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Comments on the Drug Price Negotiation Revised Information Collection Request (CMS-10849)

OMB Control Number: 0938-1452
Information Collection: Drug Price Negotiation for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act
Initial Price Applicability Year: 2029

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I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' revised information collection request for the Medicare Drug Price Negotiation Program. I am a health economist and applied econometrician whose work has examined prescription drug utilization, adherence, healthcare utilization and expenditures, benefit design, and related methodological questions in Medicare and other insured populations.

I support the collection and recommend targeted revisions to the research-evidence pathways. My companion comment on CMS-4215-P addresses how CMS should evaluate downstream healthcare resource-utilization and expenditure evidence. This comment addresses the narrower information-collection question: how the manufacturer and public forms can obtain a consistent minimum description of quantitative evidence while preserving accessible narrative submissions and pathways for submitting evidence by citation.

Necessity and practical utility

The collection is necessary for CMS to obtain evidence relevant to the section 1194(e)(2) factors, and the revised instrument has practical utility. That utility would improve if CMS applied a common evidence classification and a triggered methodological supplement to the corresponding quantitative-evidence pathways for manufacturers and for health-research and public respondents. Similar quantitative claims should arrive with similar minimum documentation regardless of the respondent's identity.

The trigger should be objective. The supplement should be required when a response presents or relies on a respondent-generated, sponsor-controlled, unpublished, or model-derived quantitative result

whose minimum methodological information is not available in a cited public source. “Minimum methodological information” should mean the applicable core fields needed to understand study design and identification, population, comparator or treatment contrast, outcomes and measurement, time horizon, economic perspective and cost construction, and estimates and uncertainty. Missing ancillary CMS-specific or provenance and attachment fields, such as relationship to a CMS therapeutic alternative, Medicare transportability, data custody, submission control, or technical appendix status, should not by themselves trigger supplementation. Those fields should be completed after the core trigger is met, with **unknown** and **not applicable** allowed. “Respondent-generated” should include analyses prepared by contractors and affiliates. CMS should also reserve the ability to request supplementation when a cited publication does not disclose enough core methods to evaluate the result.

Ordinary narrative submissions and submissions that provide evidence by citation alone should be exempt. An adequately documented peer-reviewed study ordinarily would not trigger the supplement, although peer review is relevant rather than conclusive. This rule targets an information gap, not a category of speaker or a favored study design. Respondents would provide study-level or Stage 1 information; CMS would remain responsible for evidence direction, certainty, economic materiality, Medicare applicability, and the Stage 2 synthesis of the body of evidence.

The two form pathways should also offer equivalent ways to provide technical support. Question 43 permits manufacturers to submit a dossier supplementing Questions 38–42 and already contemplates an outline identifying where information responsive to those questions appears in the dossier. CMS should strengthen this mechanism by providing a structured crosswalk through which a manufacturer can identify the dossier pages or sections satisfying each triggered field, without duplicative web-form entry. For nonmanufacturer respondents, CMS should add an equivalent technical appendix or methods report upload associated with Question 54(c) and coordinate its instructions with Questions 60 and 61. Question 60’s visual-material pathway and Question 61’s citation process remain useful, but neither alone is a substitute for a methods attachment.

Both pathways should accept methods descriptions, model documentation, data-provenance and validation materials, and code documentation where legally and practically available. CMS should not require public disclosure of proprietary data, executable code, or confidential materials. Availability to CMS, availability to the public, and unavailability should be distinct response options.

Accuracy of the burden estimate

For drugs newly selected for negotiation, CMS estimates 20 Primary Manufacturer submissions at 1,000 hours each, including 600 economist hours per submission. It separately estimates 150 individual public responses at 3 hours each and 175 organizational public responses at 30 hours each. The public-response estimate is therefore 5,700 hours and $279,414 at $49.02 per hour.

The proposed supplement would create an incremental burden for the subset of respondents that triggers it. I do not characterize that burden as zero or negligible. CMS should estimate the number and share of manufacturer and public submissions expected to trigger the supplement, the incremental hours by respondent type, and the relevant occupational mix for organizations submitting technical analyses. A single general labor rate may not represent work divided among economists, statisticians, clinicians, attorneys, and administrative staff.

The three-hour individual pathway can be preserved because ordinary narratives and submissions providing evidence by citation alone would remain outside the trigger. A patient or caregiver describing experience would not be required to complete a technical schedule. An individual submitting an unpublished quantitative analysis could complete the applicable fields, with unknown and not-applicable responses where appropriate.

Quality, utility, and clarity of the information collected

The supplement should begin with an evidence-type field allowing multiple selections. Categories should include descriptive utilization, cost-of-illness or disease burden, randomized or pragmatic comparative analysis, comparative observational analysis, budget impact, cost-effectiveness or cost-utility, other economic or disease model, and other quantitative analysis. Classification would identify what inference the result can support; it would not determine the weight CMS assigns.

The remaining fields should be concise and operational. A single schedule can collect the minimum information CMS needs without reproducing a methods tutorial in the form.

