

Supporting Statement

Medicare and Medicaid Program; Program Integrity Enhancements to the Provider Enrollment Process CMS-10576

A. BACKGROUND

On April 21, 2006, CMS published a final rule that set forth requirements in 42 CFR Part 424, subpart P that providers and suppliers must meet in order to obtain and maintain Medicare enrollment. Since its establishment in April 2006, subpart P has been updated several times to address various enrollment issues. CMS-6058-P would make additional revisions to subpart P.

Of the elements of CMS-6058-P, two are identified in the ICR section as having reasonably quantifiable burden estimates:

- **Disclosure of Affiliations (§§ 424.519 and 455.107)** – Newly enrolling and revalidating Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) providers and suppliers would be required to disclose certain affiliations with other Medicare, Medicaid, and CHIP providers and suppliers. The burden would involve the time and effort needed for the provider or supplier to prepare and submit this information.
- **Part A and B Ordering/Certifying/Referring/Prescribing (§ 424.507)** – To order, certify, refer, or prescribe any Part A or B service, item, or drug, a physician or eligible professional would have to be enrolled in or validly opted out of Medicare. The burden would be the time and effort needed for the individual to complete the applicable Medicare enrollment form or opt-out affidavit.

B. JUSTIFICATION

1. Need and Legal Basis

As indicated above, this proposed rule would implement sections of the Affordable Care Act that require Medicare, Medicaid, and Children’s Health Insurance Program providers and suppliers to disclose any current or previous direct or indirect affiliation with a currently or formerly enrolled provider or supplier that has (1) uncollected debt; (2) been subject to a payment suspension under a federal health care program; (3) been excluded from Medicare, Medicaid, or CHIP; or (4) had its Medicare, Medicaid, or CHIP enrollment denied, revoked, or terminated. Also, in order to address other program integrity concerns, this proposed rule would revise various provider enrollment provisions in Part 424, subpart P. These changes are necessary to help keep unqualified and potentially fraudulent entities and individuals out of the Medicare program, thus

protecting Medicare beneficiaries and the Medicare Trust Funds.

The following are the six principal legal authorities for our proposed provisions:

- Sections 1102 and 1871 of the Social Security Act (the Act), which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1866(j) of the Act, which provides specific authority with respect to the enrollment process for providers and suppliers.
- Section 1866(j)(5) of the Act, as amended by section 6401(a)(3) of the Affordable Care Act, which states that a provider or supplier that submits a Medicare, Medicaid, or CHIP application for enrollment or a revalidation application must disclose any current or previous affiliation (direct or indirect) with a provider or supplier that (1) has uncollected debt; (2) has been or is subject to a payment suspension under a federal health care program; (3) has been excluded from participation in Medicare, Medicaid, or CHIP; or (4) has had its billing privileges denied or revoked.
- Section 1903(kk)(3) of the Act, as amended by section 6401(b) of the Affordable Care Act, which mandates that states require providers and suppliers to comply with the same disclosure requirements established by the Secretary under section 1866(j)(5) of the Act.
- Section 1866(j)(2)(C) of the Act, which required the Secretary to impose a fee on each "institutional provider of medical or other items or services or supplier" to cover the cost of Medicare provider and supplier screening and other program integrity efforts under sections 1866(j) and 1128J of the Act. Under section 1902(kk) of the Act, the fee requirement in section 1866(j)(2) of the Act is also applicable to Medicaid and CHIP.
- Section 6401(a) of the Affordable Care Act, as amended by section 10603 of the Affordable Care Act, which amended section 1866(j) of the Act to add a new paragraph (2). Section 6401(c) of the Affordable Care Act amended section 2107(e)(1) of the Act to make the requirements of section 1902(kk) of the Act, including the disclosure requirements, applicable to CHIP.

2. Information Users

CMS and/or its Medicare contractors would use the applicable CMS-855 form or opt-out affidavit to collect the information described in this Summary Statement. For Medicaid and CHIP, the states would collect affiliation information via their state-specific forms.

3. Use of Information Technology

CMS and/or its contractors would collect much of the information submitted pursuant to this rule via the Provider Enrollment, Chain and Ownership System (PECOS). For Medicaid and CHIP, the use of information technology would vary by state.

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 in this Summary Statement would impact some small businesses. However, because of the relative infrequency with which the information would need to be submitted and the fairly minimal time involved in most of the data collections, we believe that the overall impact on small businesses would be negligible.

6. Less Frequent Collection

- **Disclosure of Affiliation** – In general, this data would be submitted once every 3-5 years.
- **Parts A/B Ordering/Certifying** – In general, this data would be submitted once every five years.

