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September 2009

RYAN WHITE CARE ACT

Effects of Certain Funding Provisions on Grant Awards

GAO-09-894

Highlights of GAO-09-894, a report to congressional requesters

September 2009

RYAN WHITE CARE ACT

Effects of Certain Funding Provisions on Grant Awards

Why GAO Did This Study

Funds are made available under the Ryan White Comprehensive AIDS Resources Emergency Act of 1990 (CARE Act) for individuals affected by HIV/AIDS. Part A provides for grants to metropolitan areas and Part B provides for grants to states and territories and associated jurisdictions for HIV/AIDS services and for AIDS Drug Assistance Programs (ADAP). The Ryan White HIV/AIDS Treatment Modernization Act of 2006 (RWTMA) reauthorized CARE Act programs for fiscal years 2007 through 2009. RWTMA requires name-based HIV case counts for determining CARE Act funding, but an exemption allows the use of code-based case counts through fiscal year 2009. RWTMA formulas include hold-harmless provisions that protect grantees' funding at specified levels. RWTMA also included provisions under which Part A and B grantees with unobligated balances over 2 percent at the end of the grant year incur a penalty in future funding.

GAO was asked to examine CARE Act funding provisions. This report provides information on (1) how many Part B grantees collect and use name-based HIV case counts for CARE Act funding; (2) the distribution of Part A hold-harmless funding; and (3) reductions in Part B grantees' funding due to unobligated balance provisions. GAO reviewed agency documents and analyzed data on CARE Act funding. GAO interviewed 19 grantees chosen by geography, number of HIV/AIDS cases, and other criteria. GAO also interviewed federal government officials and other experts.

View GAO-09-894 or key components.
For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Forty-seven of the total 59 Part B grantees had the Health Resources and Services Administration (HRSA) use their name-based HIV case counts to determine CARE Act formula funding for fiscal year 2009. The remaining 12 grantees had HRSA use their code-based HIV case counts to determine fiscal year 2009 CARE Act funding. If the exemption permitting code-based reporting is not extended, it is likely that future fiscal year funding will be based exclusively on name-based counts. Any Part B grantees who currently have name-based HIV reporting systems, but that had not been collecting name-based HIV case counts long enough to include all cases, could face a reduction in fiscal year 2010 funding.

Part A hold-harmless funding was more widely distributed among eligible metropolitan areas (EMA) in fiscal year 2009 than in fiscal year 2004, the last year for which we reported this information. Seventy-one percent of EMAs received hold-harmless funding in fiscal year 2009, whereas 41 percent received hold-harmless funding in fiscal year 2004. In fiscal year 2009, $24,836,500 in hold-harmless funding was distributed compared to $8,033,563 in fiscal year 2004. However, the range of CARE Act hold-harmless funding among EMAs, as measured by funding per case, was smaller in 2009 than in 2004. In fiscal year 2009, EMAs received from $0 to $208 in hold-harmless funding per case. In fiscal year 2004, EMAs received between $0 and $1,020 in hold-harmless funding per case. The hold-harmless funding resulted in EMAs receiving formula funding ranging from $645 to $854 per case in fiscal year 2009 and from $1,221 to $2,241 per case in fiscal year 2004.

Sixteen Part B grantees had reductions in their grant year 2009 funding due to their unobligated balances at the end of grant year 2007. Part B base grant penalties ranged from $6,433 in Palau to $1,493,935 in Ohio. ADAP base grant penalties ranged from $26,233 in Maine to $12,670,248 in Pennsylvania. Part B grantees with unobligated funds provided various reasons for these balances, and said that some of these reasons were beyond their control. Grantees and HRSA stated that a requirement to spend drug rebate funds before obligating federal funds makes it more difficult to avoid unobligated balances. Twenty-seven ADAPs 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. HRSA sought to address the interaction between drug rebate funds and the RWTMA unobligated balance provisions by requesting from the Department of Health and Human Services (HHS) permission to seek an exemption for grantees from the relevant regulations from the Office of Management and Budget. However, HHS denied this request, stating that the justification HRSA presented for requesting the exemption was "not compelling."

HHS provided technical comments on a draft of this report, which GAO incorporated as appropriate.

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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
EMA	eligible metropolitan area
FSR	Financial Status Report
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
HRSA	Health Resources and Services Administration
OIG	Office of Inspector General
RWTMA	Ryan White HIV/AIDS Treatment Modernization Act of 2006
TGA	transitional grant area

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United States Government Accountability Office
Washington, DC 20548

September 18, 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 then, 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] CDC estimates HIV/AIDS case counts based on information it receives from states, the District of Columbia, and the U.S. territories and associated jurisdictions.

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

[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.

Act programs provide assistance to over 530,000 mostly low-income, underinsured, or uninsured individuals living with HIV/AIDS. Under the CARE Act, approximately $2.2 billion in grants were made 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, including grants for jurisdictions through Part A and Part B.[5] 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.[6] Most CARE Act funding is distributed either as base or supplemental grants. Base grants are distributed by formula.[7] Supplemental grants are generally awarded through a competitive process based on the demonstration of severe need and other criteria. Base grants for EMAs, but not TGAs, are protected by a hold-harmless provision that protects grantees' funding at specified levels. Base grants for EMAs are distributed among grantees according to each grantee's share of HIV/AIDS cases among all EMAs resulting in equal funding per case for all grantees. After the preliminary funding level for an EMA is calculated based on its

[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]Title XXVI of the Public Service Act contains several parts which provide for grants for various HIV/AIDS-related services. In addition to Parts A and B, the other primary sections of the CARE Act under which HRSA awards grants are Parts C, D, and F. 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 private nonprofit and public 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 (MAI) grants. Part E does not provide for funding for HIV/AIDS services but rather includes provisions to address various administrative functions.

[6]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.

[7]HRSA uses a grantee's share of living HIV/AIDS cases to determine the amount of base grants.

percentage of HIV/AIDS cases, the amount is compared to the funding levels guaranteed by the hold-harmless provision. If the preliminary funding level is less than the guaranteed amount, the base grant is increased to the guaranteed amount and results in funding not being distributed equally per case. The funds used to meet the EMA hold-harmless requirement are deducted from the funds that would otherwise be available to EMAs and TGAs as supplemental grants before these grants are awarded. Part B provides for grants to states, the District of Columbia, and U.S. territories and associated jurisdictions to improve quality, availability, and organization of HIV/AIDS services.

RWTMA required that, beginning in fiscal year 2007, CARE Act Part A and Part B formula funding be based on the number of living HIV and AIDS cases in a grantee's jurisdiction. Previously, formula funding was based solely on the number of living AIDS cases reported in that jurisdiction. CDC provides HRSA with the number of living name-based HIV/AIDS cases in each jurisdiction and HRSA uses these counts to determine CARE Act Part A and Part B formula funding.[8] While prior to RWTMA all grantees collected AIDS counts by name, not all grantees collected HIV counts by name. Instead, some collected HIV counts by code; that is, using a coded identifier. Code-based case counts are not accepted by CDC because CDC does not consider them to be accurate and reliable, primarily because they include duplicate case counts.[9] RWTMA required Part B grantees to report name-based HIV case counts to be used by HRSA when determining the amount of base grants.[10] However, RWTMA provided for a transition period from a code-based to a name-based system. States without an accurate and reliable name-based HIV reporting system are exempt from the name-based reporting requirement if they can show specified progress toward such reporting. RWTMA provided for such

[8]Individuals with HIV/AIDS are included in the case count of the jurisdiction where they are diagnosed. These case counts are not adjusted to remove individuals who no longer reside in the jurisdiction.

[9]Since 1999, CDC has advised that all states and territories and associated jurisdictions adopt name-based HIV reporting systems. In 2005, CDC strengthened this advice to a recommendation. CDC has noted that name-based systems are more cost-effective and achieve higher levels of accuracy and reliability than systems based on other types of identifiers.

[10]RWTMA also required that name-based HIV case counts be used for determining the amount of Part A base grants. Part A grantees' HIV case counts are included in the cases reported to CDC by Part B grantees, with the exception of New York City, which reports directly to CDC.

an exemption through 2009, the period for which it reauthorized CARE Act programs.[11]

Another change in RWTMA concerned 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.[12] RWTMA provided that base and supplemental grant funds 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.[13] These RWTMA unobligated balance provisions apply to base and supplemental grants under Parts A and B.[14]

As Congress prepares to reauthorize CARE Act programs, you asked us to examine how various elements of the law affect CARE Act awards. In this report, we provide information on (1) how many Part B grantees had HRSA use their name-based HIV case counts to determine fiscal year 2009 CARE Act formula funding and how many Part B grantees are collecting name-based HIV case counts in their reporting systems; (2) the distribution of CARE Act hold-harmless funding among EMAs and the extent of funding differences per case in EMAs in fiscal years 2009 and 2004 resulting from hold-harmless provisions; and (3) the reductions in Part A and Part B grantees' funding due to the RWTMA unobligated balance provisions based on grantees' unobligated balances at the end of grant year 2007.

