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August 31, 2026

VIA REGULATIONS.GOV
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Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
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Calendar Year 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Proposed Rule

Docket ID: CMS-2026-2344

Comments of the Competitive Enterprise Institute

The Competitive Enterprise Institute (CEI) submits these comments in support of several of the provisions in the rule recently proposed by CMS. Founded in 1984, CEI is a nonpartisan public policy organization whose mission is to reform America's unaccountable regulatory state by advancing policies that eliminate unnecessary government burdens and promote a freer, healthier, and more prosperous nation.[1] Consistent with that mission, CEI opposes regulations that distort competitive markets, increase costs for consumers and businesses, and inhibit innovation.

To that end, CEI submits this comment as a response to the proposed changes to compensation for 340B drugs in Medicare. The 340B program effects significant market distortions which this rule would reduce. While 340B was originally designed to reduce costs for hospitals to provide drugs to uninsured and low-income Americans, the incentives embedded in it have caused enormous changes to the structure of the hospital industry. The 340B program directs the industry to contort itself into a structure that will not just satisfy the government's 340B rules but will allow them to maximize their benefits. This causes hospitals and providers to be directed toward profiting from poorly designed regulations and satisfying some artificial set of rules rather than appealing to patients.

Due to the rules of 340B and the incentives within it, hospitals are more likely to shift care to outpatient facilities that use more expensive, physician-administered drugs and to off-campus hospital outpatient departments or clinics. The rules lead the health care industry into a series of vertical integrations that are not a market-driven impetus to reduce costs and win customers, but are designed to expand the

[1] Competitive Enterprise Institute. "About CEI." Accessed July 20, 2026. https://cei.org/about/.

application of the 340B rules and qualify more drugs for additional revenues.

The 340B program also incentivizes hospitals to favor more expensive drugs over cheaper drugs because the financial benefits are higher.[2] This substitution increases costs for payers, patients, and the government overall, and reduces market signals and prevents the industry from evolving efficiently.

Lastly, it may even cause hospitals to change their ownership structure, as for-profit hospitals do not qualify for the program. Recently, a large hospital system in Oregon initiated a process to transition from for-profit to non-profit. Doing so will qualify it for the 340B benefit, which it named as one of the reasons for the transition.[3]

As a health care policy analyst and economist, I am well-suited to assess the proposed rule and the survey used. Further, with a deep background in statistics and econometrics and professional experience conducting and assessing claims sampling for health care disputes, I am particularly well-suited to analyze the survey and its results.

The survey conducted by CMS meets the requirements in statute

Criticism of the survey will likely focus on the specific requirements as laid out in statute. 42 U.S.C. § 1395l(t)(14)(D) describes the requirements for the surveys conducted by CMS/HHS after the original GAO surveys. In particular, section (ii) mentions the purpose of the survey "to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates" and section (iii) calls for the survey to have "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug."

The most likely directions critics will take will concentrate on whether the survey has "a large sample of hospitals," whether it generates a "statistically significant estimate" and potentially whether applying a group-based discount, uniform across all drugs, is a legal application of the statute's provisions. Additionally, critics are likely to argue that due to voluntary non-participation, the survey is not representative and should not be used.

Survey qualifies as "large sample"

CMS opened the survey to all hospitals that received OPPS payments for outpatient drugs during the survey period. Because this survey was meant to determine hospital acquisition costs for outpatient drugs paid under OPPS, this is the correct universe. As explained in the survey, 3,147 entities were eligible to complete it. Of these, 1,343 (42.7%) submitted a response and 1,304 reported acquisitions of one of the surveyed drugs. [4]

While the statutory text "a large sample" has no objective meaning, nor does it have any statistical definition, expert judgment is called for to determine whether the CMS survey's sample would qualify. There

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[2] U.S. Government Accountability Office, "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals," GAO-15-442, June 5, 2015, https://www.gao.gov/products/gao-15-442.

[3] Lucas Hellberg, "McKenzie-Willamette Poised for Nonprofit Ownership as Medicaid Cuts Loom," Lookout Eugene-Springfield, June 1, 2026, https://lookouteugene-springfield.com/story/latest-news/2026/06/01/mckenzie-willamette-poised-for-nonprofit-ownership-as-medicaid-cuts-loom/.

