Lorraine Hunt Office of Management and Budget Washington, DC 20503

Dear Ms. Hunt:

As instructed in the OMB Data Call of September 16, 2005, we are electronically submitting 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:

- <u>Tab 1 Update on HHS Special Burden Reduction Project for FY 2005</u> Last year the Department developed a new initiative titled, "Targeted Plan for Reduction among the Highest Burden Collections." This initiative identified 33 approved information collections in the Department that had at least one million hours of burden each, and that totaled 202 million hours or 73% of the Department's burden. The update shows significant reduction in the burden from these collections.
- <u>Tab 2 Information Collection Budget</u> This is a comprehensive accounting of information collection burden placed on the public in FY 2005 and planned in FY 2006. The accounting shows that in spite of burden reductions of 36 million hours for the targeted information collections, the HHS burden increased by over 283 million hours. Most of this (212 million hours) was caused by the information collection requirements in the Medicare Prescription Drug Program.
- <u>Tab 3 Examples of significant burden changes</u> As instructed, we have prepared a total of 83 short summaries for all changes over 10,000 burden hours, grouped according to type of program change in FY 2005 and FY 2006.
- Tab 4 Compliance with the Paperwork Reduction Act of 1995 The Department's report includes information on "violations due to lapse of OMB approval", and violations that are "existing collections without OMB approval (i.e., bootlegs)." HHS is reporting two violations due to lapse of OMB approval. This is a significant reduction in these types of violations (which for the last three years have ranged from 15 to 20). This reduction is primarily due to the new HHS electronic system for conducting the clearance function. The system is known as the Information Collection Request, Report and Approval System (ICRAS), which HHS has successfully expanded to OMB. The Department fully expects to eliminate all violations of this type in FY 2006. HHS is also reporting eight "bootlegs" violations. Seven of these violations have been resolved, and the Department is working closely with SAMHSA to resolve the remaining one.

As discussed above, HHS has not reduced burden in FY 2005 due to major new legislative requirements. However, 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 "robert.polson@hhs.gov" or at 202/690-6741.

Sincerely,

Charles Havekost Chief Information Officer

Enclosures

# Appendix A

# Department of Health and Human Services Special Burden Reduction Project Update for FY 2006 ICB

<u>Initiative Title</u>: Targeted Plan for Reduction among Highest Burden Collections

# **Description:**

As of September 30, 2004, HHS had 852 approved information collections that placed 277 million hours of burden on the public. Of these, 33 collections had at least one million hours of burden each, and in total accounted for 202 million hours of burden or 73% of the total HHS burden on the public. The remaining 819 collections account for only 27% of the Departmental burden. In light of these facts and in response to the OMB direction to achieve 1% reduction in burden, HHS implemented an initiative to achieve maximum possible burden reduction among these 33 largest collections located in three of the eleven HHS' Operating Divisions: CMS, FDA, and ACF.

## Update for FY 2005:

Of the 33 Departmental programs with the highest burden, 10 had burden change for a net burden reduction of 33.1 million hours. The changes were as follows:

<u>OPDIV</u>	OMB Number	<u>Change</u>	<u>Date</u>
ACF	0980-0140	-48,492 (adjustment)	10/22/2004
CMS	0938-0214	490,576 (program change)	7/18/2005
	- 0328	712,969 (adjustment)	1/27/2005
	- 0702	-2,121,132 (adjustment)	12/27/2004
	- 0753	-55,567 (adjustment)	7/08/2005
	- 0866	-33,999,999 (adjustment)	2/03/2005
FDA	0910-0001	388,553 (adjustment)	5/19/2005
	-0037	482,280 (adjustment)	6/30/2005
	-0442	616,855 (adjustment)	4/29/2005
	-0485	311,815 (adjustment)	6/06/2005

The largest burden change was in a collection for the Center for Medicare and Medicaid Services (CMS), titled, "Information Collection Requirements in HIPAA Standards for Electronic Transactions". The reduction of 34 million burden hours was due to the completion of a one-time burden on the public. The only program change was also at CMS, titled, "Medicare Secondary Payer Information Collection and Supporting Regulations." This change was required by legislative action.

The Food and Drug Administration (FDA) has been a leader in the Federal Government in promoting the use of electronic transmissions by the public for the purpose of

providing information to the government. For example, FDA has an on-going effort to request that parts of NDAs be submitted in electronic format. This affects the FDA collection titled, "Applications for FDA Approval to Market a New Drug (NDA)", 0910-0001. Currently 80 % of NDAs and Abbreviated New Drug Applications (ANDA) have electronic components. This reduces burden by reducing the time needed to photocopy and mail these submissions. FDA expects these reductions to be evident in FY 2006.

In addition, in an effort to facilitate the registration and filing requirement for Low Acid Canned Foods Registration (0910-0037), FDA developed an electronic system to permit registration and filing over the Internet. FDA expects that this initiative will result in a significant decrease in the annual burden hours to the respondents. However, before these reductions are realized, FDA will need to absorb burden increases caused by expanding the program to 6,500 foreign firms.

## Obstacles:

Although HHS had specific burden reductions of over 36 million hours in FY 2005, the HHS total burden increased by over 283 million hours. Most of this increase can be attributed to two legislative required programs: Health Insurance Reform (0938-0949) with 64.5 million hours, and the Medicare Prescription Drug Program (0938-0957) with 212 million hours. This increase illustrates that the major obstacle to burden reduction in the Department continues to be information requirements prescribed by statute and/or regulations. In order to reduce or eliminate these, changes to existing authorities would be required.

### Future Plans:

In recognition of the impact of legislative mandates on burden reduction, the Department will be cautious in developing regulations, guidance, surveys, and forms that levy the least burden on the public possible. For all these collections of information, HHS requests review and comments from the public. The Department considers the merits of each comment received and includes changes suggested by commenters that are appropriate and do not harm the integrity of the information collection.

In addition to careful review of legislative and regulatory requirements, the Department will continue to promote where feasible the use of electronic reporting as discussed earlier with reference to FDA. Finally, the Department will continue efforts to improve the efficiency of information collections and reduce burden per response,

# Department of Health and Human Services

SUMMARY TABLE OF BURDEN CHANGES	Burden Hours (millions)	Cost Burden (\$,000,000)	These cells come
FY 2004 Total Burden	277.49	1130.57	from the FY 2005 ICB. Do not
FY 2005 Program Changes Due to New Statutes	287.28	(6.00)	change.
FY 2005 Program Changes Due to Lapses in OMB Approval	0.62	0.11	These numbers
FY 2005 Program Changes Due to Agency Actions	0.60	(12.63)	should match
SUBTOTAL: FY 2005 Total Program Changes	288.50	(18.52)	our end-of-the-
FY 2005 Adjustments	(26.09)	(89.59)	/  year total.
FY 2005 Total Burden	539.90	1,022.47	These cells are set
Expected FY 2006 Program Changes Due to New Statutes	4.48	0.00	to take the same values as the first
Expected FY 2006 Program Changes Due to Lapses in OMB Approval	0.00	0.00	line of the other
Expected FY 2006 Program Changes Due to Agency Actions	9.54	0.00	tables. Make sure
SUBTOTAL: Expected FY 2006 Total Program Changes	14.02	0.00	the first line is the total for the tables
Expected FY 2006 Adjustments	0.58	457.68	using the $=SUM()$
Expected FY 2006 Total Burden	554.50	1,480.15	formula.

PROGRAM CHANGES			NEW						
OMB #	Date	Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions	NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	ТҮРЕ	NOTES
TOTAL		287,280,586	618,923	603,470	288,495,426	-26,085,579	$\times$		
0910-0001	5/9/2005				0	388553		Approved	
0910-0012	11/30/2004			-68621	-68621	0		Discontinued	Consolidated with 0910-0284
0910-0027	11/8/2004				0	-14		Approved	
0910-0032	12/21/2004				0	-42935 482280		Approved	
0910-0037 0910-0045	6/30/2005 12/21/2004				0	482280 156105		Approved	
0910-0043	2/5/2005				0	-768		Approved Approved	
0910-0033	6/30/2005				0	-33623		Approved	
0910-0130	11/9/2004				0	7168600		Approved	
0910-0133	6/30/2005				0	-25		Approved	
0910-0152	12/21/2004				0	-1490		Approved	
0910-0154	12/21/2004				0	-29900		Approved	
0910-0188	7/29/2005				0	-6102		Approved	
0910-0216	11/8/2004				0	130		Approved	
0910-0233	11/8/2004				700	0		Approved	
0910-0279	6/30/2005			-626	-626	0		Discontinued	No Violation
0910-0308	7/13/2005				0	-83071		Approved	
0910-0330 0910-0338	7/13/2005				0	720 33336		Approved	
0910-0338	9/12/2005 6/17/2005				0	53		Approved Approved	
0910-0340	9/29/2005				1401	0		Reinstatement with Change	
0910-0359	4/29/2005				0	-6950		Approved	
0910-0360	5/25/2005				0	-4200		Approved	
0910-0375	12/22/2004				0	2900		Approved	
0910-0376	10/31/2004		-33280		-33280	0	$\mathbb{N}$	Expired	No Violation
0910-0378	4/11/2005				0	8862		Approved	
0910-0387	4/11/2005				0	-24611		Approved	
0910-0389	8/12/2005				0	2240		Approved	
0910-0392	7/31/2005			-18557	-18557	0	$\sim$	Discontinued	
0910-0393	8/12/2005			212	0	1597		Approved	
0910-0395 0910-0442	11/30/2004 4/29/2005			-213	-213	616855		Discontinued	
0910-0442	10/31/2004		-659		-659	010833		Approved Expired	No Violation
0910-0477	6/17/2005		-039		-039	12108		Approved	140 ¥ iolation
0910-0483	3/31/2005			-52333	-52333	0	$\searrow$	Discontinued	
0910-0484	11/30/2004			-1417	-1417	0		Discontinued	
0910-0485	6/6/2005					311815		Approved	
0910-0486	1/31/2005			-813	-813	0		Discontinued	
0910-0489	11/30/2004			-922	-922	0		Discontinued	
0910-0493	6/30/2005			-960	-960	0		Discontinued	
0910-0509	3/10/2005				0	21		Changed	
0910-0522	9/12/2005			2	0	5570		Approved	
0910-0545	10/29/2004			281 312	281	0		Changed	
0910-0545 0910-0553	7/13/2005 10/7/2004			312 34840	312 34840	0		Changed	
0910-0553	10/ //2004			34840 27740	34840 27740	0	$\Leftrightarrow$	Approved Approved	
0910-0557	12/7/2004			6400	6400	0		Approved	
0910-0558	12/7/2004			6129	6129	0		Approved	
0910-0559	11/15/2004			283400	283400	0	$\overline{}$	Approved	
0910-0560	2/4/2005	5359000			5359000	0	$>\!\!<$	Approved	
0910-0562	5/5/2005			2998	2998	0		Approved	
0910-0563	5/13/2005			790	790	0		Approved	
0910-0564	5/27/2005			54000	54000	0	_	Approved	
0910-0565	8/12/2005			1827	1827	0		Approved	
0910-0566	6/30/2005			60	60	0		Approved	

