

November 23, 2004

Ms. Lorraine Hunt  
Office of Management and Budget  
Washington, DC 20503

Dear Ms. Hunt:

As instructed by Joshua B. Bolten, the Director of OMB, in OMB Bulletin No. 04-04, we are electronically submitting directly to you the Fiscal Year 2005 Information Collection Budget (ICB) for the Department of Health and Human Services. The ICB includes all required information organized by Tabs, as follows:

- Tab 1 – New Initiatives to Improve Information Collection – The Department is providing a new initiative to reduce the burden on the public from its highest burden information collections. Also, the Food and Drug Administration has identified initiatives to reduce burden in two of its most significant collections.
- Tab 2 - Information Collection Budget – This is a comprehensive accounting of information collection burden placed on the public in FY 2004 and planned in FY 2005.
- Tab 3 – Examples of significant burden changes – These are grouped according to different types of program changes in Fiscal Years 2004 and 2005.

In its information collection inventory as of the end of FY 2004, HHS had 852 approved information collections. Of the 852 collections, 34 collections accounted for 80% of the Departmental burden. Accordingly, the Department has developed an initiative to examine the 34 collections to identify opportunities for significant burden reduction. In addition, FDA has identified two projects for burden reduction using electronic business methods. The two projects are the following: *eMDR* - Electronic Medical Device Reporting (Center for Devices and Radiological Health) and (*eLACF*) Electronic Submission of the Low Acid Canned Foods Registration Program (Center for Food Safety and Applied Nutrition).

As shown in the Information Collection Budget in Tab 2, the Department will not be able to reduce burden in FY 2005. This is primarily due to the HHS' obligation to implement new laws and regulations, such as "Title I of the Medicare Prescription Drug Improvement and Modernization Act" from CMS, and the new "Safety Reporting Requirements for Adverse Events Reporting" from FDA. Nevertheless, as documented in Tab 3, the Department continues its efforts to reduce burden where possible by eliminating redundancy, redesigning forms and making better use of information technology.

This ICB covers all relevant activities throughout the Department. If there are questions regarding this submission, please contact Robert Polson at 202/690-6741.

Sincerely,

/s/

Charles Havekost  
Chief Information Officer

Enclosures

## Appendix A

### Department of Health and Human Services FY 2005 Information Collection Budget Burden Reduction Initiative

**Agency:** Led by HHS Departmental Management, and including Centers for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), Administration for Children and Families (ACF), Office of the Secretary (OS)

**Initiative Title:** Targeted Plan for Reduction among Highest Burden Collections

**Description:** As of September 30, 2004, HHS had 852 approved information collections that placed 277.5 million hours of burden on the public. Of these 852 collections, 34 collections each had burden over one million hours. The 34 collections are located in four of the 11 HHS Operating Divisions. Together these collections account for 220.8 million hours of burden or 80% of the HHS burden on the public. The remaining 818 collections account for on 20% of the Departmental burden.

In light of these facts and in response to the OMB direction to achieve 1% reduction in burden, HHS is undertaking an initiative to develop a plan to achieve maximum possible burden reduction among its largest collections.

The plan will be developed by first conducting an analysis of all information collections that have at least 1 million hours of burden. The analysis will identify the opportunities for burden reduction with each specific collection. The second phase will consist of establishing a schedule for achieving the burden reductions. The schedule will be based on whether the reductions can be taken immediately, must wait for the renewal of the approval, or are dependent upon new legislation or new rules. Once the schedule is established, quarterly reports will be required identifying progress toward the objectives.

**Estimated Burden Efficiencies and Reduction:** The four Operating Divisions will conduct an analysis of the selected collections to identify opportunities for burden reduction, and in cooperation with the Department establish a schedule for obtaining targeted burden reductions. The reductions targeted will be for “program changes” not “adjustments.” The initiatives will include the following burden reduction strategies:

- improve the efficiency of information collections,
- reduce burden per response,
- promote where feasible the use of electronic reporting and electronic signature,
- work with agency legislative staff to identify statutory paperwork burden and where applicable develop a strategy to remove statutory requirements,
- create partnerships with other Federal agencies to reduce duplicative reporting and maximize data sharing.

The target in the review and analysis of the selected collections is to achieve a reduction of 3 million burden hours in those collections. This will exceed the one percent OMB target.

**Collection Affected:** This will affect all collections that have over one million hours of burden as of the OMB inventory of October 2, 2004. According to this inventory, the Office of the Secretary has one collection, ACF has four, FDA has 10, and CMS has 18.

**Expected Date of Completion:** The plan will consist of actions that will most likely extend beyond the end of Fiscal Year 2005. However, in FY 2005 the following will be accomplished:

- Instructions to Operating Divisions to identify large collections with burden reduction potential – December 15, 2004.
- Report by Operating Divisions identifying potential burden reduction collections with a proposed schedule – February 28, 2005.
- Departmental approval of Operating Division plan – March 31, 2005.
- Progress report by Operating Division on implementing burden reduction – July 15, 2005.
- Report on accomplishments in FY 2005 and future actions by Operating Divisions – October 15, 2005.

**Potential Hurdles to Completion:** There are a number of potential hurdles to reducing burden. Some of them are as follows:

- Reducing burden may negatively and significantly affect achieving the purpose of the program.
- It may be disruptive to operations to attempt to reduce burden during the period of approval. In this case, the burden may not be able to be reduced before the collection is due for renewal.
- Also, the burden may be based on legislative or regulatory mandates which make the burden reduction both time-consuming and complex. Efforts here may be worth undertaking nevertheless if there are not good government and/or business reasons to collect the information.

## Appendix A

### FY 2005 Food and Drug Administration Information Collection Budget

#### Burden Reduction Initiative

**Agency:**

FDA, Center for Devices and Radiological Health

**Initiative Title:** eMDR - electronic Medical Device Reporting

**Description:** Collection of adverse event information on medical devices is mandated by Medical Device Reporting (MDR) requirements of the Food Drug and Cosmetics Act (FD&C Act) (21 USC 360i), and comes primarily from manufacturers, user facilities, importers and voluntary reporters. In 1997, the Food and Drug Administration Modernization Act (FDAMA) required that FDA move towards the goal of a paperless submission and review environment

Each year, CDRH receives approximately 67,000 initial, and several thousand supplemental and follow-up medical device adverse event reports. Currently data entry contractors enter these reports manually. Data entry of paper reports is repetitive, tedious work resulting in high employee turnover. The orientation and training of new employees adds to the increase in data entry costs due to the increased volume of reports.

The vision for electronic Medical Device Reporting, or eMDR, is to develop a module that is capable of electronic data entry and processing of all post-market medical device adverse event reports. Currently, each report costs CDRH \$15.07 for manual data entry. Early cost-benefit analyses show that eMDR can initially save approximately 50% of the data-entry cost, with potentially increased savings long term. In addition, reports will be available for review sooner and action immediately after submission.

eMDR will provide OSB an opportunity to re-engineer existing adverse event reporting business processes to realize both the tangible benefits offered by electronic submission, along with various other efficiencies. As the number of medical devices in the market place continues to increase, number of adverse event reports can be expected to increase as well. Without an electronic alternative, data entry costs will continue to increase. eMDR will require initial capital investment, but realized savings more than compensate for the initial costs.

**Total Estimated Burden Reduction:**

<b>Burden</b>	<b>Description</b>	<b>Savings</b>
Data Entry Costs	CDRH estimates eMDR will reduce data entry costs by \$7.50 per report. The	\$502,500

	electronic system will capture 67,000 reports per year.	
Industry Mailing Costs	eMDR will not require firms to mail reports.	\$18,500
Industry Processing Costs	350 firms would each save .5 FTE's. Assume average administrative salary and benefits of \$40,000/year	\$7,000,000
<b>Total Savings/year</b>		<b>\$7,521,000</b>

**Collections Affected:**

**OMB No. 0910-0437** - Reporting and Recordkeeping Requirements for Manufacturers, Importers, User Facilities, and Distributors of Medical Devices under FDAMA

**OMB No. 0910-0471** – Adverse Event Pilot Program for Medical Devices (MedSun)

**Expected Date of Completion:**

- Project planning completed by December 31, 2004
- Request for proposal developed by March 31, 2005
- Contract awarded by June 30, 2005
- Requirement gathering completed by September 30, 2005
- System rollout completed by December 31, 2005

**Potential Hurdles to Completion:**

- Enlisting industry participation – Success of eMDR largely depends on participation from reporters. Since electronic submission is not mandated via regulation, voluntary participation from industry is crucial. Participation is potentially achievable due to external influences such as technology advances, national initiatives such as Electronic Health Record implementation, vested time and interest by industry in standard development activities such as HL7, and potential long term administrative cost savings.
- Availability of Funding and resources – Budget allocation and personnel resources are crucial for the project.
- FDA Gateway – The end goal of eMDR is to provide for a seamless transfer of adverse event reports electronically. To achieve this, the vision is to leverage eMDR with the planned FDA Gateway, so authentication and validation of electronic submissions are handled at the entry point. However, until the FDA gateway is operational the eMDR project plan calls for other avenues to accept electronic submissions such as physical media and web interface.
- IT Support– Appropriate resources and support from the Agency's Office of Information Technology Shared Services and other IT organizations is crucial.

## Appendix A

### FY 2005 Food and Drug Administration Information Collection Budget Center for Food Safety and Applied Nutrition Burden Reduction Initiative

**Agency:**

FDA, Center for Food Safety and Applied Nutrition

**Initiative Title:**

(eLACF) Electronic submission of the Low Acid Canned Foods Registration Program

**Description:**

Under the authority of Section 404 of the act (21 U.S.C. 344), FDA promulgated regulations (21 CFR 108.25(a) and 108.35(a) that require low-acid and acidified food processing establishments to register their firms, file scheduled process information, maintain records of processing and production records, and fulfill the mandatory provisions of the Good Manufacturing Practices (21 CFR 113 and 114). The requirements are intended to ensure risk to public health does not increase from improper or inadequate manufacture, processing and packing of such foods, and to permit FDA to verify that appropriate procedures are being followed.

FDA regulations (21 CFR 108.25(c)(1) require each firm that manufactures, processes or packs acidified foods or thermally processed low-acid foods in hermetically sealed containers for introduction into interstate commerce to register the establishment with the Food and Drug Administration using Form FDA 2541. Federal regulations (21 CFR 108.25(c)(2), 108.35(c)(2) require each firm to provide data on the processes used to produce these foods using Form FDA 2541a for all method except aseptic processing, or Form FDA 2541c for aseptic processing of low-acid food in hermetically sealed containers. Plant registration and process filing may be accomplished simultaneously.

The Low Acid and Acidified Foods Team, Division of Field Programs, Office of Compliance under the Center manage this program initiative for Food Safety and Applied Nutrition (CFSAN). In September 2004, CFSAN began implementation of industry access to LACF electronic filing. Additionally, the LACF electronic filing system is the second major registration application to be supported by and integrated under the new FDA Unified Registration and Listing System (FURLs). This meets a major milestone in the Agency's plans to link all FDA Registration, Listing, and Notification Programs under one gateway. By the end of the year, CFSAN should have contacted all of the domestic industry to engage in the LACF electronic access. In January 2005, the foreign industry will be contacted to participate in eLACF.

The electronic submission capability of the LACF Program titled eLACF is the second major registration application to be support by and integrated under the new FDA Unified

Registration and Listing System (FURLs). This meets a major milestone in the Agency's plan to provide one place (FURLS) for industry to access multiple registration systems.

