

PUBLIC SUBMISSION

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Docket: CMS-2025-1891
CMS-367a-e (Medicaid Drug Rebate Program Labeler Reporting Format)

Comment On: CMS-2025-1891-0001
CMS-367a-e (Medicaid Drug Rebate Program Labeler Reporting Format)

Document: CMS-2025-1891-DRAFT-0007
Comment on CMS-2025-1891-0001

Submitter Information

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General Comment

This submission incorporates by reference the attached sworn “Petition for Oversight Review and Institutional Risk Disclosure” and related sworn filings entered into the administrative record.

The issues raised in the attachment concern material procedural and analytical deficiencies relating to:

- Paperwork Reduction Act burden estimation
- OMB Circular A-4 cost modeling requirements
- Executive Order 12866 alternatives analysis
- Regulatory Flexibility Act small entity impact review
- Title 41 modernization and COTS evaluation obligations

Preliminary operational modeling indicates that actual reporting burden associated with CMS-367a-e may materially exceed published estimates. If burden inflation approaches or exceeds 300–400% beyond projected levels, then:

- PRA clearance may require re-evaluation under 44 U.S.C. §3507
- OMB OIRA review may require supplemental analysis
- RFA determinations regarding small entities may be defective
- Net benefit analysis under EO 12866 may be incomplete

The administrative record does not clearly demonstrate documented evaluation of:

- Commercially available compliance automation platforms
- COTS reporting architectures capable of burden reduction
- Sensitivity analysis of burden escalation
- Distributional impacts on small labelers and technology providers

- Comparative modernization cost modeling

If commercially available automation exists that reduces reporting friction while increasing audit integrity, CMS must evaluate such alternatives before expanding or maintaining higher-burden structures.

Pursuant to 5 U.S.C. §555(e), CMS is requested to provide written determinations addressing:

Whether OMB OIRA reviewed updated burden modeling

Whether automation-based alternatives were evaluated

Whether SBA Office of Advocacy was consulted

Whether sensitivity analysis of burden escalation was performed

Whether modernization pathways were considered

This comment preserves all rights under 5 U.S.C. §§704 and 706.

The attached sworn petition is submitted for permanent inclusion in the administrative record and should be circulated to:

- OMB Office of Information and Regulatory Affairs
- SBA Office of Advocacy
- CMS Chief Financial Officer
- CMS Chief Information Officer

Respectfully submitted,
James H. Poole
CEO, Founder & Executive Chairman
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PRA COMMENT

Attachments

PAPERWORK_REDUCTION_ACT