[11]RWTMA provided for a similar transition period for EMAs and TGAs.

[12]In this report, we use the term obligate to refer to funds that have been committed for a specific purpose and will require payment during the same or a future period. Unobligated refers to funds that have not been committed.

[13]RWTMA permits a Part A or Part B grantee to request a waiver from HRSA to allow the grantee to carry forward and use for a period of 1 year all (or a portion) of any unobligated balance from their base grant.

[14]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).

To examine how many Part B grantees had HRSA use their name-based HIV case counts to determine fiscal year 2009 CARE Act formula funding and how many Part B grantees are collecting name-based HIV case counts in their reporting systems, we obtained and reviewed data from CDC and HRSA on the number of Part B grantees that have such systems and the dates they began collecting name-based HIV case counts. We also obtained data from CDC and HRSA on which grantees had name-based HIV reporting systems used to generate the case counts for determining CARE Act formula funding. We reviewed published information on HIV reporting systems. We also reviewed descriptions of steps CDC and HRSA are taking to help grantees convert to a name-based reporting system. We interviewed CDC and HRSA officials knowledgeable about the data reporting practices of grantees and the use of these data for CARE Act funding. We also interviewed officials from the National Alliance of State and Territorial AIDS Directors, the Kaiser Family Foundation, and other organizations.

To examine the distribution of CARE Act Part A hold-harmless funding among EMAs and determine the extent of formula funding differences per case in fiscal years 2009 and 2004 resulting from hold-harmless provisions, we obtained and reviewed data from HRSA on Part A grants for fiscal year 2009. We reviewed the amount of funding distributed to each EMA based on its share of HIV/AIDS cases, amount of hold-harmless funding for each EMA, and HIV/AIDS case counts used by HRSA to determine fiscal year 2009 funding. We compared the funding per HIV/AIDS case received by each EMA to determine whether funding departs from equal funding per case. We also determined the effect of the hold-harmless provision on each EMA by comparing funding with the hold-harmless provision in place to what it would be without the hold-harmless provision in place. To determine how the distribution of hold-harmless funding and funding differences per case have changed over time, we compared EMAs' funding for fiscal year 2009 to fiscal year 2004 funding. We chose fiscal year 2004 because we reported on 2004 in an earlier study and because it preceded RWTMA in 2006.[15] We interviewed HRSA officials knowledgeable about Part A grants and the funding formula. We reviewed the data and asked HRSA officials follow-up questions about the hold-harmless provision and funding calculations, and determined that the data were sufficiently reliable for our purposes.

[15]See GAO, *HIV/AIDS: Changes Needed to Improve the Distribution of Ryan White CARE Act and Housing Funds*, GAO-06-332 (Washington, D.C.: Feb. 28, 2006), 31-35.

To determine the reductions in Part A and Part B grantees' funding due to the RWTMA unobligated balance provisions, we reviewed HRSA documentation on grantees' unobligated balances at the end of the 2007 grant year. We also reviewed the effect of these 2007 balances on grantees' funding for fiscal year 2009. We interviewed HRSA officials and others knowledgeable about the unobligated balance provisions. We also interviewed 6 Part A grantees and 13 Part B grantees, which we chose based on their geographic location, number of HIV/AIDS cases, whether the grantee had an unobligated balance over 2 percent at the end of the 2007 grant year, and how the grantee purchases drugs for its clients with HIV/AIDS.[16] We reviewed the data provided by HRSA and asked follow-up questions related to the calculation of unobligated balances, and determined that the data were sufficiently reliable for our purposes.

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

CARE Act base grants are distributed through a formula that includes HIV/AIDS case counts. Through its HIV/AIDS surveillance system, CDC receives case counts from states, the District of Columbia, and U.S. territories and associated jurisdictions.[17] CDC provides these case counts to HRSA so that HRSA may determine CARE Act formula grant amounts. In fiscal year 2009, HRSA distributed approximately $410 million by formula under Part A of the CARE Act and about $1.1 billion by formula under Part B.

Fifty-six metropolitan areas received Part A funds in fiscal year 2009. Twenty-four of the metropolitan areas were classified by HRSA as EMAs

[16]We interviewed the following Part A grantees: Houston, TX; Indianapolis, IN; Memphis, TN; New York, NY; Phoenix, AZ; and Sacramento, CA. We also interviewed the following Part B grantees: Arizona, California, Delaware, Florida, Hawaii, Missouri, Nebraska, North Carolina, Ohio, Pennsylvania, Rhode Island, and Washington.

[17]Surveillance is an ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event. CDC's HIV/AIDS surveillance system observes, records, and disseminates reports about cases of HIV and AIDS.

and 32 as TGAs.[18] For fiscal years 2008 and 2009, the hold-harmless provision provided that an EMA receive at least 100 percent of the amount it had received as its base grant, including hold harmless funding, for fiscal year 2007.[19]

Part B of the CARE Act provides funds to all 50 states, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the U.S. Virgin Islands, and 5 other territories and associated jurisdictions.[20] Part B grants include grants for HIV/AIDS services that are awarded by formula, AIDS Drug Assistance Program (ADAP) grants that are awarded by formula,[21] emerging community grants that are awarded by formula for HIV/AIDS services,[22] Part B supplemental grants for HIV/AIDS services, and ADAP supplemental grants. RWTMA contained a hold-harmless provision that protects funding for Part B base grants and ADAP base grants. For fiscal years 2008 and 2009, a grantee's total Part B base and ADAP base grants would be at least 100 percent of the total of such grants in fiscal year 2007.

One condition of an ADAP grant is that grantees use every means at their disposal to secure the best price available for all products on their formularies. Best prices are determined by the prices that can be obtained

[18]Two EMAs, Nassau-Suffolk and New Haven, were classified as TGAs by HRSA after the enactment of RWTMA. As a result, Nassau-Suffolk petitioned a federal district court to prevent HRSA from changing its status from EMA to TGA. The request for a preliminary injunction to this effect was denied by the district court. On appeal, the U.S. Court of Appeals for the Second Circuit reversed, finding that Nassau-Suffolk had established a likelihood of success on the merits. *County of Nassau v. Leavitt*, 524 F.3d 408 (2d Cir. 2008). In anticipation of another possible claim, HRSA elected to reclassify New Haven as an EMA because New Haven is also located within the geographic boundaries of the Second Circuit. Nassau-Suffolk's claim with respect to fiscal years 2007 and 2008 is still pending.

[19]There were also hold-harmless provisions in the 1996 and 2000 reauthorizations of CARE Act programs.

[20]The five other grantees are American Samoa, the Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, Palau, and the Republic of the Marshall Islands.

[21]ADAPs provide medications for the treatment of HIV disease. 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.

[22]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.

under the 340B drug pricing program.[23] Generally, an ADAP purchasing drugs through the 340B program can use a direct purchasing option or rebate option. Under the 340B direct purchase option, ADAPs purchase drugs from drug manufacturers or through a third-party such as a drug purchasing agent. Using the 340B direct purchase option, ADAPs receive the 340B price discount up front. Under the rebate option, ADAPs typically contract with entities such as a pharmacy network or pharmacy benefits manager for purchase of covered drugs. ADAPs later request a rebate consistent with the section 340B price from the drug manufacturers.

Due to RWTMA's requirement that CARE Act formula funding be determined by using name-based HIV/AIDS counts, grantees collecting HIV case counts by code must transition to such a reporting system. Although all grantees had name-based AIDS reporting systems, at the time of RWTMA seven grantees still used code-based HIV reporting systems, while 17 others had recently transitioned to a name-based HIV reporting system.[24] It can take several years to transition to a name-based system because grantees must identify by name each case originally reported by code and then enter each case into the new, name-based reporting system. During the transition period from a code-based to a name-based system, a grantee can report its code-based HIV counts directly to HRSA and have these counts used to determine funding for fiscal years 2007 through 2009. However, in accordance with RWTMA, for each grantee relying on a code-based system, HRSA made a 5 percent reduction in the number of living

[23]Under section 340B of the Public Health Service Act (42 U.S.C. § 256b), drug manufacturers provide discounts on certain outpatient drugs to covered entities including community health centers, hemophilia treatment centers, and HIV early intervention projects; a 340B price, sometimes referred to as a 340B ceiling price, is established for each covered drug that these entities purchase. ADAPs are allowed to purchase drugs through the section 340B program and are required to submit quarterly HIV/AIDS drug pricing reports to HRSA that indicate what they pay for drugs. However, an ADAP's participation in the 340B program is voluntary—they may choose, for example, to negotiate drug prices themselves with drug companies.