The records of processing information are periodically reviewed during factory inspections by FDA field investigators and Center personnel to verify fulfillment of the requirements in 21 CFR 113 or 114. Scheduled thermal processes are examined and reviewed to determine their adequacy to protect public health. In the event of a public health emergency, records are used to pinpoint potentially hazardous foods rapidly and thus limit recall activity to affected lots.

**Estimated Burden Efficiencies and Reduction:**

Under the Government Paperwork Elimination Act (GPEA), food processing establishments both foreign and domestic which participates in the electronic registration of Low Acid and Acidified Canned Food process will benefit by (1) expedited filing of processing forms by submitting online, (2) the ability to review all the process filings a facility has with the FDA through online access and (3) efficiently and accurately updating company name and mailing address and/or other relevant information instantaneously.

The current estimated annualized cost to respondents for the hour burden for this collection of information is 1, 502,830 total annual burden x \$27.50/hour = \$41,318,197.

We anticipate a significant decrease in the annual burden hours to the respondent and cost to the Government. However, since this is a new initiative, actually burden reduction changes to the respondent(s) and to the Government will become available no sooner than after the first year of implementation.

The program office within CFSAN that is responsible for this regulation is working on the request for the extension of the Low Acid and Acidified Canned Food information collection that expires on August 31, 2005. Burden reduction information will be developed and should be included in that request.

**Collection Affected:**

**0910-0037** - Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

**Expected Date of Completion:** FY 2005

By the end of FY 2005, CFSAN will have notified all domestic LACF food processing establishments of the option to engage in the LACF electronic access. In January 2005, foreign food establishments will be asked to participate in eLACF as well.

**Potential Hurdles to Completion:**

None anticipated

Department of Health and Human Services

**SUMMARY TABLE OF BURDEN CHANGES**

	<b>Burden Hours (millions)</b>	<b>Cost Burden (\$,000,000)</b>
<b>FY 2003 Total Burden</b>	253.75	1,375.23
FY 2004 Program Changes Due to New Statutes	8.39	6.27
FY 2004 Program Changes Due to Lapses in OMB Approval	0.05	(0.15)
FY 2004 Program Changes Due to Agency Actions	2.54	(562.54)
<b>SUBTOTAL: FY 2004 Total Program Changes</b>	<b>10.98</b>	<b>(556.43)</b>
FY 2004 Adjustments	12.58	(203.96)
<b>FY 2004 Total Burden</b>	<b>277.31</b>	<b>614.84</b>
Expected FY 2005 Program Changes Due to New Statutes	810.84	0.00
Expected FY 2005 Program Changes Due to Lapses in OMB Approval	0.07	0.00
Expected FY 2005 Program Changes Due to Agency Actions	(24.90)	0.00
<b>SUBTOTAL: Expected FY 2005 Total Program Changes</b>	<b>786.00</b>	<b>0.00</b>
Expected FY 2004 Adjustments	0.77	0.00
<b>Expected FY 2005 Total Burden</b>	<b>1,064.08</b>	<b>614.84</b>

These cells come from the FY 2004 ICB. Do not change.

These numbers should match our end-of-the-year total.

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**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del> </del>	
0910-0016	11/18/2003			-160	-160	-37,775		
0910-0046	02/13/2004				0	59,119		
0910-0073	09/02/2004				0	-334,650		
0910-0120	05/21/2004			28,000	28,000			
0910-0131	11/17/2003				0	900		
0910-0132	11/30/2003		-2,614		-2,614			Discontinued
0910-0167	07/27/2004				0	16,379		
0910-0182	04/30/2004		-19,225		-19,225			Discontinued
0910-0185	11/30/2003		-6,000		-6,000			Discontinued
0910-0231	09/21/2004				0	6,143		
0910-0256	03/22/2004				0	408		
0910-0279	09/24/2004				0	17		
0910-0297	12/17/2003				0	93		
0910-0302	05/06/2004				0	209,778		
0910-0309	03/22/2004				0	-296,247		
0910-0320	09/21/2004				0	-2		
0910-0337	12/17/2003			-1	-1			
0910-0339	05/18/2004				0	-8,820		
0910-0345	02/29/2004		-1,000		-1,000			Discontinued
0910-0353	03/31/2004		-1,178		-1,178			Discontinued
0910-0364	04/30/2004		-30		-30			Discontinued
0910-0370	09/21/2004				0	-158		
0910-0431	03/31/2004		-842,020		-842,020			Discontinued
0910-0433	03/22/2004				0	-2,824		
0910-0445	12/03/2003			-5,112	-5,112			
0910-0448	01/13/2004				0	-400		
0910-0449	12/17/2003				0	-17,550		
0910-0450	02/13/2004			6	6			
0910-0454	03/12/2004				0	-70		

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0910-0455	11/30/2003		-1,529		-1,529			Discontinued
0910-0456	12/17/2003				0	-187		
0910-0458	03/12/2004			-193,804	-193,804			
0910-0459	05/18/2004				0	-25,331		
0910-0461	02/29/2004		-20		-20			Discontinued
0910-0466	07/27/2004				0	2,465		
0910-0467	04/30/2004		-120		-120			Discontinued
0910-0469	07/27/2004				0	-520		
0910-0470	09/21/2004				0	1,543		
0910-0471	03/19/2004			400	400			
0910-0471	09/03/2004			1,346	1,346			
0910-0472	09/24/2004			142,145	142,145			
0910-0474	08/31/2004		-141,681		-141,681			Discontinued
0910-0480	11/30/2003		-17,403		-17,403			Discontinued
0910-0492	01/31/2004		-4,000		-4,000			Discontinued
0910-0494	04/30/2004		-300		-300			Discontinued
0910-0497	08/05/2004				0	-522		
0910-0501	06/30/2004		-112		-112			Discontinued
0910-0502	10/08/2003	521,831			521,831		<del>XXXX</del>	
0910-0508	12/17/2003				0	2,900		
0910-0509	12/17/2003				0	79		
0910-0514	04/30/2004		-28,000		-28,000			Discontinued
0910-0516	10/10/2003			1,500	1,500			
0910-0519	10/27/2003			120	120			
0910-0519	09/20/2004				0	360		
0910-0520	10/08/2003	2,836,781			2,836,781		<del>XXXX</del>	
0910-0521	01/23/2004			70,550	70,550			
0910-0522	10/22/2003			5,420	5,420			
0910-0523	02/18/2004			672	672			

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0910-0524	02/13/2004			20	20			
0910-0527	02/18/2004			1,061	1,061			
0910-0528	04/06/2004			579	579			
0910-0529	06/03/2004			5	5			
0910-0529	07/31/2004		-5		-5			Discontinued
0910-0530	11/26/2003			52,344	52,344			
0910-0531	12/18/2003			576	576			
0910-0531	06/30/2004		-576		-576			Discontinued
0910-0532	03/19/2004			810	810			
0910-0532	09/30/2004		-810		-810			Discontinued
0910-0533	03/19/2004			640	640			
0910-0533	09/30/2004		-640		-640			Discontinued
0910-0537	02/17/2004			1,777,550	1,777,550		<del>XXXX</del>	
0910-0538	03/12/2004			1,023,310	1,023,310		<del>XXXX</del>	
0910-0539	03/15/2004			69	69			
0910-0540	03/15/2004			60	60			
0910-0541	06/22/2004			147	147			
0910-0543	05/06/2004			866,240	866,240			
0910-0545	09/03/2004			490	490			
0910-0546	09/29/2004			13,000	13,000			
0910-0548	09/29/2004			71	71			
0910-0549	07/09/2004			1	1			
0910-0551	09/01/2004			100	100			
0915-0028	03/31/2004			-14	-14			Discontinued
0915-0043	12/08/2003			-1,011	-1,011			
0915-0099	11/13/2003			-35	-35	-13		
0915-0108	01/28/2004			-3,434	-3,434	-16,938		
0915-0126	05/14/2004				0	-10,809		
0915-0149	12/10/2003				0	-2,025		

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0915-0157	08/09/2004				0	3,695	<del>XXXX</del>	
0915-0158	12/31/2003			-22,240	-22,240		<del>XXXX</del>	
0915-0176	11/06/2003				0	40		
0915-0185	04/30/2004			-343	-343			Discontinued
0915-0193	10/17/2003			9,834	9,834			
0915-0204	05/28/2004				0	-17		
0915-0206	12/31/2003			-9,714	-9,714			Discontinued
0915-0239	08/04/2004				0	-71,023		
0915-0244	12/31/2003			-4,725	-4,725			Discontinued
0915-0247	01/28/2004			240	240			
0915-0256	09/30/2004			-35	-35			Discontinued
0915-0265	10/31/2003			-1,000	-1,000			Discontinued
0915-0271	03/31/2004			-168	-168			Discontinued
0915-0273	06/30/2004			-204	-204			Discontinued
0915-0278	10/30/2003		41		41			In Use without an OMB Nbr
0915-0279	09/30/2004			-624	-624			Discontinued
0915-0280	11/05/2003			500	500			
0915-0281	12/08/2003			32,502	32,502		<del>XXXX</del>	
0915-0282	12/09/2003			7,500	7,500			
0915-0283	02/04/2004			211	211			
0915-0285	06/18/2004		59,375		59,375			In Use without an OMB Nbr
0915-0286	06/10/2004			18	18			
0915-0287	06/10/2004			288	288			
0915-0289	09/30/2004		14,130		14,130			In Use without an OMB Nbr
0915-0290	09/27/2004			500	500			
0915-0291	09/28/2004		8,670		8,670			In Use without an OMB Nbr
0915-0292	09/30/2004		150		150			In Use without an OMB Nbr
0915-0293	09/22/2004			3,000	3,000			
0917-0006	09/09/2004			-1,820	-1,820			

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0917-0007	06/30/2004			-313	-313			Discontinued
0917-0007	09/28/2004			514	514			Reinstatement of Discontinued ICR
0917-0025	02/29/2004			-384	-384			Discontinued
0917-0025	05/28/2004			384	384			Reinstatement of Discontinued ICR
0920-0004	11/19/2003			5	5			
0920-0007	07/08/2004			-542	-542			
0920-0007	09/30/2004			528	528			
0920-0012	12/30/2004		-71,529		-71,529			Violation
0920-0020	09/16/2004				0	-3,545		
0920-0208	09/03/2004				0	-7		
0920-0210	10/31/2003		-1,788		-1,788			Violation
0920-0210	08/09/2004		930		930			Violation Reinstatement
0920-0234	11/03/2003			-1	-1			
0920-0261	04/05/2004				0	4,481		
0920-0262	06/30/2004		-3,625		-3,625			Violation
0920-0278	05/28/2004			-5,761	-5,761			
0920-0282	04/22/2004			-144	-144			
0920-0338	10/31/2003		-296		-296			Violation
0920-0338	08/09/2004		72		72			Violation Reinstatement
0920-0353	10/31/2003			-1,008	-1,008			Discontinued
0920-0353	05/03/2004			13,375	13,375			Reinstatement of Discontinued ICR
0920-0406	05/18/2004			30	30			
0920-0428	02/20/2004			386	386			
0920-0449	03/31/2004			-2,166	-2,166			Discontinued
0920-0461	02/04/2004			125	125			
0920-0488	12/17/2003			3,600	3,600			Reinstatement of Discontinued ICR
0920-0493	11/30/2003			-9,173	-9,173			Discontinued
0920-0495	02/26/2004			-870	-870			
0920-0496	12/31/2003			-1,498	-1,498			Discontinued

