Medicare Outpatient Prospective Payment System (OPPS) Drug Acquisition Cost Survey

Public Comments and CMS Responses

After consideration of public comments, we finalized our proposal outlining a required OPPS drug acquisition cost survey for all hospitals paid under the OPPS, pending final approval from OMB (90 FR XXXXX through XXXXX and 90 FR XXXXX through XXXXX). Below are the comments and responses as they appear in the CY 2026 OPPS/ASC final rule with comment period.

This new information collection request will be submitted to OMB for review under control number 0938-1487 (CMS-10931). The OMB control number will not be valid until formally approved by OMB.

Comment: Most commenters opposed our announcement that we will be conducting a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including SCODs, and drugs and biologicals CMS historically treats as SCODs and urged CMS to reconsider the necessity and timing of the proposed survey.

Many of these commenters stated that, given the complexity and scale of the required data collection and analysis, conducting the survey will impose a significant burden on hospitals and that CMS' estimate of that burden grossly underestimates the cost, time and resources that will be necessary to complete the survey. Commenters also claimed that CMS is wrong to assume that the reporting will be done by pharmacy technicians and that the survey will actually be completed by pharmacists that will cost more. One commenter opined that completing the survey would demand the concerted effort of multi-disciplinary teams, including pharmacy, supply chain, finance, legal, and reimbursement professionals, far beyond what pharmacy technicians

alone could provide. The commenter stated that CMS' own Information Collection Review document "acknowledges the breadth of the undertaking but fails to account for the extensive coordination needed with vendors and suppliers, from whom much of the requested data must be sourced. The time and resources required to collect, clean, analyze, and accurately report thousands of distinct drug prices would divert critical personnel from patient care and other essential hospital functions". Many other commenters emphasized that the cost of completing the survey would come at the expense of the hospital's ability to provide essential care to patients and quoted the GAO's 2006 report to Congress in which the GAO concluded that the surveys it conducted "created a considerable burden for hospitals" and that to submit the required price data hospitals "had to divert staff from their normal duties, thereby incurring additional costs." Many commenters stated that the financial burden of completing the survey would be exacerbated by upcoming Medicaid and Medicare reductions under the Inflation Reduction Act.

Response: We take the burdens on hospitals of completing the survey and the GAO's conclusions relating to that burden very seriously in the design and implementation of the survey. We have created a survey instrument and survey process that we think will minimize, to the extent reasonably possible, the staffing and financial burden on hospitals of collecting and reporting the necessary information to CMS. The survey instrument consists of a streamlined online portal, where hospitals can either directly enter acquisition costs or download and reupload an excel template of acquisition costs. There will be technical assistance available for any hospital staff with any issues that arise during the submission process. We have taken the feedback from commenters into careful consideration when finalizing the survey tool.

We are also engaging in robust education and outreach efforts with hospitals to reduce the burden of completing the survey. These activities consist of:

- Obtaining user feedback from hospitals. We worked with a small group of hospital representatives to learn about their operations and business practices so that we could thoughtfully incorporate that knowledge into the survey design.
- Providing hospitals with a comprehensive communications plan. We are outlining thorough communications to support hospital representatives and system users throughout the onboarding, training, and implementation phases of the survey process.
- Providing hospitals with webinar training sessions. We plan to host two webinar sessions to provide more details on the registration and data submission processes for the survey, and to offer hospital representatives an opportunity to ask questions in a dedicated question-and-answer session.
- Providing hospitals with accessible resources. We have created a survey website (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey*) to house resources for hospital representatives and system users, including user guides, frequently asked questions, fact sheets, and a data collection template for ease of use.
- Creating a survey instrument with an intuitive design and application support. The survey instrument is being built with ease of use in mind. The screens are simple, featuring enabled tooltips, descriptive error messages, downloadable copies of the user guide, and access to dedicated helpdesk contact information.
- Providing hospitals with dedicated technical support. There is a dedicated Helpdesk email (*OPPSdrugsurvey@cms.hhs.gov*) to support users with any technical issues they may have with the system and a Helpdesk phone number is forthcoming.