[24]RWTMA identified 35 Part B grantees, of 59 total, that had name-based HIV reporting systems in place that could be used to determine CARE Act formula funding on the grounds that they had systems in place, as of December 31, 2005, that provided sufficiently accurate and reliable reporting of cases. The 35 grantees were: Alabama, Alaska, Arizona, Arkansas, Colorado, Florida, Idaho, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, West Virginia, Wisconsin, Wyoming, Guam, and the U.S. Virgin Islands. It also provided for the recognition of additional grantees with name-based reporting systems determined to provide accurate and reliable reporting.

HIV cases to adjust for potential duplicate reporting in systems that collect code-based case counts, thus reducing the award. RWTMA allowed the use of code-based HIV case counts through fiscal year 2009; it also provided that the status of a grantee under RWTMA for purposes of the transition period may not be considered after fiscal year 2009. Grantees that are transitioning to a name-based HIV reporting system determine when their name-based counts will be used by HRSA to calculate CARE Act formula funding. If the exemption permitting code-based reporting is not extended, it is likely that future fiscal year funding will be based exclusively on name-based counts. A grantee that had not completed the transition from code- to name-based case counts could face a reduction in funding because its name-based HIV reporting system could contain fewer cases than its code-based system.[25]

Once a grantee has transitioned to a name-based HIV reporting system, its system must be determined to be operational, as well as accurate and reliable, in order for a grantee's name-based case counts to be used for funding purposes. To be operational, CDC, in consultation with the grantee's HIV/AIDS surveillance program and epidemiologist, considers several factors, such as the grantee's process for ensuring HIV-positive individuals are only counted once and the number of providers and laboratories within the grantee's jurisdiction diagnosing and reporting HIV positive diagnoses to the grantee.[26] The date CDC allows grantees to report name-based HIV cases to it is considered the date the reporting system becomes operational. Once the name-based HIV reporting system is declared operational, a grantee can determine that its reporting system is accurate and reliable (i.e., its case counts are complete), and can elect to have CDC send HRSA its name-based case counts to determine CARE Act formula funding. A grantee may declare its system to be accurate and

[25]There is a time lag between when HIV/AIDS cases are reported and when they are used for determining CARE Act funding. For example, funds distributed in fiscal year 2010 will be based on case counts collected through December 2008.

[26]A reporting system being "operational" is not the same as a reporting system being "mature." CDC requires that a grantee's name-based reporting system be mature before the grantee's data can be included in CDC's national HIV estimates. Four full years are required for a reporting system to be considered mature so that CDC can adjust the case counts to take reporting delays into consideration. In CDC's 2007 HIV/AIDS Surveillance Report, CDC used only the name-based HIV case counts from 34 states and 5 U.S. territories and associated jurisdictions in its national estimates. Name-based HIV reporting had been in place in these jurisdictions since at least the end of 2003. See Centers for Disease Control and Prevention, *HIV/AIDS Surveillance Report, 2007*, Vol. 19. (Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention; 2009).

reliable anytime after the system has been determined to be operational. However, regardless of the grantee's assessment, CDC considers a HIV reporting system to be accurate and reliable no later than 4 years after the grantee began collecting name-based HIV case counts. After a grantee determines that its system is accurate and reliable, or after the 4-year period, CDC transmits the HIV case counts to HRSA to be used in the funding formulas.

RWTMA required HRSA to cancel funds from grantees' awards that are unobligated at the end of the grant year, recover funds that had been disbursed, and redistribute these funds to other grantees. These unobligated balance provisions apply to base and supplemental grant awards under Parts A and B. For 2007 grants, HRSA required grantees to estimate and report their unobligated balance to HRSA 60 days prior to the end of the grant year. Grantees were also required to submit a Financial Status Report (FSR) to HRSA 90 days after the grant year ends. Grantees must report their actual unobligated balance on the FSR and the unobligated balance can be updated by the grantee for up to 6 months after the FSR is due.[27] Unobligated balances of grant awards are canceled (with disbursed funds recovered) and then redistributed to grantees who apply for them as additional amounts for supplemental grants under Part A and Part B in the next fiscal year after the unobligated funds were reported.

For base grant funds, the impact of unobligated balances differs based on whether the unobligated amount is more than 2 percent of the grant. All unobligated base grant funds must be canceled and recovered by HRSA if the grantee has not been granted a carryover waiver.[28] HRSA takes this step following receipt of the FSR. In addition to having unobligated funds canceled and recovered unless a carryover waiver is granted, grantees with unobligated Part A, Part B, and ADAP base grant funds in excess of 2 percent of the grant award incur a penalty—a corresponding reduction in grant funds for the first fiscal year beginning after the fiscal year in

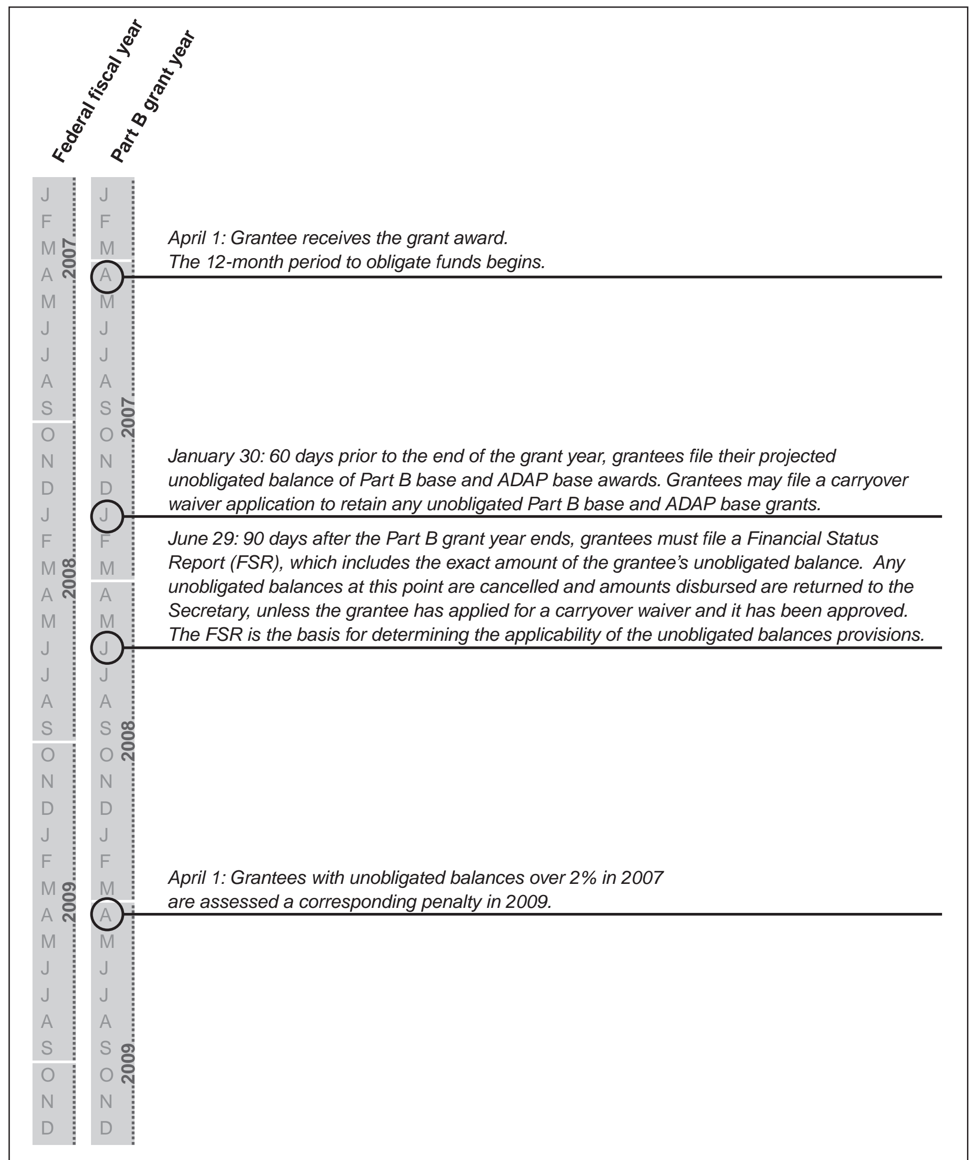
[27]A grantee may request an extension in writing if it is unable to close a grant account within the 90-day period, but the extension cannot exceed 6 months.