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0920-0499	08/02/2004				0	-2,496		
0920-0501	09/30/2004			-133	-133			Discontinued
0920-0502	06/08/2004			220	220			
0920-0503	08/31/2004			-10,525	-10,525			Discontinued
0920-0508	03/31/2004			-1,666	-1,666			Discontinued
0920-0519	08/04/2004			1,400	1,400			Reinstatement of Discontinued ICR
0920-0544	07/31/2004			-200	-200			Discontinued
0920-0548	07/30/2004			-24	-24			
0920-0562	12/31/2003			-6,969	-6,969			Discontinued
0920-0563	11/30/2003			-2,869	-2,869			Discontinued
0920-0565	10/31/2003			-200	-200			Discontinued
0920-0567	10/31/2003			-452	-452			Discontinued
0920-0569	11/30/2003			-1,083	-1,083			Discontinued
0920-0570	12/31/2003			-503	-503			Discontinued
0920-0574	12/31/2003			-2,748	-2,748			Discontinued
0920-0575	11/21/2003			227	227			Reinstatement of Discontinued ICR
0920-0576	05/25/2004			-17,299	-17,299		<del>XXXX</del>	
0920-0577	02/29/2004			-617	-617			Discontinued
0920-0578	01/31/2004			-27	-27			Discontinued
0920-0581	09/30/2004			-185	-185			Discontinued
0920-0582	05/18/2004			16	16			
0920-0583	03/31/2004			-485	-485			Discontinued
0920-0585	04/30/2004			-334	-334			Discontinued
0920-0586	04/30/2004			-2,800	-2,800			Discontinued
0920-0587	05/18/2004			1,356	1,356			
0920-0589	05/31/2004			-840	-840			Discontinued
0920-0591	10/31/2003			-450	-450			Discontinued
0920-0591	09/30/2004			450	450			Reinstatement of Discontinued ICR
0920-0592	06/30/2004			-322	-322			Discontinued

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del> </del>	
0920-0596	09/29/2004			-1,742	-1,742			
0920-0597	08/31/2004			-272	-272			Discontinued
0920-0599	12/31/2003			-759	-759			Discontinued
0920-0599	09/29/2004			555	555			Reinstatement with Change
0920-0602	10/22/2003			28,860	28,860		<del> </del>	
0920-0604	11/21/2003			70	70			
0920-0605	11/17/2003			549	549			
0920-0606	11/17/2003			440	440			
0920-0607	11/24/2003			25,000	25,000		<del> </del>	
0920-0608	11/26/2003			2,167	2,167			
0920-0609	12/18/2003			1,024	1,024			
0920-0610	12/22/2003			325	325			
0920-0611	12/18/2003			4,110	4,110			
0920-0612	11/24/2003			2,160	2,160			
0920-0614	11/21/2003			120	120			
0920-0615	10/27/2003			10	10			
0920-0615	07/31/2004			-10	-10			Discontinued
0920-0617	03/23/2004			1,000	1,000			
0920-0618	01/14/2004			4,624	4,624			
0920-0620	03/04/2004			255	255			
0920-0621	12/22/2003			18,663	18,663		<del> </del>	
0920-0622	01/22/2004			400	400			
0920-0623	01/16/2004			271	271			
0920-0624	02/26/2004			250	250			
0920-0625	05/05/2004			4,300	4,300			
0920-0627	02/26/2004			555	555			
0920-0628	03/04/2004			6,030	6,030			
0920-0629	03/15/2004			2,282	2,282			
0920-0630	04/02/2004			1,892	1,892			

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>X</del>	
0920-0631	04/16/2004			3,946	3,946			
0920-0632	02/04/2004			400	400			
0920-0633	06/18/2004			52	52			
0920-0635	09/14/2004			12,934	12,934		<del>X</del>	
0920-0636	02/20/2004			125	125			
0920-0637	06/07/2004			140	140			
0920-0638	08/23/2004			10,211	10,211		<del>X</del>	
0920-0639	05/19/2004			54	54			
0920-0641	09/30/2004			36	36			
0920-0643	06/08/2004			17,026	17,026		<del>X</del>	
0920-0646	08/31/2004			1,548	1,548			
0920-0647	08/09/2004			899	899			
0920-0648	07/01/2004			58	58			
0920-0649	09/27/2004			4,855	4,855			
0920-0652	09/22/2004			90	90			
0923-0002	10/28/2003			-1	-1			
0923-0028	02/03/2004			83	83			Reinstatement of Discontinued ICR
0923-0030	12/31/2003			-2,222	-2,222			Discontinued
0923-0035	07/22/2004			41	41			
0923-0036	07/23/2004			150	150			
0925-0001	09/17/2004			-345,509	-345,509		<del>X</del>	
0925-0208	11/21/2003			-832	-832			OMB Approval
0925-0216	08/31/2004			-8,639	-8,639			Discontinued
0925-0281	02/05/2004			-1,427	-1,427			OMB Approval
0925-0334	04/30/2004			-1,719	-1,719			Discontinued
0925-0334	09/29/2004			868	868			Reinstatement of Discontinued ICR
0925-0368	01/31/2004			-30,979	-30,979			Discontinued
0925-0378	08/09/2004			-11	-11			OMB Approval
0925-0405	02/25/2004			29,500	29,500			Reinstatement of Discontinued ICR

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0925-0406	11/21/2003				0	-9,726		OMB Approval
0925-0423	06/30/2004			-55,977	-55,977			Discontinued
0925-0438	07/31/2004			-1,727	-1,727			Discontinued
0925-0449	10/31/2003			-2,250	-2,250			Discontinued
0925-0454	07/31/2004			-216	-216			Discontinued
0925-0458	06/04/2004			895	895			OMB Approval
0925-0465	10/30/2003			814	814			Reinstatement of Discontinued ICR
0925-0474	09/03/2004			600	600			Reinstatement of Discontinued ICR
0925-0480	11/21/2003			2,000	2,000			Reinstatement of Discontinued ICR
0925-0482	02/29/2004			-1,867	-1,867			Discontinued
0925-0484	02/24/2004			-4,907	-4,907			OMB Approval
0925-0489	06/30/2004			-100	-100			Discontinued
0925-0491	05/04/2004			140	140			OMB Approval
0925-0492	10/31/2003			-60	-60			Discontinued
0925-0494	10/31/2003			-340	-340			Discontinued
0925-0496	10/31/2003			-1,556	-1,556			Discontinued
0925-0506	10/31/2003			-10,700	-10,700			Discontinued
0925-0516	05/31/2004			-379	-379			Discontinued
0925-0518	05/31/2004			-4,963	-4,963			Discontinued
0925-0524	11/21/2003			441	441			OMB Approval
0925-0525	12/15/2003			3,267	3,267			OMB Approval
0925-0526	02/04/2004			910	910			OMB Approval
0925-0527	06/07/2004			248	248			OMB Approval
0925-0528	07/13/2004			184	184			OMB Approval
0925-0530	06/08/2004			712	712			OMB Approval
0925-0531	09/21/2004			1,072	1,072			OMB Approval
0925-0534	08/04/2004			880	880			OMB Approval
0925-0536	09/15/2004			157	157			OMB Approval
0925-0537	09/30/2004			500	500			OMB Approval

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>X</del>	
0930-0074	04/19/2004			-162	-162			
0930-0080	08/26/2004			-400	-400	-2,360		
0930-0092	08/02/2004			0	0	93,473		
0930-0093	11/13/2003			-66	-66			
0930-0104	09/22/2004			-5	-5	1		
0930-0110	10/02/2003			-511	-511			
0930-0163	04/06/2004			-1	-1			
0930-0168	07/16/2004			905	905			
0930-0172	02/03/2004			0	0	16		
0930-0196	06/28/2004			9,290	9,290			Reinstatement of Discontinued ICR
0930-0203	01/31/2004			-23	-23			Discontinued
0930-0206	12/31/2003			-91	-91	91		
0930-0208	10/01/2003			4,886	4,886			
0930-0210	11/25/2003			0	0	-238		
0930-0216	10/16/2003			617	617			
0930-0217	01/31/2004			-100	-100			Discontinued
0930-0222	08/02/2004			-885	-885			
0930-0223	09/30/2004			-3,147	-3,147			Discontinued
0930-0236	12/31/2003			-224	-224			Discontinued
0930-0238	12/02/2003			5,722	5,722			
0930-0240	11/30/2003			-7,141	-7,141			Discontinued
0930-0246	09/30/2004			-354	-354			Discontinued
0930-0247	10/02/2003			6,162	6,162			
0930-0247	09/27/2004			-4,120	-4,120	1,743		
0930-0248	10/02/2003			1,123	1,123			
0930-0249	10/08/2003			928	928			
0930-0250	10/03/2003			660	660			
0930-0250	09/30/2004			-660	-660			Discontinued
0930-0251	10/20/2003			240	240			

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>X</del>	
0930-0252	12/02/2003			53	53			
0930-0253	12/11/2003			1,365	1,365			
0930-0254	12/15/2003			5,814	5,814			
0930-0255	12/22/2003			750	750			
0930-0256	03/02/2004			993	993			
0930-0257	04/21/2004			25,262	25,262		<del>X</del>	
0930-0258	04/12/2004			13	13			
0930-0260	09/16/2004			270	270			
0935-0104	03/31/2004			-49,105	-49,105			Discontinued
0935-0114	01/31/2004			-124	-124			Discontinued
0935-0115	01/31/2004			-300	-300			Discontinued
0937-0191	07/31/2004		-6,400		-6,400			Violation
0937-0200	02/29/2004		-184,200		-184,200			Violation
0937-0200	06/18/2004		220,980		220,980			Violation Reinstatement
0938-0033	11/18/2003		1,715,000		1,715,000			Violation Reinstatement
0938-0033	05/27/2004				0	-86,000		
0938-0034	10/31/2003			-9,167	-9,167			Discontinued
0938-0041	11/14/2003			196	196			
0938-0042	04/21/2004				0	-330,408		
0938-0045	11/14/2003				0	-500		
0938-0046	06/16/2004			50,000	50,000		<del>X</del>	
0938-0062	01/06/2004				0	6,821,249		
0938-0214	06/22/2004				0	-225,143		
0938-0236	06/16/2004				0	99,372		
0938-0272	12/30/2003				0	2,550		
0938-0296	04/21/2004			-8,000	-8,000			
0938-0328	01/07/2004				0	4,745,412		
0938-0334	01/07/2004				0	-1,164		
0938-0355	11/20/2003				0	-16,020		

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0938-0358	03/02/2004				0	7		
0938-0360	01/28/2004				0	-1,186		
0938-0365	05/28/2004				0	-7,694		
0938-0372	05/05/2004				0	-100		
0938-0378	09/27/2004				0	-25		
0938-0382	11/21/2003		88		88			Violation Reinstatement
0938-0447	01/28/2004			1,280	1,280			
0938-0448	01/28/2004				0	24,170		
0938-0456	11/08/2003				0	-250		
0938-0463	04/13/2004				0	-463,354		
0938-0465	11/30/2003			-296,942	-296,942			Discontinued
0938-0470	04/13/2004				0			
0938-0486	10/31/2003			-2,500	-2,500			Discontinued
0938-0501	04/13/2004				0	-14		
0938-0512	01/28/2004				0	-20		
0938-0564	11/14/2003			1	1			Reinstatement of Discontinued ICR
0938-0566	11/18/2003				0	47,941		
0938-0566	05/28/2004				0	78,004		
0938-0567	10/31/2003			-2,500	-2,500			Discontinued
0938-0580	04/30/2004			-2,110	-2,110			Discontinued
0938-0612	06/04/2004			-406,780	-406,780		<del>XXXX</del>	
0938-0650	05/31/2004			-10,000	-10,000			Discontinued
0938-0655	10/31/2003			-786	-786			Discontinued
0938-0670	05/31/2004			-1,010	-1,010			Discontinued
0938-0673	07/31/2004			-15	-15			Discontinued
0938-0688	02/27/2004				0	117		
0938-0700	04/30/2004			-45,000	-45,000			Discontinued
0938-0701	01/28/2004				0	243,278		
0938-0705	10/31/2003			-415	-415			Discontinued