But many of commenters' arguments appear to rest on a belief that CMS should *never* conduct a survey. We cannot reconcile that position with the statute, which requires the Secretary to "conduct periodic surveys," or GAO's advice to conduct those surveys every five or 10 years. The Secretary has not yet conducted any such survey. We reiterate that future surveys will be periodic in nature, which will limit the burden that hospitals face on a reoccurring basis.

Comment: Many commenters stated that the reason CMS has never previously conducted a survey of the acquisition costs for each SCOD for all hospitals paid under the OPPS is because of the immense administrative burden it would impose on both hospitals and CMS. One commenter stated that that "CMS has historically opted out of conducting this survey for several reasons—including undue burdens and inaccuracy of results—and these realities have not changed". The commenter claimed that the burden of conducting the survey was so significant that GAO recommended that the survey be used only to validate "ASP data that manufacturers report to CMS for developing SCOD rates" and that "CMS declined to conduct a survey between 2006 and 2019, influenced by GAO's analysis, and cited the survey's burden on both hospital staff and the agency." The commenter additionally noted that "[a]s recently as November 2021, HHS publicly acknowledged the significant burden the survey has on the agency and hospitals. During a Supreme Court oral argument, HHS stated that the surveys are 'very burdensome on the study takers', 'very burdensome on the hospitals', and 'do not produce results that are all that accurate.'" The hospital acquisition cost survey, the commenter concluded, "would divert resources from patient care, contribute to inefficiencies, and create financial strain on hospitals at a time when it is a CMS priority to actively reduce such inefficiencies and burdens." Similarly, several other commenters questioned the choice of conducting a survey that imposes a

significant burden on hospitals "given the Administration's goal of reducing administrative burdens".

Response: We acknowledge, as we did in the CY 2026 OPPS/ASC proposed rule, that we have not previously conducted a survey of the acquisition costs for each SCOD for all hospitals paid under the OPPS. We also acknowledge that surveys can be administratively burdensome both to recipients and administrators. However, as discussed in our response to the previous comment, we believe that the survey instrument and accompanying process that we have devised will alleviate to the greatest extent possible the staffing and financial burdens identified by the GAO and HHS. Again, regardless of the burden involved, we are required to comply with section 1833(t)(14)(D)(ii) of the Act which requires "the Secretary to conduct periodic…surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates." E.O. 14273 accordingly directs the Secretary to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments.

Comment: One commenter stated that the burden of completing the survey would be even greater for 340B covered entities not only because they typically have limited administrative resources, but because the survey would require 340B hospitals to report twice the amount of data as other hospitals.

Response: We understand the commenter's concerns; however, we believe it is prudent to collect all discounts, rebates, and other price concessions that are provided to hospitals, including 340B

discounts, so that we have data that reveals the actual acquisition costs of the drugs that hospitals purchase.

Comment: One commenter stated that the survey is broader than permitted by law because it includes drugs that are not included in the definition of specified covered outpatient drugs under section 1833(t)(14)(B) of the Act. The commenter also expressed surprise that CMS is proposing to exclude radiopharmaceuticals from the survey when those drugs are explicitly included within the statutory definition of SCODs. Conversely, one commenter agreed with CMS' decision to exclude radiopharmaceuticals, as the commenter stated that these products present unique characteristics that make their inclusion in a broad hospital acquisition cost survey problematic. They stated that radiopharmaceuticals are used in highly specialized clinical settings, often with low-volume distribution. Another commenter requested that CMS exclude all separately payable radiopharmaceuticals from the survey. The commenter recommended that doing so while using targeted alternative data sources would ensure that OPPS payment rates remain accurate, support continued patient access, and minimize administrative burden on hospitals.

Response: We acknowledge, as we did in the CY 2026 OPPS/ASC proposed rule, that the proposed survey includes both SCODs and drugs and biologicals that we have historically treated as SCODs for payment purposes. As we explained, we have historically treated non-SCOD drugs as SCODs for payment purposes since CY 2006. We believe that drug pricing and payment is a complex and dynamic issue; therefore, CMS, beneficiaries, and taxpayers would benefit from the additional details that the survey will provide on acquisition costs for non-SCODs, which represent the majority of drugs currently separately paid under the OPPS.