7. Special Circumstances

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

8. Federal Register/Outside Consultation

A Notice of Proposed Rulemaking published March 1, 2016 (81 FR 10719), providing the public with a 60-day period to submit written comments on the information collection request (ICR).

9. Payments/Gifts to Respondents

Not applicable.

10. Confidentiality

CMS and its Medicare contractors 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. **Disclosure of Affiliations**

i. Medicare

- **Initially Enrolling Providers and Suppliers (§ 424.519(b))**

Based on CMS data, an average of approximately 70,000 providers and suppliers seek to initially enroll in the Medicare program in any given 12-month period. Each of these providers and suppliers would be required to furnish the information described in § 424.519 on the appropriate Form CMS-855 enrollment application. We estimate that it would take each provider or supplier an average of 10 hours to obtain and furnish this information. With a 10-hour burden for 70,000 providers and suppliers, we estimate that the annual hourly burden for compliance with § 424.519 would be 700,000 hours.

Based on our experience, we believe that the reporting provider's or supplier's administrative staff (for example, officer managers and support staff) would be responsible for securing and listing affiliation data on the Form CMS-855. According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2014, the mean hourly wage for the general category of "Office and Administrative Support Occupations" is \$17.08 per hour (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000). With fringe benefits and overhead, the per hour rate is \$34.16. Using this per hour rate, we estimate the annual ICR cost burden for initially enrolling providers and suppliers to be \$23,912,000 (700,000 hours x \$34.16).

- **Revalidating Providers and Suppliers (§ 424.519(b))**

Medicare providers and suppliers---other than DMEPOS suppliers---are required to revalidate their Medicare enrollment every 5 years. (DMEPOS suppliers must revalidate every 3 years.) There are approximately 1.5 million providers and suppliers enrolled in Medicare; of this figure, roughly 87,000 are DMEPOS suppliers. For purposes of our ICR estimates only, we project that future revalidations will be performed in relative accordance with the aforementioned 5-year and 3-year periods.

**Table 1: Estimated Number of Non-DMEPOS
Supplier Revalidations: 2017-2021**

Calendar Year	Number of Revalidations
2017	300,000
2018	300,000
2019	300,000
2020	300,000
2021	300,000

Table 2: Estimated Number of DMEPOS Supplier Revalidations: 2017-2021

Calendar year	Number of Revalidations
2017	29,000
2018	29,000
2019	29,000
2020	29,000
2021	29,000

Table 3: Estimated Number of Revalidations: 2017-2021*

Calendar Year	Number of Revalidations
2017	329,000
2018	329,000
2019	329,000
2020	329,000
2021	329,000

* Table 3 combines the figures in Tables 1 and 2.

Using our estimate of 329,000 affected providers and suppliers each year, we project an annual ICR cost burden of \$112,386,400 (329,000 x 10 hours x \$34.16).

- New and Changed Affiliations (§ 424.519(h))

Generally speaking, the Form CMS-855 does not presently collect information regarding the provider's or supplier's (or the provider's or supplier's owning or managing individuals' and organizations') interests in other Medicare providers and suppliers. As such, we cannot reasonably estimate the number of providers and suppliers that would submit Form CMS-855 change of information applications reporting a new or changed affiliation. We have no historical data on which to base such a projection.

- Medicare --- Totals

We estimate a total annual ICR burden for Medicare providers and suppliers from § 424.519 of 3,990,000 hours (700,000 + 3,290,000) at a cost of \$136,298,400 (\$23,912,000 + \$112,386,400). We recognize that this figure would be higher if an estimate of the § 424.519(h) impact were possible.

ii. Medicaid and CHIP

- Initially Enrolling Providers (§ 455.107(b))

Based on existing data, we estimate that 56,250 providers in a given 12-month period seek to enroll in Medicaid or CHIP. The mechanism for collecting the data required under § 455.107 would lie within the state's discretion. Regardless of the specific collection vehicle, we estimate it would take each provider an average of 10 hours to obtain and furnish this information, similar to our estimate for Medicare providers and suppliers. This would result in an annual ICR hour burden of 562,500 hours. At a per hour rate of \$34.16, we estimate the annual cost burden to be \$19,215,000 (562,500 hours x \$34.16).

