August 17, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program; CMS-4215-P; Docket CMS-2026-2080

Dear Administrator Oz:

I. Introduction and Principal Recommendations

I appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' proposed rule governing the Medicare Drug Price Negotiation Program for initial price applicability year 2029 and subsequent years. My comment addresses a discrete part of that rule: how CMS should evaluate downstream healthcare resource utilization and expenditures when comparing a selected drug with its therapeutic alternatives under proposed 42 C.F.R. § 429.510(e)(1)(iii) and the factors specified in section 1194(e)(2) of the Social Security Act. The proposed rule supplies an appropriate point of entry by expressly allowing CMS to consider Medicare claims and other datasets, potentially including evidence about resource utilization and usage patterns. It does not yet explain how that evidence will be assessed across studies or integrated into the overall negotiation judgment.

Drug spending alone does not capture the full effect of treatment on Medicare-covered care. Relative to a therapeutic alternative, a selected drug may change hospitalizations, emergency department visits, physician services, monitoring, complications, or survival, with corresponding effects on total covered spending and on the shares borne by Medicare, plans, and beneficiaries. The relevant question is not whether prescription drugs generally produce “cost offsets,” but whether credible evidence identifies a material downstream effect for the selected drug, comparator, Medicare population, and time horizon at issue.

I am a health economist and applied econometrician and the founder and President of RxEconomics LLC. Before founding the firm in 2011, I spent approximately nine years at CVS Caremark, ultimately serving as Director of Strategic Research and Health Economist. My directly relevant research includes a 2011 *Health Affairs* study of medication adherence and medical spending, a 2015 *Health Affairs* analysis of medical cost offsets from prescription drug use in Medicaid, and a 2018 *Medical Care* analysis of adherence and healthcare utilization in Medicaid.

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

I offer three principal recommendations:

1. Finalize proposed § 429.510(e)(1)(iii), including its express recognition that Medicare claims and other datasets may contain relevant evidence concerning healthcare resource utilization and usage patterns of the selected drug and its therapeutic alternatives.
2. Use a transparent two-stage qualitative framework that first assesses the credibility and relevance of each study or analysis and then synthesizes the body of evidence across comparative direction, economic materiality, certainty, and Medicare applicability.
3. Disclose, in the concise justification under proposed § 429.520(b)(1)–(2) and, subject to the confidentiality requirements of proposed § 429.300, in the MFP explanation published under proposed § 429.705(b), how downstream evidence materially informed the overall section 1194(e)(2) assessment under proposed § 429.510(e).

These recommendations preserve the qualitative discretion CMS has proposed. They do not create a formula, a separate statutory factor, a presumption that drug treatment produces savings, or a request to translate an expenditure estimate into a particular price change. A companion comment on the revised Drug Price Negotiation information collection request addresses the limited structured information that would make this approach administrable without turning every citation submission into a dossier.

II. Why Clarification Is Needed: Statutory Relevance and the Administrative Record

The proposed methodology moves through a sequence. CMS identifies therapeutic alternatives, establishes a starting point from their prices under § 429.510(d), evaluates the section 1194(e)(2) evidence under § 429.510(e), and then considers the manufacturer-specific factors in section 1194(e)(1) under § 429.510(f). Proposed § 429.510(e)(1)(iii) places resource-utilization evidence within the body of material available for the section 1194(e)(2) evaluation. The preamble also identifies sensible review attributes, including methodological rigor, limitations, risk of bias, uncertainty, time horizon, generalizability, and relevance to Medicare populations. The remaining gap concerns relevance and integration: which expenditure consequences bear on the listed factors, how limits are applied, and how multiple forms of evidence become a reasoned overall assessment.

Downstream expenditures are not a freestanding fifth factor under section 1194(e)(2). Depending on the evidence and the clinical pathway, they may inform factors CMS is already required to evaluate. Under section 1194(e)(2)(A), and as reflected in proposed §§ 429.510(e)(1)(iii) and 429.510(e)(4)(i), evidence concerning utilization and expenditure consequences may be relevant to assessing therapeutic advance and the costs associated with the selected drug and its therapeutic alternatives. Under section 1194(e)(2)(C) and proposed § 429.510(e)(3), utilization outcomes may also inform comparative effectiveness, including effects on specified populations such as older beneficiaries, people with disabilities, and people who are terminally ill. The connection must be shown; it should not be inferred merely because a dollar amount appears in a study.

