Supporting Statement

Letter Requesting Waiver of Medicare/Medicaid Enrollment Application Fee; Submission of Fingerprints; Submission of Medicaid Identifying Information; Medicaid Site Visit and Rescreening

A. Background

On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111-148. Section 6401 of the law establishes a number of important payment safeguard provisions, several of which have been incorporated into CMS Proposed Rule 6028, entitled "Medicare, Medicaid, and Children's Health Insurance Programs (CHIP); Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers," and published in the *Federal Register* on September 23, 2010. The provisions are designed to improve the integrity of the Medicare, Medicaid, and CHIP programs so as to reduce fraud, waste and abuse.

Of the elements of CMS-6028-F, six were listed in the ICR section:

- **Medicare Enrollment Application Fee Waiver Request (Proposed 42 CFR § 424.514)**: Certain providers and suppliers enrolling in Medicare will be required to submit a fee with their application. Under proposed 42 CFR § 424.514, if the applicant believes it has a hardship that justifies a waiver of the application fee, it may submit a letter describing said hardship. The burden associated with this requirement would be the time and effort necessary to draft and submit the letter.

- **Fingerprints (Proposed 42 CFR § 424.518 and § 455.434):** Certain providers and suppliers enrolling in Medicare, Medicaid, and CHIP will be required to submit fingerprints – either digitally or via the FD-258 standard fingerprint card - of their owners. . The burden associated with this requirement would be the time and effort necessary for the provider or supplier to obtain and submit the fingerprint cards.

- **Suspension of Medicaid Payments (Proposed 42 CFR § 455.23):** A State Medicaid agency shall suspend all Medicaid payments to a provider when there is a pending investigation of a credible allegation of Medicaid fraud against an individual or entity, unless it has good cause not to suspend payments or to suspend payment only in part. The State Medicaid agency may suspend payments without first notifying the provider of its intention to suspend such payments. A provider may request, and must be granted, administrative review where State law so requires. The burden associated with this requirement is the time and effort necessary for a provider to request administrative review. While this requirement is subject to the PRA, we believe the associated burden is exempt in accordance with 5 CFR 1320.4; information collected subsequent to an

administrative action is not subject.

- **Collection of SSNs and DOBs for Medicaid and CHIP providers (Proposed § 455.104(b)(1)):** The State Medicaid agency or CHIP agency must require that all persons with an ownership or control interest in a Medicaid or CHIP provider submit their SSNs and DOBs. The burden associated with this requirement will be the provider's acquisition and submission of this data.

- **Site Visits for Medicaid-only or CHIP-only providers (Proposed § 455.450(b)):** A State Medicaid agency or CHIP agency must conduct on-site visits for providers it determines to be "moderate" or "high" categorical risk. The burden associated with this requirement is the time and effort the State Medicaid agency or CHIP agency will need to perform the site visit.

- **Rescreening of Medicaid and CHIP Providers Every 5 Years (Proposed § 455.414):** A State Medicaid agency or CHIP agency must screen all providers at least every 5 years. This is consistent with the Medicare requirement in current 42 CFR § 424.515 that providers and suppliers revalidate their enrollment information at least every 5 years. The burden associated with this requirement would be the time and effort necessary for Medicaid-only or CHIP-only providers to re-enroll in Medicaid or CHIP, and the time and effort necessary for the State Medicaid agency or CHIP agency to conduct the provider screening.

B. Justification

1. Need and Legal Basis

The provisions of CMS-6028-F, and the information collection elements described above, are necessary to carry out Section 6401 of the Affordable Care Act.

2. Information Users

CMS and/or its Medicare contractors will use the letters referred to in proposed 42 CFR § 424.514, and the Medicare fingerprint collection in 42 CFR § 424.518.

States and/or their agents will use the information collections related to: (1) fingerprinting for Medicaid and CHIP providers, (2) SSNs and DOBs for Medicaid and CHIP providers, (3) site visits for Medicaid-only or CHIP-only providers, and (4) rescreening of Medicaid and CHIP providers every 5 years.

3. Use of Information Technology

For Medicare, the standard electronic system used by Medicare contractors is the Provider Enrollment, Chain and Ownership System (PECOS). PECOS will likely be used to indicate whether the provider or supplier has submitted an application waiver letter and the necessary fingerprinting materials. The letter will need to be submitted via hard copy, as this requirement does not lend itself to electronic submission at this time. The provider or supplier will, however, be able to submit fingerprints either digitally or via the FD-258 standard fingerprint card.

For Medicaid and CHIP, the use of information technology may vary by State. Each State is responsible for administering its own Medicaid and CHIP programs. To the extent possible, we will encourage States to use automated, electronic, or other technological techniques.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

Each of the data collections described above will impact small businesses. However, because of the relative infrequency with which the information will need to be submitted and the minimal time involved in each data collection, we believe that the overall impact on small businesses will be extremely negligible.