As discussed in the draft Supporting Statement A for this data collection, for the NDCs included in the survey template we excluded radiopharmaceutical NDCs from our proposed list of NDCs. Radiopharmaceuticals are unique products with various forms in which they can be purchased—The GAO explicitly acknowledged these unique characteristics in the original survey. While GAO still collected information, and analyzed data, for radiopharmaceuticals, it specifically acknowledged that "their complex nature as compared with drugs poses challenges for collecting and interpreting cost data" and the "GAO found that the diversity of forms in which they can be purchased—ready-to-use unit doses, multidoses, or separately purchased radioactive and non-radioactive substances— complicates CMS' efforts to select a data source that can provide reasonably accurate price data efficiently". [1] We believe that, due to these unique characteristics and challenges, the burdens of collection for radiopharmaceuticals outweigh the benefits, and so we should not include radiopharmaceuticals in the survey at this time. This will also reduce hospital reporting burden. We thank the one commenter for their support regarding our proposal, and finalized policy, to exclude radiopharmaceuticals from the OPPS drug acquisition cost survey at this time. With respect to the commenter that suggested that we exclude all radiopharmaceuticals from the survey, we confirm that we are doing so.

Comment: One commenter, noting that the survey does not have an OMB approval number, indicated it had already received email communications regarding the survey and cautioned CMS that it should not be taking efforts to conduct the survey before it has been finalized via rulemaking.

[1] Government Accountability Office. "Medicare Hospital Pharmaceuticals: "Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS" April 2006. Available at *https://www.gao.gov/assets/gao-06-372.pdf*.

Response: We can assure the commenter that CMS has not begun collecting drug acquisition cost data prior to OMB approval of the survey package. CMS has alerted hospitals paid under the OPPS of our intent to conduct the survey so that they would be aware of the survey if finalized in this rulemaking and assigned an approved OMB control number.

Comment: One commenter stated that CMS' survey methodology contradicts GAO guidance and will consequently lead to unreliable results. The commenter stated that when conducting the 2004 survey, the GAO worked with knowledgeable interested parties to develop a survey instrument before sending it to its sample population. According to the commenter, the GAO pretested the survey instrument, made adjustments based on hospital feedback, and engaged a data collection contractor to pilot the revised instrument with a larger group. As a result of the pilot, the commenter contended, GAO adjusted the instructions and changed its procedures before engaging in a multifaceted effort to collect data from about half as many hospitals as CMS intends to survey. The commenter stated that CMS' survey methodology, instrument, and instructions do not compare, "although it intends to undertake a larger survey under the same statutory authority, with the same goal, but far more serious consequences." To illustrate the alleged deficiencies of CMS' survey as compared to the GAO's, the commenter provided the following example: CMS instructs hospitals to report purchase prices on an NDC-by-NDC basis, net of all discounts, rebates, and price concessions. The commenter pointed out that discounts, rebates and price concessions are not aways reflected in hospitals' purchasing systems. When the GAO faced this same problem in 2004 and 2005, the commenter contended, it determined that "it was generally not feasible to allocate rebates to specific drugs" and limited its review solely to hospital purchase price information, excluding any rebates paid after the hospital's

receipt of the product. In contrast, the commenter alleged, CMS instructs hospitals to "estimate the approximate discount received for NDC, deduct that amount from the NDC cost, and report the final cost with all deductions in the template." CMS, the commenter concluded, provides no further instructions regarding the estimation methodology or even a field for hospitals to indicate which of their reported prices include estimated discounts.

Response: We thank the commenter for their feedback. As we create a survey instrument, we are engaging with hospitals and experts within the hospital and drug purchasing industry, and we are incorporating the valuable feedback received through the notice and comment rulemaking process. The survey will go through extensive user testing, and there will be a thorough onboarding process once an OMB control number is received, which will involve webinars, user guides, fact sheets, additional communications as well as a dedicated email inbox, phone number, and website in order to ensure hospitals are able to respond to the survey. We disagree with commenters to the extent they suggest the statute requires us to mimic the GAO survey in every particular. The statute instead requires us to craft our survey "taking into account" the GAO's recommendations. We have done so. We also note that the world has changed since 2004 and 2005, when GAO conducted its survey tool. For example, hospital systems in 2026 have technology far more advanced and sophisticated than the technology hospitals had over 20 years ago in 2004 and 2005. Similarly, CMS is able to create a more streamlined, sophisticated, and modern survey tool more than 20 years after GAO created its survey tool, while still adhering to relevant principles that GAO used when crafting the original survey in 2004. We thus believe it is reasonable, for example, to require hospitals to report drug discounts to us. Drug pricing and discounts have also drastically changed since 2004 and 2005. For example,