[28]Unobligated base grant funds awarded under Parts A and B are available for expenditure by the grantee for a 1-year period, beginning at the end of the grant year with HRSA approval of a carryover waiver. For 2007 grants, HRSA required carryover waivers to be requested 60 days before the end of the grant year. If funds are not expended at the end of the 1-year waiver period, the funds will be canceled, recovered and redistributed to Part A and B grantees as supplemental awards. Grantees cannot carryover supplemental funds.

which the Secretary receives the FSR.[29] Grantees are assessed the reduction even if they were granted a waiver. Because FSRs are submitted 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 1 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 3 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. Figure 1 shows such a time line for 2007 Part B grant distribution and the unobligated balance provisions.

[29]The amount of the reduction corresponds to the amount of the grantee's unobligated balance. RWTMA provides for the reduction in funding for the first fiscal year beginning after the fiscal year in which the Secretary obtains the information necessary for determining that the balance was unobligated at the end of the grant year.

Figure 1: Time Line for 2007 Part B Grants and Unobligated Balance Provisions



Source: GAO analysis of HRSA guidance.

In addition, grantees with unobligated balances of greater than 2 percent of Part A or Part B base grants are ineligible to receive supplemental grants for the year in which the reduction takes place. For Part A grantees this means that they are not eligible to receive Part A supplemental grants. For Part B base grantees this results in ineligibility to receive 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 is based on a grantee not obligating at least 75 percent of its entire Part B grant award within 120 days.[30] Table 1 lists the triggers and penalties for the unobligated balance provisions.

Table 1: RWTMA Unobligated Balance Provision Triggers and Penalties as Applied by HRSA

RWTMA Part	Trigger	Unobligated balance penalty
Part A Base Grant	Grantee reports unobligated balance of greater than 2 percent of base grant on the FSR, which is due 90 days after conclusion of the grant year.	1. Reduction in base grant equal to the amount of the unobligated balance. 2. Ineligibility for Part A supplemental award.
Part B Base and ADAP Base Grant	Grantee reports unobligated balance of greater than 2 percent of total Part B base and ADAP base grant funding on the FSR, which is due 90 days after conclusion of the grant year.	1. Reduction in base grants equal to the amount of the unobligated balance (with reductions from Part B base and ADAP base grants as applicable). 2. Ineligibility for Part B supplemental award.

Source: GAO analysis of HRSA guidance.

Note: Although there were unobligated balances for grant year 2007, the penalties were applied to the 2009 grants because HRSA does not require grantees' FSRs until 90 days after the grant year has ended, at which time the grants for 2008 had already been awarded.

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 as supplemental grants. States had 150 days to meet this requirement in the first year of the program and have had 120 days in all 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.

[30]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 as supplemental grants. States had 150 days to meet this requirement in the first year of the program and have had 120 days in all 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.

Not All Grantees Had HRSA Use Their Name-Based HIV Case Counts for Fiscal Year 2009 Formula Funding, but Most Part B Grantees Are Collecting Name-Based HIV Case Counts in Their Reporting Systems

Most Part B grantees were collecting name-based HIV case counts in their reporting systems as of December 31, 2007, but not all grantees had HRSA use these case counts to determine fiscal year 2009 CARE Act funding.[31] For 47 of the 59 Part B grantees, HRSA used name-based HIV case counts, as provided by CDC, to determine CARE Act funding. The remaining 12 grantees had HRSA use their code-based HIV case counts to determine fiscal year 2009 CARE Act funding. Seven of the 12 grantees—California, the District of Columbia, Illinois, Maryland, Massachusetts, Oregon, and Rhode Island—were collecting name-based HIV case counts as of December 31, 2007, but submitted their code-based case counts to HRSA to determine CARE Act funding.[32] Five of the 12 grantees—Hawaii, Vermont, the Federated States of Micronesia, Palau, and the Republic of the Marshall Islands—were not collecting name-based case counts as of December 31, 2007.[33] Table 2 lists the 12 grantees for which code-based HIV case counts were used for fiscal year 2009 CARE Act formula funding, and the month and year that they began collecting name-based case counts. Each of these 12 grantees could require 4 years from the date they began collecting name-based HIV case counts for their name-based HIV reporting systems to be considered accurate and reliable. However, grantees can determine that their reporting systems are accurate and reliable in less than 4 years.[34]

[31]Fiscal year 2009 CARE Act formula funding is based on case counts as of December 31, 2007.

[32]Six of the seven grantees—California, the District of Columbia, Illinois, Massachusetts, Oregon, and Rhode Island—could have had HRSA use their name-based HIV case counts to determine CARE Act funding but instead had HRSA use their code-based counts. The seventh grantee—Maryland—was collecting name-based HIV case counts as of December 31, 2007, but their name-based HIV reporting system had not been determined to be operational; therefore, Maryland was not yet reporting name-based case counts to CDC and did not have the option to have HRSA use its name-based case counts.

[33]Hawaii and Vermont transitioned to a name-based HIV reporting system in 2008.

[34]Eight grantees—Connecticut, Delaware, Kentucky, Maine, Montana, New Hampshire, Pennsylvania, and Washington—with systems less than 4 years old determined that their name-based HIV reporting systems were accurate and reliable such that case counts from these systems were used by HRSA to determine fiscal year 2009 CARE Act funding.

Table 2: Grantees That Had HRSA Use Code-Based HIV Case Counts to Determine CARE Act Formula Funding, Fiscal Year 2009

Part B grantee	Month and year grantee began collecting name-based HIV case counts
California	April 2006
District of Columbia	November 2006
Hawaii	March 2008
Illinois	January 2006
Maryland	April 2007
Massachusetts	January 2007
Oregon	April 2006
Rhode Island	July 2006
Vermont	April 2008
Federated States of Micronesia	NA
Palau	NA
Republic of the Marshall Islands	NA

Source: CDC.

Note: The Federated States of Micronesia, Palau, and the Republic of the Marshall Islands are not currently collecting HIV cases by name. If the exemption permitting code-based reporting is not extended, it is likely that future fiscal year funding will be based exclusively on name-based counts. Consequently, the Federated States of Micronesia, Palau, and the Republic of the Marshall Islands' fiscal year 2010 base funding would be based solely on their AIDS case counts.

Although 56 of the 59 Part B grantees are currently collecting name-based HIV case counts,[35] some grantees could face a reduction in fiscal year 2010 funding if HRSA uses these counts to determine fiscal year 2010 funding. RWTMA allows grantees to submit code-based case counts to HRSA to determine funding for fiscal years 2007 through 2009; without an extension as part of the upcoming reauthorization, it is likely that HRSA would determine CARE Act funding for fiscal year 2010 using name-based case counts collected through December 2008. However, this could be problematic for some grantees. For example, as of December 2008, Vermont had only been collecting name-based case counts for 8 months. If Vermont's system is not considered to be accurate and reliable—which could take up to 4 years—but its December 2008 name-based case count is nevertheless used to determine fiscal year 2010 funding, Vermont may not actually receive funding commensurate with the number of HIV/AIDS

[35]The Federated States of Micronesia, Palau, and the Republic of the Marshall Islands have not begun collecting name-based HIV case counts.

cases in the state, which is the intended basis for the formula grant. Further, its funding may be a reduction from what it received for fiscal year 2009.

CDC has provided assistance for grantees transitioning from a code-based to a name-based HIV reporting system. CDC has provided grantees with technical assistance materials, ongoing assistance via conference calls, and additional assistance upon request. According to CDC, the District of Columbia and Massachusetts were the only Part B grantees that requested additional assistance in transitioning to a name-based system. CDC and HRSA plan to meet with grantee officials from the Federated States of Micronesia, Palau, and the Republic of the Marshall Islands to discuss HIV reporting.

Hold-Harmless Funding Was More Widely Distributed among EMAs in Fiscal Year 2009 Than in Fiscal Year 2004, but the Range of Funding Differences per Case Decreased

Part A hold-harmless funding was more widely distributed among EMAs in fiscal year 2009 than in fiscal year 2004. A larger percentage of EMAs qualified for hold-harmless funding in fiscal year 2009 than in fiscal year 2004, the last year for which we reported this information.[36] About 71 percent of EMAs received hold-harmless funding in fiscal year 2009, while 41 percent received hold-harmless funding in fiscal year 2004.[37] Furthermore, the percentage of the total hold-harmless funding received by the EMA with the most hold-harmless funding was smaller in fiscal year 2009 than in fiscal year 2004. In fiscal year 2009, New York received 52.7 percent of the hold-harmless funding, while in fiscal year 2004, San Francisco received 91.6 percent of the hold-harmless funding. In addition to hold-harmless funding being more widely distributed in fiscal year 2009 than in fiscal year 2004, the total amount of hold-harmless funding provided to EMAs was larger in fiscal year 2009 than in fiscal year 2004. In fiscal year 2009, $24,836,500 in hold-harmless funding was distributed

[36]GAO-06-332.