OMB #  TOTAL  0910-0567  0910-0569  0915-0036  0915-0127  0915-0140  0915-0151  0915-0184  0915-0188  0915-0188  0915-0193  0915-0226  0915-0227  0915-0230  0915-0233  0915-0233  0915-0234  0915-0254  0915-0254  0915-0254	7/13/2005 8/26/2005 9/30/2005 7/29/2005 11/5/2004 6/13/2005 12/2/2004 1/31/2005 10/31/2004 5/6/2005 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 5/6/30/2005 5/31/2005	Due to Statutory Changes 287,280,586	9142 -300 -1297	Due to Agency Actions  603,470 845 1500  952 52590	NET PROGRAM CHANGES  288,495,426  845  1500  0  952  52950  0  -9142  -530  0  -300  -1297	-26,085,579 -26,085,579 0 0 1191 0 0 125 14597 0 0 2-2736		Approved Approved Approved Approved Approved Approved Approved Expired Expired Approved Approved	NOTES  Discontinued, not a violation Discontinued, not a violation
0910-0567 0910-0569 0915-0036 0915-0036 0915-0127 0915-0140 0915-0184 0915-0184 0915-0188 0915-0188 0915-0193 0915-0226 0915-0227 0915-0230 0915-0233 0915-0233 0915-0234 0915-0234	8/26/2005 9/30/2005 7/29/2005 11/5/2004 6/13/2005 12/2/2004 1/31/2005 10/31/2004 5/6/2005 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005	287,280,586	-9142 -530	845 1500 952	845 1500 0 952 52950 0 0 -9142 -530 0	0 0 1191 0 0 125 14597 0 0 0 -2736		Approved Approved Approved Approved Approved Approved Expired Expired Approved	Discontinued, not a violation
0910-0569 0915-0036 0915-0127 0915-0127 0915-0140 0915-0151 0915-0184 0915-0188 0915-0193 0915-0226 0915-0227 0915-0227 0915-0230 0915-0233 0915-0233 0915-0234 0915-0253	8/26/2005 9/30/2005 7/29/2005 11/5/2004 6/13/2005 12/2/2004 1/31/2005 10/31/2004 5/6/2005 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005		-530 -300	1500 952	1500 0 952 52950 0 0 -9142 -530 0	0 -1191 0 0 125 14597 0 0 -2736 0		Approved Approved Approved Approved Approved Approved Expired Expired Approved	Discontinued, not a violation
0915-0036 0915-0127 0915-0140 0915-0140 0915-0151 0915-0184 0915-0188 0915-0188 0915-0226 0915-0227 0915-0223 0915-0233 0915-0233 0915-0234 0915-0234	9/30/2005 7/29/2005 11/5/2004 6/13/2005 12/2/2004 1/31/2005 10/31/2004 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 10/31/2005 5/31/2005 5/31/2005		-530 -300	952	0 952 52950 0 0 -9142 -530 0	-1191 0 0 0 125 14597 0 0 -2736		Approved Approved Approved Approved Approved Expired Expired Approved	Discontinued, not a violation
0915-0127  0915-0140  0915-0151  0915-0184  0915-0188  0915-0188  0915-0193  0915-0227  0915-0230  0915-0233  0915-0234  0915-0254	7/29/2005 11/5/2004 6/13/2005 12/2/2004 1/31/2005 10/31/2004 5/6/2005 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005		-530 -300		52950 0 0 -9142 -530 0 -300	0 0 125 14597 0 0 -2736		Approved Approved Approved Approved Expired Expired Approved	Discontinued, not a violation
0915-0140 0915-0151 0915-0184 0915-0186 0915-0188 0915-0188 0915-0193 0915-0226 0915-0227 0915-0230 0915-0233 0915-0234 0915-0234 0915-0254	11/5/2004 6/13/2005 12/2/2004 1/31/2005 10/31/2004 5/6/2005 10/31/2004 10/31/2004 9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005		-530 -300		52950 0 0 -9142 -530 0 -300	125 14597 0 0 -2736		Approved Approved Approved Expired Expired Approved	Discontinued, not a violation
0915-0151 0915-0184 0915-0188 0915-0188 0915-0193 0915-0227 0915-0227 0915-0230 0915-0233 0915-0233 0915-0234 0915-0253	6/13/2005 12/2/2004 1/31/2004 5/6/2005 10/31/2004 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005		-530 -300	52590	0 0 -9142 -530 0 -300	125 14597 0 0 -2736		Approved Approved Expired Expired Approved	Discontinued, not a violation
0915-0184 0915-0186 0915-0188 0915-0193 0915-0226 0915-0227 0915-0230 0915-0230 0915-0234 0915-0234 0915-0253 0915-0254	12/2/2004 1/31/2005 10/31/2004 5/6/2005 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 4/30/2005 5/31/2005		-530 -300		-530 0 -300	14597 0 0 -2736 0		Approved Expired Expired Approved	Discontinued, not a violation
0915-0186 0915-0188 0915-0193 0915-0226 0915-0227 0915-0230 0915-0233 0915-0233 0915-0253 0915-0254	1/31/2005 10/31/2004 5/6/2005 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 4/30/2005 5/31/2005		-530 -300		-530 0 -300	0 0 -2736 0		Expired Expired Approved	Discontinued, not a violation
0915-0188 0915-0193 0915-0226 0915-0227 0915-0223 0915-0233 0915-0234 0915-0253 0915-0254	10/31/2004 5/6/2005 10/31/2004 10/31/2004 8/31/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005		-530 -300		-530 0 -300	0 -2736 0		Expired Approved	Discontinued, not a violation
0915-0193 0915-0226 0915-0227 0915-0230 0915-0233 0915-0234 0915-0253 0915-0254	5/6/2005 10/31/2004 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005		-300		-300	0		Approved	·
0915-0226 0915-0227 0915-0230 0915-0233 0915-0234 0915-0253 0915-0254	10/31/2004 10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005					0			
0915-0227 0915-0230 0915-0233 0915-0234 0915-0253 0915-0254	10/31/2004 8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005					0			
0915-0230 0915-0233 0915-0234 0915-0253 0915-0254	8/31/2005 9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005		-1297		-1297			Expired	Not a violation
0915-0233 0915-0234 0915-0253 0915-0254	9/1/2005 9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005					0		Expired	Not a violation
0915-0234 0915-0253 0915-0254	9/30/2005 12/2/2004 10/31/2004 4/30/2005 5/31/2005			1	0	1150	ļ	Approved	
0915-0253 0915-0254	12/2/2004 10/31/2004 4/30/2005 5/31/2005				0	675		Approved	Nr. 11.2
0915-0254	10/31/2004 4/30/2005 5/31/2005			-1200	-1200	0		Discontinued	Not a violation
	4/30/2005 5/31/2005			12440	12440	-1652		Approved	
10915-0260	5/31/2005	_		-13440	-13440	0		Collection Discontinued	
				-750	-750	0		Discontinued	Not a violation
0915-0261	44 (00 (000 )		000	-400	-400	0		Discontinued	Not a violation
0915-0266	11/30/2004		-808	27100	-808	0		Expired	Discontinued, not a violation
0915-0275	12/2/2004			25199	25199	0		Approved	
0915-0276	8/31/2005			-13063	-13063	0	$\sim$	Discontinued	Not a violation
0915-0277	12/31/2004		#00	-1393	-1393	0		Discontinued	Not a violation
0915-0280	10/31/2004		-500		-500	0		Expired	Discontinued, not a violation
0915-0283	4/30/2005			-211	-211	0		Discontinued	Not a violation
0915-0287	6/30/2005			-288	-288	0		Discontinued	Not a violation
0915-0293	8/31/2005			400	0	-600		Approved	
0915-0294	1/18/2005			428	428	0		Approved	
0915-0295	2/3/2005			2750	2750	0		Approved	
0915-0296	6/3/2005			170	170	0		Approved	
0915-0297	9/1/2005			108	108	0		Approved	
0917-0024	5/31/2005			-1875	-1875	0		Discontinued	
0917-0027	8/31/2005			-202	-202	0		Discontinued	
0920-0004	7/25/2005			103	103	0		Changed	
0920-0012	2/3/2005			66775	66775	0	_	Reinstatement with Change	
0920-0017	1/26/2005			200	200	0		Changed	
0920-0033	5/31/2005			-3800	-3800	0		Discontinued	
0920-0102	4/30/2005			-90	-90	0		Discontinued	
0920-0109	11/8/2004				0	687		Approved	
0920-0138	2/18/2005			-14	-14	0		Approved	
0920-0212	9/1/2005			-522	-522	0		Approved	
0920-0214	12/17/2004			-33	-33	0		Approved	
0920-0237	11/23/2004			6954	6954	0		Approved	
0920-0260	11/8/2004				0	-192		Approved	
0920-0260	4/29/2005			90	90			Changed	
0920-0274	10/14/2004			205	205	0		Approved	
0920-0307	1/18/2005			1842	1842	0		Approved	<u> </u>
0920-0337	10/31/2004		-600		-600	0		Expired	Violation
0920-0337	5/6/2005			672	672	0		Reinstatement with Change	Bootleg
0920-0338	3/23/2005			18766	18766	0		Changed	No exhibit. Merged from 0444.
0920-0406	11/30/2004				0	-97902	<b>l</b>	Approved	
0920-0417	2/2/2005				0	-19490		Approved	
0920-0428	5/26/2005			238	234	0		Changed	
0920-0444 0920-0489	3/31/2005 4/28/2005			-18766 3960	-18766 3960	0		Discontinued Reinstatement with Change	No exhibit. Merged with 0338.

Dots			PROGRAM CHANGES					1		
1923-0936	OMB#	Date	Due to Statutory	Due to Lapse of	Due to Agency		ADJUSTMENTS	ЕХНІВІТ	ТҮРЕ	NOTES
1920.0456   228.2005   2.246   2.146   0   Discontinued	TOTAL		287,280,586	618,923	603,470	288,495,426	-26,085,579	$\mathbb{N}$		
100,00407							0		Reinstatement with Change	
1930-051   9-93-02005   -1-400   -1-4							0		Discontinued	
1930.053   1031.2006   1.900										
1930458							•			
19304577   831,0005   1-10										
1939-1575   930-2005   2238   233										
1-10   1-10										
1939/1956   1931/2098					-					
10920458							·			
1990.0172										
10,000   1							•			
					-685		0			
9920-957   3232005   960   960   960   970   0   Changed										This an adjustment. 83-C submitted.
929-0065   1031/2004   4-40										
0920-0666   1031/2004							0			
1920-0699   1231/2004										
0920-0611   12/31/2004   4-10   4-110   4-110   0   Discontinued										
							0			
				1-0.1	-4110					N
0920-0627   8/31/2005   5.555   5.555   0   Discontinued				-4624	10662					
0920-0631   3/31/2005							·			No exhibit. One -1ime Survey .
0920-0633   3/31/2005   -52   -52   0   Discontinued										
12934   12							·			
1920-0636   12/2/2004   42   42   0   Approved										N. F. Lillian C. Tr. C.
0920-0637   3/31/2005   -140   -140   0   Discontinued							0			No Exhibit. One -1ime Survey.
9920-0646   3/23/2005   817   817   0   Changed										N. E.L. L. O. Time Comme
0920-0650							0			No Exhibit. One-Time Survey.
0920-0650   977/2005   42   42   42   0   Changed										
0920-0651   11/15/2004   381   381   0							·			
0920-0654   11/10/2004   32   32   0   Approved										
0920-0654         9/30/2005         -32         -32         0         Discontinued           0920-0655         11/15/2004         100         100         0         Approved           0920-0656         11/10/2004         311         311         0         Approved           0920-0657         11/10/2004         1111         111         0         Approved           0920-0658         11/10/2004         1462         1462         0         Approved           0920-0659         12/20/2004         230         230         0         Approved           0920-0669         12/3/2005         109         109         0         Approved           0920-0661         1/3/2005         382         382         0         Approved           0920-0661         9/30/2005         36         36         0         Discontinued           0920-0662         1/4/2005         36         36         0         Discontinued           0920-0662         1/4/2005         36         36         0         In Use without an OMB NBR         Bootleg           0920-0666         2/3/2005         65817         65817         0         Approved           0920-0667         12/2/2004							•			
0920-0655         11/15/2004         100         100         0         Approved           0920-0656         11/10/2004         311         311         0         Approved           0920-0657         11/10/2004         1111         111         0         Approved           0920-0658         11/10/2004         1462         1462         0         Approved           0920-0659         12/20/2004         230         230         0         Approved           0920-0660         2/3/2005         109         109         0         Approved           0920-0661         1/3/2005         382         382         0         Approved           0920-0661         9/30/2005         -382         -382         0         Discontinued           0920-0662         1/4/2005         36         36         0         In Use without an OMB NBR         Bootleg           0920-0666         2/3/2005         65817         65817         0         Approved           0920-0666         2/3/2005         55817         65817         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0669         1/3/2/2005										
0920-0656         11/10/2004         311         311         0         Approved           0920-0657         11/10/2004         1111         111         0         Approved           0920-0658         11/10/2004         1462         1462         0         Approved           0920-0659         12/20/2004         230         230         0         Approved           0920-0660         2/3/2005         109         109         0         Approved           0920-0661         1/3/2005         382         382         0         Approved           0920-0661         9/30/2005         -382         -382         0         Discontinued           0920-0662         1/4/2005         36         36         0         In Use without an OMB NBR         Bootleg           0920-0664         11/16/2004         225067         225067         0         Approved           0920-0666         2/3/2005         65817         65817         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005							•			
0920-0657         11/10/2004         111         111         0         Approved           0920-0658         11/10/2004         1462         1462         0         Approved           0920-0659         12/20/2004         230         230         0         Approved           0920-0660         2/3/2005         109         109         0         Approved           0920-0661         1/3/2005         382         382         0         Approved           0920-0661         9/30/2005         -382         -382         0         Discontinued           0920-0662         1/4/2005         36         36         0         In Use without an OMB NBR         Bootleg           0920-0664         11/16/2004         225067         225067         0         Approved           0920-0666         2/3/2005         65817         65817         0         Approved           0920-0666         12/3/2004         250         250         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0669         1/24/2005         570         570         0         Approved           0920-0670         3/17/2005										
0920-0658         11/10/2004         1462         1462         0         Approved           0920-0659         12/20/2004         230         230         0         Approved           0920-0660         2/3/2005         109         109         0         Approved           0920-0661         1/3/2005         382         382         0         Approved           0920-0661         9/30/2005         -382         -382         0         Discontinued           0920-0662         1/4/2005         36         0         In Use without an OMB NBR         Bootleg           0920-0664         11/16/2004         225067         0         Approved           0920-0666         2/3/2005         65817         65817         0         Approved           0920-0666         2/3/2005         55817         0         Approved         0           0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300										
0920-0659         12/20/2004         230         230         0         Approved           0920-0660         2/3/2005         109         109         0         Approved           0920-0661         1/3/2005         382         382         0         Approved           0920-0661         9/30/2005         -382         -382         0         Discontinued           0920-0662         1/4/2005         36         0         In Use without an OMB NBR         Bootleg           0920-0664         11/16/2004         225067         225067         0         Approved           0920-0666         2/3/2005         65817         65817         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0672         2/18/2005         718							·			
0920-0660         2/3/2005         109         109         0         Approved           0920-0661         1/3/2005         382         382         0         Approved           0920-0661         9/30/2005         -382         -382         0         Discontinued           0920-0662         1/4/2005         36         0         In Use without an OMB NBR         Bootleg           0920-0664         11/16/2004         225067         225067         0         Approved           0920-0666         2/3/2005         65817         68817         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved										
0920-0661         1/3/2005         382         382         0         Approved           0920-0661         9/30/2005         -382         -382         0         Discontinued           0920-0662         1/4/2005         36         36         0         In Use without an OMB NBR         Bootleg           0920-0664         11/16/2004         225067         225067         0         Approved           0920-0666         2/3/2005         65817         65817         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0673         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved							•			
0920-0661         9/30/2005         -382         -382         0         Discontinued           0920-0662         1/4/2005         36         0         In Use without an OMB NBR         Bootleg           0920-0664         11/16/2004         225067         225067         0         Approved           0920-0666         2/3/2005         65817         65817         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved										
0920-0662         1/4/2005         36         0         In Use without an OMB NBR         Bootleg           0920-0664         11/16/2004         225067         225067         0         Approved           0920-0666         2/3/2005         65817         65817         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved							•			
0920-0664         11/16/2004         225067         225067         0         Approved           0920-0666         2/3/2005         65817         68817         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved				36			0			Bootles
0920-0666         2/3/2005         65817         65817         0         Approved           0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved				30				_		Doolog
0920-0667         12/2/2004         250         250         0         Approved           0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved								$\sim$		
0920-0668         2/18/2005         570         570         0         Approved           0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved							· · ·	$\overline{}$		
0920-0669         1/24/2005         672         672         0         Approved           0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved							0			
0920-0670         3/17/2005         300         300         0         Approved           0920-0671         1/31/2005         609         609         0         Approved           0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved										
0920-0671         1/31/2005         609         609         0         Approved           0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved										
0920-0672         2/18/2005         718         718         0         Approved           0920-0673         2/18/2005         1750         1750         0         Approved							•			
0920-0673 2/18/2005 1750 1750 0 Approved							•			
							· · ·			
02/0-00/4 1 1/31/30/1 1 1 101 301 0 I IApproved	0920-0674	1/31/2005		1	301	301	0		Approved	