- Revalidating Providers (§ 455.107(b))

According to State Program Integrity Assessment data, there are approximately 1.9 million Medicaid-enrolled and CHIP-enrolled providers nationwide. These providers must revalidate their enrollments every 5 years pursuant to § 455.414. For purposes of our ICR estimates only, we project that an average of one-fifth or 380,000 (1.9 million x .20), of existing Medicaid and CHIP providers would be required to revalidate their enrollment each year and, consequently, furnish the information required under § 455.107(b). This would result in an annual ICR hour burden of 3,800,000 hours. Using an hourly rate of \$34.16, we estimate the annual ICR cost burden for revalidating Medicaid and CHIP providers to be \$129,808,000 (3,800,000 hours x \$34.16).

- New and Changed Affiliations (§ 455.107(h))

Some states do not collect information regarding the provider's (or the provider's owning or managing individuals' and organizations') interests in other Medicaid or CHIP providers or in Medicare providers or suppliers. Therefore, we cannot reasonably estimate the number of Medicare and CHIP providers that would report data regarding new or changed affiliations. We have no past data on which to base such a projection.

- Medicaid/CHIP ---- Totals

We estimate a total annual ICR burden for Medicaid and CHIP providers from § 455.107 of 4,362,500 hours at a cost of \$149,023,000 (\$19,215,000 + \$129,808,000).

iii. Total --- Disclosure of Affiliations

We estimate the total annual ICR hour burden on Medicare, Medicaid, and CHIP providers and suppliers from our proposal of 8,352,500 hours at a cost of \$285,321,400.

b. Part A/B Ordering/Certifying

Based on CMS statistics, we estimate that approximately 200,000 non-enrolled and non-opted out physicians and eligible professionals are ordering, certifying, referring or prescribing Part A or B services, items, or drugs. Per revised § 424.507, these individuals would be required to enroll in or opt-out of Medicare by January 1, 2018. __

We believe that these persons, assuming they do not opt-out, would complete the Form CMS-855O in lieu of the Form CMS-855I because the former application is shorter and the applicants are not seeking Medicare Part B billing privileges. As we are unable to precisely determine the percentage of the 200,000-individual universe that consists of physicians as opposed to non-physician practitioners, we will assume that 100,000 physicians and 100,000 non-physician practitioners would be affected, though we welcome comments on this estimate.

According to the most recent wage data provided by the Bureau of Labor Statistics (BLS) for May 2014 (see http://www.bls.gov/oes/current/oes_nat.htm#43-0000), the mean hourly wage for the general category of "Physicians and Surgeons" is \$93.74, and the mean hourly wage for the general BLS category of "Health Diagnosing and Treating Practitioners, All Other" is \$40.89. With fringe benefits and overhead, the respective per hour rates are \$187.48 and \$81.78.

On average, we project that it takes individuals approximately 0.5 hours to complete and submit the Form CMS-855O or an opt-out affidavit. This results in an ICR burden for physicians of \$9,374,000 (50,000 hours x \$187.48); the burden for non-physician practitioners would be \$4,089,000 (50,000 hours x \$81.78).

The total ICR burden would thus be 100,000 hours at a cost of \$13,463,000. We believe this burden would generally be incurred in 2017, prior to the January 1, 2018 effective date.

c. Proposed Regulatory Provisions for Which Estimates Could Not Be Made

i. ICRs Related to Denying/Revoking Provider/Supplier under Different Name, Numerical Identifier, or Business Identity (§§ 424.530(a)(12) and 424.535(a)(18))

We do not have historical data to predict the number of instances in which we would determine that a revoked provider or supplier is attempting to enroll in Medicare or is enrolled under a different name, numerical identifier or business identity. Since evidence of these activities are confined to the results of unique investigations, we believe the examples cited in the preamble

text cannot form the basis of a representative sample from which to inform projections. Consequently, we cannot estimate the ICR burden that may result from such denials and revocations, which would primarily involve the submission of Form CMS-855 applications following denials or following the expiration of reenrollment bars. To enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on-- (1) whether an annual figure of 8,000 potentially affected providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate because we do not have sufficient data to provide an estimate at this time.

ii. ICRs Related to Terminating Additional Provider/Supplier Locations if Provider/Supplier Bills for Non-Compliant Location (§ 424.535(a)(20))

We do not have sufficient historical data to form an estimate of the potential ICR burden of this proposal, which would primarily involve the submission of Form CMS-855 applications following the expiration of reenrollment bars. While there is data concerning the number of locations that are terminated from Medicare for non-compliance each year, we cannot predict the number of "additional" locations that would be terminated due to § 424.535(a)(20). In other words, if a provider or supplier has five locations and one is terminated for non-compliance, we have no way to predict whether any or all of the remaining four locations would be terminated. This is because each provider's and supplier's circumstances are different. Accordingly, we are unable to project the total number of terminated locations.