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0938-0708	02/29/2004			-744	-744		<del>XXXX</del>	Discontinued
0938-0709	02/27/2004			-29,917	-29,917		<del>XXXX</del>	
0938-0722	09/30/2004			-100	-100			Discontinued
0938-0748	12/31/2003			-12,420	-12,420			Discontinued
0938-0767	08/31/2004			-75	-75			Discontinued
0938-0768	05/31/2004			-750	-750			Discontinued
0938-0778	01/28/2004				0	-1,170		
0938-0780	09/30/2004		-833		-833			Discontinued 10/06/04 OMB NOA
0938-0787	09/16/2004				0	500		
0938-0791	05/28/2004				0	-5,543		
0938-0792	02/10/2004				0	-228		
0938-0796	04/13/2004			2,840	2,840			
0938-0808	10/31/2003			-4,735	-4,735			Discontinued
0938-0810	11/30/2003			-146,070	-146,070			Discontinued
0938-0812	11/21/2003				0	463		
0938-0813	12/31/2003			-500	-500			Discontinued
0938-0817	11/30/2003			-684	-684			Discontinued
0938-0818	01/28/2004		75,294		75,294			Violation Reinstatement
0938-0819	05/31/2004			-100	-100			Discontinued
0938-0823	04/30/2004			-50	-50			Discontinued
0938-0824	05/31/2004			-3	-3			Discontinued
0938-0826	02/29/2004			-3,200	-3,200			Discontinued
0938-0828	06/30/2004			-500	-500			Discontinued
0938-0829	05/28/2004				0	4,126		
0938-0832	09/30/2004				0	125		
0938-0837	03/31/2004			-782	-782			Discontinued
0938-0841	08/18/2004				0	143,974		
0938-0842	06/22/2004				0	152,689		
0938-0844	11/08/2003				0	716		

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0938-0844	09/30/2004		-1,798		-1,798			Discontinued OMB NOA 10/01/04
0938-0850	02/12/2004				0	116,588		
0938-0859	09/30/2004		-5,000		-5,000			Discontinued OMB NOA 10/01/04
0938-0888	02/29/2004			-608	-608			Discontinued
0938-0890	03/27/2004		1,078		1,078			Discontinued, reinstated on 3/27/04
0938-0891	02/29/2004			-6,223	-6,223			Discontinued
0938-0896	12/31/2003			-300	-300			Discontinued
0938-0898	12/31/2003			-2,360	-2,360			Discontinued
0938-0898	05/09/2004			2,360	2,360			Reinstatement of Discontinued ICR
0938-0901	01/28/2004				0	-8,800		
0938-0903	02/27/2004				0	-2,200		
0938-0906	02/23/2004	1,087			1,087			
0938-0907	12/02/2003	720,000			720,000		<del>XXXX</del>	
0938-0909	10/03/2003				0			
0938-0909	04/30/2004			-102	-102			Discontinued
0938-0910	03/11/2004	68,000			68,000		<del>XXXX</del>	
0938-0911	03/09/2004	4,160			4,160			
0938-0912	02/23/2004			6,667	6,667			
0938-0913	12/30/2003				0			
0938-0913	01/31/2004			-4,500	-4,500			Discontinued
0938-0915	05/25/2004			3,331	3,331			
0938-0916	03/26/2004			20,400	20,400		<del>XXXX</del>	
0938-0917	02/27/2004			9,556	9,556			
0938-0918	06/01/2004	239,200			239,200		<del>XXXX</del>	
0938-0919	03/19/2004			1,800	1,800			
0938-0920	04/29/2004	3,917,643			3,917,643		<del>XXXX</del>	
0938-0921	03/29/2004	480			480			
0938-0921	09/08/2004				0	14,880		
0938-0924	06/28/2004	20,417			20,417		<del>XXXX</del>	

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0938-0925	07/08/2004				0			
0938-0925	09/30/2004		-110		-110			Discontinued OMB NOA 09/23/04
0938-0929	09/01/2004	31,250			31,250		<del>XXXX</del>	
0970-0030	08/31/2004		-24		-24			Violation
0970-0033	12/31/2003			-1,350	-1,350			Discontinued
0970-0033	05/13/2004			669	669			Reinstatement of Discontinued ICR
0970-0036	03/02/2004			744	744			Reinstatement of Discontinued ICR
0970-0043	11/10/2003			217	217			Reinstatement of Discontinued ICR
0970-0043	08/31/2004		-217		-217			Violation
0970-0062	01/31/2004			-20,300	-20,300			Discontinued
0970-0085	12/31/2003		-593,226		-593,226			Violation
0970-0121	10/30/2003			2,660	2,660			Reinstatement of Discontinued ICR
0970-0123	04/30/2004		-62,012		-62,012			Violation
0970-0123	09/28/2004		58,557		58,557			Violation Reinstatement
0970-0139	04/29/2004				0	419,136		
0970-0142	12/31/2003			-48	-48			Discontinued
0970-0148	11/14/2003				0	268,992		Increase in number of grantees
0970-0151	10/02/2003				0	1,422		Increase in respondents
0970-0154	05/28/2004				0	964,174		Increase in respondents
0970-0160	12/22/2003				0	-300		Fewer Respondents
0970-0163	12/31/2003		-1,792		-1,792			Violation
0970-0163	03/02/2004		1,120		1,120			Violation Reinstatement
0970-0166	04/21/2004				0	29		
0970-0214	10/31/2003		14,072		14,072			Violation Reinstatement
0970-0218	04/07/2004			16,998	16,998			Report Required by Statute
0970-0221	11/30/2003			-216	-216			Discontinued
0970-0222	09/30/2004		-120,653		-120,653			Violation
0970-0226	09/30/2004			-975	-975			Discontinued
0970-0228	09/30/2004			-360	-360			Discontinued

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del>XXXX</del>	
0970-0239	11/17/2003				0	503		Increase in respondents
0970-0239	06/30/2004			-548	-548			Discontinued
0970-0246	01/15/2004			123	123			Discontinued
0970-0251	07/22/2004			1	1			
0970-0255	10/17/2003			1,120	1,120			
0970-0256	10/17/2003			-220	-220			Discontinued
0970-0257	01/07/2004			499	499			
0970-0259	12/22/2003			9	9			
0970-0259	03/31/2004			-9	-9			Discontinued
0970-0260	01/16/2004			1,670	1,670			
0970-0260	06/30/2004			-1,670	-1,670			Discontinued
0970-0261	03/12/2004	18,200			18,200		<del>XXXX</del>	
0970-0262	03/31/2004			332	332			
0970-0263	04/07/2004			18,200	18,200			Report Required by Statute
0970-0264	04/07/2004			18,200	18,200			Report Required by Statute
0970-0265	06/04/2004			300	300			
0970-0266	08/02/2004	12,000			12,000		<del>XXXX</del>	
0970-0267	08/12/2004			2,744	2,744			
0970-0268	09/30/2004			864	864			
0980-0204	10/16/2003			650	650			
0980-0229	10/31/2003			1,200	1,200			
0980-0270	12/31/2003		-2,508		-2,508			Violation
0980-0274	11/21/2003			24,300	24,300			
0980-0274	03/31/2004			-24,300	-24,300			Discontinued
0985-0006	09/16/2004			4,040	4,040			
0985-0008	03/09/2004			-14,113	-14,113		<del>XXXX</del>	
0985-0016	07/31/2004			-75	-75			Discontinued
0985-0017	09/30/2004			-5,560	-5,560			Discontinued
0985-0018	03/31/2004			5,000	5,000			

**FY 2004 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769	<del> </del>	
0985-0019	06/14/2004			500	500			
0990-0124	05/31/2004			-41,600	-41,600			Discontinued
0990-0128	08/31/2004			-1,102	-1,102			Discontinued
0990-0150	04/30/2004			-1	-1			Discontinued
0990-0150	09/22/2004			1	1			Reinstatement of Discontinued ICR
0990-0162	03/10/2004		2,744		2,744			Violation Reinstatement
0990-0220	11/17/2003			800	800			
0990-0221	04/09/2004			1,067	1,067			
0990-0223	12/31/2003			-3,496	-3,496			Discontinued
0990-0232	10/31/2003			-503	-503			Discontinued
0990-0236	02/29/2004			-620	-620			Discontinued
0990-0238	08/31/2004			-9,819	-9,819			Discontinued
0990-0243	06/03/2004				0	16,000		
0990-0244	03/31/2004			-1,000	-1,000			Discontinued
0990-0253	06/30/2004			-1,288	-1,288			Discontinued
0990-0265	12/31/2003			-480	-480			Discontinued
0990-0273	03/27/2004			286	286			
0990-0274	03/16/2004			175	175			
0990-0275	06/07/2004			2,772	2,772			
0990-0276	08/23/2004			75	75			
0990-0277	06/23/2004			2	2			
0990-0277	09/30/2004			-2	-2			Discontinued
0992-0003	03/12/2004			1,136	1,136			Reinstatement of Discontinued ICR
0992-0003	04/30/2004			-1,136	-1,136			Discontinued
<b>TOTAL</b>		8,391,049	49,027	2,542,670	10,982,746	12,575,769		

**FY 2004 CHANGES IN COST BURDEN (\$,000)**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	Notes
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		6,268	-152	-562,544	-556,428	-203,960	<del>XXXX</del>	
0910-0016	11/18/2003			560	560			
0910-0185	11/30/2003		-9		-9			Discontinued
0910-0309	03/22/2004			19,470	19,470			
0910-0354	12/17/2003			9,406	9,406			
0910-0364	04/30/2004		-15		-15			Discontinued
0910-0455	11/30/2003		-1		-1			Discontinued
0910-0480	11/30/2003		-56		-56			Discontinued
0910-0520	10/08/2003	6,268			6,268			
0915-0193	10/17/2003			23,449	23,449			
0915-0206	12/31/2003			-403	-403			Discontinued
0915-0239	08/04/2004				0	1,967		
0917-0028	05/06/2004				0	-20,000		Correction
0920-0556	08/10/2004			-1	-1			
0925-0001	09/17/2004				0	20		
0930-0092	08/02/2004			0	0	14		
0930-0206	12/31/2003			-728	-728	728		
0935-0114	01/31/2004			-50,000	-50,000			Discontinued
0935-0115	01/31/2004			-50,000	-50,000			Discontinued
0935-0106	11/30/2004			-515,732	-515,732			Discontinued
0937-0191	07/31/2004		-226		-226			Violation
0938-0470	04/13/2004				0	-471		
0938-0566	11/18/2003				0	-122,700		
0938-0578	07/27/2004				0	-983		
0938-0898	12/31/2003			-100	-100			Discontinued
0938-0898	05/09/2004			41	41			Reinstatement of Discontinued ICR
0970-0036	03/02/2004			27	27			Reinstatement of Discontinued ICR
0970-0123	04/30/2004		-330		-330			Violation
0970-0123	09/28/2004		512		512			Violation Reinstatement
0970-0163	12/31/2003		-3		-3			Violation

**FY 2004 CHANGES IN COST BURDEN (\$,000)**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	Notes
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		6,268	-152	-562,544	-556,428	-203,960	<del>XXXX</del>	
0970-0166	04/21/2004				0	-61,400		
0970-0222	09/30/2004		-22		-22			Violation
0970-0239	11/17/2003				0	350		
0970-0239	06/30/2004			-350	-350			Discontiued ICR
0970-0255	10/17/2003			22	22			
0970-0266	08/02/2004			763	763			
0980-0229	10/31/2003			43	43			
0980-0270	12/31/2003		-2		-2			Violation
0985-0004	08/30/2004				0	-1,426		
0985-0005	11/01/2004				0	-58		
0985-0009	11/01/2004				0	-1		
0990-0221	04/09/2004			989	989			
<b>TOTAL</b>		6,268	-152	-562,544	-556,428	-203,960		