according to a GAO Report[2] on Prescription Drug Spending, the amount of money spent on prescription drugs has increased dramatically over the past two decades. They specifically list pharmaceutical rebates as one of the several factors that affect prescription drug prices in the U.S. The rapid growth of drug spending and drug discounts and rebates since the original GAO survey emphasizes the need and increased importance for today's survey to incorporate these factors into the acquisition cost.

Comment: The same commenter faulted the CY 2026 OPPS/ASC proposed rule for failing to recognize the importance of a well-developed survey instrument, clear instructions, and accessible technical support. The commenter found this perplexing, given GAO's experience. The commenter stated that despite the GAO's careful planning and testing, its 2004 survey required extensive, continuous engagement with respondent hospitals: "On average, [contracted] interviewers called each hospital 8 times before receiving a complete data submission". It was only after this "rigorous, labor intensive" activity by the GAO that the GAO reported that the survey produced accurate hospital drug price data. The commenter stated that it is reasonable to expect that hospitals will similarly need ongoing guidance to navigate the complexities of responding to CMS' proposed survey but states that CMS' proposal gives no indication that hospitals will have any opportunity to seek clarification or technical support during the survey process. This lack of robust instructions and practical support, the commenter alleged, will almost certainly result in inconsistent data, undermining the reliability of the survey results.

Response: We agree with the commenter that it is reasonable to expect that hospitals will need ongoing guidance to navigate the complexities of responding to our proposed survey similarly to

[2] *https://www.gao.gov/prescription-drug-spending*.

how they did with the GAO's survey. However, we disagree that our proposal gives no indication that hospitals will have any opportunity to seek clarification or technical support during the survey process. We also do not agree with the commenter's conclusion that our survey lacks a well-developed survey instrument, clear instructions, and accessible technical support. We have created a survey instrument that we believe minimizes, to the extent reasonably possible, the amount of effort necessary for hospitals to collect and report the required information to CMS. We have established a communication method for the hospitals subject to the survey. We have also established extensive written instructions and several real-time training sessions to provide guidance and receive feedback. For technical assistance we have multiple guidance documents (FAQs, user guides, fact sheets, among others), which will be available on our new dedicated website (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/outpatient-prospective-payment-system-opps-drug-acquisition-cost-survey*), as well as a dedicated phone line (forthcoming, to be announced on the above referenced website) and email address (*OPPSdrugsurvey@cms.hhs.gov)* that hospitals can contact for assistance before and throughout the survey process. There will be additional assistance tools available within the survey itself to facilitate the completion of the survey by hospitals.

Comment: The same commenter expressed concern that if CMS performs a "deficient survey", it could undermine the purpose of the 340B program. The commenter cited a finding from GAO's 2005 report that it "could not fully account for rebates or payments from group purchasing organizations". The commenter stated that many 340B-participating hospitals are subject to a prohibition on purchasing covered outpatient drugs through a group purchasing organization or

other group purchasing arrangement, "so the GPO payment issue may not substantially affect them" but "non-340B hospitals may be unable to reasonably allocate GPO payments on an NDC-by-NDC basis, leading to overreporting of their acquisition prices, and creating an artificial gap between 340B and non-340B providers". The commenter listed other consequences that they alleged would occur as a result of a "deficient survey". "For example, the price discerned through a retrospective acquisition cost survey will not reflect the true net cost to 340B covered entities for any drugs that, in the future, are subject to both the Medicare Drug Price Negotiation Program (DPNP) under Part B and HRSA's proposed 340B rebate pilot program. For such drugs, HRSA has proposed that 340B covered entities will be required to purchase the drugs at the WAC price, then wait for manufacturers to pay rebates to bring the price down to the 340B ceiling price." The commenter stated that "[u]nless every manufacturer pays every covered entity every requested rebate—which seems unlikely for the reasons stated in our letter to HRSA regarding its rebate pilot program, which we incorporate here by reference—covered entities' costs for these drugs will be, on average, higher than the 340B ceiling price. Because the CMS survey is retrospective and based on historical acquisition costs, it will systematically understate the actual net cost to 340B covered entities for these drugs. Any payment rates set using such survey data will therefore fail to accurately reimburse covered entities for their true acquisition costs". The commenter requested that CMS acknowledge this limitation and, if it proceeds with its survey proposal and anticipated reimbursement cuts, clarify how it will ensure that payment rates for Part B drugs subject to both the DPNP and the 340B rebate pilot will fully account for the additional rebate liability imposed on 340B covered entities. The commenter alleged that the complexities associated with the CY 2026 OPPS/ASC proposed survey have only increased since the GAO's report and that the approach proposed by CMS is the wrong solution to resolve