iii. ICRs Related to Revoking Provider/Supplier for Abusive Ordering, Certifying, Referring or Prescribing of Part A or B Services, Items, or Drugs (§ 424.535(a)(21))

As this is a new provision for which there is no historical data, we cannot project the number of instances in which we would revoke enrollment under § 424.535(a)(21). Therefore, we are unable to estimate the total potential ICR burden associated with this proposal, which would primarily involve the submission of Form CMS-855 applications following the expiration of reenrollment bars. To enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on--(1) whether an annual figure of 4,000 potentially affected physicians and eligible professionals could serve as a reasonable approximation; and (2) the potential cost burden to physicians and eligible professionals. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

iv. ICRs Related to Revoking Provider/Supplier for Referral of Debt to the United States Department of Treasury (§ 424.535(a)(17))

Each year on average, roughly 2,000 Medicare providers and suppliers have debts that are referred to the Department of Treasury. However, we are unable to predict the number of

revocations that would result from our proposal because the circumstances of each case would be different. We believe that any ICR burden associated with this proposal would principally involve the submission of Form CMS-855 applications following the expiration of reenrollment bars. We note that as with several of our other proposals, § 424.535(a)(17) is a new provision for which there is no historical data, and it cannot be assumed that all 2,000 providers and suppliers would have their Medicare enrollments revoked. Therefore, to enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on--(1) whether 2,000 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden on providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

v. ICRs Related to Revoking Provider/Supplier for Failure to Report New/Changed Enrollment Information (§ 424.535(a)(9))

We believe there would be an increase in the number of revoked providers and suppliers resulting from our expansion of § 424.535(a)(9). However, we cannot estimate this number, for the specific facts of each case would be different. As such, we cannot project the potential collection burden associated with this proposal, which would primarily involve the submission of Form CMS-855 applications following the expiration of reenrollment bars. To enhance our ability to formulate a projection of potential collection burden associated with this proposal, we are soliciting comment on-- (1) whether an annual figure of 10,000 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers.

vi. ICRs Related to Payment Suspensions (§ 424.530(a)(7) and § 405.371)

We are unable to estimate the total ICR burden of these provisions, for we cannot predict the number of instances in which we would deny enrollment under § 424.530(a)(7) or suspend payment under § 405.371. Nor do we have sufficient historical data on which we can estimate the burden of payment suspensions, which would consist mostly of potential lost payments the amount of which we are unable to quantify; the principal ICR burden associated with § 424.530(a)(7) would be the submission of Form CMS-855 applications following denials. To enhance our ability to formulate an estimate of the burden associated with this provision, we are soliciting comment on--(1) whether an annual figure of 1,000 potentially affected providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

vii. ICRs Related to Denial/Revocation of Provider/Supplier for Other Federal Program Termination or Suspension (§ 424.530(a)(14))

The principal ICR burden associated with this provision would involve the submission of Form CMS-855 applications following denials or following the expiration of reenrollment bars. However, we cannot project the total ICR burden associated with these new provisions because we cannot predict the number of instances in which we would deny or revoke enrollment. To enhance our ability to formulate projections of the ICR burden associated with this provision, we are soliciting comment on-- (1) whether an annual figure of 2,500 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

viii. ICRs Related to Extension of a Provider's/Supplier's Revocation to Other Enrollments (§ 424.535(i))

As this is a new provision and there is no historical data on which to make an estimate, we cannot predict the number of instances in which we would revoke enrollment for this reason or the number of locations or enrollments that would be involved; thus, we are unable to estimate the total potential collection burden, which would mostly involve the submission of Form CMS-855 applications following the expiration of reenrollment bars. To enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on--(1) whether annual figures of 5,000 potentially impacted providers and suppliers and 12,000 potentially revoked enrollments and terminated practice locations could serve as reasonable approximations; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

ix. Voluntary Termination Pending Revocation (§ 424.535(j))

As this is a new provision and there is no historical data on which to base a projection, we are unable to predict the number of instances in which we would revoke enrollment. Therefore, we cannot estimate the potential collection burden associated with § 424.535(j), which would principally involve the submission of Form CMS-855 applications following the expiration of reenrollment bars. Moreover, since evidence of these activities is confined to the results of unique investigations, we believe the examples cited in the preamble text cannot form the basis of a representative sample from which to inform projections. However, to enhance our ability to project of the ICR burden associated with this provision, we are soliciting comment on--(1) whether an annual figure of 2,000 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not a projection since we do not have sufficient data on which to make a projection at this time.

