009. Grantees must approve the Service Provider Reports and the Client Reports entered by service providers by September 15, 2009.

[c]Only Part F Minority AIDS Initiative grantees must complete this report.

While most grantees submitted a Grantee Report to HRSA by the July 31, 2009 deadline, some did not do so. For the initial RSR reporting period, 538 of 638 (about 84 percent) CARE Act grantees submitted Grantee Reports to HRSA by the deadline. According to HRSA officials, as of August 13, 2009, of the 100 grantees and service providers that had not submitted their required reports, 50 had started the submission process and 50 had not begun. HRSA officials told us that they are contacting the grantees to determine the cause of the reporting delays. HRSA officials also stated that they are aware that some grantees have had problems generating data in the RSR-required format.

The Number and Size of ADAP Waiting Lists Is Increasing

The number of individuals on ADAP waiting lists increased during grant year 2008 and has continued to increase in 2009. In the first quarter of grant year 2008 (April 1, 2008, through June 30, 2008), 2 ADAPs had waiting lists with a total of 55 people on those lists. In the fourth quarter of grant year 2008 (January 1, 2009, through March 31, 2009), there were 3 ADAPs with waiting lists, but the number of individuals on the lists had increased to 112. By August 10, 2009, the most recent date for which data were available at the time of our analysis, these numbers had grown to 136 individuals on 4 ADAP waiting lists. Overall, this represents an increase of 147 percent (from 55 to 136) in the number of individuals on waiting lists from the first quarter of grant year 2008 to August 2009. Kentucky, Montana, Nebraska, and Wyoming all had waiting lists in August 2009. Nebraska had the largest ADAP waiting list with 71 individuals while Wyoming had the smallest list with 5 individuals. Five ADAPs had waiting lists at some point during the time period we examined. Montana had a waiting list at all three points while Kentucky and Wyoming had a waiting list at one of those times. Indiana and Nebraska had a waiting list at two points. Table 3 lists the grantees with ADAP waiting lists and the number of individuals on those lists.

Table 3: ADAPs with Waiting Lists and the Number of Individuals on Those Lists, Grant Year 2008 First Quarter, Grant Year 2008 Fourth Quarter, and as of August 10, 2009

	Number of individuals on waiting lists		
Grantee	**Grant year 2008 first quarter**	**Grant year 2008 fourth quarter**	**August 10, 2009[a]**
Indiana	50	51	0
Kentucky	0	0	36
Montana	5	19	24
Nebraska	0	42	71
Wyoming	0	0	5
Total	**55**	**112**	**136**

Source: GAO analysis of ADAP Quarterly Reports and HRSA.

[a]Waiting list information as of August 10, 2009 was the most recent data available at the time of our analysis.

We also found that the total number of individuals enrolled in ADAPs increased during grant year 2008.[42] In the first quarter of grant year 2008, 164,849 individuals were enrolled in ADAPs. The number enrolled by the fourth quarter of grant year 2008 was 177,746, an increase of 7.8 percent. Similarly, the number of individuals receiving at least one medication from an ADAP increased. In the first quarter of grant year 2008, 121,075 received at least one medication while 134,019 individuals received at least one medication in the fourth quarter of grant year 2008, an increase of 10.7 percent.

The increase in the number and size of ADAP waiting lists, as well as the increase in the number of individuals enrolled in and receiving medications through ADAPs, indicates increased financial pressure on ADAPs as ADAPs balance client needs with available resources. HRSA officials told us that because of financial pressures they are closely monitoring five ADAPs—Arizona, Arkansas, California, Kentucky, and Iowa—for the initiation or expansion of waiting lists or other cost-control measures. For example, Arkansas is considering establishing an ADAP waiting list while Kentucky projects that additional individuals will be added to its waiting list. Arizona's ADAP reduced the number of drugs on its formulary effective July 1, 2009, because of a budgetary shortfall.[43] Additionally, Arizona's ADAP still anticipates a budgetary shortfall this grant year even with the reduced number of drugs on its formulary and is considering additional cost-control measures.

ADAP officials we interviewed also indicated that ADAPs were under increasing financial pressure. For example, Hawaii officials expressed concern that they will have to establish a waiting list. They stated that they are facing higher drug prices and an increasing number of people enrolled in their ADAP. Washington state officials noted that they are facing ADAP budget constraints. An advisory committee has developed a number of possible cost-control measures to stay within budget, including reducing the number of drugs on the ADAP formulary and reducing payments to pharmacies and medical laboratories.

[42]Individuals who are enrolled in an ADAP are eligible to receive medications through the program; however, they may not actually receive ADAP medications. For example, this could occur if an individual was receiving medications from another source.