[37]In fiscal year 2009, 17 of the 24 EMAs received hold-harmless funding. In fiscal year 2004, 21 of the 51 EMAs received hold-harmless funding. Prior to RWTMA, all metropolitan areas that received Part A funding were classified as EMAs. RWTMA created a new category of metropolitan areas called TGAs. As a result, the number of EMAs was reduced from 51 to 24. The other EMAs were reclassified as TGAs. TGAs are not eligible for hold-harmless funding.

compared to $8,033,563 in fiscal year 2004.[38] Table 3 lists the EMAs and their base grant and hold-harmless funding in fiscal years 2009 and 2004.

Table 3: EMA Base Grant and Hold-Harmless Funding, Fiscal Years 2009 and 2004

EMA	Base grant (including hold-harmless funding), FY 2009[a]	Hold-harmless funding, FY 2009	Percent of hold-harmless funding, FY 2009	Base grant (including hold-harmless funding), FY 2004	Hold-harmless funding, FY 2004	Percent of hold-harmless funding, FY 2004
New York, N.Y.	$74,871,159	$13,098,284	52.7%	$60,276,790	$0	0%
Los Angeles, Calif.	24,264,522	0	0	18,540,316	0	0
Washington, D.C.	18,764,167	0	0	14,431,645	0	0
Chicago, Ill.	17,524,988	0	0	12,801,123	0	0
Miami, Fla.	16,015,311	587,606	2.4	12,806,009	0	0
Philadelphia, Pa.	14,921,528	268,926	1.1	12,038,992	0	0
San Francisco, Calif.	14,672,553	3,571,649	14.4	16,171,607	7,358,239	91.6
Baltimore, Md.	13,826,195	0	0	10,195,952	0	0
Houston, Tex.	12,781,667	592,067	2.4	9,416,722	0	0
Atlanta, Ga.	12,224,515	697,534	2.8	9,268,937	0	0
San Juan, P.R.	9,415,738	2,271,091	9.1	8,139,880	41,011	0.5
Dallas, Tex.	9,654,841	0	0	6,425,600	0	0
Ft. Lauderdale, Fla.	9,444,694	100,799	0.4	7,330,631	0	0
Boston, Mass.	9,091,554	30,093	0.1	7,434,884	60,284	0.8
Newark, N.J.	9,090,344	747,165	3.0	8,151,371	10,975	0.1
San Diego, Calif.	7,463,078	0	0	5,201,792	0	0
Tampa-St. Petersburg, Fla.	6,330,428	357,808	1.4	4,777,696	44,908	0.6
West Palm Beach, Fla.	5,769,721	989,815	4.0	4,577,648	8,523	0.1
Detroit, Mich.	5,649,097	103,139	0.4	4,382,256	0	0
Orlando, Fla.	5,503,874	7,048	0	4,021,954	0	0
Phoenix, Ariz.	5,367,535	0	0	3,480,889	0	0
New Orleans, La.	4,944,359	158,635	0.6	3,852,184	0	0

[38]Total Part A base and supplemental funding were also larger in 2009 than in 2004. In fiscal year 2009, Part A grantees received $590,290,260 in base and supplemental funding, while in 2004 they received $552,083,998. However, even with this increased funding, hold-harmless funding was still a larger percentage of total funding in fiscal year 2009 than in fiscal year 2004. In fiscal year 2009, hold harmless was 4.2 percent of total Part A base and supplemental funding, while it was 1.5 percent in fiscal year 2004. We did not include Minority AIDS Initiative funding in the calculations of the total funding because fiscal year 2009 Minority AIDS Initiative grants were not available at the time of our analysis.

EMA	Base grant (including hold-harmless funding), FY 2009[a]	Hold-harmless funding, FY 2009	Percent of hold-harmless funding, FY 2009	Base grant (including hold-harmless funding), FY 2004	Hold-harmless funding, FY 2004	Percent of hold-harmless funding, FY 2004
New Haven, Conn.[b]	4,604,295	717,147	2.9	3,639,492	42,573	0.5
Nassau-Suffolk, N.Y.[b]	4,091,917	537,694	2.2	3,182,104	21,212	0.3
Metropolitan areas that were EMAs in FY 2004 but not in FY 2009	NA	NA	NA	55,158,431	445,838	5.5
Total[c]	**$316,288,080**	**$24,836,500**	**100%**	**$305,704,561**	**$8,033,563**	**100%**

Source: GAO analysis of HRSA data.

Note: In fiscal year 2009, an EMA's base funding was determined according to its proportion of living HIV/AIDS cases. If an EMA qualified for hold-harmless funding, that amount was added to the base funding and distributed together as the base grant.

In fiscal year 2004, an EMA's base funding was determined according to its proportion of estimated living AIDS cases, not its proportion of living HIV/AIDS cases. If an EMA qualified for hold-harmless funding, that amount was added to the base funding and distributed together as the base grant.

[a]Funding amounts for fiscal year 2009 base grants do not include funding that resulted from the stop-loss provision contained in the Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, div. F, title II, 123 Stat. 524, 763-64. For more information on stop loss, see GAO, *Ryan White CARE Act: Estimated Effect of Proposed Stop-Loss Provision on Urban Areas*, GAO-09-472R (Washington, D.C.: March 6, 2009).

[b]Two EMAs, Nassau-Suffolk and New Haven, were classified as TGAs by HRSA after the enactment of RWTMA. As a result, Nassau-Suffolk petitioned a federal district court to prevent HRSA from changing its status from EMA to TGA. The request for a preliminary injunction to this effect was denied by the district court. On appeal, the U.S. Court of Appeals for the Second Circuit reversed, finding that Nassau-Suffolk had established a likelihood of success on the merits. *County of Nassau v. Leavitt*, 524 F.3d 408 (2d Cir. 2008). In anticipation of another possible claim, HRSA elected to reclassify New Haven as an EMA because New Haven is also located within the geographic boundaries of the Second Circuit. Nassau-Suffolk's claim with respect to fiscal years 2007 and 2008 is still pending.

[c]Individual entries do not sum to total because of rounding.

The range of CARE Act funding differences among EMAs, as measured by funding per case, was smaller in 2009 than in 2004. In fiscal year 2009, EMA base funding per case ranged from $645 to $854, a range of $209. In fiscal year 2004, the funding per case ranged from $1,221 to $2,241, a range of $1,020. The smaller funding range resulted from San Francisco receiving less hold-harmless funding in fiscal year 2009 than in fiscal year 2004. In both years, San Francisco received the most hold-harmless funding per case. However, in fiscal year 2009, San Francisco received $208 in hold-harmless funding per case,[39] while in fiscal year 2004 it received $1,020 in

[39]The $1 difference in the range in fiscal year 2009 base funding per case ($209) and the range in hold-harmless funding per case ($208) is attributable to rounding error.

hold-harmless funding per case.[40] Table 4 lists the 24 EMAs and their base grant and hold-harmless funding per case in fiscal years 2009 and 2004.

Table 4: EMA Base Grant and Hold-Harmless Funding per Case, Fiscal Years 2009 and 2004

EMA	Base grant (including hold-harmless funding) per HIV/AIDS case, FY 2009[a]	Hold-harmless funding per HIV/AIDS case, FY 2009[b]	Base grant (including hold-harmless funding) per AIDS case, FY 2004[c]	Hold-harmless funding per AIDS case, FY 2004[d]
San Francisco, Calif.	$854	$208	$2,241	$1,020
San Juan, P.R.	852	205	1,228	6
New York, N.Y.	784	137	1,221	0
West Palm Beach, Fla.	780	134	1,224	2
New Haven, Conn.[e]	766	119	1,236	14
Nassau-Suffolk, N.Y.[e]	744	98	1,230	8
Newark, N.J.	704	58	1,223	2
Atlanta, Ga.	686	39	1,221	0
Tampa-St. Petersburg, Fla.	685	39	1,233	12
Houston, Tex.	678	31	1,221	0
Miami, Fla.	671	25	1,221	0
New Orleans, La.	668	21	1,221	0
Philadelphia, Pa.	658	12	1,221	0
Detroit, Mich.	658	12	1,221	0
Ft. Lauderdale, Fla.	653	7	1,221	0
Boston, Mass.	649	2	1,231	10
Orlando, Fla.	647	1	1,221	0
Baltimore, Md.	646	0	1,221	0
Chicago, Ill.	646	0	1,221	0
Dallas, Tex.	646	0	1,221	0
Los Angeles, Calif.	646	0	1,221	0
Phoenix, Ariz.	646	0	1,221	0
Washington, D.C.	646	0	1,221	0
San Diego, Calif.	645	0	1,221	0

Source: GAO analysis of HRSA data.