Nor is every downstream dollar necessarily relevant to the statutory evaluation. An expenditure consequence should have a reasoned relationship to the selected drug–alternative comparison and to a listed statutory factor. Directly experienced outcomes such as an avoided hospitalization, an additional emergency department visit, or a monitoring requirement have a different relationship to the evaluation than remote fiscal effects with no demonstrated treatment pathway. Evidence about other

programs, households, or employers may be informative in a separate sensitivity analysis, but it does not become part of the core Medicare analysis by label alone. This bounded treatment respects the statutory structure while allowing CMS to evaluate the economic consequences of clinical outcomes it already considers.

In the final rule or accompanying guidance, CMS should explain whether and how the expenditure consequences of an avoided hospitalization or another outcome directly experienced by the beneficiary enter the assessment, how the agency limits the causal and fiscal chain, and how it documents that reasoning. A short explanation would give submitters a common target, help reviewers distinguish relevant evidence from overextended claims, and create a stable administrative record of the agency's method. It would also allow CMS to preserve case-specific judgment while showing that similar evidence receives similar treatment across drugs and negotiation cycles.

Section 1198 and proposed § 429.30(a)(3) preclude administrative and judicial review of determinations of the MFP under section 1194(b) or (f). That limitation heightens the value of ex ante methodological commitments as an internal consistency safeguard; it does not require rigid weights or thresholds. Published principles can discipline both CMS and submitters by making clear which questions an analysis must answer and why a limitation changes the weight assigned to a finding. They can also reduce disputes about whether an analysis was ignored when the actual issue is that it did not identify the relevant comparator, payer perspective, or period.

CBO's aggregate budget-estimating relationship illustrates why CMS should ask the question without assuming the answer. In 2012, the Congressional Budget Office estimated that, for policies that directly affect the number of prescriptions filled, a 1 percent increase in prescriptions filled would reduce Medicare program expenditures for medical services by roughly 0.2 percent. This was CBO's judgment for its budget estimates of such policies, not a drug-level result, and it should not be applied to an individual drug, class, or negotiation. Drug-specific assessment requires evidence that is comparative, population-specific, and appropriately timed.

My coauthors and I have reported associations between greater medication use or adherence and lower nondrug spending in several chronic conditions and populations, while recognizing confounding, transportability, and design limitations. In my view, the relevant lesson from this literature is heterogeneity rather than a universal offset. Real-world adherence and persistence differences may be related to comparative effectiveness and downstream utilization, but adherence may also be related to disease severity, treatment selection, benefit design, tolerability, and patient behavior. I would not treat adherence as a self-validating explanation for a favorable outcome; adherence evidence should be evaluated under the same causal standards as other observational evidence.

III. Stage 1: Study-Level Assessment

Stage 1 should ask whether an individual study or analysis credibly addresses the negotiation question. Respondents should provide the available study-level information; CMS should evaluate evidence direction, certainty, economic materiality, Medicare applicability, and the body of evidence through Stage 2 synthesis. The framework below retains eight common domains. They are review principles, not pass-fail thresholds, and no single design label determines the result. CMS should use the domains to understand the comparative direction and magnitude supported by a study, the limits on that

interpretation, and its relevance to Medicare. It should not use them to mechanically convert utilization into a price adjustment.

Stage 1 domain	Core inquiry and review considerations
Study design and causal identification	Does the design support the claimed treatment effect? Identify the estimand and principal threats such as confounding by indication, treatment selection, healthy-adherer effects, reverse causation, immortal-time bias, time-varying confounding, informative censoring, treatment switching, measurement error, and competing mortality; explain design and sensitivity responses.
Population and Medicare applicability	How directly does the population represent affected Medicare beneficiaries? Describe age, disability, comorbidity, disease severity, dual eligibility, baseline utilization, persistence, care setting, and other plausible effect modifiers; justify transport from younger or differently insured groups.
Comparator and treatment contrast	Does the analysis compare the selected drug with a relevant CMS-identified therapeutic alternative and estimate the margin at issue? Distinguish initiation, adherence, persistence, switching, and drug-versus-nonuse questions; justify any alternative contrast.
Outcome definition and measurement	Are utilization and expenditure endpoints clinically coherent, reliably measured, and separately interpretable? Define inpatient, emergency, outpatient, physician, procedure, post-acute, and other material categories; distinguish disease-specific from all-cause outcomes and utilization from prices.
Time horizon and timing	Does follow-up fit the clinical and economic pathway? Separate observed, extrapolated, and modeled effects; describe treatment exposure, latency, censoring, discounting where relevant, validation, and the timing of expenditure consequences.
Economic perspective and cost measurement	Whose spending is measured, and how? Identify Medicare program expenditures, plan liability, beneficiary financial effects, total Medicare-covered spending, or another perspective; state price year, payment source, costing assumptions, rebates or subsidies where applicable, and double-counting protections.
Statistical uncertainty and economic materiality	How stable and consequential are the results? Report intervals, specification and sensitivity analyses, alternative costing assumptions, heterogeneity, and the assumptions that would change the conclusion; assess materiality separately from statistical significance.
Transparency, sponsorship, and reproducibility	Can CMS reconstruct the result and evaluate potential reporting bias? Disclose data provenance, protocol and prespecification, post hoc analyses, code or model availability, parameter sources, funder or sponsor, design and specification control, data custody or access, publication or submission control, peer-review status, and independent validation where available.