		PRO	GRAM CHANGI	ES					
OMB#	Date	Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions	NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	ТҮРЕ	NOTES
TOTAL		287,280,586	618,923	603,470	288,495,426	-26,085,579	X		
0920-0675	2/7/2005			156	156	0		Approved	
0920-0677	2/3/2005			47	47	0		Approved	
0920-0678	4/28/2005			158	158	0		Approved	D
0920-0679 0920-0680	5/6/2005 1/31/2005			396	396	0		Approved Approved	Bootleg
0920-0681	5/6/2005			145	145	0		Approved	Bootleg
0920-0682	7/15/2005			460	460	0		Approved	Bootieg
0920-0683	5/25/2005			700	700	0		Approved	Bootleg
0920-0684	6/24/2005			5922	5922	0		Approved	
0920-0686	7/1/2005			178	178	0		Approved	
0920-0687	4/20/2005			1125	1125	0		Approved	
0920-0688	7/29/2005			2708	2708	0		Approved	
0920-0689	8/22/2005			56	56	0		Approved	
0920-0691	8/26/2005			26	26	0		Approved	
0920-0692	8/26/2005			2000	2000	0		Approved	
0923-0006	3/31/2005		-3053	024	-3053	0		Expired	Not a Violation.
0923-0006	4/27/2005			834	834	0		Reinstatement with Change	
0923-0008	5/20/2005			-1306	-1306	0		Approved	
0925-0177 0925-0216	7/31/2005 12/20/2004			-163 6886	-163 6886	0		Discontinued Reinstatement with Change	
0925-0210	11/10/2004			0000	0000	862		Approved	
0925-0240	6/24/2005			16427	16427	802	<del></del>	Approved	
0925-0438	12/2/2004			2033	2033	0	$\overline{}$	Reinstatement with Change	
0925-0454	1/18/2005			396	396	0		Reinstatement with Change	
0925-0466	10/31/2004			-7774	-7774	0		Discontinued	
0925-0467	9/30/2005			-7864	-7864	0		Discontinued	
0925-0474	5/8/2005			93	93	0		Changed	
0925-0495	10/31/2004			-400	-400	0		Discontinued	
0925-0498	4/30/2005			-520	-520	0		Discontinued	
0925-0500	6/30/2005			-746	-746	0		Discontinued	
0925-0501	11/10/2004				0	-253		Approved	
0925-0513	4/30/2005			-1750	-1750	0		Discontinued	
0925-0514	10/31/2004 1/31/2005			-2820	-2820 -762	0		Discontinued	
0925-0515 0925-0521	10/31/2004			-762 -990	-/62 -990	0		Discontinued Discontinued	
0925-0521	10/31/2004			1872	1872	0		Approved	
0925-0534	12/14/2004			320	320	0		Changed	
0925-0535	11/10/2004			625	625	0		Approved	
0925-0537	2/28/2005			-500	-500	0		Discontinued	
0925-0538	11/22/2004			4036	4036	0		Approved	
0925-0539	12/2/2004			367	367	0		Approved	
0925-0539	12/31/2004			-367	-367	0		Discontinued	
0925-0540	12/7/2004			759	759	0		Approved	
0925-0541	12/22/2004			150	150	0		Approved	
0925-0542	4/20/2005			434	434	0	_	Approved	
0925-0543	3/14/2005			15380	15380	0		Approved	
0925-0544	5/9/2005			9375	9375	0		Approved	
0925-0546	5/9/2005			4000	4000	0		Approved	
0925-0547 0925-0548	6/17/2005 6/24/2005		-	40 132	40 132	0		Approved	
0925-0548	9/30/2005			132 88	132 88	0		Approved Approved	
0925-0549	7/20/2005			706	706	0		Approved	
0930-0110	10/28/2004			-4	-4	0		Approved	
0930-0110	7/1/2005			10,370	10370	0		Approved	Ongoing cyclical
0930-0195	11/19/2004			-409	-409	0		Approved	. g. g-j

		PRO	GRAM CHANG	ES	NET						
OMB#	Date	Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions	PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	ТҮРЕ	NOTES		
TOTAL		287,280,586	618,923	603,470	288,495,426	-26,085,579	X				
0930-0197	12/7/2004			4,850	4850	0		Approved			
0930-0208	6/23/2005			-5,469	-5469	0		Approved			
0930-0226	11/19/2004			6,947	6947	0		Approved			
0930-0230	1/31/2005		-1212		-1212	0		Expired	Not a Violation.		
0930-0230	3/2/2005			642	642	0		Reinstatement without Change			
0930-0231	2/28/2005			-577	-577	0		Discontinued			
0930-0232	3/14/2005			-430	-430	0		Approved			
0930-0233	5/31/2005			-170	-170	0		Discontinued			
0930-0235	9/30/2005			-2034	-2034	0		Discontinued			
0930-0238	2/28/2005			-12,600	-12600	0		Discontinued	One-time survey		
0930-0241	6/30/2005			-2804	-2804	0		Discontinued			
0930-0243	7/1/2005			-1080	-1080	0		Discontinued			
0930-0251	10/31/2004			-240	-240	0		Discontinued			
0930-0253	12/31/2004			-1365	-1365	0		Discontinued			
0930-0256	6/30/2005			-993	-993	0		Discontinued			
0930-0258	11/2/2004			21	21	0		Approved			
0930-0261	10/28/2004			4,886	4886	0		Approved			
0930-0262	11/19/2004			770	770	0		Approved			
0930-0264	12/2/2004			25	25	0		Approved			
0930-0264	5/31/2005			-25	-25	0		Discontinued			
0930-0265	5/6/2005			51	51	0		Approved			
0930-0266	5/6/2005			81,318	81318	0	$\langle$	Approved			
0930-0267	6/17/2005			91	91	0		Approved			
0930-0269	9/20/2005			335	335	0		Approved			
0930-0270	9/16/2005			741	741	0		Approved			
0935-0106	1/3/2005			-4311	-4311	0		Approved			
0935-0108	2/28/2005			-23216	-23216	0	$\times$	Discontinued			
0935-0110	2/3/2005			-269	-269	0		Approved			
0935-0120	12/31/2004		-6011		-6011	0		Expired	Not a violation		
0935-0121	4/30/2005			-557	-557	0		Discontinued			
0935-0122	11/10/2004			250	250	0		Approved			
0935-0123	11/5/2004			6000	6000	0		Approved			
0935-0123	4/30/2005			-6000	-6000	0		Discontinued			
0935-0124	1/31/2005			5200	5200	0		Approved			
0935-0125	7/29/2005			403	403	0		Approved			
0937-0095	9/30/2005			-40	-40	0		Discontinued			
0937-0191	2/3/2005			4400	4400	0		Reinstatement without Change			
0938-0023	7/8/2005				0	-450		Approved			
0938-0037	1/27/2005			-9,800	-9800	0		Approved			
0938-0050	5/6/2005	66,200			66260	0	$\sim$	Approved			
0938-0101	9/19/2005				0	-448		Approved			
0938-0151	8/18/2005				0	-375		Approved			
0938-0170	9/30/2005			-682	-682	0		Discontinued			
0938-0214	7/18/2005	490,576			490576	0		Approved			
0938-0266	2/5/2005			506	506	0		Approved			
0938-0300	10/31/2004			-6,891	-6891	0		Discontinued	Discontinued on 10/31/2004. Not a violation.		
0938-0328	1/27/2005				0	712969		Approved			
0938-0338	7/8/2005				0	-107		Approved			
0938-0359	3/16/2005				0	-15057		Approved			
0938-0373	9/12/2005				0	-63		Approved			
0938-0469	9/21/2005			-3,068	-3068	0		Approved			
0938-0490	1/31/2005			-400	-400	0		Discontinued			
0938-0534	9/16/2005				0	124000		Approved			
0938-0618	1/31/2005			-2,880	-2880	0		Discontinued	Discontinued on 1/31/2005. Not a violation.		
0938-0618	4/15/2005			3,200	3200	0		Reinstatement without Change			

	PROGRAM CHANGES		NEW						
OMB #	Date	Due to Statutory Changes	Due to Lapse of OMB Approval		NET PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	ТҮРЕ	NOTES
TOTAL		287,280,586	618,923	603,470	288,495,426	-26,085,579	$\bigvee$		
0938-0679	9/16/2005			-315,000	-315000	0	$\times$	Approved	
0938-0690	4/30/2005			-451	-451	0		Discontinued	
0938-0702	12/27/2004				0	-2121132		Changed	
0938-0707	5/5/2005				0	-3520		Approved	
0938-0746	8/8/2005	-184			-184	0		Approved	
0938-0753	7/8/2005				0	-55567		Approved	
0938-0760	7/8/2005				0	543982		Approved	
0938-0761	7/8/2005				0	82863		Approved	
0938-0763	4/11/2005			4,946	4946	0		Approved	
0938-0770	9/22/2005				0	2972		Approved	
0938-0779	9/16/2005				0	-23548		Approved	
0938-0802	6/13/2005	10			10	0		Approved	
0938-0806	7/12/2005				0	-7620		Approved	
0938-0819	9/16/2005			100	100	0		Reinstatement without Change	
0938-0827	5/31/2005			-194	-194	0		Discontinued	
0938-0827	9/22/2005			194	194	0		Reinstatement without Change	
0938-0833	5/6/2005				0	-164500		Approved	
0938-0843	10/31/2004			-58,000	-58000	0	>	Discontinued	Discontinued on 10/31/2004. Not a violation.
0938-0846	11/5/2004	422,007			422007	0	$\sim$	Approved	
0938-0847	1/14/2005			-667	-667	0		Discontinued	
0938-0848	5/4/2005			-80	-80	0		Discontinued	
0938-0852	11/30/2004			-768	-768	0		Discontinued	Discontinued on 11/30/2004. Not a violation.
0938-0857	1/27/2005				0	-1408		Approved	
0938-0860	3/11/2005				0	-70		Approved	
0938-0863	2/28/2005			-1,914	-1914	0		Discontinued	
0938-0866	2/3/2005					-33999999		Approved	
0938-0873	9/30/2005				0	-1380		Approved	
0938-0876	1/31/2005			-348	-348	0		Discontinued	
0938-0877	7/31/2005			-5,465	-5465	0		Discontinued	
0938-0880	10/29/2004			-5,940	-5940	0		Changed	
0938-0880	10/29/2004			5,940	5940	0		Changed	
0938-0880	8/2/2005			-5,867	-5867	0		Changed	
0938-0922	1/25/2005			2,464	2464	0		Approved	
0938-0926	12/20/2004			1,500	1500	0	_	Approved	
0938-0930	11/8/2004	250,000			250000	0	>	Approved	
0938-0931	2/23/2005	448,128			448128	0	$\sim$	Approved	
0938-0932	1/13/2005			1,300	1330	0		Approved	
0938-0933	1/25/2005			100	100	0		Approved	
0938-0934	1/28/2005	4			4	0		Approved	
0938-0934	7/31/2005	-4			-4	0		Discontinued	
0938-0935	1/21/2005	20,100			20100	0	$\gg \leq$	Approved	
0938-0936	1/21/2005	20,081			20081	0	$\sim$	Approved	
0938-0937	3/2/2005			800	800	0		Approved	
0938-0937	8/31/2005			-800	-800	0		Discontinued	
0938-0938	4/26/2005			792	792	0		Approved	
0938-0939	6/10/2005			16,000	16000	0		Approved	
0938-0940	3/9/2005			1,238	1238	0		Approved	
0938-0940	8/31/2005			-1,238	-1238	0		Discontinued	
0938-0941	4/26/2005	15,200			15200	0	$\sim$	Approved	
0938-0942	5/6/2005			790	790	0		Approved	
0938-0943	5/6/2005			1,625	1625	0		Approved	
0938-0944	4/11/2005	12,050			12050	0	$\times$	Approved	
0938-0948	3/16/2005	500		500	500	0		In Use without an OMB NBR	Bootleg
0938-0949	3/16/2005	64,539,263			64539263	0	$>\!\!<$	In Use without an OMB NBR	Bootleg
0938-0950	7/8/2005	6,819			6819	0	]	Approved	