Note: This table lists only the 24 metropolitan areas that were EMAs in fiscal year 2009. In fiscal year 2004, there were a total of 51 EMAs, including the 24 listed here.

[40]Prior to RWTMA, formula funding was determined using the number of estimated living AIDS cases in a jurisdiction rather than the number of HIV/AIDS cases. For a description of how this estimate was calculated, see GAO-06-332, 5.

In fiscal year 2009, an EMA's base funding was determined according to its proportion of living HIV/AIDS cases. If an EMA qualified for hold-harmless funding, that amount was added to the base funding and distributed together as the base grant.

In fiscal year 2004, an EMA's base funding was determined according to its proportion of estimated living AIDS cases, not its proportion of living HIV/AIDS cases. If an EMA qualified for hold-harmless funding, that amount was added to the base funding and distributed together as the base grant.

[a]This amount was calculated by dividing the base grant, including any hold-harmless funding, received by each EMA by the number of living HIV/AIDS cases in the EMA.

[b]This amount was calculated by dividing the hold-harmless funding received by each EMA by the number of living HIV/AIDS cases in the EMA.

[c]This amount was calculated by dividing the base grant, including any hold-harmless funding, received by each EMA by the number of living AIDS cases in the EMA.

[d]This amount was calculated by dividing the hold-harmless funding received by each EMA by the number of living AIDS cases in the EMA.

[e]Two EMAs, Nassau-Suffolk and New Haven, were classified as TGAs by HRSA after the enactment of RWTMA. As a result, Nassau-Suffolk petitioned a federal district court to prevent HRSA from changing its status from EMA to TGA. The request for a preliminary injunction to this effect was denied by the district court. On appeal, the U.S. Court of Appeals for the Second Circuit reversed, finding that Nassau-Suffolk had established a likelihood of success on the merits. *County of Nassau v. Leavitt*, 524 F.3d 408 (2d Cir. 2008). In anticipation of another possible claim, HRSA elected to reclassify New Haven as an EMA because New Haven is also located within the geographic boundaries of the Second Circuit. Nassau-Suffolk's claim with respect to fiscal years 2007 and 2008 is still pending.

Hold-harmless funding accounted for a larger percentage of San Francisco's total base funding than it did for any other EMA in fiscal years 2009 and 2004, but the percentage was smaller in fiscal year 2009 than in fiscal year 2004. In fiscal year 2004, hold-harmless funding accounted for approximately 46 percent of San Francisco's base grant while in fiscal year 2009 hold-harmless funding accounted for approximately 24 percent of San Francisco's base grant. Table 5 lists the 24 EMAs and their hold-harmless funding as a percent of their base grants in fiscal years 2009 and 2004.

Table 5: Hold-Harmless Funding as a Percent of EMA's Base Grants in Fiscal Year 2009 and 2004

EMA	Hold-harmless as a percent of base grant, FY 2009	Hold-harmless as a percent of base grant, FY 2004
San Francisco, Calif.	24.3%	45.5%
San Juan, P.R.	24.1	0.5
New York, N.Y.	17.5	0.0
West Palm Beach, Fla.	17.2	0.2
New Haven, Conn.[a]	15.6	1.2
Nassau-Suffolk, N.Y.[a]	13.1	0.7
Newark, N.J.	8.2	0.1
Atlanta, Ga.	5.7	0.0
Tampa-St. Petersburg, Fla.	5.7	0.9
Houston, Tex.	4.6	0.0
Miami, Fla.	3.7	0.0
New Orleans, La.	3.2	0.0
Detroit, Mich.	1.8	0.0
Philadelphia, Pa.	1.8	0.0
Ft. Lauderdale, Fla.	1.1	0.0
Boston, Mass.	0.3	0.8
Orlando, Fla.	0.1	0.0
Baltimore, Md.	0.0	0.0
Chicago, Ill.	0.0	0.0
Dallas, Tex.	0.0	0.0
Los Angeles, Calif.	0.0	0.0
Phoenix, Ariz.	0.0	0.0
San Diego, Calif.	0.0	0.0
Washington, D.C.	0.0	0.0

Source: GAO analysis of HRSA data.

Note: This table lists only the 24 metropolitan areas that were EMAs in fiscal year 2009. In fiscal year 2004, there were a total of 51 EMAs, including the 24 listed here.

[a]Two EMAs, Nassau-Suffolk and New Haven, were classified as TGAs by HRSA after the enactment of RWTMA. As a result, Nassau-Suffolk petitioned a federal district court to prevent HRSA from changing its status from EMA to TGA. The request for a preliminary injunction to this effect was denied by the district court. On appeal, the U.S. Court of Appeals for the Second Circuit reversed, finding that Nassau-Suffolk had established a likelihood of success on the merits. *County of Nassau v. Leavitt*, 524 F.3d 408 (2d Cir. 2008). In anticipation of another possible claim, HRSA elected to reclassify New Haven as an EMA because New Haven is also located within the geographic boundaries of the Second Circuit. Nassau-Suffolk's claim with respect to fiscal years 2007 and 2008 is still pending.

In some cases, hold-harmless funding in fiscal year 2009 accounted for a significant portion of a grantee's Part A base funding. For example, San Francisco, which received the most hold-harmless funding per HIV/AIDS case in fiscal year 2009, received a total of $14,672,553 in base funding. Of this amount, $3,571,649 or 24.3 percent was due to the hold-harmless provision. Because of its hold-harmless funding, San Francisco, which had 17,173 HIV/AIDS cases, received a base grant equivalent to what an EMA with approximately 22,713 HIV/AIDS cases (32 percent more) would have received without hold-harmless funding.

A significant portion of the differences in funding per case between San Francisco and the other EMAs results from how the San Francisco case counts are determined. The San Francisco EMA continues to be the only metropolitan area whose formula funding is based on both living and deceased AIDS cases. In February 2006 and October 2007, we reported that the San Francisco EMA was the only EMA still receiving CARE Act formula funding based on the number of living and deceased cases in a metropolitan area.[41] All other EMAs received formula funding based on an estimate of the number of living cases. We showed that the fiscal year 2004 CARE Act formula funding for the San Francisco EMA was determined in part with reference to its fiscal year 1995 funding, which was based on both living and deceased AIDS cases. Because the San Francisco EMA also received hold-harmless funding in fiscal years 2005, 2006, 2007, and 2009, its fiscal year 2009 CARE Act formula funding continues to be based, in part, on the number of deceased cases in the San Francisco EMA as of 1995.[42] Hold-harmless funding for other EMAs does not trace back to 1995

[41]GAO-06-332, 34-35; and GAO, *Ryan White CARE Act: Impact of Legislative Funding Proposal on Urban Areas*, GAO-08-137R (Washington, D.C.: Oct. 5, 2007), 16.

[42]Fiscal year 2009 funding for the San Francisco EMA can be traced to its fiscal year 1995 funding due to the relationship between the amount it received in fiscal year 1995 and the amounts it was guaranteed by law to receive in fiscal years 2000, 2006, 2007, and 2009 due to the operation of the hold-harmless provisions. No other EMA was held harmless in all these years and, consequently, their funding cannot be linked back to 1995. In fiscal year 2000, the San Francisco EMA received 95 percent of the amount it received from its grant in fiscal year 1995. In fiscal year 2006, it received 85 percent of the amount it received from its grant in fiscal year 2000. In fiscal year 2007, it received 95 percent of the amount it received from its grant in fiscal year 2006. In fiscal year 2009, it received 100 percent of the amount it received in fiscal year 2007. Taken together, the hold-harmless provisions meant that in fiscal year 2009 the San Francisco EMA received approximately 76.7 percent of its fiscal year 1995 grant of $19,126,679, or $14,672,553. We calculated the guaranteed percentage by multiplying the hold-harmless amounts (95, 85, 95, and 100 percent) for each year together. For more discussion on how the hold-harmless provision operates and how it has affected funding for the San Francisco EMA, see GAO-06-332, 31-35.

or earlier, a period when CARE Act funding was based on cumulative counts of AIDS cases, both living and deceased.