[43]Because fewer drugs are covered, reducing the number of drugs on a formulary may reduce costs.

Conclusions

HRSA has been working to implement the unobligated balance provisions of RWTMA since its enactment in December 2006. As a result of the requirement to cancel unobligated balances and, in some cases, penalize grantees, HRSA implemented complex processes that have been difficult for grantees to comply with, thus delaying HRSA's first implementation of the requirement. To implement the unobligated balance provisions, HRSA has required information on the amount of unobligated balances at the end of the grant year that some grantees either did not provide in a timely manner or that was inaccurate, or both. Three years after enactment of RWTMA, HRSA was continuing to develop its process for implementing the provisions and making adjustments based on some grantees' continued inability to comply with the process that HRSA established. In addition, at least one key provision, the use of Part B supplemental grants to redistribute unobligated funds, has yet to occur for the first time. Because funds for these grants are only available until September 30, 2009, HRSA is at risk of losing the authority to make these grants.

HRSA officials told us that, for grant years 2008 and 2009, they have changed their process for implementing the unobligated balance provisions in order to alleviate the burden on staff and to ensure that HRSA has the information it needs to implement the unobligated balance provisions in a timely manner. However, even with a changed process, HRSA will continue to depend upon grantees to provide useful information on their unobligated balances in a timely manner. This will not be achieved if grantees continue to provide information after the deadline by which it is required. HRSA must have complete, accurate, and timely information from grantees to complete the entire process to redistribute unobligated balances as supplemental grants within the period given for obligation of funds for Part A and Part B of the CARE Act.

Recommendations for Executive Action

To help ensure that HRSA is able to implement the unobligated balance provisions in a timely manner, we recommend that the Secretary of HHS instruct the administrator of HRSA to take the following two actions to obtain timely and accurate information on grantees' unobligated balances:

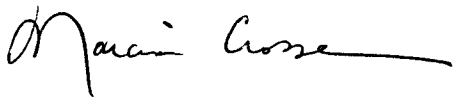
- Identify the causes of grantees' difficulties in providing a timely and accurate accounting of their unobligated balances.
- Ensure that grantees adhere to deadlines for submission of their unobligated balances by developing steps to assist them in overcoming the causes of difficulties identified in accounting for unobligated balances.

Agency Comments

HHS reviewed a draft of the report, but did not comment on our conclusions and recommendations. HHS' comments are reprinted in appendix I. We incorporated HHS comments and technical comments as appropriate.

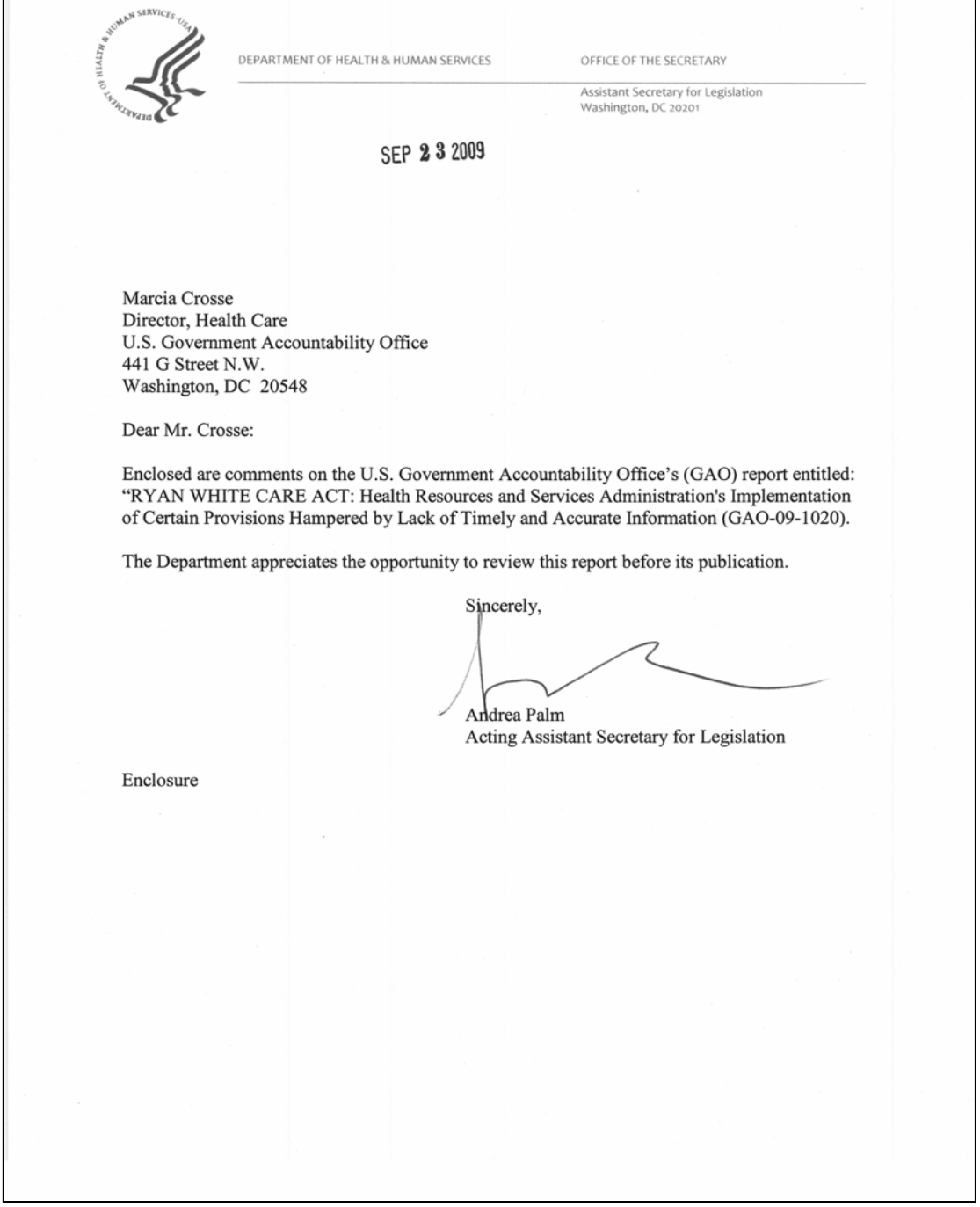
We are sending copies of this report to the Secretary of Health and Human Services. The report is also available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staffs have any questions, please contact me at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may found on the last page of this report. Other staff who made major contributions to this report are listed in appendix II.