		PRO	OGRAM CHANG	ES	NET				
OMB#	Date	Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions	PROGRAM CHANGES	ADJUSTMENTS	EXHIBIT	ТҮРЕ	NOTES
TOTAL		287,280,586	618,923	603,470	288,495,426	-26,085,579	$>\!<$		
0938-0951	6/24/2005	36,400	)		36400	0	$\bigvee$	Approved	
0938-0952	5/9/2005	634,000	)		634000	0	$\langle$	Approved	
0938-0953	6/20/2005	379,400	)		379400	0	$\langle$	Approved	
0938-0954	7/8/2005	80			80	0		Approved	
0938-0955	7/5/2005	1,000			1000	0		Approved	
0938-0956	7/8/2005	1,125	i		1125	0		Approved	
0938-0957	8/1/2005	2,025,000	)		2025000	0	$\leftarrow$	Approved	
0938-0958	8/8/2005	10,710			10710	0	$\langle$	Approved	
0938-0959	6/10/2005			100	100	0		Approved	
0938-0959	9/30/2005			-100	-100	0		Discontinued	
0938-0960	7/29/2005			45,000	45000	0	$\overline{}$	Approved	
0938-0963	8/18/2005			4,940	4940	0		Approved	
0938-0964	8/5/2005	212,044,545	i		212044545	0		Approved	1
0938-0965	8/18/2005		1	133	133	0		Approved	1
0938-0969	9/15/2005	483,333			483333	0	$\sim$	Approved	1
0970-0017	11/29/2004				0	114		Approved	
0970-0030	2/1/2005			24	24	0		Reinstatement with Change	
0970-0037	12/31/2004			-14	-14	0		Expired	Collection discontinued
0970-0037	7/21/2005			14	14	0		Reinstatement without Change	
0970-0043	3/4/2005			217	217	0		Reinstatement without Change	
0970-0076	1/19/2005			-5	-5	0		Approved	
0970-0085	1/19/2005		662138		662138	0		Reinstatement with Change	Not in use during lapse
0970-0106	1/31/2005			-531	-531	0		Expired	
0970-0106	4/15/2005			531	531	0		Reinstatement without Change	
0970-0139	4/29/2005			10000	10000		$\sim$	Changed	
0970-0139	4/29/2005			400	400	0		Changed	
0970-0145	7/31/2005			-1782	-1782	0		Expired	
0970-0145	9/26/2005			891	891	0		Reinstatement without Change	
0970-0152	1/3/2005				0	-2457		Approved	
0970-0153	1/3/2005				0	19902		Approved	
0970-0157	12/1/2004				0	120		Approved	
0970-0159	7/6/2005				0	-400		Approved	
0970-0171	6/21/2005				0	69520		Approved	
0970-0173	11/23/2004				0	-490		Approved	
0970-0175	6/21/2005					67040		Approved	
0970-0177	8/30/2005			162	162	0		Approved	
0970-0183	4/15/2005		1	100	100	908		Approved	lone real
0970-0186	2/28/2005		1	-15552	-15552	0			Collection discontinued
0970-0195	4/15/2005		1	-116	-116	0		Approved	+
0970-0196	10/14/2004				0	582	-	Approved	+
0970-0198	8/26/2005			17015	17217	57		Approved	+
0970-0202	8/31/2005			-17215	-17215	0	$\overline{}$	Approved	Notice and Justine Lance
0970-0222	2/1/2005			123507	123507	0		Reinstatement with Change	Not in use during lapse
0970-0230	7/31/2005			-1728	-1728	0		Expired	Collection discontinued
0970-0232	3/31/2005		+	-150	-150	0		Discontinued	+
0970-0238	6/30/2005			-820	-820	0		Discontinued	O.B. c. B. c. J.
0970-0255	12/31/2004			-1120	-1120	0		Expired Characteristics of Characteristics	Collection discontinued
0970-0255	7/6/2005		+	1120	1120	Ü		Reinstatement without Change	Collection discontinued
0970-0256	12/31/2004			-220	-220	0	-	Expired	Collection discontinued
0970-0272	1/13/2005		ļ	***	*****	-3786		Changed	
0970-0273	3/17/2005			29520	29520	0		Approved	
0970-0274	2/16/2005			318	318	0		Approved	
0970-0274	9/30/2005			-318	-318	0		Discontinued	
0970-0275	2/25/2005			468	468	0		Approved	+
0970-0275	5/31/2005			-468	-468	0		Discontinued	

		PRO	GRAM CHANGI	ES	NET				
OMB#	Date	Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions	PROGRAM CHANGES	ADJUSTMENTS	ЕХНІВІТ	ТҮРЕ	NOTES
TOTAL		287,280,586	618,923	603,470	288,495,426	-26,085,579	X		
0970-0276	4/29/2005			2371	2371	0		Approved	
0970-0277	5/9/2005			3468	3468		0 Approved		
0970-0278	6/21/2005			4250	4250	0		In Use without an OMB NBR	
0970-0280	5/17/2005	1398			1398	0		Approved	KCFS Act of 2003
0970-0281	7/19/2005			270	270	0		Approved	
0970-0282	5/17/2005			104	104	0		Approved	
0970-0282	5/23/2005			52	52	0		Changed	
0970-0283	8/8/2005			440	440	0		Approved	
0970-0284	8/9/2005			1223	1223	0		Approved	
0970-0285	8/15/2005			875	875	0		Approved	
0970-0286	8/30/2005			237	237	0		Approved	
0970-0287	8/22/2005	13845			13845	0	>	Approved	
0970-0289	8/8/2005			61000	61000	0	$>\!<$	Approved	
0980-0017	11/30/2004			-9748	-9748	0		Expired	
0980-0017	4/21/2005			10760	10760	0		Reinstatement with Change	Not in use during lapse
0980-0140	10/22/2004				0	-48492		Approved	
0980-0196	4/30/2005			-3120	-3120	0		Discontinued	
0980-0241	12/10/2004				0	210		Approved	
0980-0266	2/16/2005				0	120		Approved	
0980-0267	8/18/2005				0	-35787		Approved	
0980-0270	3/4/2005			2508	2508	0		Reinstatement without Change	
0980-0271	1/10/2005				0	-56965		Approved	
0980-0275	1/12/2005				520	0		Approved	
0985-0012	2/28/2005			-1000	-1000	0		Discontinued	
0985-0013	2/28/2005			-1713	-1713	0		Discontinued	
0985-0020	12/27/2004			2250	2250	0		Approved	
0985-0021	5/3/2005			657	657	0		Approved	
0990-0115	11/10/2004			-102375	-102375	0	$>\!\!<$	Approved	
0990-0208	11/15/2004				0	-9333		Approved	
0990-0250	10/31/2004		-150		-150	0		Expired	No Violation
0990-0256	2/28/2005			-12744	-12744	0	$\langle$	Discontinued	
0990-0257	5/31/2005			-1436	-1436	0		Discontinued	
0990-0264	6/30/2005			-4378	-4378	0		Discontinued	
0990-0278	1/19/2005		22500		22500	0	$\sim$	In Use without an OMB NBR	Bootleg
0990-0279	1/19/2005		3500		3500	0		In Use without an OMB NBR	Bootleg
0990-0280	4/4/2005			1300	1300	0		Approved	
0990-0281	12/7/2004			712	712	0		Approved	
0990-0281	6/16/2005			3488	3488	0		Approved	
0990-0282	3/23/2005			1285	1285	0		Approved	
0990-0285	6/24/2005			50	50	0		Approved	
0990-0286	8/26/2005			30	30	0		Approved	
0990-0287	6/30/2005			19728	19728	0		Approved	
0990-0288	8/31/2005			1343	1343	0		Approved	
0990-0289	9/20/2005			1635	1635	0		Approved	
0990-0290	9/20/2005			6300	6300	0		Approved	
0990-0291	9/20/2005			41500	41500	0		Approved	
0990-0292	7/7/2005			462	462	0		Approved	
0992-0005	11/30/2004		-7085		-7085	0		Expired	Violation
0992-0005	4/21/2005			5751	5751	0		Reinstatement with Change	
0992-0007	1/31/2005			-4320	-4320	0		Expired	
0992-0007	5/9/2005			4320	4320	0		Reinstatement without Change	No Violation
0992-0008	12/21/2004			2547	2547	0		Approved	
		287,280,586	618,923	603,470	288,495,426	-26,085,579			

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

		PR	OGRAM CHANG	ES	NET				
OMB#	Date	Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions		ADJUSTMENTS	EXHIBI T	ТҮРЕ	Notes
TOTAL		-6,000	112	-12,629	-18,517	-89,589	$>\!\!<$		
0910-0338	9/12/2005				0	-349		Approval	
0910-0392	7/31/2005			-80000	-80000	0	$\times$	Discontinued	
0910-0395	11/30/2004			-83	-83	0		Discontinued	
0910-0486	1/31/2005			-1	-1	0		Discontinued	
0910-0560	2/4/2005				0	0		Approval	
0910-0562	5/5/2005				0	0		Approval	
0915-0036	9/30/2005				0	-4		Approval	
0915-0140	11/5/2004				0	-3		Approval	
0915-0188	10/31/2004		-10		-10	0		Expired	Not a Violation
0915-0193	5/6/2005				0	-90366		Approval	
0920-0012	2/3/2005			47520	47520	0	$>\!\!<$	Reinstatement with Change	Incorrect. 83-C submitted.
0920-0417	2/2/2005				0	5		Approval	
0920-0666	2/3/2005			39600	39600	0	$\mathbb{X}$	Approval	Incorrect. 83-C submitted.
0938-0469	9/21/2005	-6000			-6000	0		Approval	
0938-0714	11/5/2004				0	400		Approval	
0938-0761	7/8/2005				0	1759		Approval	
0970-0030	2/1/2005			384	384	0		Reinstatement with Change	
0970-0173	11/23/2004				0	80		Approval	
0970-0196	10/14/2004			-140	-140	0		Approval	
0970-0222	2/1/2005			11	11	0		Reinstatement with Change	
0970-0234	5/2/2005				0	-157		Approval	
0970-0255	12/31/2004			-22400	-22400	0		Expired	Collection discontinued
0970-0255	7/6/2005			22		0		Reinstatement with Change	
0970-0278	6/21/2005		122		122	0		In Use with No OMB NBR	Bootleg
0980-0267	8/18/2005				0	-180		Approval	
0980-0270	3/4/2005			1710	1710	0		Reinstatement	
0980-0271	1/10/2005				0	-26		Approval	
0985-0009	8/12/2005			748	748	-748		Approval	
		-6,000	112	-12,629	-18,517	-89,589			