budget shortfalls. “It serves only to harm 340B covered entities – threatening this country’s safety net front line – in contravention of clear Congressional intent. This approach therefore functionally guts the 340B Program’s benefits.”

Response: We thank the commenter for their detailed comment outlining their concerns. We note that HRSA’s 340B pilot program is out of scope for purposes of this rulemaking and CMS defers to HRSA for specifics on this program. This pilot program has yet to go into effect, and the period of the survey does not overlap with the pilot program, but we can consider how to incorporate any potential intersection between that program and Medicare payment policy in future rulemaking or future drug surveys released by us. We acknowledge that drug pricing and payment is dynamic and evolving, but that this survey will provide valuable insight into this topic, and will help address some of the same issues that this commenter raises. The survey will bring greater transparency to drug acquisition costs, which also will help address some of the same broader issues that the commenter raises. Whereas not conducting a survey because it might prove difficult only serves to leave the issue opaque for all interested parties.

Comment: Many commenters stated that the survey results would be unrepresentative or quickly obsolete given the volatility in drug pricing and policy due to various factors such as proposed pharmacy benefit manager reform, the implementation of negotiated drug prices under the IRA, 340B drug pricing program rebate policies, the “most favored-nation” policy and pharmaceutical tariffs. They stated that this volatility will preclude a survey conducted in CY 2026 collecting data from 2024 to 2025 from serving as an accurate basis for future Medicare reimbursement policies. Some of these commenters suggested that CMS should use the proposed survey timeframe to instead conduct a test survey, incorporate interested parties’ feedback, and learn

from GAO's findings of technical challenges while these changes are implemented. Other commenters went further and suggested that the constantly fluctuating nature of drug prices generally would render survey results questionable regardless of when the survey was conducted. These commenters stated that any survey will only yield a point-in-time estimate of a drug's acquisition cost, which can change wildly quarter to quarter and will fail to account for new, expensive drugs that enter the market after the survey is completed.

Response: We acknowledge that surveys are inherently a snapshot of data at a given point in time (indeed, that is their purpose) and that there are multiple factors which can affect drug costs at any given point in time. To a significant extent, the value of a survey is providing a snapshot of data at given point of time which reflects all of the factors that are affecting the data at that point of time. The statute requires that to conduct a survey of drug acquisition costs to inform drug payment amounts to do so on a periodic basis. We note that commenters' observations cut both ways: if drug pricing changes significantly over time, then that supports our decision to collect data now instead of continuing to rely on drug pricing policies set based on GAO surveys from two decades ago. The statute also provides that we do not have to rely solely on survey data to inform our drug pricing policies. For example, as discussed in the CY 2026 OPPS/ASC proposed rule (90 FR 33654), we could consider pricing from the Federal Supply Schedule (FSS), 340B ceiling pricing, ASP plus 6 percent, zero percent or another percentage; or other recognized drug pricing to inform future CMS payment policy. Such policies have been, and will continue to be, set in advance every year through notice and comment rulemaking.

Comment: Some commenters supported our announcement that we will be conducting a survey. These commenters stated that doing so would promote transparency and bring greater alignment of payment with acquisition costs.

Response: We thank commenters for their support.

Comment*:* Many commenters suggested refinements to various aspects of the proposed survey. Several commenters supported CMS conducting the survey but were concerned about using its results for CY 2027. These commenters cautioned CMS against making "abrupt changes" to the 340B payment policy as a result of the survey. These commenters maintained that CY 2027 is too soon to make changes and 1 year of data is an insufficient basis upon which to make changes. These commenters argued that careful consideration of data validity and analysis is necessary before making changes to payment policy and that inaccurate data collection could lead to reimbursement policies that directly impact Medicare beneficiaries rather than correct any inequities in hospital payment.