x. ICRs Related to Temporary Moratorium (§ 424.570)

We are unable to estimate the number of applications that would be approved or denied as a result of our changes to § 424.570, for we have insufficient data on which to base a precise projection. Consequently, we cannot estimate the ICR burden of these revisions; which would mostly involve the submission of Form CMS-855 applications by previously denied providers and suppliers following the lifting of a moratorium. To enhance our ability to formulate an estimate of the ICR burden associated with this provision, we are soliciting comment on-- (1) whether an annual figure of 2,000 potentially impacted providers and suppliers could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

xi. ICRs Related to Surety Bonds (§ 424.57(d))

We believe that CMS may reject some new and existing surety bonds based on surety non-payment, which would require the DMEPOS supplier to obtain a new surety bond in order to enroll in or maintain its enrollment in Medicare. This would require a supplier to do additional paperwork to obtain and submit a new surety bond and to report this information to Medicare via the Form CMS-855S. This burden is approved under OMB Control Number 0938-1065 and is estimated to take 3 hours to complete. However, we do not have adequate data to help us estimate the number of suppliers whose bonds would be rejected, or the number that would obtain new bonds, though we welcome public feedback regarding the possible burden.

xii. ICRs Related to Reactivations (§ 424.540(b))

We are unable to project the number of certifications that would be submitted versus the number of complete Form CMS-855 applications; therefore, we cannot predict the number of instances in which a Form CMS-855 would be requested. To enhance our ability to formulate a projection of the ICR burden associated with this provision, we are soliciting comment on-- (1) whether an annual figure of 10,000 instances in which a Form CMS-855 would be requested could serve as a reasonable approximation; and (2) the potential cost burden to providers and suppliers. However, we stress that this is not an estimate since we do not have sufficient data on which to make an estimate at this time.

d. Totals

Tables 4 and 5 outline the total cost burdens of our proposed provisions over the first three years of this rule.

Table 4: Estimated Annual Reporting/Recordkeeping Hour Burden

	Year 1	Year 2	Year 3
Affiliations	8,352,500	8,352,500	8,352,500
Part A/B Ordering	100,000	0	0
Total	8,452,500	8,352,500	8,352,500

Table 5: Estimated Annual Reporting/Recordkeeping Cost Burden

	Year 1	Year 2	Year 3
Affiliations	\$285,321,400	\$285,321,400	\$285,321,400
Part A/B Ordering	\$13,463,000	0	0
Total	\$298,784,400	\$285,321,400	\$285,321,400

Since 3 years is the maximum length of an OMB approval, we must average these totals over a 3-year period. This results in an annual burden of 8,385,833 hours at a cost of \$289,809,067.

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 table below identifies the annual costs to the Federal government – through CMS, its Medicare contractors, and/or its agents – over the first three years of the rule.

Provision	Documents to be Collected and Processed/Tasks to be Performed	Time Needed to Process Document/ Complete Task	Total Annual Processing/ Task Burden (hours)	Per Hour Cost of Processing/Task Burden (\$) *	Total Cost of Processing/
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		(hours)			Task Burden (\$)
424.519	399,000	2	798,000	41.26	32,925,480
455.107 **	436,250	2	872,500	41.26	35,999,350
424.507	66,667	3	200,000	41.26	8,252,000
424.530(a)(12) and 424.535(a)(18) ***	8,000	N/A	N/A	N/A	N/A
424.535(a)(21) ***	4,000	N/A	N/A	N/A	N/A
424.535(a)(17) ***	2,000	N/A	N/A	N/A	N/A
424.535(a)(9) ***	10,000	N/A	N/A	N/A	N/A
424.530(a)(7) and 405.371 ***	1,000	N/A	N/A	N/A	N/A
424.530(a)(14) ***	2,500	N/A	N/A	N/A	N/A
424.535(i) ***	5,000	N/A	N/A	N/A	N/A
424.535(j) ***	2,000	N/A	N/A	N/A	N/A
424.570 ***	2,000	N/A	N/A	N/A	N/A
424.540(b) ***	10,000	N/A	N/A	N/A	N/A
Total	901,917	N/A	1,870,500	N/A	77,176,830

* Per hour cost based on Grade 7/Step 1 salary in Washington, DC area for Calendar Year 2015 (\$20.63) with 100 percent overhead.

** Per year average over first three years of rule.

*** Figures included solely for purposes of comment solicitation and do not represent estimates.

15. Changes to Burden

This is a new information collection request.

16. Publication/Tabulation Dates

N/A

17. Expiration Date

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