**FY 2005 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB	Due to Agency Actions				
<b>TOTAL</b>		810,836,334	66,775	-24,901,551	786,001,558	769,555		
0910-NEW				810,982	810,982			Reqs Humn Blood Transfusion
0910-NEW				501,383	501,383			Amending Rx drug labeling
0910-NEW				196,342	196,342			Elec subm estab regis info
0910-NEW				86,656	86,656			CGMPs - PET Drugs
0910-NEW				18,400	18,400			Use of Foreign clincial trials
0910-NEW				4,070	4,070			GMPs/Label med gas containrs
0910-NEW				2,520	2,520			ANDA Bioequiv studies
0910-NEW				1,000	1,000			Study - Triptans/Migranes
0910-NEW				800	800			Subm of Pharmacogenic data
0910-NEW				790	790			Policy Handling CGMP disputes
0910-NEW				760	760			Rpt info - falsification of data
0910-NEW				360	360			Fixed-Combination Drugs
0910-NEW				144	144			Study - Miscnduct in resrch stdies
0910-NEW				5,799,477	5,799,477			
0910-0030					0	1250		
0910-0308					0	-83071		
0910-0338					0			Burden unknown now.
0910-0387					0	-24611		
0910-0389					0	2240		
0910-0442					0	616855		
0910-0460				723,264	723,264			
0910-0473				283,400	283,400			
0915-0140				46,950	46,950			Program increase
0915-0186				-9,142	-9,142			Will be discontinued
0915-0184					0	14,597		Revised burden estimate
0915-0188				-530	-530			Will be discontinued
0915-0226				-300	-300			Will be discontinued
0915-0227				-1,297	-1,297			Will be discontinued
0915-0253					0	-1,652		Revised burden estimate
0915-0254				-13,440	-13,440			Elimination of one time survey
0915-0260				-750	-750			Will be discontinued
0915-0266				-808	-808			Will be discontinued
0915-0276				-13,063	-13,063			Elimination of one time survey
0915-0277				-1,393	-1,393			Will be discontinued
0915-0280				-500	-500			Will be discontinued

**FY 2005 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB	Due to Agency Actions				
<b>TOTAL</b>		810,836,334	66,775	-24,901,551	786,001,558	769,555	<del>XXXX</del>	
0915-0283				-211	-211			Will be discontinued
0915-0287				-288	-288			Will be discontinued
0915-NEW				428	428			
0915-NEW		11,483			11,483		<del>XXXX</del>	NPRM
0915-NEW				4,900	4,900			New grant reviewer form
0915-0275					0	25,200		83 C submitted in 2003, but OMB did not change burden
0915-NEW				264	264			
0917-0024					0	2,000		Increase of 125 hrs
0917-0026					0	3,920		Increase of 200 hrs
0917-0027					0	-202		Will not continue
0920-0012			66,775		66,775			
0920-0102				-90	-90			
0920-0406					0	100,821		Corrected a math error
0920-0495				-214	-214			
0920-0497				-1,052	-1,052			
0920-0525				-1,960	-1,960			
0920-0535				-233	-233			
0920-0551				-1,993	-1,993			
0920-0552				-140	-140			
0920-0566				-8,000	-8,000			
0920-0568				-100	-100			
0920-0608				-2,167	-2,167			
0920-0611				-4,110	-4,110			
0920-0618				-4,624	-4,624			
0920-0627				-555	-555			
0920-0631				-3,946	-3,946			
0920-0633				-52	-52			
0920-0637				-140	-140			
0920-0444				-18,663	-18,663			combined with 0920-0338
0920-0621				-18,663	-18,663			data collection completed
0920-NEW				105	105			
0920-NEW				1,341	1,341			
0920-NEW				96	96			
0920-NEW				47	47			

**FY 2005 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB	Due to Agency Actions				
<b>TOTAL</b>		810,836,334	66,775	-24,901,551	786,001,558	769,555	<del>XXXX</del>	
0920-NEW				1,842	1,842			
0920-NEW				267	267			
0920-NEW				153,400	153,400		<del>XXXX</del>	
0920-NEW				2,100	2,100			
0920-NEW				480	480			
0920-NEW				158	158			
0920-NEW				3,241	3,241			
0920-NEW				718	718			
0920-NEW				753	753			
0920-NEW				396	396			
0920-NEW				609	609			
0920-NEW				2,500	2,500			
0920-NEW				1,980	1,980			
0920-NEW				25	25			
0920-NEW				197	197			
0920-NEW				311	311			
0920-NEW				197	197			
0920-NEW				600	600			
0920-NEW				3,419	3,419			
0920-NEW				6,848	6,848			
0920-NEW				70	70			
0920-NEW				381	381			
0920-NEW				1,728	1,728			
0920-NEW				550	550			
0920-NEW				100	100			
0920-NEW				100	100			
0920-NEW				6,115	6,115			
0920-NEW				624	624			
0920-NEW				2,100	2,100			
0920-NEW				360	360			
0920-NEW				4,200	4,200			
0920-NEW				590	590			
0920-NEW				1,800	1,800			
0920-NEW				714	714			
0920-NEW				32	32			

**FY 2005 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB	Due to Agency Actions				
<b>TOTAL</b>		810,836,334	66,775	-24,901,551	786,001,558	769,555	<del>X</del>	
0920-NEW				1,700	1,700			
0920-NEW				237	237			
0920-NEW				360	360			
0920-NEW				20	20			
0920-NEW				125	125			
0920-NEW				609	609			
0920-NEW				17	17			
0920-NEW				127	127			
0920-NEW				3,750	3,750			
0920-NEW				109	109			
0920-NEW				1,800	1,800			
0920-NEW				3,000	3,000			
0920-NEW		50			50			
0920-NEW				715	715			
0920-NEW				80	80			
0920-NEW				208	208			
0920-NEW				13	13			
0920-NEW				475	475			
0920-NEW				81	81			
0920-NEW				264	264			
0920-NEW				120	120			
0920-NEW				600	600			
0920-NEW				173	173			
0920-NEW				27	27			
0920-NEW				36	36			
0920-NEW				100	100			
0920-NEW				230	230			
0920-NEW				250	250			
0920-NEW				69	69			
0920-NEW				300	300			
0920-NEW				83	83			
0920-NEW				1,000	1,000			
0920-NEW				86	86			
0920-NEW				667	667			
0920-NEW				717	717			

**FY 2005 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB	Due to Agency Actions				
<b>TOTAL</b>		810,836,334	66,775	-24,901,551	786,001,558	769,555		
0920-NEW				16,800	16,800			
0920-NEW				1,250	1,250			
0920-NEW				45	45			
0920-NEW				212	212			
0920-NEW				849	849			
0920-NEW				300	300			
0920-NEW				465	465			
0920-NEW				120	120			
0920-NEW				120	120			
0920-NEW				100	100			
0920-NEW				150	150			
0920-NEW				15,480	15,480			
0920-NEW				65,817	65,817			will replace 0920-0012, 0442, & 0417
0920-NEW				100	100			
0920-NEW				1,733	1,733			
0920-NEW				5,229	5,229			
0920-NEW				1,521	1,521			
0920-NEW				130	130			
0920-NEW				301	301			
0920-NEW				12,000	12,000			
0920-NEW				2,313	2,313			
0920-NEW				1,250	1,250			
0920-NEW				2,000	2,000			
0920-NEW				4,000	4,000			
0920-NEW				4,000	4,000			
0920-NEW				58,903	58,903			
0920-NEW				5,922	5,922			
0920-NEW				66,775	66,775			
0923-0006				2,219	2,219			
0923-0008				1,306	1,306			
0923-NEW				225	225			
0923-NEW				250	250			
0923-NEW				825	825			
0923-NEW				680	680			
0923-NEW				4,463	4,463			

**FY 2005 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB	Due to Agency Actions				
<b>TOTAL</b>		810,836,334	66,775	-24,901,551	786,001,558	769,555	<del> </del>	
0923-NEW				1,050	1,050			
0923-NEW				250	250			
0925-0348				360	360			Revision
0925-NEW				691	691			New
0925-NEW				204	204			New
0925-0503					0	500		Revision
0925-NEW				1,254	1,254			New
0925-NEW				638	638			New
0925-NEW				23	23			New
0925-NEW				140	140			New
0925-NEW				450	450			New
0925-NEW				800	800			New
0925-NEW				12,000	12,000			New
0925-NEW				15,380	15,380		<del> </del>	New
0925-NEW				162	162			New
0930-0100				-4	-4			
0930-0258				21	21			
0930-0260				4,886	4,886			
0930-0195				-409	-409			
0930-0197				3,586	3,586			
0930-0208				3,897	3,897			
0930-0226				4,539	4,539			
0930-0230				-476	-476			
0930-0231				310	310			
0930-NEW				770	770			
0930-NEW				25	25			
0930-NEW				2	2			
0930-NEW				417	417			
0930-NEW				2,950	2,950			
0930-NEW				1,681	1,681			
0930-NEW				78,779	78,779		<del> </del>	
0930-NEW				8,434	8,434			
0930-NEW				91	91			
0930-NEW				51	51			
0930-NEW				3,000	3,000			

**FY 2005 CHANGES IN BURDEN HOURS**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	NOTES
		Due to Statutory Changes	Due to Lapse of OMB	Due to Agency Actions				
<b>TOTAL</b>		810,836,334	66,775	-24,901,551	786,001,558	769,555		
0930-NEW				13,888	13,888			
0930-0233				-170	-170			Discontinue 5/31/05
0930-0235				-2,034	-2,034			Discontinue 6/30/05
0930-0238				-12,600	-12,600			Discontinue 11/30/04
0930-0253				-1,365	-1,365			Discontinue 12/31/04
0930-0256				-993	-993			Discontinue 3/31/05
0935-0120				-6,011	-6,011			Discontinued
0935-NEW				320	320			
0935-NEW				5,200	5,200			
0937-0095				40	40			
0938-0279				-294,783	-294,783			
0938-0328		712,969			712,969			
0938-0679				-100,000	-100,000			Obsolete CMN form
0938-0685		699,622			699,622			CMS-6002-F
0938-0761				-24,301	-24,301			CMS-3006-F
0938-0866				-34,000,000	-34,000,000			
0938-0875				-56,148	-56,148			Obsolete CMN form
0938-NEW		115,974			115,974			CMS-4069-P
0938-NEW		25			25			CMS-1263-P
0938-NEW		1,976			1,976			CMS-2198-P
0938-NEW		433,770			433,770			CMS-6017-P
0938-NEW		4			4			CMS-1429-FC
0938-NEW		2,049,805			2,049,805			CMS-3844-P
0938-NEW				1,625	1,625			Demo Evaluation
0938-NEW		806,459,406			806,459,406			CMS-4068-P
0938-NEW		1,250			1,250			CMS-6024-P
0938-NEW				260,000	260,000			Wheelchairs CMN
0938-NEW				285,525	285,525			HCAHPS Survey
0938-NEW		350,000			350,000			CMS-4004-FC
0990-0115					0	102375		
0990-0208					0	9333		
0990-0256				12,744	12,744			Discontinued
<b>TOTAL</b>		810,836,334	66,775	-24,901,551	786,001,558	769,555		

**FY 2005 CHANGES IN COST BURDEN (\$,000)**

OMB #	Date	PROGRAM CHANGES			NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	Notes
		Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions				
<b>TOTAL</b>		0	0	0	0	0	<del> </del>	
					0			
<b>TOTAL</b>		0	0	0	0	0	<del> </del>	

## **2004 Changes in Burden**

### **REDUCTIONS**

#### **Change in Regulations:**

##### **Cutting Redundancy:**

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0915-0158  
**Title:** Grantee Reporting Requirements for the Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Title III.  
**Purpose of the collection:** This report collected information from Title III Ryan White CARE Act grantees on early intervention diagnostic, preventive, and therapeutic services, as part of a continuum of comprehensive primary health care and support.  
**How Reduction Achieved:** Information collected from this activity was incorporated into the Ryan White CADR data collection project in order to consolidate the information collected under the Titles of the Ryan White Comprehensive AIDS Resources Emergency Act.  
**Change in Burden:** -22,240 hours.