Response*:* We agree with commenters that a careful consideration of data validity and analysis of that data is necessary before making changes to payment policy and, as we stated in the CY 2026 OPPS/ASC proposed rule, we intend to propose and seek comment on any payment rates for SCODs, and drugs historically treated as SCODs, after taking into consideration the survey results in CY 2027 rulemaking. We do not agree, however, that 1 year of data is necessarily an insufficient basis upon which to make changes. The commenter cites no statistical support for such a categorical conclusion, which is likely overbroad. And under the statute, we adjust payment rates for drugs on an annual basis, suggesting Congress anticipated year-to-year policy updates. Indeed, the further we get from the survey to make payment policy the more likely it is

that we run into the problem of there being too long of a lag. We have to strike an appropriate balance, and 1 full year of data from the most recent year seems reasonable.

Comment: One commenter stated that the proposed start of the survey is too soon. The commenter stated that hospitals need time to identify, validate and coordinate drug cost information across internal departments and that without additional advance notice and technical guidance hospitals may be unable to respond comprehensively within the proposed survey window. The commenter requested that CMS extend the timeline for survey development and hospital response to ensure robust participation and accurate data collection.

Response: We appreciate commenters' concerns about hospitals having sufficient time to identify, validate and coordinate drug cost information across internal departments and the need to provide hospitals with advance notice of the survey and technical guidance with respect to it. However, we do not believe it is necessary to delay the proposed start of the survey to address these concerns. As we have stated in our previous responses to comments, our survey has been designed to minimize the amount of effort required by hospitals to collect and report the information. With respect to notice, in addition to the notice provided by the CY 2026 OPPS/ASC proposed rule itself, we have alerted all hospitals subject to the survey to make them aware of the potential for a survey. With respect to technical assistance, in addition to multiple guidance documents on our website, we will conduct training sessions for hospitals, hold webinars, publish extensive onboarding materials, and we have established a dedicated helpline to provide one-on-one support and assistance.

Comment: Several commenters expressed concern about the length of the survey window, arguing that 90 days was not enough time given that survey completion will require a multi-disciplinary team at any hospital, including but not limited to pharmacy, supply chain, finance, and reimbursement. One commenter argued that smaller/independent 340B-eligible hospitals that lack the appropriate infrastructure or the support of system resources would struggle to meet a 90-day deadline.

Response: As discussed in the previous comment, we have designed our survey to require as little effort as possible on the part of the hospital to collect and report the required data. Consequently, we believe that 90 days is enough time for hospitals to collect and report this data to us. Hospitals have been on notice regarding the fundamentals of the survey since the proposed rule publication in July of 2025, and the associated PRA packaged contains the outline of the survey, which is nearly identical to the final survey. Therefore, in July of 2025 hospitals were aware of the approximate drugs that would be surveyed as well as the information that they would be required to provide. Even if hospitals had not been provided this notice, we still believe 90 days is more than adequate time given that this acquisition cost information should already be at the hospitals disposal and can easily be compiled into the minimal data fields of the survey.

Comment: One commenter supported the CY 2026 OPPS/ASC proposed scope of data to be collected, stating that CMS' proposal to collect data on purchases during a 1-year timeframe of July 1, 2024 through June 30, 2025 was an "optimal" timeframe. The commenter stated that since the acquisition costs of drugs frequently change, an average acquisition cost calculated over a shorter timeframe might be skewed by temporary supply-chain issues or other factors that would cause the average acquisition cost to be under-or over-stated. In contrast, the commenter

contended, a 1-year acquisition timeframe would appropriately capture the range of acquisition costs for each surveyed drug in that year. The commenter also stated that responding to the survey with acquisition data for a 1-year timeframe would be no more burdensome than responding with acquisition data for a shorter timeframe.

Response: We thank the commenter for their support.