The domains should be applied proportionately to the claim. A published comparative study reporting observed inpatient use ordinarily needs enough information for CMS to evaluate cohort construction, exposure, endpoint definition, identification, censoring, and transportability. A model that converts an event effect into longer-term expenditures additionally needs a transparent structure, empirical parameter sources, validation, and sensitivity analysis. A citation-only submission may rely on information in the public article and supplement, while an original or unpublished analysis should supply the additional methods needed for critical review. The purpose is comparable visibility into the basis of a claim, not identical paperwork for unlike evidence.

The treatment contrast is the organizing element. A study comparing adherent and nonadherent users of one drug may illuminate a pathway without estimating the incremental effect of that drug against the therapeutic alternative. Similarly, a randomized trial may identify a hospitalization effect while providing limited information on routine Medicare payments, whereas a claims analysis may measure those payments directly but require stronger control of selection and censoring. CMS should identify the inferential distance between the reported estimate and the question the negotiation poses rather than treating either design as categorically superior.

Outcome measurement should keep utilization and expenditures decomposable. A change in allowed spending may reflect fewer admissions, a change in unit payments, site-of-care differences, coding, or a modeled assumption. Reporting the underlying service categories helps CMS determine whether the economic estimate is consistent with the observed clinical pathway. It also prevents a large aggregate dollar estimate from receiving weight merely because its construction is difficult to inspect.

Time horizon requires the same discipline. Some utilization changes appear within months; others follow from complications that develop over years. Longer-term evidence should not automatically receive less weight, but increasing extrapolation should bring increasingly explicit justification, empirical support, validation, and uncertainty analysis. CMS should also distinguish disease-specific savings from additional spending associated with longer survival. Those effects can occur together, and neither should be hidden by a net total that obscures timing and mechanism.

IV. Stage 2: Body-of-Evidence Synthesis

Stage 2 should synthesize the credible evidence rather than count studies or average estimates that answer different questions. CMS should examine whether findings are directionally consistent, whether stronger identification strategies support the same interpretation, whether Medicare-specific results agree with transported evidence, whether expenditure findings correspond to observable utilization, and whether observed, extrapolated, and modeled components point in the same direction. A qualitative synthesis can preserve disagreement rather than force a pooled estimate that conceals it.

Apparent replication requires particular scrutiny. CMS should determine whether papers share or overlap in samples, datasets, follow-up periods, authors, sponsors, model structures, or parameter sources. It should also consider publication bias, selective outcome reporting, and selective presentation of sensitivity analyses. Several papers generated from the same claims cohort or economic model do not automatically constitute independent corroboration. Conversely, related analyses can still be informative when their dependence is disclosed and the distinct contribution of each is clear.

Prespecification and negative evidence help CMS interpret that record. A prospective protocol can show whether treatment contrasts, endpoints, subgroups, and model assumptions were selected before results were known; a post hoc analysis can still contribute when its status and rationale are explicit. CMS should also look for registered but unpublished studies, null endpoints omitted from otherwise favorable reports, and sensitivity analyses reported only when they strengthen the preferred conclusion. These checks do not require CMS to infer misconduct. They identify ordinary mechanisms through which an available literature can overstate certainty or independence.

When a selected drug has multiple conditions or indications, CMS should first report the comparative findings separately by condition. A single drug-wide conclusion should then disclose either transparent weighting based on relevant prevalence and utilization or a reasoned qualitative synthesis explaining why weighting is not appropriate. This is a reasonable implementation implication of applying one negotiation outcome to a drug used across conditions; it is not an express statutory command. The method should be stable enough to prevent a small, unusually favorable subgroup from dominating a conclusion without explanation.