If there had been no hold-harmless provision in fiscal year 2009, most grantees would have received more funding in fiscal year 2009 than they did. Seventeen of the 24 EMAs would have received more funding if there had been no hold-harmless provision and if the $24.8 million that was used for hold-harmless funding had instead been distributed across all EMAs as supplemental grants, that is, in the same proportions as the supplemental grants.[43] The funds used to meet the EMA hold-harmless requirement are deducted from the funds that would otherwise be available for supplemental grants before these grants are awarded. As a consequence, the pool of funds for supplemental grants is reduced by the amount of funding needed to meet the hold-harmless provision. Although 17 EMAs received hold-harmless funding in fiscal year 2009, only 7 (New York, San Francisco, San Juan, West Palm Beach, Newark, New Haven, and Nassau-Suffolk) received more funding because of the hold-harmless provision than they would have received through supplemental grants in the absence of the hold-harmless provision.

Sixteen Grantees Had Reductions in Their 2009 Grants Due to Their Unobligated Part B Balances at the End of Grant Year 2007

Sixteen Part B grantees received reduced funding in grant year 2009 because they had unobligated balances over 2 percent in grant year 2007. Grantees we interviewed provided reasons why it is difficult to obligate all but 2 percent of their grant award. Grantees and HRSA said that drug rebates complicate grantees' efforts to obligate grant funds.

[43]This analysis shows how the hold-harmless funding would have been distributed if it had been allocated as supplemental grants, that is, in the same proportions as the supplemental grant funding. For example, Houston received about 4.4 percent of the funds available for supplemental grants and, consequently, we allocated 4.4 percent of the $24,836,500 hold-harmless funding to Houston. It is not possible to determine the exact effect of the hold-harmless provision on the amount of supplemental funding for each EMA because it is not known how the funds would have been distributed in the absence of the hold-harmless awards.

Sixteen Part B Grantees Were Assessed Penalties Under the RWTMA Unobligated Balance Provisions Because They Had Unobligated Balances over 2 Percent

Nine states and seven territories and associated jurisdictions were assessed penalties in grant year 2009 because they had unobligated balances over 2 percent in grant year 2007. Arizona, Arkansas, Colorado, Delaware, Idaho, Maine, Nebraska, Ohio, and Pennsylvania were all assessed penalties along with seven of the U.S. territories and associated jurisdictions (American Samoa, Commonwealth of the Northern Mariana Islands, the Federated States of Micronesia, Guam, Palau, the Republic of Marshall Islands, and the U.S. Virgin Islands). Table 6 shows the Part B grant year 2007 unobligated balances. No Part A grantees had unobligated balances over 2 percent.

Table 6: Part B Grantees' Unobligated Balances in Grant Year 2007

Part B grantee	Total grant year 2007 Part B unobligated balance	Grant year 2007 Part B unobligated balance as a percentage of Part B base and ADAP base grants
Arizona	$1,065,435	7.9%
Arkansas	614,033	7.8
Colorado	1,099,874	8.2
Delaware	713,904	14.3
Idaho	41,018	3.7
Maine	33,971	2.4
Nebraska	285,982	12.0
Ohio	2,315,763	10.2
Pennsylvania	12,936,735	33.7
American Samoa	18,720	36.0
Commonwealth of the Northern Mariana Islands	10,319	19.1
Federated States of Micronesia	18,525	33.7
Guam	52,975	18.2
Palau	6,433	12.9
Republic of the Marshall Islands	27,998	52.9
U.S. Virgin Islands	435,798	38.1

Source: GAO analysis of HRSA data.

Note: Although unobligated balances were attributable to the 2007 grants, the reduction occurred in the 2009 Part B grants because HRSA does not require grantees' FSRs until 90 days after the grant year has ended, at which time the 2008 grants had already been awarded.

To establish if an unobligated balance penalty applied to a grantee's 2009 grant, HRSA summed the Part B base and ADAP base unobligated balances to determine if the total was more than 2 percent of the grantee's total award (Part B base and ADAP base) for grant year 2007. As the provisions were applied by HRSA, Part B grantees can incur a penalty in both their Part B base and ADAP base grants even if the unobligated balance for one of these grants is less than 2 percent as long as the sum of the Part B base and ADAP base balances is greater than 2 percent. HRSA assesses unobligated balance penalties based on the sum of the Part B base and ADAP base unobligated balances.[44] For example, in grant year 2007 Maine had an unobligated balance of more than 2 percent in its ADAP base grant but less than 2 percent in its Part B base grant. The total unobligated funding was 2.4 percent. Because the total was above 2 percent, HRSA reduced both the Part B base and ADAP base grants in grant year 2009.

While 16 Part B grantees incurred unobligated balance penalties, some incurred penalties in both their Part B base grants and ADAP base grants and others only had penalties in their Part B base grants because they did not have unobligated ADAP balances. In grant year 2009, six states and one territory were assessed penalties in both their Part B base and ADAP base grants. Because penalties apply to both base grants only when grantees have unobligated balances in both grants, three states and six territories and associated jurisdictions had penalties assessed only on their Part B base grants, because they did not have unobligated ADAP base balances. Part B base funding penalties ranged from $6,433 in Palau to $1,493,935 in Ohio. (See table 7.) ADAP base funding penalties ranged from $26,233 in Maine to $12,670,248 in Pennsylvania. (See table 8.) Pennsylvania's ADAP base grant penalty accounted for 84 percent of the total amount of penalties for unobligated ADAP funds levied on 2009 grants.

[44]If the unobligated balances were determined to be greater than 2 percent, HRSA subtracted the grant year 2007 Part B base unobligated balance amount from the 2009 Part B base award, and the grant year 2007 ADAP base unobligated balance amount from the 2009 ADAP base award. Some grantees did not incur penalties in their 2009 ADAP base award because they did not report grant year 2007 ADAP unobligated balances. HRSA applies unobligated balance penalties to both Part B base grants and ADAP base grants only when grantees have reported unobligated balances in both grants.

Table 7: Part B Base Grant Penalties in Grant Year 2009

	Grant Year 2009 Part B base grant			
Part B grantee	Preliminary grant year 2009 Part B base grant	Hold-harmless amount	Unobligated balance penalty	Final grant year 2009 Part B base grant
Arizona	$4,006,304	–	$325,240	$3,681,064
Arkansas	3,634,977	21,615	411,984	3,244,608
Colorado	3,666,928	166,716	734,240	3,099,404
Delaware	2,453,761	–	223,319	2,230,442
Idaho	532,766	–	41,018	491,748
Maine	762,807	–	7,738	755,069
Nebraska	1,169,371	–	285,982	883,389
Ohio	7,739,752	347,714	1,493,935	6,593,531
Pennsylvania	12,225,623	–	266,487	11,959,136
American Samoa	50,000	–	18,720	31,280
Commonwealth of the Northern Mariana Islands	50,000	–	10,319	39,681
Federated States of Micronesia	50,000	–	18,525	31,475
Guam	200,000	–	52,975	147,025
Palau	50,000	–	6,433	43,567
Republic of the Marshall Islands	50,000	–	27,998	22,002
U.S. Virgin Islands	500,000	–	308,201	191,799

Source: HRSA.

Note: Although unobligated balances were attributable to the 2007 grants, the reduction occurred in the 2009 Part B base grant because HRSA does not require grantees' FSRs until 90 days after the grant year has ended, at which time the 2008 grants had already been awarded.

In order to calculate the final Part B base and ADAP base grant awards, the penalty attributable to an unobligated balance is applied after other calculations are made, including hold harmless funding. If hold-harmless funds were added after the unobligated balance penalties were applied, hold-harmless funds would negate the effect of the unobligated balance penalties because they would increase funding. For example, Colorado had a preliminary 2009 Part B base grant award of $3,666,928. Under the hold-harmless provision in RWTMA, Colorado was guaranteed Part B base grant funding of $3,683,544. Application of the RWTMA unobligated balance provision reduced the amount of its Part B base grant award (after the addition of hold harmless funding) by $734,240, leaving Colorado with a final Part B base grant award of $3,099,404. In comparison, if hold-harmless funding had been added after the application of the unobligated

balance penalty, Colorado would have received $3,683,544, the same as if it had incurred no unobligated balance penalty.