Domain	Concise fields	Response format and missing-information handling
Study design and causal identification	Evidence type (multiple selections); research question; data source; study design; index date; follow-up; identification method; principal applicable bias controls	Checkboxes plus short text; **unknown/not applicable** for third-party information
Population and Medicare applicability	Study population; inclusion/exclusion features material to interpretation; Medicare transportability; Medicare benefit and care setting	Categories plus short explanation; **unknown/not applicable** allowed
Comparator and treatment contrast	Selected treatment; comparator; relationship to a CMS therapeutic alternative; initiation, adherence, persistence, discontinuation, switching, or other modeled treatment margin	Multiple selection plus short text; **unknown** for unavailable third-party information and **not applicable** for noncomparative analyses
Outcome definition and measurement	Utilization outcomes and expenditure outcomes reported separately; outcome definition; measurement source; result fields reported under statistical uncertainty and economic materiality	Repeatable structured fields; **unknown** for unavailable third-party information and **not applicable** when an outcome category or source does not apply
Time horizon and timing	Study period; follow-up or model horizon; result identified as observed, extrapolated, or modeled; key timing assumptions	Categories plus dates or duration and short text; **unknown/not applicable** allowed
Economic perspective	Perspective; cost year; inflation method;	Categories plus short text;

Domain	Concise fields	Response format and missing-information handling
and cost measurement	observed payment versus standardized unit-cost construction; unit-cost source; drug-price basis: list, net, historical, assumed MFP, or another constructed price	**unknown/not applicable** allowed
Statistical uncertainty and economic materiality	Point estimate and absolute effect where applicable; unit; uncertainty interval; principal sensitivity or specification analyses	Numeric/unit fields plus short text; **unknown** for unavailable third-party information and **not applicable** where an estimate, interval, or sensitivity analysis is not produced or does not apply; respondent does **not** self-rate certainty or materiality
Transparency, sponsorship, and reproducibility	Technical appendix availability; funder/sponsor; design and specification control; data custody/access; publication/submission control; independent validation; methods, model, provenance, validation, and code-documentation availability; proprietary/public status	Categories plus short text; separate **public, CMS-only where lawful, unavailable, unknown,** and **not applicable** options

The economic-perspective field requires a defined taxonomy. **Medicare program expenditures or federal Medicare liability** should mean payments ultimately borne by Medicare trust funds or federal general revenues, including applicable federal subsidies or reinsurance. **Plan liability** should be identified separately where relevant and should not be equated automatically with federal spending. **Beneficiary financial effects** should include cost sharing and premiums reported separately. The form should caution against counting both as independent effects without explaining incidence and avoiding double counting. **Total Medicare-covered spending** should mean allowed spending for Medicare-covered services across Medicare, plan, beneficiary, and other applicable payment shares. **Other-payer or societal outcomes** should be reported separately.

Medicaid or other federal health-program spillovers may be supplementary fields, but they should not be core Medicare outcomes. SNAP and unemployment effects should be excluded from the recommended core fields. These distinctions would keep a change in utilization separate from the payment perspective and accounting assumptions used to value it.

CMS should use categorical fields for comparable facts and short narrative explanations for identification, transportability, modeling assumptions, validation, and limitations. The form should not ask respondents to assign an overall certainty grade or decide whether their own estimate is economically material. Those are agency judgments after review of the full record.

Burden minimization through automated techniques

The supplement can minimize burden if its implementation permits reuse. In renegotiation, CMS should prepopulate prior entries and ask respondents to report only changed data, assumptions, methods, or results. A respondent should be able to confirm unchanged information rather than reenter it.

CMS should also provide a standardized multi-analysis upload using the same field names as the online schedule. That option would be more efficient for a dossier or technical appendix containing several analyses and would provide CMS with structured, readily sortable fields. Categorical fields should be paired with short narrative boxes rather than long duplicative essays. The Question 43 dossier crosswalk and the equivalent nonmanufacturer technical appendix pathway should permit reuse of existing documentation while showing where each required item appears.

These features would not eliminate respondent burden, but they would direct effort toward information CMS needs and reduce repetitive entry. They should also lower agency extraction burden by making design, population, comparator, outcome, horizon, perspective, uncertainty, and provenance information comparable across submissions.

Recommendations

I recommend that CMS apply a common evidence classification and objective trigger to the quantitative-evidence pathways for manufacturers and for health-research and public respondents. Ordinary narratives, submissions providing evidence by citation alone, and peer-reviewed studies that already provide adequate methodological documentation should remain exempt. CMS should add a structured crosswalk to the Question 43 dossier pathway and an equivalent nonmanufacturer technical appendix or methods report upload coordinated with Questions 60 and 61. It should adopt the compact schedule above, estimate incremental burden for the expected triggered subset, and use prepopulation, changed-information reporting, multi-analysis uploads, and document reuse to minimize burden.

Conclusion

A narrow triggered supplement would improve the practical utility and clarity of the revised ICR while preserving access for individual and narrative respondents and those submitting evidence by citation alone. The appropriate division of labor is straightforward: respondents describe the evidence they ask CMS to consider, and CMS evaluates and synthesizes it.

References

1. Centers for Medicare & Medicaid Services. *Drug Price Negotiation for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act. Information Collection Request Forms, CMS-10849, OMB Control No. 0938-1452. Revised information collection request, June 12, 2026 (base year IPAY 2029)*. Official CMS-10849 listing and package.
2. Centers for Medicare & Medicaid Services. *Supporting Statement—Part A: Drug Price Negotiation for Initial Price Applicability Year 20XX under Sections 11001 and 11002 of the Inflation Reduction Act. CMS-10849, OMB Control No. 0938-1452. June 2026. Supporting material accompanying the revised information collection request*.

3. Centers for Medicare & Medicaid Services. *Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program; Proposed Rule.* CMS-4215-P. 91 Fed. Reg. 36236–36368 (June 16, 2026). Official Federal Register text.
4. Paperwork Reduction Act of 1995, 44 U.S.C. § 3506(c)(2)(A). Official U.S. Code text.

Paperwork Reduction Act of 1995, 44 U.S.C. § 3506(c)(3), particularly § 3506(c)(3)(B)–(E), (J).

RxEconomics advises pharmaceutical and life-sciences clients. This comment was prepared independently; no client funded, requested, commissioned, or reviewed it.

Respectfully submitted,

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