6. Less Frequent Collection

- **Waiver of Application Fee –** In general, providers and suppliers will submit this letter only once.
- **Fingerprints** – In general, fingerprints will be collected from the affected providers and suppliers only once.
- **Collection of SSNs and DOBs** – This information will be collected upon initial enrollment, revalidation every 5 years, and if/when the provider adds a new individual with an ownership or control interest. We therefore estimate that the provider will need to furnish the SSN or DOB of at least one individual no more than twice in a 5-year period.
- **Site Visits** – In general, site visits of the affected providers will be performed only once – specifically, upon initial enrollment.
- **Rescreening** – Rescreening of Medicaid providers will occur once every five years.

7. Special Circumstances

There are no special circumstances associated with this information collection request.

8. Federal Register/Outside Consultation

The proposed rule published in the *Federal Register* on September 23, 2010 (75 FR 58204). The final regulation published on February 2, 2011 (76 FR 5862)..

9. Payments/Gifts to Respondents

Not applicable.

10. Confidentiality

CMS, its Medicare contractors, State Medicaid agencies and its agents, will comply with all Federal and State laws – including, but not limited to, the Federal Privacy Act and Freedom of Information Act – that apply to this collection. Privileged or confidential commercial or financial information is protected from public disclosure by Federal law 5 U.S.C. 522(b)(4) and Executive Order 12600.

11. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Burden Estimates (Hours & Wages)

a. Medicare Enrollment Application Fee Waiver Request

We estimate that 12,000 providers per year will submit waiver request letters. We further estimate that it will take the provider 1 hour to prepare and submit the letter, at a per hour labor cost of $50. This results in a 12,000 hour burden and a total annual cost of $600,000.

12,000 providers X 1 hour X $50 = $600,000.

b. Fingerprints

i. Medicare

We estimate that 7,000 home health agencies (HHAs) and suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) will be required to submit the

fingerprints of an average of 5 individuals within its organization per year, or 35,000 individuals per year. We believe it will take the provider/individual 2 hours to obtain and submit the fingerprints, at a per hour labor cost of $50. This results in a 70,000 hour burden and a total annual cost of $3,500,000.

7,000 providers X 5 individuals X 2 hours X $50 = $3,500,000

We also estimate that an additional 2,000 "high-risk" Medicare providers will be required each year to submit the fingerprints of an average of 5 individuals within its organization. Again, we believe it will take the provider/individual 2 hours to obtain and submit the fingerprints, at a per hour labor cost of $50. This results in a 20,000 hour burden and a total annual cost of $1,000,000.

2,000 providers X 5 individuals X 2 hours X $50 = $1,000,000

We further estimate 500 physicians will be required each year to submit fingerprints We believe it will take the individual 2 hours to obtain and submit the fingerprints, at a per hour labor cost of $50. This results in a 1,000 hour burden and a total annual cost of $50,000.

500 physicians X 2 hours X $50 = $50,000

We therefore estimate that the aforementioned Medicare fingerprinting requirements will result in a combined hourly burden of 91,000 (70,000 + 20,000 + 1,000), at a total cost of $4,550,000 ($3,500,000 + $1,000,000 $ 50,000).

ii. Medicaid

We anticipate that Medicaid and CHIP will request 26,000 individuals to submit fingerprints prior to enrollment, and that it will take the individual 2 hours to obtain and submit the fingerprints - at a per hour labor cost of $50. This results in a 52,000 hour burden and a total annual cost of $2,600,000.

26,000 physicians X 2 hours X $50 = $2,600,000

c. Collection of SSNs and DOBs

According to data taken from the State Program Integrity Assessment (SPIA) program (approved under OCN 0938-1033) for FFYs 2007 and 2008, there has been an average of 1,855,070 existing Medicaid providers nationally over the 2-year period of FFY 2007 and FFY 2008. We estimate that one-fifth, or 371,014 (1,855,070 x 20 percent) of existing Medicaid providers would be required to re-enroll each year. Additionally, we estimate that there will be 56,250 newly enrolling Medicaid providers each year, for a total of 427,264 Medicaid providers that will be subject to the SSN and DOB reporting requirements each year.

We further estimate that it will take each provider an average of 2 minutes to report the SSN and DOB for all persons with an ownership or control interest, at a per hour labor rate of $50. Thus, the estimated annual burden associated with this requirement for Medicaid providers is 14,242 hours at a cost of $712,100.

427,264 providers X 2 minutes, divided by 60 minutes = 14,242 hours

14,242 hours X $50 = $712,000

d. Site Visits

We estimate that State Medicaid agencies will conduct approximately 5,000 site visits for Medicaid-only providers nationally per year. We further estimate that it will take one individual 8 hours to perform each on-site visit (including travel time). Thus, the total estimated annual burden associated with this requirement for Medicaid is 40,000 hours (5,000 site visits X 8 hours) at a cost of $2,000,000 (40,000 hours X $50 per hour).