[4] Centers for Medicare & Medicaid Services, "2026 Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey (ODACS)," July 2026, https://www.cms.gov/files/document/opps-drug-acquisition-cost-survey-technical-report.pdf.

are several reasons to believe it does. For one, this sample is larger than the original GAO survey conducted in 2005. In that survey, the original, official survey conducted as required by statute, only 1,157 hospitals responded. GAO determined that this sample was "reliable for estimating [Specified Covered Outpatient Drugs] prices." It went on to say that estimates of prices were more precise for drugs purchased by many hospitals.[5]

Further, the responding hospitals included hospitals across the relevant categories defined by GAO and frequently used in health care policy, such as teaching and non-teaching, urban and rural. Because each category was represented in the final sample, there was data CMS was able to use to transform the results such that they would match the population of hospitals, similar to how political polls feature weights such that they can reflect an entire voting population.

Survey generates a "statistically significant estimate"

Like "large," whether a survey can generate a "statistically significant estimate" has little meaning to a statistician, particularly if it's being used to determine an average. An average can be produced based on data from any positive number of participants. An average cannot be deemed "statistically significant." Generally, when speaking of statistical significance, one number is being compared to another, and the difference is determined to be either statistically significant or not. So, in this case, we could determine if the average is statistically significant from zero or whether the groups' averages are different from each other, but designing a survey to achieve "statistical significance" is a misunderstanding of the concept.

What the legislators probably meant by this was the survey should be large enough that its estimates were not substantially different from the overall population, so as not to misprice the drugs being reimbursed. And the 2026 survey would likely qualify under that definition based on GAO's assessment of the smaller 2004-05 survey.

Additional information seems to strengthen that conclusion. In both the GAO survey and the CMS survey, several factors are suggestive that dispersion across hospitals was small. For one, the coefficients reported in the GAO publications indicated that the hospital characteristics only had small effects on the prices.[6] In the CMS survey, the 95% confidence intervals were relatively narrow as well, and showed more overlap across hospital types than across drugs (i.e. prices of different drugs were markedly different from each other, while prices of the same drug were similar across different hospitals). This suggests that the variation across drugs was much greater than the variation across hospitals. In other words, the survey seems to have identified drug prices that were consistent for a specific drug across hospitals but nevertheless varied across different drugs. This is the result you would expect from a well-executed survey of hospital drug acquisition prices. To be clear, none of the factors described here allow one to conclude with certainty the level of dispersion, but they all seem to point toward that reading.

Further, the survey was designed to identify the difference in acquisition costs between 340B drugs and non-340B drugs. The survey estimated a difference of approximately 33.4%. The mean was the same as the median, suggesting the price distribution was relatively unskewed. Further, when removing outliers and reweighting the sample, the price difference didn't change at all, or it dropped to 31.1%, meaning that the estimates are not driven by extreme data. The analysis of the survey results all separated the results by drug class and found more variation there, but still, the smallest difference cited was 28.8%. Taken together, these

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[5] U.S. Government Accountability Office, "Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting," GAO-05-581R, June 30, 2005, https://www.gao.gov/assets/gao-05-581r.pdf.
[6] U.S. Government Accountability Office, "Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting."

results imply that there is consistently a difference in the acquisition prices for 340B that is approximately 30% or higher.

Additionally, this difference was statistically significant as well. You can see this from the confidence intervals for the non-340B price compared to the 340B price. Since their confidence intervals don't overlap, and are actually quite distant from each other, one can say with confidence that the prices for these drugs were different, at generally accepted levels of statistical significance.

Survey representativeness

Taking the statute's requirements together, critics may also argue that a large sample producing statistically significant estimates is effectively arguing that the sample needs to be representative. In other words, that the sample must contain enough information about the entire population of hospitals that the sample average is near the population average.

Critics will also point to the discrepancy in the responses as an indicator that the sample was biased, as the response rate for 340B hospitals was smaller than that for non-340B hospitals. Not only that, the decision of hospitals to respond was correlated with other factors that would tend to bias the results.

CMS tried to anticipate this issue by performing its reverse-weighting estimates. Basically, CMS recognized the potential for bias, and overweighted the types of hospitals with lower response rates relative to those with higher response rates. The idea was to reshape the sample to better match the population.

Critics will surely argue that this is insufficient because the non-responding hospitals were fundamentally different from the responding hospitals and you can't overcome a non-response bias by overweighting data of those who responded.

The correctness of this overweighting approach is entirely dependent on whether the non-responding hospitals are fundamentally different, *on the variable of interest*, from the responding hospitals. To know for certain if this method corrects for the missing respondents or just produces a different set of biased estimates, one must first determine whether the acquisition costs of the drugs for the non-responding hospitals was different, and if so, whether they were higher given that the uniform price adjustment would only harm hospitals if their acquisition costs were higher than the average.

There are a number of reasons to believe this isn't the case.