Comment: One commenter also supported CMS' statement that it anticipated conducting the survey no more than every 4 years, noting that this would minimize survey burden. The commenter additionally noted that a revised survey is not necessary to adjust the payment amount under section 1833(t)(14)(A)(iii)(I) of the Act. By statute, the commenter pointed out, the average acquisition costs for the drug and hospital group must be determined "taking into account the hospital acquisition cost survey data," and consequently CMS can use other data to keep payment amounts current. The commenter concluded, "Thus, if the survey indicates that the average acquisition cost for a particular drug for non-340B hospitals is equal to 3percent more than the ASP, the average acquisition cost should automatically update with CMS' quarterly updates to its ASP data so that it does not fall below or increase above the survey-determined amount of 3 percent more than the ASP."

Response: We thank the commenter for their support and input on potential ways to adjust payment amounts following the survey.

Comment: One commenter provided input on balancing data validation with confidentiality. The commenter acknowledged that some data transparency is necessary to ensure the integrity of

the payment system and appropriateness of payment but expressed concern that if data is identifiable to individual hospitals, it might suppress responses in light of the sensitivity of drug pricing data. To promote a broad response while still ensuring that third parties can replicate CMS' acquisition cost estimates by drug and class of hospital, the commenter recommended that all four data fields (total units and net acquisition costs for 340B and non-340B drugs) be made available at the hospital level with pseudonymized provider numbers, but that all hospital identifiers (for example, state or location data, NPIs, etc.) be excluded from the data sets that can be accessed by the public or those with data use agreements.

Response: We agree with the commenter that it is necessary to balance data transparency with confidentiality and appreciate the suggestion as to how we might do so. We believe that the survey we have designed achieves this balance. We of course intend to follow relevant privacy laws. Only the Department of Health and Human Services (HHS) and relevant component agencies, their contractors and representatives, and the Executive Office of the President (EOP) will have access to these data unless such data are otherwise required to be released to other parties by law. Following the collection of data and its analysis, the aggregate results of the survey will be considered when determining proposed payment rates. The proposed payment rates and calculations with aggregate data could appear in notice and comment rulemaking to ensure transparency and replicability; however, the confidentiality of individual hospitals and proprietary information would be maintained to the extent permitted by law. To the extent that acquisition costs are deemed sensitive and/or confidential, we do not intend to make such prices available in an individually identifiable manner.

Comment: Another commenter requested that Disproportionate Share (DSH) eligible Covered Entities be allowed to submit unified responses via their system Chain Home Office, be exempted from any consequences of not responding to the survey (as the commenter expects all covered entities will participate) and "limit the survey to only the information necessary to carry out the Agency's immediate policy objectives."

Response: We are not treating any hospital type or group differently for purposes of conducting this survey. All hospitals paid under the OPPS are required to respond to the survey. We note that Critical Access Hospitals are not included in the survey pool since they are not paid under the OPPS.

Comment: Many commenters opined that limiting data collection to hospitals would provide an incomplete picture of acquisition costs and that to ensure accuracy and comprehensiveness, CMS should use supplemental data sources and engage drug manufacturers and distributors and other entities involved in the supply chain to incorporate data points such as the cost of goods sold and any applicable discounts and rebates.

Response: We agree with commenters to the extent that CMS should incorporate information from supplemental data sources into the survey, and we have designed our survey to allow for the incorporation of information from supplemental data sources, including manufacturers and distributors, that are available to the hospitals. We encourage hospitals to engage with their partners, such as wholesale distributors, to ensure the accuracy of their survey submission. Additionally, we note that when considering any future payment policy, we will consider taking into account the results of the survey, as well as any additional appropriate external sources of information, such as those suggested by the commenter.

Comment: One commenter requested that CMS provide clear, detailed technical instructions well in advance of the survey opening and asked the following questions about the survey methodology:

- What specific acquisition cost elements will be required (for example, invoice price, discounts, rebates, administrative fees)?
- How will CMS ensure comparability across hospitals with different purchasing arrangements (for example, group purchasing organizations, 340B participation, direct contracts)?
- How will CMS protect sensitive hospital purchasing data from public disclosure?
- How will CMS reconcile acquisition cost data with existing manufacturer reported ASP to avoid duplication or conflicting datasets?