		PROC	GRAM CHAN	NGES	NET PROGRAM CHANGES	S		NOTES
OMB#	Date	Due to Statutory Changes		Due to Agency Actions			EXHIBIT	
TOTAL		4,481,886	0	9,540,515	14,022,401	575,485	$\mathbb{X}$	
0910-0030					0	-245		
0910-0037					0	482278		
0910-0052					0	-216		
0910-0116					0	84062		
0910-0206					0			Unknown at present
0910-0437				30,379	30,379		$\geq \leq$	
0910-0460				723,264	723,264		$\geq \leq$	
0910-0472				-142,145	-142,145		$\times$	Consolidated with 0910-0116
0910-0491				?	0			
0910-0495					0	-19965		
0910-0509		25			25			
0910-NEW				1,196,869	1,196,869		$\times$	
0910-NEW				720	720			
0910-NEW				1,795	1,795			
0910-NEW				501,383	501,383		>	
0910-NEW				86,656	86,656		>	
0910-NEW				12,580	12,580		$>\!\!<$	
0910-NEW				1,000	1,000			
0910-NEW				144	144			
0910-NEW				18,400	18,400		>	
0910-NEW				5,799,477	5,799,477		>	
0910-NEW				196,342	196,342		>	
0910-NEW				23,084	23,084		$\sim$	
0910-NEW				4,070	4,070			
0910-NEW				2,520	2,520			
0910-NEW				760	760			
0910-NEW				360	360			
0910-NEW				1,824	1,824			
0910-NEW				579	579			
0910-NEW				6	6			
0910-NEW 0910-NEW				2,640	2,640			
0910-NEW				5,230 36	5,230 36			
0910-NEW 0915-NEW		11,518		30	11,518			New NPRM
0915-NEW	3/31/2006	11,318		-648	-648		$\overline{}$	Activity no longer needed
0915-0219	2/28/2006			-505	-505			, ,
0915-0209	3/31/2006			-303	-303 -483			one time evaluation
0915-0274	8/31/2006	+		-1,395	-1,395			one time evaluation one time survey
0915-0274	10/31/2005			-1,395 -500	-1,395 -500			·
0915-0290	4/30/2006			-500 -170	-500 -170			one time survey one time survey
0915-0296	9/30/2006			-170	-170			one time survey
0913-0297	9/30/2000	+		-4,004	-108 -4,004			one unic survey
0920-0009				-4,004 144	-4,004 144			
0920-0010				144	0	-778		
0920-0026				-126	-126	-//6		
0720-0120				-120	-120			

PROGRAM CHANGES				NGES	1			
OMB#	Date	Due to Statutory Changes		Due to Agency Actions	NET PROGRAM CHANGES	ADJUSTMENT S	EXHIBIT	NOTES
TOTAL		4,481,886	0	9,540,515	14,022,401	575,485	$\mathbb{X}$	
0920-0134				225,015	225,015		$\mathbb{N}$	
0920-0298				4,595	4,595			
0920-0315				6,124	6,124			
0920-0332				-50	-50			
0920-0334				11,231	11,231			
0920-0353				-13,375	-13,375			
0920-0442				-6,300	-6,300			
0920-0450				-1,625	-1,625			
0920-0461				-375	-375			
0920-0463				-50	-50			
0920-0472				-2,179	-2,179			
0920-0479				-236	-236			
0920-0487				-173	-173			
0920-0497				-1,248	-1,248			
0920-0530					0			
0920-0555					0			
0920-0557					0	-11350		
0920-0584				-4,367	-4,367	-23808		
0920-0587				-1,000	-1,000	-195		
0920-0590				-688	-688			
0920-0603				-84	-84			
0920-0617				255	0			
0920-0620				-255	-255	4000		
0920-0621				18,644	18,644	-1000		
0920-0623 0920-0629				-250	-250 -2,282			No subjet. This is a subject data subjection
0920-0629				-2,282 -899	-2,282 -899			No exhibit. This is a cyclical data collection.
0920-0647								
0920-0648				58 -311	-311			
0920-0656				-225,067	-225,067		$\overline{}$	
0920-0667				-223,067	-223,067		$\sim$	
0920-0683				-700	-230 -700			
0920-0687				-2,313	-2,313			
0920-0688				-1,066	-1,066			
0920-0693				646	646			
0920-0696				122,172	122,172			
0920-0698				25	25		_ \	
0920-0700				18,970	18,970			No exhibit. ICR approved 10/7/2005.
0920-NEW		+		210	210			170 Standing 1011 approved 10/1/2000.
0920-NEW		+		3,165	3,165			
0920-NEW				641	641			
0920-NEW				2,552	2,552			
0920-NEW				586	586			
0920-NEW		†		614	614			
0920-NEW		†		351	351			
0720 TIL II		1		331	331	<u> </u>	1	

		PROC	GRAM CHAI	NGES				
OMB#	Date	Statutory Changes	Lapse of OMB	Due to Agency Actions	NET PROGRAM CHANGES	S	EXHIBIT	NOTES
TOTAL		4,481,886	0		14,022,401	575,485	$\mathbb{X}$	
0920-NEW				11,011	11,011		$\mathbb{X}$	
0920-NEW				54	54			
0920-NEW				1,000	1,000			
0920-NEW				2,084	2,084			
0920-NEW				2,750	2,750			
0920-NEW				90	90			
0920-NEW				1,833	1,833			
0920-NEW				102	102			
0920-NEW				402	402			
0920-NEW				20	20			
0920-NEW				15	15			
0920-NEW				1,058	1,058			
0920-NEW				101	101			
0920-NEW				9,084	9,084			
0920-NEW				266	266			
0920-NEW				597	597			
0920-NEW				20,438	20,438		$\sim$	
0920-NEW				846	846			
0920-NEW				250	250			
0920-NEW				375	375			
0920-NEW				45	45			
0920-NEW				212	212			
0920-NEW				3,968	3,968			
0920-NEW				300	300			
0920-NEW				90	90			
0920-NEW				10,000	10,000 935		$\overline{}$	
0920-NEW 0920-NEW				935 382	382			
0920-NEW 0920-NEW							$\overline{}$	
0920-NEW 0920-NEW				12,000 2,000	12,000 2,000		$\overline{}$	
0920-NEW 0920-NEW				3,840	3,840			
0920-NEW				1,313	1,313			
0920-NEW				1,313	1,313			
0920-NEW				9	9			
0920-NEW				56	56			
0920-NEW				50	50			
0920-NEW				250	250			
0920-NEW				80	80			
0920-NEW		<del> </del>		5,268	5,268			
0920-NEW				285	285			
0920-NEW		<del> </del>		140	140			
0920-NEW		+ +		72	72			
0920-NEW		+ +		400	400			
0920-NEW		+ +		87	87			
0920-NEW		<del> </del>		715	715			
0720 IND 11		I		/13	/13			

		PROC	GRAM CHAI	NGES				
OMB#	Date	Due to Statutory Changes	Lapse of OMB	Due to Agency Actions	NET PROGRAM CHANGES	ADJUSTMENT S	EXHIBIT	NOTES
TOTAL		4,481,886	0	9,540,515	14,022,401	575,485	$\mathbb{N}$	
0920-NEW				250	250			
0920-NEW				12	12			
0920-NEW				18,200	18,200		$\mathbb{X}$	
0920-NEW				2,233	2,233			
0920-NEW				58,903	58,903		$\times$	
0920-NEW				733	733			
0920-NEW				178	178			
0920-NEW				1,142	1,142			
0920-NEW				780	780			
0920-NEW				1,000	1,000			
0920-NEW				451	451			
0920-NEW				834	834			
0920-NEW				375	375			
0920-NEW				17	17			
0920-NEW				1,633	1,633			
0920-NEW				200	200			
0920-NEW				167	167			
0920-NEW				16,800	16,800		$\sim$	
0923-0016				-285	-285			
0923-0034				-42	-42			
0923-NEW				375	375			
0923-NEW				680	680			
0925-0002					0	38,355		revision
0925-0299				360	360	2000		revision
0925-0348				10.7.52	0			extension
0925-0406				40,563	40,563		$\Longrightarrow$	revision
0925-0407				-12,511	-12,511	0.405	_	revision
0925-0414				00	0	-8,195		revision
0925-0417				-80	-80			revision
0925-0475 0925-0479				108	108			revision
0925-0479		-			0			extension
0925-0483				200	200			extension
0925-0505				-840	-840			revision
0925-0519		+		-840	-640			discontinue extension
0925-0522		+			0			extension
0925-0522		1			0			extension
0925-0525		1			0			extension
0925-0546		+		-4,000	-4,000			discontinue
0925-0546		+ +		1,155	1,155			new
0925-0551 0925-NEW		+		3,489	3,489			new
0925-NEW		+		638	638			new
0925-NEW		+		757	757			new
0925-NEW		+		100	100			new
0925-NEW		+		50	50			new
UJZJ-INE W		1			30			IICW

		PROC	GRAM CHAN	IGES					
OMB#	Date	Due to Statutory Changes		Due to Agency Actions	NET PROGRAM CHANGES	ADJUSTMENT S	EXHIBIT	NOTES	
TOTAL		4,481,886	0	9,540,515	14,022,401	575,485	$\mathbb{X}$		
0925-NEW				2,468	2,468			new	
0925-NEW				3,615	3,615			new	
0930-0078					0	61,682			
0930-0106				6,517	6,517	1,200			
0930-0110				3,204	3,204				
0930-0114				14,625	14,625			Ongoing cyclical	
0930-0192				-14,164	-14,164			One-time survey	
0930-0205				1,612	1,612				
0930-0209				-14,040	-14,040			One-time survey	
0930-0230				96	96				
0930-0234				67	67				
0930-0241				-2,804	-2,804				
0930-0244				-19,456	-19,456			One-time survey	
0930-0245				614	614				
0930-0254				5,814	5,814				
0930-0260				270	270				
0930-0266				81,318	81,318		$>\!\!<$		
0930-0267				91	91				
0930-NEW				9,702	9,702				
0930-NEW				60	60				
0930-NEW				11,322	11,322			One-time survey	
0930-NEW				9,610	9,610				
0930-NEW				6,608	6,608				
0930-NEW				191	191				
0930-NEW				732	732				
0930-NEW				64	64				
0935-NEW				45	45				
0935-NEW				5,200	5,200				
0938-0065					0	420		Extension/Approved	
0938-0610					0	-36,380		Extension/Approved	
0938-0847				1,350	1,350			Reinstatement without Change	
0938-NEW				285,525	285,525		$\gg$	CMS-10102	
0938-NEW		528,000			528,000		$\sim$	CMS-10146 (Part D)	
0938-NEW		583,333			583,333		>	CMS-10147 (Part D)	
0938-NEW		400,000			400,000		$\sim$	CMS-10164 (Public Law 104-191 HIPAA)	
0938-NEW		12,416			12,416		>	CMS-10172 (MMA/Public Law 108-173)	
0938-NEW				20,634	20,634		>	CMS-R-210	
0938-NEW		58,680			58,680		>	CMS-10166 (Improper Payment Information Act of 2002/Public Law 107-300)	
0938-NEW		1,850,000			1,850,000		>	CMS-10170 (MMA)	
0938-NEW		1,017,914			1,017,914		$\ll$	CMS-10171 (MMA/Part D)	
0938-NEW		20,000			20,000		$\ll$	CMS-10167 (Section 303(d) of the MMA)	
0938-NEW				260,000	260,000		$>\!\!<$	CMS-10116	
0970-0229		<u> </u>		-13,162	-13,162			Study complete	
0970-0242		<u> </u>		-4,124	-4,124				
0970-NEW				583	583				

	Date	PROC	GRAM CHAI	NGES	NET PROGRAM CHANGES	ADJUSTMENT S	EXHIBIT	
OMB#		Due to Statutory Changes	Lapse of OMB	Due to Agency Actions				NOTES
TOTAL		4,481,886	0	9,540,515	14,022,401	575,485	><	
0970-NEW				60	60			
0970-NEW				656	656			
0970-NEW				177	177			
0970-NEW				899	899			
0970-NEW				702	702			
0970-NEW				1,500	1,500			
0970-NEW				600	600			
0970-NEW				3,000	3,000			
0970-NEW				1,425	1,425			
0970-NEW				998	998			
0970-NEW				10,000	10,000		> <	
0970-NEW				15,000	15,000			
0970-NEW				1,000	1,000			
0985-0005					0	7,620		
		4,481,886	0	9,540,515	14,022,401	575,485		

# FY 2006 CHANGES IN COST BURDEN (\$,000)

		PR	OGRAM CHANG	ES			EXHIBIT	Notes
OMB #	Date	Due to Statutory Changes	Due to Lapse of OMB Approval	Due to Agency Actions	NET PROGRAM CHANGES	ADJUSTMENTS		
TOTAL		0	0	0	0	457,679	$\mathbb{X}$	
0935-0106					0	515732		
0935-0116					0	14.5		
0985-0005					0	-58,068		
TOTAL	0	0	0	0	0	457,679	$\bigvee$	

# Department of Health and Human Services Significant Changes in Burden

## **REDUCTIONS (2005)**

# **Change in Regulations:**

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0990-0256

**Title:** Survey of SCHIP Enrollees and Disenrollees for the

Congressionally Mandated Evaluation of the State Children's

Health Insurance Program

**Purpose of the collection:** This information collection, part of the congressionally mandated

Evaluation of the SCHIP program will collect data about children currently and previously covered by the program by conducting

surveys in 10 states.