First, GAO showed that acquisition costs for large, and teaching hospitals tended to be lower. Urban hospitals' acquisition costs were also lower on average, but this difference was not statistically significant.[7] These are, in general, the characteristics of the hospitals that didn't respond to the survey. Of course, this isn't direct evidence of the 340B discrepancy at these hospitals, but the reason for the overall low prices probably applies also to the 340B prices. Namely, that these hospitals likely have more bargaining power and use that to exact greater discounts. This bargaining power is relevant both to the non-340B drugs and the 340B drugs. Further, studies show that hospitals in more concentrated markets use bargaining power to increase their margins on 340B drugs.

Second, the variation in prices across hospitals for the available sample is very small. Importantly,

[7] U.S. Government Accountability Office, "Medicare: Drug Purchase Prices for CMS Consideration in Hospital Outpatient Rate-Setting."

that fact does not change when the sample is weighted to adjust for the non-responding hospitals. In both cases the price dispersion is small, and so is the gap. Given this is the case for the hospitals in the sample regardless of characteristics, a natural (though certainly not probative) assumption is that that price consistency exists also in the non-responding hospitals. To my knowledge, there is no evidence that exists that says otherwise.

Further, if the hospitals' argument that the survey should be thrown out due to sampling issues is accepted, that would effectively nullify the survey component of the statute altogether, because it would create a situation where similar hospitals could choose not to participate and thereby prevent any survey from being accepted by CMS.

While I've gone through the criticisms I could imagine, given the complexity of the hospitals and drugs involved and the nature of statistics, there could potentially be an infinite number of ways to compare hospitals to each other and claim the differences are relevant enough to negate any survey. This would be another effective nullification of the statute. No survey can ever be perfect, even one with a 100% response rate. Similarly, no pricing system can be perfect such that some recipients aren't winners and some are losers. The statute does not call for perfection and even the current system produces winners and losers. That should not be used as a reason to disqualify this survey.

GAO Recommendation against survey

Critics may also point to GAO's recommendation, from its original report, against using surveys. GAO noted the administrative burden and challenges of conducting a survey were large and the information obtained was not worth the effort given alternative approaches that were available.

It is true that data collection when the GAO conducted its survey was onerous and difficult, and this is the main reason they recommended against using surveys in the future. But developments since then and a difference in objectives suggests that those recommendations are obsolete.

First, GAO conducted its survey in 2004/05. Health care data and reporting were substantially less sophisticated then. Over the ensuing twenty years, multiple platforms developed to record, store, and transmit data, particularly on drugs. Consequently, the administrative burden on hospitals is much lower now.

In 2008, fewer than 1 in 10 hospitals had an Electronic Health Record system; by 2024, 99% did.[8] Since 2024, hospitals participating in the Outpatient Prospective Payment System (OPPS) have been required to identify drugs that are acquired through the 340B program, too.

Another indication that the administrative burden of the survey wasn't the determining factor in the recent CMS survey is that in the GAO study, response rates were relatively unrelated to the size of the hospital. If anything, it was the smaller hospitals that had a lower response rate. However, in the 2026 survey, it is the larger hospitals that didn't respond. The reporting issue that existed in 2004/05 that caused GAO to recommend against surveys is unlikely to be the reason that larger, 340B hospitals, chose not to participate.

In addition to the changes in technology, the purposes of this survey differ from the original GAO survey. That survey was to determine acquisition costs for drug-specific pricing across hospitals. As such, the information they needed did not need to be hospital specific. It needed to be drug-specific. Drug-specific

[8] Office of the National Coordinator for Health Information Technology, "National Trends in Hospital and Physician Adoption of Electronic Health Records," Health IT Quick-Stat #61, last updated June 2026, https://healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.

price information was attainable from the manufacturers and with a lower administrative burden. This method for price determination was also allowable by the statute. So the GAO decided, comparing the hospital survey to manufacturer data, to achieve drug-specific prices, it was unnecessary to conduct an annual survey of hospitals.

However, CMS wants to pay differentially for 340B drugs versus non-340B drugs. This creates an additional reason for needing a hospital survey, which changes the relative cost-benefit analysis in favor of a survey. Further, the controlling statute only requires that the Secretary *consider* the recommendations in the GAO survey; it does not require the Secretary to follow them. What it does require the Secretary to do is conduct surveys periodically, which this survey contributes to.

Conclusion

The 340B program, while well-intentioned, has caused enormous distortions to the health care industry and needs reform. The rule proposed by CMS, while not solving the problem at its core, would at least remedy some of those distortions by redirecting taxpayer funds from artificially inflated drug prices to a less-distortionary, but coherent, pricing system. Critics will surely name many of the criticisms mentioned above to prevent this, but those criticisms should not prevail.

Sincerely,

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