Table 8: ADAP Base Grant Penalties in Grant Year 2009

	Grant year 2009 ADAP base grant			
ADAP grantee	Preliminary grant year 2009 ADAP base grant	Hold-harmless amount	Unobligated balance penalty	Final grant year 2009 ADAP base grant
Arizona	$10,398,958	–	$740,195	$9,658,763
Arkansas	4,376,738	–	202,049	4,174,689
Colorado	9,612,191	–	–	9,612,191
Delaware	2,870,482	441,676	490,585	2,821,573
Idaho	623,246	–	–	623,246
Maine	892,354	–	26,233	866,121
Nebraska	1,367,964	–	–	1,367,964
Ohio	14,627,126	–	821,828	13,805,298
Pennsylvania	29,011,307	–	12,670,248	16,341,059
American Samoa	2,803	–	–	2,803
Commonwealth of the Northern Mariana Islands	5,606	–	–	5,606
Federated States of Micronesia	7,475	–	–	7,475
Guam	84,096	6,988	–	91,084
Palau	–	–	–	–
Republic of the Marshall Islands	934	2,034	–	2,968
U.S. Virgin Islands	532,609	112,668	127,597	517,680

Source: HRSA.

Note: Although unobligated balances were attributable to the 2007 grants, the reduction occurred in the 2009 ADAP base grant because HRSA does not require grantees' FSRs until 90 days after the grant year has ended, at which time the 2008 grants had already been awarded.

Grantees Provided Reasons Why Obligating All but 2 Percent of Their Grant Awards Is Difficult

Five of the 13 Part B grantees we interviewed had unobligated balances over 2 percent; these 5 grantees told us that they had varying reasons for their unobligated balances, some of which they said were beyond their control. For example, Arizona explained that it had an unobligated balance from its ADAP base grant, in part, because it had a dispute with a vendor it had contracted with to provide prescription drugs to clients. The vendor claimed that it had not been paid for services. According to state officials, to settle the dispute and comply with applicable state rules Arizona had to pay the vendor twice. When the vendor realized that it had been overpaid, it reimbursed Arizona in the amount of $670,000. Arizona received the

reimbursement at the end of the grant year. Arizona was unable to spend this amount, leaving it with an unobligated balance of over 2 percent and a subsequent penalty.

Grantees we interviewed, which included those that had unobligated balances of over 2 percent and those that did not, explained that they experienced difficulty obligating grant funds within the grant year. Three of the 13 Part B grantees we interviewed explained that they are currently dealing with economic factors such as state hiring freezes, spending caps, and furloughs of staff. One grantee explained that because of economic difficulties, his state has implemented new procedures as a means to limit state spending, including reclaiming state funding balances that are not spent quickly. Because of this new procedure, the grantee must allocate state funding, federal funding, and program income simultaneously, which he finds difficult. One grantee said the existence of the state hiring freeze has limited the amount of grant funding that could be obligated to fund staff positions. The grantee stated that the hiring freeze has been implemented as a means to limit state spending, but the state has imposed the hiring freeze on all programs, including those that receive federal funds.

One Part B grantee explained that, while the grantee can to some extent control the contracts that are entered into and types of services that are provided, the grantee cannot control factors that affect the demand for program services. For example, the grantee cannot control the number of people who become infected; those who will lose their jobs and private health insurance and need to receive services supported with grant funds; and changes that occur with Medicaid and Medicare that can affect clients. Additionally, two grantees stated that because the grant awards can arrive after April 1, it can be helpful to carry over funds from the previous year's grant award so that they can award contracts, rather than delay them until HRSA awards grant funds. These grantees said that they would like to be able to carry over funds without risking a reduction in future funding.

One grantee explained that because grant awards are based on a formula and can fluctuate from year to year, it is helpful for the grantee to have funding on hand to maintain consistent service levels even if formula funding is decreased without risking a penalty. Six grantees expressed concern that the level of oversight required to obligate all but 2 percent of their grants leaves them unable to deal with unpredictable situations, such as a contractor going out of business. Six of the 13 grantees we interviewed said that they consider the 2 percent threshold too low, and some suggested that a 5 percent threshold would be more reasonable. Two

of these grantees told us that if grantees had to obligate all but 5 percent of their funding, they would have more room to manage their budgets. However, only 2 of the 16 Part B grantees that received penalties for unobligated balances had unobligated balances of less than 5 percent.

Grantees and HRSA Said Drug Rebates Make It Difficult for Grantees to Obligate Grant Funds

According to information provided by HRSA, 7 of the 13 Part B grantees we interviewed received drug rebates. In addition, Delaware informed us that they also receive rebates. Four of the eight grantees that received rebates said that the requirement that they spend drug rebates before spending grant funds makes it more difficult for them to obligate all but 2 percent of their grant awards, even though drug rebates are not subject to the unobligated balance provisions. The 27 Part B grantees that exclusively use the federal 340B rebate option to purchase their ADAP drugs typically contract with pharmacy networks or pharmacy benefit managers for the purchase of covered drugs who then request rebates from the pharmaceutical companies in order to obtain the 340B drug price and pass these savings on to the grantee. Under RWTMA, drug rebates that grantees receive are not considered part of the grant award and are not subject to the unobligated balance provisions.[45] However, federal regulations generally applicable to state and local government grantees require them to disburse rebates (along with program income and certain other amounts) before requesting additional cash payments.[46] Accordingly, HRSA requires rebates to be spent before grantees obligate additional grant funds. 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.

While only three of the nine states that had a reduction in their ADAP base grants for grant year 2009 due to an unobligated balance received rebates, five of the eight grantees we interviewed that received rebates expressed

[45]In August 2007, HRSA provided guidance consistent with RWTMA to grantees that states "Drug rebate dollars are not considered to be part of the grant award, therefore any unobligated drug rebate funds are not subject to the unobligated balance provisions."

[46]HRSA sent a letter in January 2007 to the 27 grantees using the rebate option stating that rebates are considered program income under 45 C.F.R. § 92.21(f)(2). In a subsequent letter, HRSA advised that rebates should not be considered program income for purposes of reporting on the FSR, but, under section 92.21(f)(2), grantees must disburse rebates before requesting additional cash payments. Cash payments requested by grantees would be for the purpose of liquidating or making payments associated with obligations of grant funds.

concern about the requirement that drug rebate funds be spent before grant funds.[47] One grantee explained that though it did not have an unobligated balance for grant year 2007, it took a great deal of effort to avoid one. Before RWTMA and the budget challenges in this state, this grantee saved state funds to spend at the end of the grant year so it could ensure that Part B funds were obligated and rebate funds were spent. However, because of state spending requirements put in place due to economic factors this state is currently facing, the grantee can no longer do this. In addition, spending rebates first can be difficult because rebate states often do not know when they will receive rebates; the state may send out requests every quarter, but may not receive the rebates until well into the next quarter or grant year. Rebate states may also not know the rebate amount beyond what they can estimate based on trends over the past year. Several grantees said that because of the variability of the rebate amounts and their timing, they could receive a large rebate check late in the year. They then could have unobligated balances of grant funds of greater than 2 percent at that time because they use the rebate amounts when they become available rather than grant funds.

Pennsylvania had an unobligated ADAP base grant balance of $12,670,248 in grant year 2007, and state officials said that a large part of the reason was its ADAP drug rebates. In grant year 2007, Pennsylvania received $11 million in rebates. These rebate funds had to be spent before it could obligate its ADAP base funding for grant year 2007. According to Pennsylvania officials, the Pennsylvania grantee has an administrative structure that only allows it to spend its rebates on the purchase of drugs, limiting how it could spend its rebate funds. Other states we spoke to can use rebate funds to provide Part B medical services as well, providing them with greater flexibility in spending these funds. Pennsylvania officials told us that they also had an unobligated balance of its ADAP base grant of over $2.4 million in grant year 2008. The Pennsylvania state government is working to revise its current structure.

HRSA sought to address the interaction between drug rebate funds and the RWTMA unobligated balance provisions by requesting from HHS permission to seek an exemption from the regulation for grantees from the Office of Management and Budget. HRSA told us that requiring ADAP rebate funds to be spent before grant funds increases the risk of

[47] Maine and Pennsylvania are drug rebate states. Delaware is a hybrid state; they use direct 340B pricing and participate in a drug rebate program.

unobligated balance penalties, and that the loss of grant funding and ineligibility for supplemental funding can pose difficulties for grantees. HRSA requested permission to seek an exemption from the otherwise applicable federal regulations for drug rebate states from HHS. HRSA believes the unobligated balance requirements were intended to ensure that federal funds are spent promptly, not to create a mechanism through which federal grants would be reduced. However, HRSA's request for permission to seek an exemption for drug rebate states was denied by HHS in November 2007. HHS stated that while federal regulations and the unobligated balance provisions create significant challenges for rebate states, the justification HRSA presented for the class deviation was "not compelling."

Agency Comments

HHS provided technical comments on a draft of the report, which we incorporated 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 I.

Marcia Crosse
Director, Health Care

Appendix I: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff 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.

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