Marcia Crosse
Director, Health Care

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

SEP 23 2009

Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street N.W.
Washington, DC 20548

Dear Mr. Crosse:

Enclosed are comments on the U.S. Government Accountability Office's (GAO) report entitled: "RYAN WHITE CARE ACT: Health Resources and Services Administration's Implementation of Certain Provisions Hampered by Lack of Timely and Accurate Information (GAO-09-1020).

The Department appreciates the opportunity to review this report before its publication.

Sincerely,

Andrea Palm
Acting Assistant Secretary for Legislation

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville MD 20857

SEP 23 2009

TO: Marcia Crosse
Director, Health Care
U.S. Government Accountability Office

FROM: Administrator

SUBJECT: Government Accountability Office Draft Report:
"RYAN WHITE CARE ACT: Health Resources and Services Administration's Implementation of Certain Provisions Hampered by Lack of Timely and Accurate Information" (GAO-09-1020)

This is in response to the GAO's request for comments on the draft report, "RYAN WHITE CARE ACT: Health Resources and Services Administration's Implementation of Certain Provisions Hampered by Lack of Timely and Accurate Information" (GAO-09-1020). Attached are the Health Resources and Services Administration's comments. If you have any questions, please contact Patricia A. Reese in HRSA's Office of Federal Assistance Management at (301) 443-0270.

Mary K. Wakefield, Ph.D., R.N.

Attachment

Health Resources and Services Administration's Comments on the GAO Draft Report – "RYAN WHITE CARE ACT: Health Resources and Services Administration's Implementation of Certain Provisions Hampered by Lack of Timely and Accurate Information" (GAO-09-1020)

GENERAL COMMENTS

The Health Resources and Services Administration has reviewed the GAO's draft report and has the following comments. In addition, the tables in this draft are not in sequential order: table 7 is on page 15, table 1 is on page 23, table 3 is on page 24, and there is no table 2 listed.

Appendix II: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7114 or crossem@gao.gov

Acknowledgments

In addition to the contact above, Thomas Conahan, Assistant Director; Robert Copeland, Assistant Director; Leonard Brown; Romonda McKinney Bumpus; Cathleen Hamann; Sarah Resavy; Rachel Svoboda; and Jennifer Whitworth made key contributions to this report.

GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday afternoon, GAO posts on its Web site newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to www.gao.gov and select "E-mail Updates."

Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's Web site, http://www.gao.gov/ordering.htm.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm
E-mail: fraudnet@gao.gov
Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Ralph Dawn, Managing Director, dawnr@gao.gov, (202) 512-4400
U.S. Government Accountability Office, 441 G Street NW, Room 7125
Washington, DC 20548

Public Affairs

Chuck Young, Managing Director, youngc1@gao.gov, (202) 512-4800
U.S. Government Accountability Office, 441 G Street NW, Room 7149
Washington, DC 20548