**How Reduction Achieved:** Change in requirements

Change in Burden: -12,744

Does this change impact small entities with fewer than 25 employees? No

**Cutting Redundancy:** 

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0679

**Title**: Durable Medicare Equipment Regional Carrier, Certificate of

Medical Necessity

**Purpose of the Collection**: For Medicare to consider item for coverage and payment. **How Reduction Achieved**: 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.

**Change in Burden:** -315,000 hours

Does this change impact small entities with fewer than 25 employees? No

## **Changing Forms:**

# **Using Information Technology and E-Government:**

## **Statutory Reductions:**

(Use format above but add a line for "statute title and public law"

# Other:

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-0376

**Title:** Transmittal of Advertisements and Promotional Labeling for

Drugs and Biologics for Human Use

Purpose of the Collection: Manufacturers, packers, and distributors ("sponsors") who

advertise prescription human drugs, including biological products for humans, must disclose in advertisements and promotional labeling certain information about the advertised product's uses

and risks.

**How Reduction Achieved:** Allowed to expire.

Change in Burden: -33,280

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-0483

**Title:** Foreign Establishment Registration and Listing

**Purpose of the Collection:** FDA will use the information to identify foreign establishments

that import or offer to import drugs and devices into the United States. This information will help FDA schedule inspections of the

foreign establishment

How Reduction Achieved: Discontinued information collection

Change in Burden: -52,333

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-0392

**Title:** Regulations Requiring Manufacturers to Assess the Safety and

Effectiveness of New Drugs and Biological Products in Pediatric

**Patients** 

**Purpose of the Collection:** The purpose of these reporting requirements is to address the lack

of adequate pediatric labeling of drugs and biological products by requiring the submission of evidence on pediatric safety and effectiveness for products with clinically significant use in

children.

**How Reduction Achieved:** Discontinued information collection

Change in Burden: -18,557

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0915-0254

**Title:** U.S. Component of the 2001/2002 World Health Organization

Study of Health

Behavior in School Children (WHO-HPSC)

**Purpose of the collection:** To collect data on health behavior of school children for the U.S.

survey component of the WHO study

**How Reduction Achieved:** Data collection and analysis were completed and the survey

activity was discontinued

Change in Burden: -13,440

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0915-0276

**Title:** The National Survey of Registered Nurses, 2004

**Purpose of the collection:** To obtain data on the population of registered nurses in the U.S.

for evaluating the availability and supply of nursing resources at

the national level.

**How Reduction Achieved:** The survey was completed and the data collection activity was

discontinued

Change in Burden: -13,063

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0935-0108

**Title:** Medical Expenditures Panel Survey – Medical Provider

Component (MEPS-MPC) for 2001 and 2002

**Purpose of the collection:** The MEPS-MPC is the collection of data from medical providers

that served as an imputation source for medical utilization and expenditure data report by household respondents. This data supplements information provided by household respondents about the charges, payments, and sources of payment associated with specific health care encounters and the missing expenditure data.

How Reduction Achieved: Study expired.

Change in Burden: -23.216

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

OMB Control Number: 0938-0843

**Title:** Healthy Aging Smoking Cessation Demonstration

**Purpose of the Collection:** The goals of the Healthy Aging Project were to test the

effectiveness of three possible Medicare smoking cessation benefits and to make inferences that may be generalized to the Medicare program. Using a comparison trial with restricted randomization of study locales, this study will compare three variations in a potential Medicare smoking cessation benefit on

smoking cessation and abstinence rates.

**How Reduction Achieved:** Discontinued.

Change in Burden: -58,000

Does this change impact small entities with fewer than 25 employees? No

**Agency**: Department of Health and Human Services

OMB Control Number: 0970-0202

**Title:** National Survey of Child and Adolescent Well-Being

**Purpose of the Collection:** Longitudinal survey that provides national estimates on the

characteristics related to children and families who enter the child

welfare system.

**How Reduction Achieved**: Reduces sample size due to cost relative to the utility of larger

sample size.

Change in Burden: -17,215

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0990-0115

Title: HHS Acquisition Regulation – Solicitation and Contracts

**Purpose of the collection:** Information is needed to evaluate feasibility of contractor(s)

scientific or technical approach, management plan, and cost to accomplish the program, or services required by the government.

**How Reduction Achieved:** The estimated burden is revised based on more accurate data

obtained from the procurement burden review

Change in Burden: -102,375

Does this change impact small entities with fewer than 25 employees? No

# **INCREASES (2005)**

# **Statutory Increases:**

**Agency**: Department of Health and Human Services

**OMB Number:** 0910-0560

**Title:** Recordkeeping and Records Access Requirements for Food

**Facilities** 

**Purpose of the Collection:** Data collected as a result of the recordkeeping and records access

requirements will be used to aid FDA in their investigative and enforcement activities and to inform the appropriate individuals

and food facilities of specific terrorist threats.

Why Increase Occurred: New Collection. Requirement of the Public Health Security and

Bioterrorism Preparedness and Response Act of 2002

**Change in Burden:** 5,359,000

Does this change impact small entities with fewer than 25 employees? Yes

**Agency**: Department of Health and Human Services

**OMB Control Number**: 0925-0361

Title: National Institutes of Health Loan Repayment Programs

Purpose of the Collection: To provide repayment of existing loans of up to \$35,000 per year

to qualified health professionals performing research in fields

required by the NIH to support its mission.

Why Increase Occurred: Changes are due to statutory expansion of the program.

Change in Burden: 16,427

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0050

Title: Hospital/Healthcare Complex Cost Report

**Purpose of the Collection:** The form is used by Hospitals participating in the Medicare

program. This form reports the health care costs to determine the amount of reimbursable costs for services rendered to Medicare

beneficiaries

Why the increase occurred: Revision of section 1814(i) of the Social Security Act.

Change in Burden: 66,200

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0214

Title: Questions on Other Insurance Available to Medicare Beneficiaries,

**MSP** 

**Purpose of the Collection:** Medicare Secondary Payer (MSP) refers to those situations where

Medicare does not have primary responsibility for paying the medical expenses of a Medicare beneficiary. Medicare Fiscal Intermediaries, Carrier, and now Part D Plans, need information about primary payers in order to perform various tasks to detect

and process MSP cases and make recoveries.

Why the increase occurred: MMA/Addition of Part D Program

Change in Burden: 490,576

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0953

**Title**: Expedited Review Notices (CMS-4004-FC)

Purpose of the Collection: Provide for the establishment of expedited determination

procedures for providers

Why Increase Occurred: Public law.
Change in Burden: 379,400 hours
Statute Title and Public Law: BIPA 521

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0964

**Title**: Medicare Prescription Drug Benefit (CMS-4068-P)

**Purpose of the Collection:** To implement the Medicare Part D – Voluntary Prescription Drug

Benefit Program.

Why Increase Occurred: Public law.

**Change in Burden:** 212.044.545 hours

Statute Title and Public Law: Title I of the Medicare Prescription Drug, Improvement and

Modernization Act of 2003 (MMA).

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0930

Title: Medicare Authorization to Disclose Health Information

**Purpose of the Collection:** Medicare beneficiaries will use the "Medicare Authorization to

Disclose Personal Health Information" to authorize Medicare to disclose their protected health information to a third party.

Why the increase occurred: Legal Authority: "Standards for Privacy of Individually

Identifiable Health Information" contained in 45 CFR Parts 160

and 164.

Change in Burden: 250,000

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0931

**Title:** National Provider Identifier (NPI) Application Update Form

**Purpose of the Collection:** The form is used by health care providers to apply for NPIs and to

update the information collected from them whenever it changes.

Why the increase occurred: Health Insurance Portability and Accountability Act

Change in Burden: 448,128

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0935

**Title:** Medicare Advantage Applications

Purpose of the Collection: Health plans must meet certain regulatory requirements to enter

into a contract with CMS to provide health benefits to Medicare beneficiaries. These applications are the collection forms to obtain the information from a health plan that will allow CMS staff to

determine compliance with the regulations.

Why the increase occurred: Title II of the MMA

Change in Burden: 20,100

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0936

**Title:** Medicare Advantage Applications for Part D

**Purpose of the Collection:** The Application for Prescription Drug Plans (PDP), the

Application Medicare Advantage Prescription Drug (MA-PD),

and the Application for Cost Plans to Offer a Qualified

Prescription Drug Coverage are completed by entities seeking approval to offer Part D Benefits under the Medicare Prescription Drug Benefit program established by Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D of the Social Security Act

(the Act).

Why the increase occurred: Title I of the MMA

Change in Burden: 20,081

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0941

Title: Medicare Care Management Performance Demonstration

Purpose of the Collection: The Centers for Medicare & Medicaid Services intends to use

these forms to collect information needed to implement Congressionally-mandated and high priority Medicare

demonstrations. These forms in will be used to reward physician groups for improvements in the quality of care and services

delivered to Medicare fee-for-service beneficiaries.

Why the increase occurred: MMA Section 649

Change in Burden: 15,200

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0944

Title: Bid Pricing Tool for Medicare Advantage Plans and Prescription

**Drug Plans** 

Purpose of the Collection: Under the Medicare Modernization Act, Medicare Advantage

Organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing bid to CMS for approval. This software is used by MAOs and PDPs to price their plan benefit package. This software is used by CMS to review and

approve the plan pricing proposed by each organization.

Why the increase occurred: Title I and Title I of the MMA

Change in Burden: 12,050

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0949

**Title:** Health Insurance Reform: Security Standards; Final Rule **Purpose of the Collection:** This final rule adopts standards for the security of electronic

protected health information to be implemented by health plans, health care clearinghouses and certain health care providers. The

use of the security standards will improve the Medicare and

Medicaid programs, and other Federal health programs, and private

health programs.

Why the increase occurred: HIPAA Change in Burden: 64,539,263

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0951

**Title:** Collection of Drug Pricing and Network Pharmacy Data from

Medicare Prescription Drug Plans

**Purpose of the Collection:** Both stand alone prescription drug plans (PDPs) and Medicare

Advantage Prescription Drug (MA-PDs) plans will be required to submit drug pricing and pharmacy network data to CMS. These data will be made publicly available to people with Medicare through the new Medicare prescription drug plan finder tool that will be launched in the fall of 2005 on <a href="www.medicare.gov">www.medicare.gov</a>. The purpose of the data is to enable people with Medicare to compare, learn, select and enroll in a plan that best meets their needs.

Why the increase occurred: Title I and Title II of the MMA

Change in Burden: 36,400

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0952

**Title:** Federal Funding of Emergency Health Services (Section 1011):

Provider Payment Determination and On-Call Cost Forms

Purpose of the Collection: Section 1011 of MMA provides that the Secretary will establish a

process for eligible providers to request payment. The Secretary must directly pay hospitals, physicians, and ambulance providers

(including Indian Health Service, Indian tribe and tribal

organizations) for their otherwise un-reimbursed costs of providing

services required by Section 1867 of the Social Security Act (EMTALA) and related hospital inpatient, outpatient and

ambulance services.

Why the increase occurred: Section 1011 of the MMA

Change in Burden: 634,000

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0957

**Title:** Retiree Drug Subsidy Program Application

**Purpose of the Collection:** Under the Medicare Prescription Drug, Improvement,

Improvement, and Modernization Act of 2003, sponsors who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs.

In order to qualify, plan sponsors must submit a complete application to CMS with a list of retirees for whom it intends to

collect the subsidy.

Why the increase occurred: Subpart R of the MMA

**Change in Burden**: 2,025,000

Does this change impact small entities with fewer than 25 employees? Yes

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0958

Title: Monthly State File of Medicaid/Medicare Dual Eligible Enrollees

**Purpose of the Collection:** The monthly file of dual eligible enrollees will be used to

determine those duals with drug benefits for the phased down State contribution process required by the Medicare Modernization Act

of 2003 (MMA).

Why the increase occurred: Section 103 of the MMA

Change in Burden: 10,710

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0960

Title: CMS Real-time Eligibility Agreement and MDCN Access Request

**Purpose of the Collection:** Federal law requires that CMS take precautions to minimize the

security risk to federal information systems. The information will be used to assure that those entities that access the Medicare database are aware of applicable provisions and penalties.

Why the increase occurred: HIPAA/Compliance with Section 164.312(a) (2) (i)

Change in Burden: 45,000

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0969

**Title:** Medicare Program: Complex Medical Review

Purpose of the Collection: Medicare contractors conduct complex medical review to

determine whether items or services billed are covered, correctly coded, and are reasonable and necessary for the condition of the patient. Under complex medical review the provider or supplier

must submit a copy of the medical records

Why the increase occurred: New Collection. (CMS-6022-P)

Change in Burden: 483,333

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0846

**Title:** Physician's Referrals to Health Care Entities With Which They

Have Financial Relationships

**Purpose of the Collection:** Under section 1877, if a physician or a member of a physician's

immediate family has a financial relationship with a healthy care entity, the physician may not refer Medicare patients to that entity for the furnishing of 11 designated health services, unless an

exception applies.