##### **Changing Forms:**

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0985-0008  
**Title:** State Program Report for Title III and VII of the Older Americans Act  
**Purpose of the collection:** The Older Americans Act (OAA) requires annual program performance reports from the States to meet statutory requirements under the OAA including evaluation of program operations, preparation of reports for the Congress, and response to other Federal.  
**How Reduction Achieved:** AoA has greatly streamlining the client detail reports so that a net reduction in the per respondent burden can be achieved over that shown in AoA's last submission for OMB approval. AoA consulted with states in developing approved requirements and has limited the burden to the extent practical and allowable under the OAA.  
**Change in Burden:** -14,133 hours.

#### **Using Information Technology:**

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0925-0001  
**Title:** Research and Research Training Grant Applications and Related Forms  
**Purpose of the collection:** Used by Researchers and Research Institutions to apply for funds to conduct biomedical, behavioral and other health related research under 42 USC 241 and ssq.  
**How Reduction Achieved:** Consolidation of required reporting and use of electronic and information technology  
**Change in Burden:** - 345,000 hours

**Agency:** Department of Health and Human Services  
**OMB#:** 0938-0709  
**Title:** Data Collection for Second Generation Social HMO (S/HMO-II) Demonstration

**Purpose of the Collection:** To collect the necessary data elements from members of the treatment group for the risk-adjusted S/HMO-payment methodology; and gather information from members of the treatment group to enable the participating S/HMO-II site to identify high-risk beneficiaries

**How Reduction Achieved:** The reduction is due to a decrease in the number of respondents and a simplification of the process.

**Change in Burden:** -29,917

**Statutory Reductions:**

**Agency:** **Department of Health and Human Services**  
**OMB#:** 0938-0612  
**Title:** Clinical Laboratory Improvement Amendment (CLIA) of 1988 reg. HSQ-176FC  
**Purpose of the Collection:** The information requested is necessary to determine an entity's compliance with the Congressionally-mandated program with respect to the regulation of laboratory testing (CLIA).  
**How Reduction Achieved:** Implementation of quality control requirements.  
**Change in Burden:** -50,000  
**Statute Title and Public Law:** The Clinical Laboratory Improvement Amendments of 1988 (CLIA)

**Other:**

**Agency:** **Department of Health and Human Services**  
**OMB Number:** 0910-0458  
**Title:** Biological Products: Reporting or Biological Product Deviations  
**Purpose of the Collection:** The objectives of the biological product deviation reporting requirement are to: (1) Enable FDA to respond when public health may be at risk; (2) expedite reporting of biological product deviations in manufacturing; (3) provide FDA with uniform data to track trends that may indicate broader threats to the public health; (4) create a uniform reporting requirement that can be enforced against non-complying entities; and (5) help ensure licensed manufacturers and unlicensed blood establishments are taking appropriate actions to investigate and correct biological product. The reporting system is not intended to overlap quality assurance programs (QA), but instead builds on those QA programs to assure better protection of the public health. Reporting of biological product deviations will enable FDA to identify areas in which further regulation or guidance is needed to assist licensed manufacturers and unlicensed blood establishments in decreasing the occurrence of these events.  
**How Reduction Achieved:** It is attributed to the elimination of the one-time information collection activities to implement the final rule for staff review of the requirements of the rule, establishing or making adjustments to new systems, SOP, and staff training.  
**Change in Burden:** - 193,804 hours

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0920-0576  
**Title:** Possession, Use, and Transfer of Select Agents and Toxins  
**Purpose of the Collection:** CDC was delegated the responsibility of registering entities that possess, use, or transfer select agents or toxins. In performance of its responsibility, CDC has modified a previously approved OMB data collection (0920-0199) to include registration of entities; transfer of select agents and toxins; clinical and diagnostic laboratory report form; notification of theft, loss, or release; and application for exemption. As mandated in the law, these forms have been jointly developed by CDC and USDA/APHIS.  
**Why Reduction Occurred:** The number of respondents was adjusted.  
**Change in Burden:** -17,299

## INCREASES

### Statutory Increases:

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0910-0502  
**Title:** Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002  
**Purpose of the Collection:** The Bioterrorism Act requires registration of facilities that manufacture/process, pack or hold food intended for consumption in the U.S.  
**Why Increase Occurred:** Compliance with the Bioterrorism Act.  
**Change in Burden:** 521,831 hours.  
**Statute Title and Public Law:** Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188.

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0910-0520  
**Title:** Prior Notice of Imported Food Shipments.  
**Purpose of the Collection:** To obtain prior notice regarding imported food shipments.  
**Why Increase Occurred:** The item represents a new collection.  
**Change in Burden:** 2,836,781 hours.  
**Statute Title and Public Law:** Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188.

**Agency:** Department of Health and Human Services  
**OMB#:** 0938-0910  
**Title:** Detailed Explanation of Non-Coverage/Important Medicare Message of Non-Coverage (M+C)  
**Purpose of the Collection:** Pursuant to 42 CFR 422.624(b)(1), providers in skilled nursing facilities, home health agencies and comprehensive outpatient rehabilitation facilities must deliver to M+C enrollees a 2-day advance notice of termination of services. Per requirements at 42 CFR 422.626(e)(1), M+C organizations must deliver detailed notices to the QIO and enrollees upon request for appeal of the termination of services. These notices fulfill the regulatory requirement.  
**Why the Increase Occurred:** This is a new collection  
**Change in Burden:** 68,000 hours

**Agency:** Department of Health and Human Services  
**OMB#:** 0938-0907  
**Title:** Collecting Hospital Occupation-Adjusted Wage Index  
**Purpose of the Collection:** Section 304(c) of BIPA of 2000 mandates the use of occupational mix data for the FY 2005 wage index, requiring the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program.  
**Why the Increase Occurred:** This is a new collection.  
**Change in Burden:** 720,000  
**Statute Title and Public Law:** Section 304(c) of BIPA of 2000

**Agency:** Department of Health and Human Services  
**OMB#:** 0938-0920  
**Title:** Medicaid Managed Care - New Provisions  
**Purpose of the Collection:** These information collection requirements implement regulations that allow states greater flexibility to implement mandatory managed care programs,

implement new beneficiary protections, and eliminate certain requirements viewed by state agencies as impediments to the growth of managed care programs. Information collected includes information about managed care programs, grievances and appeals, enrollment broker contracts, and managed care organizational capacity to provide health care services.

**Why the Increase Occurred:**

This is a new collection.

**Change in Burden:**

3,917,643

**Statute Title and Public Law:**

Balanced Budget Act of 1997 (BBA)

**Agency:**

**Department of Health and Human Services**

**OMB#:**

0938-0924

**Title:**

Application for Participation in Medicare Replacement Drug Demonstration

**Purpose of the Collection:**

The information acquired in the collection will be used to pay, under Medicare Part B, for drugs and biologicals that are prescribed as replacements for existing Medicare drugs that are furnished as incident to physician's professional service and that are not usually self-administerable.

**Why the Increase Occurred:**

The increase in burden reflects changes made to the instrument.

**Change in Burden:**

20,417

**Statute Title and Public Law:**

Section 641 of the MMA (Public Law 108-173)

**Agency:**

**Department of Health and Human Services**

**OMB#:**

0938-0929

**Title:**

Federal Funding of Emergency Health Services (Section 1011): Enrollment Application

**Purpose of the Collection:**

These information collections will allow hospitals and other providers to document the citizenship of individuals for which they are seeking section 1011 reimbursement and support other activities that promote effective coordination of enrollment and payment of section 1011 claim submissions.

**Why the Increase Occurred:**

This is a new collection.

**Change in Burden:**

31,250

**Statute Title and Public Law:**

Section 1011 of the MMA

**Agency:**

**Department of Health and Human Services**

**OMB Control Number:**

0970-0261

**Title:**

Grants Application Data Summary Administrative for Native Americans SEDS Application Information

**Purpose of Collection:**

The Native American Programs Act of 1974 as amended requires the Administration for Native Americans (ANA) Social and Economic Development Strategies (SEDS) projects to use the data in the preparation of annual reports to Congress. The data describes the social and economic conditions of Native Americans and assists the Secretary in preparing an annual report to the Congress.

**Why Increase Occurred:**

To provide legislatively mandated annual report to Congress.

**Change in Burden:**

18,200 hours

**Statue Title and Public Law:**

Native American Programs Act of 1974, enacted as Title VIII of the Economic Opportunity Act of 1964 [PL 88-452] or [42 USC 2991 et seq.]

**Agency:**

**Department of Health and Human Services**

**OMB Control Number:**

0970-0266

**Title:**

Mentoring Children of Prisoners Data Collection Process

**Purpose of Collection:**

The information collection is necessary to provide funding for nonprofit agencies that recruit, screen, train, and support mentors for children with an incarcerated parent or parents. It requires grantees to provide information that can be used to evaluate outcomes for participating children and demonstrate compliance with requirements by the Secretary.

**Why Increase Occurred:** New Collection  
**Change in Burden:** 12,000 hours  
**Statute Title and Public Law:** Promoting Safe and Stable Families Amendments Act of 2001 (Pub. L. 107-133) as amended Title-B of the Social Security Act

**Other:**

**Agency:** **Department of Health and Human Services**  
**OMB Number:** 0910-0472  
**Title:** Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents; and Requirements for Donor Notification  
**Purpose of the Collection:** The donor notification process is intended to prevent further donations from donors who have been deferred for positive test results for markers of communicable disease agents(s) as prescribed in § 610.41 or for failing to satisfy the donor eligibility criteria under §§ 640.3 or 640.63 prior to collection. Deferred donors are informed of: (1) the reason for the decision, (2) the types of donation that the donor should not donate in the future, if appropriate, (3) the results of the tests for evidence of infection due to communicable disease agents that were the basis for deferral, if applicable, and (4) information concerning medical follow-up and counseling. By having this information, the deferred donor may make informed decisions as to his or her medical welfare. Since autologous donors donate blood or blood components for their own use per prescription by their physician, reactive test results for a communicable disease agent on an autologous donor are sent to the referring physician. Awareness of reactive test results will aid the referring physician in the treatment and counseling of the autologous donor.

**Why Increase Occurred:** FDA is consolidating the OMB Control No. 0910-0474 into 0910-0472. The previous burden estimate under 0910-0474 was 141,681 hours, and under 0910-0472 was 3,125 hours (combined total of 144,806 hours). The increase in burden in the current package (0910-0472) to 145,270 hours is due to the consolidation of packages.

**Change in Burden:** 142,145 hours

**Agency:** **Department of Health and Human Services**  
**OMB Number:** 0910-0543  
**Title:** Eligibility Determination for Donor of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)  
**Purpose of the Collection:** The collection provides more appropriate oversight for the wide spectrum of HCT/Ps. It will improve the protection of the public health and increase public confidence in new technologies, while permitting significant innovation and keeping regulatory burden at a minimum. Documentation of donor eligibility determination provides the user with the donor's medical history and social behavior that are reviewed for high risk for or clinical evidence of communicable diseases, and that all required testing has been completed. Other reporting and recordkeeping requirements are designed to disclose fully the screening and testing results to the user when using the products from donors who are determined to be ineligible or whose eligibility has not yet been determined in an urgent medical need. The distributing establishment is also to document that the HCT/P establishment notified the physician that the screening and testing are not completed.