e. Rescreening of Medicaid Providers

i. Providers Reenrolling

As stated previously, according to data taken from SPIA for FFYs 2007 and 2008, there has been an average of 1,855,070 existing Medicaid providers nationally over that 2-year period. We estimate that one-fifth, or 371,014 (1,855,070 x 20 percent) of existing Medicaid providers would be required to re-enroll each year. Although provider enrollment requirements vary by State, we believe it will take each provider an average of 2 hours to complete the Medicaid re-enrollment requirements. Consequently, the estimated annual burden associated with this requirement for Medicaid providers is 742,028 hours (371,014 x 2 hours) at a cost of $37,101,400 (742,028 hours X $50 per hour).

ii. State Agency Processing of Reenrollment Applications

We estimate that 80 percent of Medicaid providers also participate in Medicare, and thus would have provider screening activities performed by the Medicare contractors. Thus, we believe that States would be required to conduct provider screening activities for 74,203 (371,014 x 20 percent) re-enrolling, Medicaid-only providers each year. We further estimate that it will take States, on average, 4 hours to perform the required provider screening activities – noting that currently enrolled providers would generally be categorized as lower risk than newly-enrolling providers. The estimated burden associated with this requirement for State Medicaid agencies is 296,812 hours (74,203 x 4 hours) at a cost of $14,840,600 (296,812 hours x $50 per hour). We

believe that the burden on States will be in large part offset by the application fees collected and by the Federal share for the amounts not covered by the application fee.

The total estimate annual burden associated with the rescreening requirement is 1,038,840 hours (742,028 + 296,812) at a cost of $51,942,000 ($37,101,400 + $14,840,600).

f. Total

As indicated in the following chart, we estimate that the total hourly burden of the aforementioned elements of CMS-6028-P will be 1,248,082 hours, at a total cost of $62,404,100.

Provision	OMB Control No.	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Labor Cost of Reporting ($)	Total Cost ($)
Application Fee Waiver (424.514)	0938-0685; 0938-1056	12,000	12,000	1	12,000	50	600,000	600,000
Medicare F-printing (HHA/DMEPOS) (424.518)	0938-New	35,000	35,000	2	70,000	50	3,500,000	3,500,000
Medicare F-printing (High-risk) (424.518)	0938-New	10,000	10,000	2	20,000	50	1,000,000	1,000,000
Medicare F-printing (Physicians) (424.518)	0938-New	500	500	2	1,000	50	50,000	50,000
Medicaid F-printing (455.434)	0938-New	26,000	26,000	2	52,000	50	2,600,000	2,600,000
SSN/DOB Collection (455.104)	0938-New	427,264	427,264	.033	14,242	50	712,100	712,100
Site Visits (455.450)	0938-New	5,000	5,000	8	40,000	50	2,000,000	2,000,000
Provider Rescreening (455.414)	0938-New	371,014	371,014	2	742,028	50	37,101,400	37,101,400
State Medicaid Agency Processing of Rescreening Application (455.414)	0938-New	74,203	74,203	4	296,812	50	14,840,600	14,840,600
TOTAL		**960,981**	**960,981**		**1,248,082**			**62,404,100**

13. Estimates of other Total Annual Cost Burden to Respondents or Record Keepers (Capital Costs)

There are no additional record keeping/capital costs.

14. Annualized Cost to the Federal Government

The following chart identifies the annual cost to the Federal Government – through CMS, its Medicare contractors, Medicaid State agencies and/or its agents - to execute the activities outlined in this Supporting Statement.

Provision	Documents to be Collected/Tasks to be Performed	Time Needed to Process Document/ Complete Task (hours)	Total Annual Processing/ Task Burden (hours)	Per Hour Cost of Processing/Task Burden ($)	Total Cost of Processing/ Task Burden ($)
Application Fee Waiver (424.514)	12,000	.5	6,000	20.22 *	121,320
Medicare F-printing (HHA/DMEPOS) (424.518)	35,000	.25	8,750	20.22 *	176,925
Medicare F-printing (High-risk) (424.518)	10,000	.25	2,500	20.22 *	50,550
Medicare F-printing (Physicians) (424.518)	500	.25	125	20.22 *	2,528
Medicaid F-printing (455.434)	26,000	.25	6,500	20.22 *	131,430
SSN/DOB Collection (455.104)	427,264	.5	213,632	20.22 *	4,319,639
Site Visits (455.450)	5,000	8	40,000	30.03 **	1,201,200
Provider Rescreening (455.414) ***	N/A	N/A	N/A	N/A	N/A
State Medicaid Agency Processing of Rescreening Application (455.414)	74,203	4	296,092	20.22 *	5,986,980
TOTAL			**573,599**		**11,990,572**

* Per hour cost based on Grade 7/Step 1 salary in Washington, DC area.
** Per hour cost based on Grade 11/Step 1 salary in Washington, DC area.
*** The burden associated with the processing of reenrollment applications is covered under the "State Medicaid Agency Processing of Rescreening Application" category.

15. Changes to Burden

No changes to burden hours.

16. Publication/Tabulation Dates

N/A

17. Expiration Date

This collection does not lend itself to displaying an expiration date.

18. Certification Statement

There are no exceptions to item 19 of OMB Form 83-I.