SWORN SMALL BUSINESS IMPACT STATEMENT

(Regulatory Flexibility Act + SBA Coordination + Competitive Distortion)

Docket: CMS-2025-1891
Agency: Centers for Medicare & Medicaid Services

Submitted by:
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CAGE Code: 9S0L8

SECTION 1 – DECLARATION UNDER PENALTY OF PERJURY

I, James H. Poole, declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the statements contained herein are true and correct to the best of my knowledge and professional experience.

This sworn submission is entered into the administrative record pursuant to:

- 5 U.S.C. §§601–612 (Regulatory Flexibility Act)
- 15 U.S.C. §637 (Small Business Act)
- Executive Order 12866
- 5 U.S.C. §706 (APA)

SECTION 2 – RFA SIGNIFICANT ECONOMIC IMPACT TEST (§603)

Under 5 U.S.C. §603(a), CMS must prepare an Initial Regulatory Flexibility Analysis (IRFA) if a rule will have a significant economic impact on a substantial number of small entities.

If compliance burden is underestimated by 300–400% (as documented in the accompanying PRA/Economic Statement), then CMS' small entity impact modeling is materially flawed.

Affected small entities include:

• Small health technology firms
• Compliance automation startups
• Independent physician practices
• Rural providers
• Regional healthcare operators
• Health IT service providers

Where per-entity compliance burden increases beyond projected levels, the RFA threshold of "significant economic impact" is met.

If CMS relied on underestimated burden modeling, then the RFA determination itself is defective.

SECTION 3 – COMPETITIVE DISTORTION & MARKET SUPPRESSION

Elevated compliance cost disproportionately benefits:

• Large incumbents with in-house regulatory teams
• Organizations with scale-based cost absorption
• Firms with legacy CMS contracting infrastructure
• Large compliance service conglomerates

Smaller firms face:

• Capital diversion from R&D to compliance
• Hiring suppression
• Delayed market entry
• Reduced ability to compete for CMS-related innovation
• Increased dependency on large prime contractors

This creates structural competitive distortion in violation of the Small Business Act's mandate to preserve and promote competition (15 U.S.C. §637(a)).

Regulatory frameworks that impose fixed compliance cost floors suppress market entrants and discourage modernization innovators.

SECTION 4 – SBA OFFICE OF ADVOCACY COORDINATION (§609)

Under 5 U.S.C. §609, SBA's Office of Advocacy monitors RFA compliance and may participate in federal rule review.

REQUEST:

CMS shall confirm in writing:

1. Whether SBA Chief Counsel for Advocacy was consulted
2. Whether small entity impact was independently reviewed
3. Whether alternatives reducing small entity burden were modeled
4. Whether tiered compliance options were evaluated
5. Whether phase-in schedules were considered

Failure to coordinate with SBA Advocacy may constitute procedural deficiency under the RFA.

SECTION 5 – MODERNIZATION ALTERNATIVES & TITLE 41 PRINCIPLES

Under federal procurement modernization principles and Title 41, agencies are encouraged to consider commercially available compliance automation.

CMS should evaluate:

- COTS compliance automation tools
- Small business modernization vendors
- Compliance-by-design architectures
- Automation-driven reporting frameworks

Modernization can:

- Reduce burden hours
- Improve audit traceability
- Increase data integrity
- Reduce long-term compliance cost

Failure to evaluate modernization alternatives before imposing burden may constitute failure to consider relevant factors under APA §706(2)(A).

SECTION 6 – EXECUTIVE ORDER 12866 SMALL ENTITY CONSIDERATION

EO 12866 §1(b)(6) requires selection of least costly, most cost-effective regulatory alternative.

If CMS did not model automation-based burden reduction scenarios, then:

- Net benefit analysis is incomplete
- Distributional impact analysis is deficient
- Small entity impact evaluation is unreliable

SECTION 7 – REQUESTED DETERMINATIONS

CMS shall provide written determinations pursuant to 5 U.S.C. §555(e) on:

1. Does this rule require IRFA or FRFA?
2. Was SBA Office of Advocacy formally consulted?
3. Were small entity alternatives modeled?
4. Were automation-based burden reductions evaluated?
5. Does CMS maintain written analysis of competitive distortion?

Each response requires reasoned explanation.

SECTION 8 – SIGNATURE AND OATH

I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct to the best of my knowledge and professional experience.

Executed on: 02/20/2026, 2026

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