Why the increase occurred: Requirements in CMS-1810-IFC were revised which increased

burden.

Change in Burden: 422,007

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0970-0289

**Title:** Annual Report; on Progress – University Centers for Excellence in

Developmental Disabilities Education, Research, and Service

**Purpose of the Collection:** The Act requires that grantees be monitored through an

accountability system in addition to an annual report.

**Why Increase Occurred:** Compliance with the Act.

**Change in Burden:** 61,000 hours.

Statute Title and Public Law: Development Disabilities Assistance and Bill of Rights Act of

2000, 42 USC 15004

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0970-0287

Title: Fourth National Incidence Study of Child Abuse and

Neglect (NIS-4) 2<sup>nd</sup> submission

Purpose of the Collection: Provide national estimates of child maltreatment in the United

States

Why Increase Occurred: Compliance with the Act

**Change in Burden:** 13,845 hours

**Statute Title and Public Law:** Keeping Child and Families Safe Act of 2003 (P.L. 108-36)

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0910-0278

**Title:** Registration of Food Facilities Under the Public Health Security

and Bioterrorism Preparedness and Response Act of 2002

**Purpose of the Collection:** The FWA is designed to provide a simplified procedure for

institutions engaged in HHS-conducted or supported research to satisfy the assurance requirements of Section 491(a) of the Public Health Service Act and of HHS regulations for the protection of

human subjects at 45 CFR 46.103.

**Why Increase Occurred:** Compliance with 45 CFR 46.103.

**Change in Burden:** 22,500 hours.

**Statute Title and Public Law:** Public Health Service Act (the PHS, Act); and HHS

regulations for the protection of human subjects at 45 CFR 46.103.

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0990-0278

**Title:** Registration of Food Facilities Under the Public Health Security

and Bioterrorism Preparedness and Response Act of 2002

**Purpose of the Collection:** The FWA is designed to provide a simplified procedure for

institutions engaged in HHS-conducted or supported research to satisfy the assurance requirements of Section 491(a) of the Public

Health Service Act and of HHS regulations for the protection of

human subjects at 45 CFR 46.103.

**Why Increase Occurred:** Compliance with 45 CFR 46.103.

**Change in Burden:** 22,500 hours.

**Statute Title and Public Law:** Public Health Service Act (the PHS, Act); and HHS

regulations for the protection of human subjects at 45 CFR 46.103.

Does this change impact small entities with fewer than 25 employees? No

# Other (2005)

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-0555

**Title:** Presubmission Conference

**Purpose of the Collection:** The regulation establishes the procedures for requesting,

conducting and documenting presubmission conferences.

Presubmission conferences give FDA and a potential applicant a means to identify the least burdensome appropriate requirements

that have a reasonable likelihood of resulting in approval.

Why Increase Occurred: New Collection

Change in Burden: 27,740

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-0553

Title: Recommended Glossary and Educational Outreach to Support Use

of Symbols on Labels and in Labeling of In Vitro Diagnostic

Devices Intended for Professional Use

**Purpose of the Collection**: The purpose of this guidance is to helps IVD manufacturers to

create uniform labels and labeling for the United States and European Union (and any other countries that may permit use of symbols from these international standards), instead of needing designated labels for each marketplace. Because symbols take up less space than the text for which they may substitute, the use of symbols promotes less crowded and more legible IVD labels.

Why Increase Occurred: New collection.

**Change in Burden:** 34,840

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-0564

**Title:** Performance Standard for Diagnostic X-ray Systems and their

**Major Components** 

**Purpose of the Collection:** Users of fluoroscopic x-ray systems will use the information

provided to select appropriate modes of operation of the equipment

and to understand the patient radiation dose implications of

selected operational parameters.

**Why Increase Occurred:** This is a new collection.

**Change in Burden:** Industry costs of this information collection burden will be about

\$1.2 million in year one, and then decrease to \$0.6 million per year

in subsequent years. 54,000 hours

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-0559

**Title:** Current Good Tissue Practice (CGTP) for Human Cell, Tissue, and

Cellular and Tissue-Based Product Establishments; Inspection and

Enforcement

**Purpose of the Collection:** 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.

Why Increase Occurred: New program. Change in Burden: 283,400

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0915-0140

**Title:** Nursing Education Loan Repayment Agreements

**Purpose of the collection:** To provide loan repayments to registered nurses for educational

loans

**Why Increase Occurred:** The Nursing Program substantially increased funding levels for the

loan program.

**Change in Burden:** 52,950

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0915-0275

**Title:** Ryan White Comprehensive AIDS Resources Emergency Act of

1990, Title III-IV Client-Level Data Project (CDP) Reporting

System

**Purpose of the collection:** To collect client level data from Ryan White CARE Act Title III

and IV grantees.

Why Increase Occurred: The project had conditional clearance of 1 hour until responding to

Terms of Clearance, after which the full burden level was

approved.

**Change in Burden:** 25,199

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB** #: 0920-0666

**Title:** National Healthcare Safety Network (NHSN)

**Purpose of the collection:** This data will be used to determine the magnitude of various

healthcare-associated adverse events and trends in the rates of these events among patients and healthcare personnel with similar risks or exposures. Data will be gathered on antibiotic resistance to

describe the epidemiology of antibiotic resistance and to understand the role of antimicrobial therapy to this growing

problem.

Why Increase Occurred: Three surveillance systems (0920-0012, 0920-0442, 0920-0417)

were expanded will be merged into one system over time.

**Change in the Burden:** 65,817

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB** #: 0920-0664

**Title:** Passenger Locator Forms

**Purpose of the Collection:** The Airline Passenger Locator Form will allow CDC to carry out

its quarantine activities by providing CDC quarantine stations with quick, accurate, up-to-date contact information for passengers exposed to a communicable disease en route, as well as passengers returning from areas in which an active outbreak is taking place. These forms will eventually be made merged with the Foreign

Quarantine Regulations clearance (0920-0134).

Why Increase Occurred: New submission

Change in the Burden: 225,067

Does this change impact small entities with fewer than 25 employees? No

**OMB** #: 0920-0012

Title: The National Nosocomial Infections Surveillance (NNIS) System

Purpose of the Collection: The purpose of the NNIS system is to provide national data on the

incidence of nosocomial infections and their risk factors, and on

emerging antibiotic resistance.

Why Increase Occurred: Re-instatement with Change

**Change in the Burden:** 66,775

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-0939

Title: Medicare Advantage Applications for Part D

**Purpose of the Collection:** The information collected will be used to validate the Medicare

payment amounts for those products/services and institute

revisions of payment amounts where necessary. The respondents will be the companies that have provided the product/service under

review to Medicare beneficiaries.

Why the increase occurred: New Collection.

Change in Burden: 16,000

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0970-0139

**Title:** ACF Uniform Project Description

**Purpose of the Collection:** Generic clearance for discretionary program announcements

Why Increase Occurred: Added programs Change in Burden: 10,000 hours

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0970-0273

**Title:** Building Strong Families

Purpose of the Collection: Research study to determine the effect of intervention on unwed

parents

Why Increase Occurred: New study Change in Burden: 29,520 hours

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0990-0287

**Title:** HHS Research Misconduct Final Rule

Purpose of the Collection: The information is needed so HHS can carry out is statutory

responsibilities to: (1) ensure that institutions applying funding for research or research training have procedures for responding to

allegations of research misconduct; and (2) oversee the

implementation of those procedures and the response of those

institutions to such allegations.

Why Increase Occurred: Burden hours estimates are set forth in the preamble of the final

rule.

**Change in Burden:** 19.728 hours.

**Statute Title and Public Law:** Public Health Service (PHS) Act, 42 U.S.C. 289b **Does this change impact small entities with fewer than 25 employees?** No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0990-0291

**Title:** Adolescent Family Life Pregnancy Prevention Core Evaluation

**Purpose of the Collection:** Adolescent Family Life Pregnancy Prevention Programs provide

service to promote abstinence for adolescents. The instruments developed for this evaluation provide core measures of teen

attitudes, beliefs, and behavioral intentions.

Why Increase Occurred: There are no annualized capital/startup or ongoing operation and

maintenance costs associated with collecting the information.

There are no direct monetary costs to respondents

**Change in Burden:** 19,728 hours.

**Statute Title and Public Law:** Title XX of the Public Health Service Act **Does this change impact small entities with fewer than 25 employees?** No

### **REDUCTIONS (2006)**

## **Change in Regulations:**

# **Cutting Redundancy:**

**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 written application would describe the intended use of the

blood or blood component, including identification of all

consignees and the procedures for collecting, handling, labeling, and shipping the blood. The disclosure requirements ensure that personnel handling human blood or blood components that have

tested repeatedly reactive for markers of infection with

communicable disease agents are aware of this fact and can take

appropriate safety precautions.

How Reduction Achieved: The decrease is attributed to the consolidation of this package into

0910-0116.

Change in Burden: -142,145

Does this change impact small entities with fewer than 25 employees? No

### **Changing Forms:**

### **Using Information Technology and E-Government:**

### **Statutory Reductions:**

(Use format above but add a line for "statute title and public law")

### Other:

**Agency:** Department of Health and Human Services

**OMB** #: 0920-0353

**Title:** National Nursing Home Survey, Main Study

**Purpose of Collection:** Types of data collected include characteristics of the facilities,

residents, and nursing assistants; such as facility ownership and

certification status and resident and nursing assistant

demographics. Nursing assistants provided data on their education and training, job history, family life, management and supervision,

client relations, job satisfaction, organizational culture, and work-

related injuries.

Why Reduction Occurred: Data collection completed

**Change in the Burden:** -13,375 hours

Do these changes impact small entities with fewer than 25 employees? Yes

**Agency**: Department of Health and Human Services

**OMB Control Number**: 0925-0407

**Title**: Prostate, Lung, Colorectal and Ovarian (PLCO)

**Purpose of the Collection**: Collection designed to determine if screening for prostate, lung,

colorectal and ovarian cancer can reduce mortality from these

cancers.

**Why Increase Occurred**: There was no increase. The reason for the decrease can be

attributed to the tapering off and conclusion of screening exams.

Change in Burden: -16,511

Does this change impact small entities with fewer than 25 employees? No

## **INCREASES (2006)**

## **Statutory Increases:**

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0915-NEW

**Title:** Expansion of the National Practitioner Data Bank for Adverse

Information on Physicians and Other Health Care Practitioners:

Section 1921 of the Social Security Act.

**Purpose of the Collection:** Section 1921 authorizes an expansion of the collection of

information contained in the National Practitioner Data Bank.

Why Will Increase Occur: Implementation of Section 1921expands the type of information

currently collected by the National Practitioner Data Bank.

**Change in Burden:** 11,518 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.

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

**Title**: Notice of Denial of Prescription Drug Coverage

**Purpose of the Collection**: Pursuant to 42 CFR 423.568(c), if a Part D plan denies drug

coverage, the Part D plan must give the enrollee written notice of

the coverage determination.

Why Increase Occurred: New Collection. (CMS-10146) MMA Part D

**Change in Burden**: 528,000 hours

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

**Title:** Medicare Prescription Drug Coverage and Your Rights

**Purpose of the Collection**: Pursuant to 42 CFR 423.562(a)(3), a Part D plan sponsor must

arrange with its network pharmacies to post or distribute notices informing enrollees to contact their plan to request a coverage determination or an exception if the enrollee disagrees with the

information provided by the pharmacy.

**Why Increase Occurred**: New Collection. MMA Part D (CMS-10147)

**Change in Burden**: 583,333 hours

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

**Title:** Electronic Data Interchange (EDI) Enrollment Form and the

Medicare EDI Registration Form

**Purpose of the Collection:** Health care providers, clearinghouses, and health plans that wish

access to the Medicare system are required to complete this form. The information will be used to assure that those entities that access the Medicare system are aware of applicable provisions and

penalties.

Why the increase occurred: New Collection. (CMS-10164) HIPAA of 1996; Public Law 104-

191

Change in Burden: 400,000

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

**Title:** Coordination of Benefits between Part D Plans and Other

**Prescription Coverage Providers** 

**Purpose of the Collection:** The information is necessary to assist with coordination of

prescription drug benefits provided to the Medicare beneficiary at

the pharmacy.

Why the increase occurred: New Collection. (CMS-10171) MMA

**Change in Burden**: 1,017,914

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

Title: Medicare Health Support Program Medical Records Abstraction

**Purpose of the Collection:** To monitor the performance of the Medicare Health Support

(MHS) Program and promptly identify signs of program effects, CMS requests permission to extract data from the medical records

of beneficiaries residing in eight pilot program areas.

Why the increase occurred: New Collection. (CMS-10172) MMA/Public Law 108-173

Change in Burden: 12,416

**OMB Control Number:** 0938-NEW

**Title:** Payment Error Rate Measurement in Medicaid and the State

Children's Health Insurance Program (SCHIP)

**Purpose of the Collection:** The Improper Payments Information Act (IPIA) of 2002 requires

CMS to produce national error rates for Medicaid and SCHIP. To comply with the IPIA, CMS needs the information to be collected

from states and providers in order to sample and review adjudicated claims in a randomly selected number of states.