The synthesis should distinguish comparative direction, economic materiality, certainty, and Medicare applicability. Direction asks whether the evidence favors the selected drug, favors the alternative, or remains null or indeterminate on the utilization or expenditure outcome. Economic materiality asks whether the magnitude is consequential, not merely statistically detectable. Certainty reflects identification, consistency, robustness, and dependence on extrapolation. Medicare applicability reflects both population transport and the relevance of the measured services and payment perspective. These dimensions are descriptive rather than a scoring rubric.

Heterogeneity should be explained where possible and retained where it cannot be resolved. Differences in population, disease severity, comparator, adherence, follow-up, outcome definition, site of care, or costing method may legitimately produce different results. CMS should identify the assumptions or new evidence most likely to change its interpretation. This approach permits a conclusion such as: hospitalization evidence is directionally favorable and economically material for Medicare beneficiaries, but the precise expenditure magnitude remains uncertain. It does not require a single dollar estimate or a factor-specific weight.

V. Economic Perspective, Materiality, and Integration Into the Overall Assessment

Perspective should be stated with enough precision that quantities are not combined merely because all are denominated in dollars. For this framework, Medicare program expenditures or federal Medicare liability means 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 rather than assumed to be identical to federal spending. A study using plan-paid claims may be informative, but CMS should know which portion represents a plan obligation, a federal subsidy, or another payment source.

Beneficiary financial effects include cost sharing and premiums. They should be reported separately from Medicare program expenditures and from one another. An estimated reduction in cost sharing and an estimated premium effect should not be added as independent savings without explaining incidence and preventing double counting. The same dollar may otherwise appear once when a claim is paid and again when that payment is reflected in a premium or subsidy estimate.

Total Medicare-covered spending is the allowed spending for Medicare-covered services across Medicare, plan, beneficiary, and other applicable payment shares. It is a useful broad measure of covered-service use, but it is not a measure of Medicare program expenditures or federal Medicare liability. A total-allowed-amount analysis should therefore be labeled as such, with the shares reported or estimated where they matter to interpretation. Disease-specific and all-cause versions may both be useful; the former can be closer to the mechanism, while the latter can better capture net consequences within Medicare-covered care.

Other-payer and societal outcomes should remain separate from the core Medicare analysis. Material spillovers to Medicaid or another federal health program may be presented as supplementary sensitivity information. SNAP, unemployment benefits, productivity, caregiver time, and a general taxpayer or societal perspective do not belong in the core framework proposed here. Their exclusion from the core calculation does not deny their possible policy relevance; it prevents a Medicare negotiation judgment from becoming an unbounded aggregation of consequences borne by different parties under different authorities.

Economic materiality is distinct from statistical significance. Large administrative datasets can precisely estimate differences that are immaterial to the treatment comparison or the affected Medicare population. Conversely, clinically coherent evidence may indicate a potentially consequential direction while leaving the exact magnitude uncertain. CMS need not adopt a universal numerical threshold. It should explain whether the observed or projected effect is large enough, relative to the relevant population and covered services, to warrant consideration and why uncertainty does or does not alter that judgment.

Integration should remain qualitative and bounded. CMS should not deduct projected savings dollar for dollar, add projected costs mechanically, assign a separate factor weight, or identify a discrete dollar contribution to the MFP. Instead, it should record the comparative direction, economic materiality, certainty, and Medicare applicability of the evidence and state whether that evidence materially informed the overall section 1194(e)(2) assessment under proposed § 429.510(e). This formulation respects the agency's proposed qualitative approach to considering the section 1194(e)(2) factors and avoids assigning unsupported precision to estimates that depend on population, horizon, prices, and modeling assumptions.

VI. Comparator Identification, Transparency, and Renegotiation

Comparator selection affects both the starting point and the subsequent interpretation of evidence. CMS should describe how FDA labeling defines the indicated populations and treatment settings; how clinical guidelines and recognized compendia identify recommended or accepted alternatives; how clinician input addresses actual sequencing, contraindications, and practice patterns; and how observed Medicare utilization shows which alternatives beneficiaries receive in routine care. No single source answers the entire question. Labeling may be precise but narrow, guidelines may lag emerging practice, and claims reveal use without necessarily identifying indication or clinical appropriateness.

The evidence framework should follow the reasonable comparator set CMS identifies. Where more than one set is plausible and the choice materially changes the utilization or expenditure conclusion, CMS should disclose sensitivity to that choice. The disclosure need not catalogue every rejected option. It

should be sufficient to show whether the result is robust to reasonable alternatives and whether a finding is driven by comparison with a rarely used, clinically limited, or otherwise atypical treatment.