**Why Increase Occurred:** This is a new collection.  
**Change in Burden:** 866,240 hours

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0910-0538  
**Title:** Supplements and Other Changes to an Approved Application Final Rule.

<b>Purpose of the Collection:</b>	To review and approve dietary supplements and marketing applications.
<b>Why Increase Occurred:</b>	Revisions to existing regulations to improve the quality of the information submitted in the supplements to an Approved Application
<b>Change in Burden:</b>	1,023,310 hours.
<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0910-0537
<b>Title:</b>	Bar Code Label Requirement for Human Drug Products and Blood.
<b>Purpose of the Collection:</b>	To reduce the number of medication errors in hospitals and other health care settings by requiring bar code scanning equipment to verify that the right drug, in the right dose, and right route of administration, is being given to the right patient at the right time.
<b>Why Increase Occurred:</b>	It is a new requirement.
<b>Change in Burden:</b>	1,776,590 hours.
<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0915-0281
<b>Title:</b>	AIDS Education and Training Centers
<b>Purpose of the Collection:</b>	The AETC data collection activities gather data on training programs and technical assistance programs conducted by the AETCs and the individuals who attend these training sessions.
<b>Why Increase Occurred:</b>	HRSA administers funds for the CARE Act and the AETCs, and this information is needed to monitor training activities and assess program performance under GPRA.
<b>Change in Burden:</b>	32,502 hours.
<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0920-0602
<b>Title:</b>	Work Organization, Cardiovascular Disease, and Depression Study.
<b>Purpose of the Collection:</b>	To examine the relationships between job stress, CVD and depression, and ascertain exposures and outcomes.
<b>Why Increase Occurred</b>	New submission.
<b>Increase in Burden:</b>	+28,860 hours.
<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0920-0607
<b>Title:</b>	National Violent Death Reporting System
<b>Purpose of the Collection:</b>	This state-based surveillance system will collect data on violent deaths in a more detailed and timely information than is currently available. The system utilizes records from medical examiners, police, crime labs and coroners.
<b>Why Increase Occurred:</b>	New submission.
<b>Change in the Burden:</b>	+ 25,000
<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0920-0621
<b>Title:</b>	National Youth Tobacco Survey (NYTS)
<b>Purpose of the Collection:</b>	The NYTS provides nationally representative data for students in grades 6-12 in the United States and covers several tobacco related topics. The monitoring of national trends in current tobacco use and smoking cessation attempts in adolescents is recommended by the Secretary of DHHS, and is of utmost importance in monitoring and evaluating the Office of Smoking and Health=s Tobacco Control Program.
<b>Why Increase Occurred:</b>	New Submission
<b>Change in the Burden:</b>	+18,663

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0920-0635  
**Title:** Epidemiological Study of Gastrointestinal Health Effects and Exposure to Disinfection Byproducts Associated with Consumption of Conventional Treated Groundwater  
**Purpose of the Collection:** The National Center for Environmental Health is conducting this survey of gastrointestinal disease occurrence in a public water system to provide data on waterborne disease occurrence as mandated by Congress as part of the 1996 Safe Drinking Water Act Amendments. NCEH is determining exposure to disinfection byproducts to inform decisions made by the water industry about how to effectively balance the microbial and chemical risks associated with public drinking water supplies.  
**Why Increase Occurred:** New submission  
**Change in the Burden:** +12,934

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0920-0638  
**Title:** Survey of Chronic Fatigue Syndrome and Chronic Unwellness in Georgia  
**Purpose of the Collection:** This submission will allow CDC to collect information to estimate the burden in racial and ethnic minorities from metropolitan, urban, and rural communities to devise control and prevention strategies.  
**Why Increase Occurred:** New submission  
**Change in the Burden:** +10,211

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0920-0643  
**Title:** Assessment Information about the National Center for Injury Prevention and Control (NCIPC) Publications  
**Purpose of the Collection:** This assessment will allow the program to evaluate NCIPC publications and allow the program to identify audience need and other gaps.  
**Why Increase Occurred:** New submission  
**Change in the Burden:** +17,026

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0925-NEW  
**Title:** Longitudinal Investigation of Fertility and the Environment  
**Purpose of the Collection:** Conduct long range study of effects of environmental exposures on fertility of married couples  
**Why increase occurred:** National Institute of Child Health and Human Development is authorized by 42 USC 285j to carry our research on causes of fertility and infertility in the U.S. population and to ensure reproductive health of individuals  
**Change in burden:** 15,580 hours

**Agency:** Department of Health and Human Services/NIH  
**OMB Control Number:** 0930-0257  
**Title:** National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program  
**Purpose of the Collection:** The Community Mental Health Services Program for Children with Serious Emotional Disturbances supports a broad array of community-based and family-centered services delivered through the system of care model. This submission is for a 6 ½ year evaluation of services provided by grantees receiving initial support in FY 2002-2004. Most data collection instruments and procedures are built upon those used in the evaluation of Phase Three grantees. Dat will be used for both national local evaluation.  
**Why Increase Occurred:** This is a new project.  
**Change in Burden:** 25,262

**Agency:** Department of Health and Human Services/NIH  
**OMB#:** 0938-0918  
**Title:** Hospital Reporting Initiative--Hospital Quality Measures  
**Purpose of the Collection:** To identify opportunities for improvement and to effectively target quality improvement initiatives in order to meet the statutory requirements for Quality Improvement Organizations (QIOs)  
**Why the Increase Occurred:** Increased numbers of respondents  
**Change in Burden:** 239,200  
**Statute Title and Public Law:** Medicare Prescription Drug, Improvement, and Modernization Act of 2003

**Agency:** Department of Health and Human Services/NIH  
**OMB#:** 0938-0916  
**Title:** Paid Feeding Assistants in Long Term Care Facilities and Supporting Regulations Contained in 42 CFR 483.160  
**Purpose of the Collection:** To ensure that feeding assistants are properly trained and able to completely feed nursing home residents  
**Why the Increase Occurred:** This is a new collection.  
**Change in Burden:** 68,000

**Agency:** Department of Health and Human Services  
**OMB:** 0938-0046  
**Title:** End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration and Supporting Regulations in 42 CFR, 405.2133; PL 95-292; CFR Parts 401 and 422; Social Security Act  
**Purpose of the Collection:** Collection of these data are necessary for entitlement of ESRD patients to Medicare benefits and also for the establishment and maintenance of a single, nationwide kidney disease registry for dialysis, transplant, and prospective transplant patients, and will store pertinent medical facts on each registrant.  
**Why the Increase Occurred:** The increase is due to an increase in the number of respondents and to the addition and deletion of items to be reported.  
**Change in Burden:** 50,000 hours

## **2005 Changes in Burden**

### **REDUCTIONS**

#### **Change in Regulations:**

#### **Cutting Redundancy:**

#### **Changing Forms:**

**Agency:** Department of Health and Human Services  
**OMB Control Number:** 0938-0761  
**Title:** Medicare and Medicaid Programs: Reporting Outcome and Assessment Information Set Data as Part of the Conditions of Participation for Home Health Agencies (HHA) (OASIS)  
**Purpose of the Collection:** HHAs are required to report data from the OASIS as a condition of participation. These requirements are necessary to achieve broad-based, measurable improvement in the quality of care furnished through Federal programs, and to establish a prospective payment system for HHAs.  
**How Reduction Achieved:** The decrease in burden hours reflects a decrease in the number of participating respondents and consolidation and simplification of the collection instrument.  
**Change in Burden:** -24,301 hours.

#### **Using Information Technology:**

**Agency:** Department of Health and Human Services  
**OMB Control:** 0938-0279  
**Title:** Medicare Uniform Institutional Provider Bill  
**Purpose of the Collection:** To standardize the form used in the Medicare/Medicaid program to apply for reimbursement of covered services by all institutional providers that accept Medicare/Medicaid.  
**How Reduction Achieved:** Pub. L. 107-105 established the requirements and exceptions under the Medicare Program for the mandatory submission of bills submitted in electronic form.  
**Change in Burden:** -294,783

#### **Statutory Reductions:**

#### **Other:**

**Agency:** Department of Health and Human Services  
**OMB Control:** 0938-0866  
**Title:** HIPAA Standards for Electronic Transactions  
**Purpose of the Collection:** To standardize electronic health care claims transactions.  
**How Reduction Achieved:** The rule imposed a one-time burden, necessary for the adoption of the standards. The one time burden has been satisfied.  
**Change in Burden:** -34,000,000

## INCREASES

### Statutory Increases:

<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0938-0328
<b>Title:</b>	Hospital Conditions of Participation
<b>Purpose of the Collection:</b>	To outline the standards necessary for hospital participation in the Medicare program.
<b>Why the Increase Occurred:</b>	To account for the addition of critical access hospitals requirements, and the updating of the Conditions of Participation.
<b>Change in Burden:</b>	712,969
<b>Statute Title and Public Law:</b>	Sections 1102, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v), (I)(G), and (z), 1864, 1871, 1883, 1902(a)(30), 1905(a) and 1913 of the Social Security Act.
<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0938-0685
<b>Title:</b>	Requirements for Establishing and Maintaining Medicare Billing Privileges and Provider Enrollment Process
<b>Purpose of the Collection:</b>	To enroll in the Medicare program and obtain and activate a Medicare provider or supplier billing number, §424.510(a) requires a provider or supplier to complete and submit a CMS 855 to us, demonstrating that the provider or supplier meets all of the requirements.
<b>Why the Increase Occurred:</b>	Regulatory requirements associated with maintaining Medicare billing privileges.
<b>Change in Burden:</b>	699,662
<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0938-NEW
<b>Title:</b>	HIPAA Administrative Simplification: Standard Unique Health Identifier Plans
<b>Purpose of the Collection:</b>	The use of this standard unique health identifier for health plans in standard transactions would improve the operation of Federal (including Medicare and Medicaid) and private health programs. Each health plan must apply for an NPlanID and use it to identify itself on all standard transactions where its identifier is required.
<b>Why Increase Occurred:</b>	This is a new collection.
<b>Change in Burden:</b>	433,770 hours
<b>Statute Title and Public Law:</b>	Administrative Simplification Subtitle of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191.
<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0938-NEW
<b>Title:</b>	Expedited Determination Procedures for Provider Service Determinations (CMS-4004-FC)
<b>Purpose of the Collection:</b>	Provide for the establishment of expedited determination procedures for providers
<b>Why the Increase Occurred:</b>	Public law.
<b>Change in Burden:</b>	350,000
<b>Statute Title and Public Law:</b>	BIPA 521
<b>Agency:</b>	<b>Department of Health and Human Services</b>
<b>OMB Control Number:</b>	0938-NEW
<b>Title:</b>	Medicare Prescription Drug Benefit (CMS-4068-P)

**Purpose of the Collection:** To implement the Medicare Part D – Voluntary Prescription Drug Benefit Program.  
**Why the Increase Occurred:** Public law.  
**Change in Burden:** 806,459,406  
**Statute Title and Public Law:** Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0938-NEW  
**Title:** Medicare Program; Establishment of the Medicare Advantage Program (CMS-4069-P)  
**Purpose of the Collection:** Replace the Medicare + Choice Program with the Medicare Advantage Program while retaining most key features of the Medicare + Choice Program.  
**Why the Increase Occurred:** Public law.  
**Change in Burden:** 115,974  
**Statute Title and Public Law:** Title II of MMA.