Why the increase occurred: New Collection. (CMS-10166) Improper Payment Information

Act of 2002/Public Law 107-300)

Change in Burden: 58,680

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

**Title:** Retiree Drug Subsidy (RDS) Payment Request and Instructions **Purpose of the Collection:** Under the Medicare Prescription Drug, Improvement, and

Modernization Act of 2003 and implementing regulations at 42 CFR Subpart R plan sponsors (employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs.

In order to qualify, plan sponsors must submit required prescription cost data to CMS in order to receive the subsidy.

Why the increase occurred: New Collection. (CMS-10170) MMA

**Change in Burden**: 1,850,000

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

**Title:** Competitive Acquisition Program for Medicare Part B Drugs:

Physician Election Agreement

Purpose of the Collection: The CAP Physician Election Agreement will be used by physicians

to elect to participate in the CAP beginning in the Fall of 2005.

Why the increase occurred: New Collection. (CMS-10167) Section 303(d) of the MMA

Change in Burden: 20,000

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0970-NEW

**Title:** Annual Performance Improvement Report

**Purpose of the Collection:** Performance measure **Why Will Increase Occur:** Compliance with the statute

**Change in Burden:** 10,000 hours

**Statute Title and Public Law:** Contingent on TANF Reauthorization

Does this change impact small entities with fewer than 25 employees? No

**OMB Control Number:** 0970-NEW

**Title:** Program characteristics report

**Purpose of the Collection:** Performance measure

Why Will Increase Occur: Compliance with the statute

Change in Burden: 15,000

Statute Title and Public Law: Contingent on TANF Reauthorization

Does this change impact small entities with fewer than 25 employees? No

Other (2006)

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-0437

Title: Medical Device Reporting: Manufacturer Reporting, Importer

Reporter, User Facility Reporting, and Distributor Reporting

**Purpose of the Collection:** Information from these reports will be used to evaluate risks

associated with medical devices and to enable FDA to take appropriate regulatory measures to protect the public health.

**Why Will Increase Occur:** The total amount of burden hours increased by 30,379 hours

because of two changes. First, although reports no longer need to be submitted to FDA, device distributors must still maintain

records of complaints. Second, the burden formerly associated with

distributors' reports was not previously transferred from the

reporting to the recordkeeping burden section.

Change in Burden: 30,379

Does this change impact small entities with fewer than 25 employees? No

**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); Final Rule

**Purpose of the Collection:** This collection of information provides important information to

consignees and/or recipients of prior collections of blood and blood components from a donor who later returned to donate and

tested repeatedly reactive for antibody to HIV or HCV.

Why Increase Occurred: New Program.

Change in Burden: 723,264

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-XXXX

Title: Requirements for Human Blood and Blood Components Intended

for Transfusion or For Further Manufacturing Use

**Purpose of the Collection:** The information collected from these reporting and recordkeeping

requirements help to 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:** New program. **Change in Burden:** 1,196,869

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-XXX; final rule

**Title:** Labeling for Human Prescription Drugs; Revised Format

**Purpose of the Collection:** Amend regulations at 21 CFR 201.56 and 201.57 governing the

format and content of prescription drug labeling. This may publish

11/05 or 12/05.

**Why Increase Occurred:** Revision **Change in Burden:** 501,383

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-XXXX

**Title:** CGMPs for Positron Emission Tomography (PET) drugs; proposed

rule

Purpose of the Collection: Section 121 of the FDA Modernization Act directs FDA to

establish CGMP requirements for PET drugs.

Why Increase Occurred: New Regulation

**Change in Burden:** 86,656

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-XXXX

**Title:** Draft Guidance for Industry on the Pediatric Research Equity Act **Purpose of the Collection:** Provide guidance on interpreting the Pediatric Research Equity Act

Why Increase Occurred: New Guidance Change in Burden: 12,580

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

OMB Number: 0910-XXXX

Title: Human Subject Protection; Foreign Clinical Studies Not

Conducted Under an IND - Final Rule

**Purpose of the Collection:** Use of foreign clinical studies in drug marketing approval

applications.

Why Increase Occurred: New Collection

**Change in Burden**: 18,400 (Program Change

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-XXXX

**Title:** Safety Reporting Requirements for Human Drugs; final rule

**Purpose of the Collection:** This rule provides information about safety reporting requirements

for human drugs.

**Why Increase Occurred:** This is the total burden in the proposal. The final rule will be

published in parts. Therefore, each final rule (part) will have a lower burden than was in the proposal. There is a possibility that

one or more parts will publish in 2006.

**Change in Burden?** 5,799,477

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Number:** 0910-XXXX

**Title:** Foreign and Domestic Establishment Registration and Listing

Requirements; proposed rule

**Purpose of the Collection:** Electronic submission of drug establishment registration

information and drug product listing information (revises 21 CFR

207). Will replace currently approved 0910-0045.

Why Increase Occurred: New Collection

Change in Burden: 196,342

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

OMB Number: 0910-XXXX

**Title:** Treatment use of Investigational Drugs; proposed rule

Purpose of the Collection: Amend the IND regulations to describe the way patients may

obtain investigational drugs for treatment use.

**Why Increase Occurred:** Revision **Change in Burden:** 23,084

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB#:** 0920-0134

**Title:** Foreign Quarantine Regs (42 CFR 71)

**Purpose of the Collection:** 2 CFR Part 71 authorizes quarantine officers and other personnel

to inspect and undertake necessary control measures with respect to conveyances, persons, and shipment of animals and etiologic

agents in order to protect the public's health.

Why Increased Occurred: Addition of the passenger locator forms.

Change in the Burden: 225,015

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB** #: 0920-0696

**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, approved 10/6/2005.

Change in the Burden: 122,172

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB#:** 0920-NEW

**Title:** Estimating the Cost of Sigmoidoscopy and Colonoscopy for

Colorectal Cancer Screening in U.S. Healthcare Facilities

**Purpose of Collection**: The estimated procedure costs will be compared to the

reimbursement rates for both screening procedures, to determine whether the difference between payments to facilities and costs incurred is a potential barrier to expansion of CRC screening to

uninsured or underinsured populations.

Why Increase Occurred: New submission

Change in Burden: 11,011

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB** # 0920-NEW

Title: A Site Specific Modular Evaluation Instrument for Behavior

Outcome Measurement

**Purpose of Collection:** A standardized methodology to monitor outcomes associated with

agency intervention will provide the data needed for demonstrating

effectiveness and efficiency as well as identifying areas for

improvement.

**Why Increase Occurred:** New submission

**Change in Burden:** 20,438

Does this Change Impact Small Entities with Fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB** #: 0920-NEW

**Title:** Centers of Excellence for Autism and Developmental Disabilities

Research and Epidemiology (CADDRE)

**Purpose of the Collection:** The purpose of this study is to conduct a multi-site, collaborative

epidemiological investigation of possible causes for autism

spectrum disorders.

Why Increase Occurred: New submission

Change in Burden: 10,000

Does this Change Impact Small Entities with Fewer than 25 employees? No

**OMB** #: 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

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB** #: 0920-NEW

**Title:** Morbidity Monitoring Project

Purpose of the Collection: The purpose of this data collection is to supplement HIV/AIDS

surveillance programs in 26 selected state and local health

departments by collecting data on behaviors and clinical outcomes

Why Increase Occurred: New submission

Change in the Burden: 18,200

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB#:** 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

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB#:** 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 in better identifying and assessing environmental factors contributing to foodborne

outbreaks.

Why Increase Occurred: New submission.

Change in the Burden: 16,800

Does this change impact small entities with fewer than 25 employees? No

**OMB Control Number**: 0925-0406

**Title**: Agriculture Health Study

**Purpose of the Collection**: To learn why farmers and other agriculture workers are at a greater

risk of certain cancers compared to the rest of the population.

**Why Increase Occurred**: The number of CAT1 interviews is very large, so program may

need to extend data collection for a fourth year.

Change in Burden: 40,563

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0930-0266

**Title:** Access to Recovery (ATR) Program

**Purpose of the collection:** States 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.

Why Increase Occurred: New Project Change in Burden: 81,318

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

Title: National Implementation of the Hospital CAHPS Survey

Purpose of the Collection: HCAHPS includes a nationaly recognized and quality approved

standardized survey instrument and data collection protocol

allowing for flexibility in the mode of administration.

Why Increase Occurred: New Collection. (CMS-10102)

**Change in Burden**: 285,525 hours

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

**Title:** Wheelchairs (Including POV)

**Purpose of the Collection**: For Medicare to consider item for coverage and payment.

**Why Increase Occurred**: New Collection. (CMS-10116)

**Change in Burden**: 260,000 hours

Does this change impact small entities with fewer than 25 employees? No

**Agency:** Department of Health and Human Services

**OMB Control Number:** 0938-NEW

**Title:** ICRs for Ambulance Services and Supporting Regulations

Contained in 42 CFR 410.40, 410.41, and 414.610

**Purpose of the Collection**: The Ambulance Supplier form will be used by Medicare Carriers

to ensure that established compliance requirements are met. By separate submission suppliers will be required to submit additional

information to Medicare Carriers when operational changes occur, this ensures that Carrier records are up-to-date

Why Increase Occurred: New Collection.
Change in Burden: 20,634

Does this change impact small entities with fewer than 25 employees? No

## Appendix C Violatons Due Lapse of OMB Approval

OMB	Title	Date of	Date of	Date
Number		Expiration	Reinstatement	Discontinued
0920-0337	National Blood Level Lead Surveillance System	10/31/2004	5/6/2005	N/A
0992-0005	45 CFR Part 95, Subpart F—Automatic Data Processing Equipment and Services— Conditions for Federal Financial Participation	11/30/2004	4/21/2005	N/A

## **Appendix C Bootleg Collections**

- Operating Division/OMB Number: CDC/0920-0337
- Title: National Blood Lead Surveillance System
- Date of Approval: 5/6/2005
- Explanation of How the Bootleg was Found:

The CDC clearance office discovered that since its inception the adult lead data were always collected without an OMB number.

• A Description of the Resolution:

OMB clearance granted. Both the childhood and adult blood lead data collections were merged into one collection.

- Operating Division/OMB Number: CDC/0920-0602
- Title: Participatory Research and the Dissemination and Translation of Research Findings
- Date of Approval: 1/4/2005
- Explanation of How the Bootleg was Found: CDC clearance office received a report that data were collected prior to the program receiving OMB clearance.
- A Description of the Resolution: OMB clearance was granted.
- Operating Division/OMB Number: CDC/0920-0679
- Title: Cardiovascular Health Branch Management Information System
- Date of Approval: 5/6/2005
- Explanation of How the Bootleg was Found: During a conference call with OMB, it was discovered that the data collected using focus groups during the pretesting of the instruments should have received OMB clearance.
- A Description of the Resolution: OMB clearance was granted.
- Operating Division/OMB Number: CDC/0920-0681
- Title: Comprehensive Cancer Control (CCC) Implementation Case Study
- Date of Approval: 5/10/2005
- Explanation of How the Bootleg was Found: During the preparation of the OMB submission, it was discovered that the reports which were submitted prior to this clearance should have received OMB clearance.
- A Description of the Resolution: OMB clearance was granted.
- Operating Division/OMB Number: CDC/0920-0683
- Title: Operations and Scope of Public STD Clinics in the US States and Territories
- Date of Approval: 5/16/2005
- Explanation of How the Bootleg was Found: CDC clearance office received a report that data were collected prior to the program receiving OMB clearance.
- A Description of the Resolution: OMB clearance was granted.

- Operating Division/OMB Number: CMS/0938-0948
- Title: HIPAA Administrative Simplification Non-Privacy Enforcement
- Date of Approval: 9/8/2005
- Explanation of How the Bootleg was Found: The bootleg was found by the CMS clearance office in a report from the CMS componant after HIPAA was implemented.
- A Description of the Resolution: OMB clearance was granted.
- Operating Division/OMB Number: CMS/0938-0949
- Title: Health Insurance Reform: Security Standards; Final Rule
- Date of Approval: 3/16/2005
- Explanation of How the Bootleg was Found: The bootleg was found by the CMS clearance office in a report from the CMS componant after HIPAA was implemented.
- A Description of the Resolution: OMB emergency clearance was granted.
- Operating Division/OMB Number: SAMHSA/0935-XXXX
- Title: Targeted Capacity Expansion Grants for Jail Diversity Programs
- Date of Approval: 60 Day Notice published on April 7, 2005.
- Explanation of How the Bootleg was Found: The SAMHSA clearance officer became aware of this violation when the program office requested consultation about revisions to the forms.
- A Description of the Resolution: A 60 Day Notice was published on April 7, 2005. The Department is working with SAMHSA to complete an information collection request package for OMB.