Transparency should focus on the evidentiary judgment rather than a claimed price effect. The concise justification under proposed § 429.520(b)(1)–(2) should identify the relevant treatment contrast and population, summarize the type of utilization or expenditure evidence considered, describe the principal limitations, and report the comparative direction, economic materiality, certainty, and Medicare applicability. It should then state whether the evidence materially informed the overall section 1194(e)(2) assessment under proposed § 429.510(e). Public explanations under proposed § 429.705(b)(1) should provide the same high-level account, subject to the confidentiality requirements of proposed § 429.300, and CMS should retain a dated evidence set for each negotiation.

CMS already publishes selected-drug information, negotiated prices, and drug-specific MFP explanation files on its official program page. Using that channel for a concise explanation of material downstream evidence would place the information where affected parties already look for the agency's reasoning. It would also avoid creating a separate reporting mechanism or inviting disclosure of confidential manufacturer material.

Because section 1194(f)(4)(B) requires the renegotiation process, to the extent practicable, to remain consistent with the negotiation methodology and to operate in accordance with section 1194(e), CMS should apply the same framework in renegotiation and may supplement voluntary submissions with its own literature review, Medicare claims or other datasets, clinical data, and other relevant information where informative.

VII. Guardrails and Limitations

First, the framework should be symmetric. Evidence may be favorable to the selected drug, null or indeterminate, or adverse. A selected drug may reduce hospitalizations, require additional monitoring, cause treatment-related utilization, or extend survival while increasing total service use. Each result is admissible if credibly identified. The same standards should govern manufacturer and public submissions, and the absence of a favorable finding should be treated as an empirical result rather than a failure of the method.

Second, downstream expenditure analysis is not conventional cost-effectiveness analysis. It need not monetize a health state, a year of life, a quality-adjusted life year, or life extension for an older, disabled, or terminally ill person. An observed or estimated Medicare payment associated with an avoided admission is a program expenditure linked to a clinical event. CMS should continue to enforce the limitations in section 1194(e)(2), section 1182(e), and proposed § 429.505(e)(1)–(2), while recognizing that a properly bounded utilization-and-expenditure analysis does not become a prohibited QALY or similar measure merely because it reports expenditures in dollars.

Third, CMS should protect against double counting. A hospitalization difference may inform comparative effectiveness and may also have an expenditure consequence. Those are related but distinct descriptions of the same underlying event. CMS should record the clinical and budgetary implications separately and explain how it prevented the same consequence from exerting duplicated influence. The same discipline applies when a utilization difference is translated into total allowed spending and then

into a separate estimate of plan liability, beneficiary financial effects, or Medicare program expenditures or federal Medicare liability.

Fourth, observed, extrapolated, and modeled effects should remain distinguishable throughout the synthesis. A model can be the most decision-relevant evidence for a long-latency disease when its structure and parameters are well supported. It should not borrow the certainty of an observed endpoint, however, and a short observational study should not be treated as definitive merely because it avoids extrapolation. The weight assigned should reflect validity, empirical support, validation, and uncertainty rather than a categorical preference for one evidence form.

Fifth, survival requires explicit treatment. Preventing an event may lower disease-specific expenditure during observed follow-up while longer survival increases future Medicare-covered use. A net estimate should disclose whether and how those additional years and services are included. CMS should not interpret higher total spending caused by longer survival as evidence of inferior clinical effectiveness, nor should it omit the fiscal consequence when the analysis claims to measure all-cause Medicare program expenditures.

Finally, sponsorship should trigger neutral scrutiny rather than automatic acceptance or rejection. CMS should consider who funded the work, who controlled the design and analysis, who held or accessed the data, who selected endpoints and parameters, and who controlled publication or submission. The same questions apply to industry, academic, consulting, and advocacy sources. Transparent sponsorship and reproducibility information help CMS assess selective reporting and analytical control; they do not substitute for evaluating the design itself.

VIII. Implementation and Concise Conclusion

Downstream utilization and expenditure evidence is most useful when it remains comparative, bounded to the listed statutory factors, and explicit about population, perspective, timing, and uncertainty. Study-specific credibility and coherence across the available evidence are distinct judgments. Keeping them separate allows CMS to preserve genuine heterogeneity, identify dependence among studies, and avoid unsupported arithmetic while still recognizing economically material clinical pathways.

A disciplined treatment can recognize informative evidence without presuming savings and reject overextended claims without categorically ignoring the expenditure consequences of clinical outcomes. That is an appropriately modest role for this evidence within the Negotiation Program.

Respectfully submitted,

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