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0938-NEW  
**Title:** Medicare and Medicaid Programs: Hospice Conditions of Participation (CMS-3844-P)  
**Purpose of the Collection:** The revision of the Medicare and Medicaid hospice requirements, used to focus on a patient-centered, outcome-oriented processes that promotes patient care.  
**Why the Increase Occurred:** Public law.  
**Change in Burden:** 2,049,805  
**Statute Title and Public Law:** Balanced Budget Act of 1997, MMA

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0915-NEW  
**Title:** National Practitioner Data Bank: Section 1921 of the Social Security Act.  
**Purpose of the Collection:** Section 1921 authorizes the collection of information on adverse actions taken by State licensing Boards and authorities against all health care practitioners and health care entities as well as any negative action or finding taken by a private accreditation entity.  
**Why Increase Occurred:** The publication of the NPRM will implement Section 1921 of the Social Security Act which then expands the type of information collected by the National Practitioner Data Bank.  
**Change in Burden:** 11,483 hours.  
**Statute Title and Public Law:** Section 1921 of the Social Security Act, as amended by Section 5(b) of the Medicare and Medicaid Patient and Program Protection Act of 1987, Public Law 100-93.

**Other:**

**Agency:** **Department of Health and Human Services**  
**OMB Number:** 0910-0460  
**Title:** Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (Lookback)  
**Purpose of the Collection:** Collecting establishments must review previous testing records of a donor who tests reactive for evidence of human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection either on a repeat donation or after a review of historical testing records. The review of records is to identify previously donated blood and blood components that may be at risk of transmitting HIV or HCV infection to a recipient. The purpose of the final rule is to help ensure the continued safety of the blood supply. This collection of information provides

important information to consignees and/or recipients of prior collections of blood and blood components, including Source Plasma and Source Leukocytes, from a donor who later returned to donate and tested repeatedly reactive for antibody to HIV or HCV. This makes it possible for consignees to quarantine prior collections that remain in inventory and that may be at increased risk for transmitting HCV. It also provides the opportunity for recipients of prior collections to be informed of the need for HIV or HCV testing and counseling.

New program.

**Why Increase Occurred:**  
**Change in Burden:**

723,264

**Agency:**  
**OMB Number:**  
**Title:**

**Department of Health and Human Services**  
0910-0473

**Purpose of the Collection:**

Current Good Tissue Practice (CGTP) for Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Establishments; Inspection and Enforcement  
These regulations provide more appropriate oversight for the wide spectrum of HCT/Ps that are marketed now or may be marketed in the future. FDA's action would improve protection of the public health and increase public confidence in new technologies, while permitting significant innovation and keeping regulatory burden at a minimum. The CGTP information collection provisions are intended to provide (1) additional measures for preventing the introduction, transmission, or spread of communicable disease; (2) step-by-step consistency in the manufacturing of the product; (3) necessary information to FDA for the purpose of protecting public health and safety; (4) accountability in the manufacturing of cellular and tissue-based products; and (5) information facilitating the tracking of a product back to its original source or to final disposition.

**Why Increase Occurred:**  
**Change in Burden:**

New program.  
283,400

**Agency:**  
**OMB Number:**  
**Title:**

**Department of Health and Human Services**  
0910-XXXX

**Purpose of the Collection:**

Requirements for Human Blood and Blood Components Intended for Transfusion or For Further Manufacturing Use  
The proposed rule would revise and update the regulations to add donor requirements for consistency with current practices in the blood industry. FDA is taking this action to help ensure the safety of the national blood supply and to help protect donor health by providing provisions for evaluating donors for factors that may adversely affect the safety, purity, and potency of human blood and blood components or the health of a donor during the donation process.

**Why Increase Occurred:**  
**Change in Burden:**

New program.  
810,982

**Agency:**  
**OMB Control Number:**  
**Title:**  
**Purpose of the Collection:**  
**Why Increase Occurred:**

**Department of Health and Human Services**  
0910-NEW  
Safety Reporting Requirements (SADR) Final Rule.

**Change in Burden:**

Information concerning adverse reactions to marketed drugs  
Regulations improved the information received in adverse event reporting so FDA and health care providers can make changes that lead to improvements in the public's health and safety  
5,799,477 hours.

**Agency:**  
**OMB Control Number:**  
**Title:**  
**Purpose of the Collection:**

**Department of Health and Human Services**  
0910-NEW  
Labeling for Human Prescription Drugs Final Rule.  
Requirements for labeling submitted as part of a new drug application.

**Why Increase Occurred:** Revisions to existing regulations to improve the labeling on Human Prescription Drugs making it easier for consumers to use and understand.  
**Change in Burden:** 501,383 hours.

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0915-0140  
**Title:** The Nursing Education Loan Repayment Agreements  
**Purpose of the Collection:** The Nursing Education Loan Repayment Agreements provide information that is used to determine whether applicants meet the eligibility requirements for repayment of education loan balances for registered nurses.

**Why Increase Occurred:** The program received a substantial increase in funding which will permit a significant growth in the number of applications received and funded.  
**Change in Burden:** 46,950 hours.

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0920-NEW  
**Title:** Environmental Health Specialists Network (EHS-Net) Data Collection Methodology and Instrument  
**Purpose of the Collection:** The National Center for Environmental Health (NCEH) plans to use the Environmental Health Specialists Network (EHS-Net) system to assist public health officials to better identify and assess environmental factors contributing to foodborne outbreaks and the prevention efforts needed to reduce or ameliorate these events. The instrument was developed by CDC in collaboration with the FDA and a group of eight EHS-Net participating states. This project will use the instrument in all 50 states. Eventually, the EHS-Net data collection instrument and methodology will be made available to all public health officials in the United States.

**Why Increase Occurred:** New submission.  
**Change in Burden:** +16,800

**Agency:** **Department of Health and Human Services**  
**OMB Number:** 0920-NEW  
**Title:** Program Evaluation and Monitoring System (PEMS)  
**Purpose of the collection:** The purpose of this data collection will be to collect standardized data from grantees regarding: 1) agency or organizational identifiers and descriptors; 2) intervention activities; 3) behavioral or service outcomes at the client level; and 4) program performance indicators.

**Why Increase Occurred:** New submission.  
**Change in Burden:** +153,400

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0920-NEW  
**Title:** Final Evaluation of the Effectiveness of Targeted Lookback for Identifying Transfusion Recipients Who Received Blood that may have Contained Hepatitis C Virus

**Purpose of the Collection:** Under FDA guidance issued in September 1998, blood collection establishments identified all donors who tested positive for anti-HCV using the multiantigen screening assays that were licensed for use in 1992, identified prior collections from these donors dating back to January 1, 1988, and notified the transfusion services to which blood and blood components from these prior collections had been shipped. The transfusion services identified the patients to whom these components were transfused and notified them either directly or through their physicians. During the time period that targeted lookback based on the 1998 FDA guidance was being performed, FDA issued a draft for comment of a revised guidance document that expanded the scope of the targeted lookback to include prior recipients of blood components from donors who tested positive

for anti-HCV using single antigen assays (used during 1990-1992) and that the search for records from donors testing anti-HCV positive on any licensed assay and their prior recipients extend further back in time. However, performance of the expanded lookback was dependent on a final guidance for implementation document to be issued by FDA.

**Why Increase Occurred:** New submission  
**Change in Burden:** +15,480

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0920-NEW  
**Title:** Public Health Injury Surveillance and Prevention Programs  
**Purpose of the Collection:** This project will develop and maintain injury surveillance programs including those that focus on traumatic brain injury. Program recipients will collect information from pre-existing state data sets to calculate injury indicators in their state.

**Why Increase Occurred:** New submission  
**Change in the Burden:** +12,000

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0920-NEW  
**Title:** The National Electronic Data Surveillance System (NEDSS)  
**Purpose of the Collection:** NEDSS is an initiative that promotes the use of data and information system standards to advance the development of efficient, integrated, and interoperable surveillance systems at federal, state, and local levels.

**Why Increase Occurred:** New submission.  
**Change in the Burden:** +58,903

**Agency:** **Department of Health and Human Services**  
**OMB Control Number:** 0930-NEW  
**Title:** Monitoring Outcomes in the Access To Recovery Program  
**Purpose of the Collection:** States funded in the Access To Recovery (ATR) program will use these outcome measures to meet the reporting requirements of the Government Performance and Results Act (GPRA) by quantifying the effects and accomplishments of the funded programs. The ATR Program is part of a Presidential initiative to: 1) provide client choice among substance abuse clinical treatment and recovery support service providers, 2) expand access to a comprehensive array of clinical treatment and recovery support options (including faith-based programmatic options), and 3) increase substance abuse treatment capacity. Monitoring outcomes, tracking costs, and preventing waste, fraud and abuse to ensure accountability and effectiveness in the use of Federal funds are also important elements of the ATR program. Grantees, as a contingency of their award, are responsible for collecting data from their clients at intake, discharge, at 30 days after intake, and every two months during an episode of care. An episode of care is defined as a client's entry to and exit from the ATR.

**Why Increase Occurred:** This is a new project.  
**Change in Burden:** 78,779

**Agency:** **Department of Health and Human Services**  
**OMB Number:** 0930-NEW  
**Title:** Testing for Illegal Drugs  
**Purpose of the Collection:** E.O. 12564 requires the head of each Executive agency to establish a program to test for the use of illegal drugs by federal employees in sensitive positions and requires the Secretary of HHS to promulgate scientific and technical guidelines for drug testing programs. Included are the recordkeeping and reporting requirements in the Mandatory Guidelines, the application form and Sections B, C and D of the Inspection Checklist for the National Laboratory Certification

program, and the Federal Drug Testing Custody and Control Form. These Guidelines expand testing to hair, seat, and oral fluid specimens, establish scientific and technical guidelines for using on-site tests to test urine and oral fluids at the collection, set requirements for certification of instrumented initial test facilities, and add standard for collectors, on-site testers, and medical review officers.

**Why Increase Occurred:**  
**Change in Burden:**

This is a new project.  
13,888

**Agency:**  
**OMB Control Number:**  
**Title:**

**Department of Health and Human Services**  
0938-NEW

National Implementation of the Hospital CAHPS Survey Purpose of the Collection: Hospital CAHPS, part of the Hospital Quality Alliance, is an effort to provide comparative performance information on hospitals to the public. HCAHPS includes a nationally recognized and quality approved standardized survey instrument and data collection protocol allowing for flexibility in the mode of administration. The goals of HCAHPS are to offer consumers choice, if applicable and create incentives for hospitals to improve performance in areas that are important to patients.

**Why the Increase Occurred:**  
**Change in Burden:**  
**Statute Title and Public Law:**

Quality Improvement, Consumer Choice.  
285,525  
None

**Agency:**  
**OMB Control Number:**  
**Title:**  
**Purpose of the Collection:**  
**Why the Increase Occurred:**

**Department of Health and Human Services**  
0938-NEW

Wheelchairs (Including POV); Certificate of Medical Necessity For Medicare to consider item for coverage and payment.

In consolidating CMS form number 843(OMB 0938-0875), 844(OMB 0938-0679) and 850(OMB 0938-0679) into one unified CMS form number 10116, the initial burden of processing and reviewing three CMNs has now reduced by the use of a single CMN. This burden takes into account current CMS statistics as well as adheres to the provisions stated in the regulations. By revising the questions on the CMN but adhering to the basis format, CMS can increase the accuracy of the document while eliminating the need to re-educate CMN users. By combining the CMN for manual wheelchairs, motorized wheelchairs, and power operated vehicles into a single CMN, a hierarchical approach can be used to determine coverage.

**Change in Burden:**

260,000 hours.