Response: We are asking hospitals to incorporate all rebates and discounts in their acquisition cost for each NDC – including discounts directly applicable to an individual NDC – but also those discounts that are not necessarily linked to a single NDC. That discount could be one linked to a certain invoice, or discounts linked to purchases made over a certain time period such as prompt pay discounts, wholesaler discounts, or other discounts. We understand that certain discounts may depend on whether an eligible patient receives the drug. That is true, for example, for drugs acquired through the 340B program. We are therefore asking for hospitals to separately list their acquisition costs for drug NDCs acquired through the 340B program and those drug NDCs acquired outside of the 340B program in order to ensure that all of the discounts are accurately captured and represent the hospital's acquisition costs.

We will follow all privacy laws. Only the Department of Health and Human Services (HHS) and relevant component agencies, their contractors and representatives, and the Executive Office of

the President (EOP) will have access to these data unless release of such data to other parties is otherwise required by law. In accordance with section 1833(t)(14)(A)(iii)(I) of the Act, the agency plans to use the data collected to determine acquisition costs for SCODs, and drugs historically treated as SCODs. Following the collection of data and its analysis, the aggregate results of the survey will be considered when determining proposed payment rates. The proposed payment rates and calculations with aggregate data could appear in notice and comment rulemaking; however, the confidentiality of individual hospitals and proprietary information would be maintained to the extent permitted by law. To the extent that acquisition prices for certain SCODs, and drugs historically treated as SCODs, are deemed sensitive and/or confidential, we do not intend to make such prices available in an individually identifiable manner. Acquisition cost data collected through a survey is directed by sections 1833(t)(14)(A)(iii)(I) and 1833(t)(14)(D)(ii) of the Act. We are authorized to obtain the data to inform payment for drugs paid under the OPPS.

Finally, we note this data collection is separate from ASP data collection where manufacturers submit data to CMS regarding their average sales price.

Comment: One commenter stated that CMS does not need to collect data from all institutions when it could instead use a statistical sampling method and that CMS could avoid the entire survey process by using the 340B ceiling price as the proxy for hospital acquisition costs. Another commenter suggested CMS adopt one of two sampling approaches that would reduce survey burden while ensuring accurate results. Under the first suggested approach, CMS would survey a representative sample of drugs and use the survey data and appropriate statistical analysis to determine the hospital acquisition cost for each drug.

Under the second proposed approach, CMS would confine the survey to those drugs that account for the vast majority of OPPS spending. Under this approach, CMS would use the resulting data to set payments only for the surveyed drugs based on the average acquisition cost for 340B hospitals and for non-340B hospitals pursuant to section 1833(t)(14)(A)(ii) of the Act. Because hospital acquisition cost data for the non-surveyed drugs would not be available to CMS, CMS would be required to continue to set payment for these non-surveyed drugs for all hospitals using its current average sales price methodology pursuant to section 1833(t)(14)(A)(iii)(II) of the Act.

Response: We appreciate commenters' suggested alternatives to conducting a survey of all hospitals paid under the OPPS. As mentioned previously in this section, drug acquisition cost and payment is dynamic, complex, and of great importance. No drug acquisition cost survey has been conducted for decades. Therefore, for this initial survey, we will start by surveying the universe to obtain a comprehensive data set. We intend to conduct surveys periodically, and could consider some of the sampling methodologies suggested by commenters for future surveys once we've established a baseline dataset.

Comment: One commenter referenced the following observation from the GAO's 2006 report: "Other options available to CMS for validating price data could include audits of manufacturers' price submissions or an examination of proprietary data the agency considers reliable for validation purposes." The commenter requested that CMS make it explicit in the final rule as to whether they considered these alternatives and why CMS decided to propose a hospital survey versus those alternatives.

Response: We did consider these alternatives. We decided to proceed with conducting a survey because that is the rate-setting methodology prescribed by statute. We do not believe the statute

envisions that the Secretary will rely on surveys from 2004 and 2005 to set payment rates for SCODs forever. As we have stated previously, we intend to conduct surveys periodically, and could consider some of these additional GAO suggestions for future data validation exercises and survey design once we've established a baseline dataset.

Comment: One commenter recommended that CMS refine its instructions on the calculation of the total units purchased and total net acquisition cost to account for certain situations that are not informative of the actual acquisition cost. The commenter indicated that they believed that the reporting of total units purchased should be net of units returned to the manufacturer and that such returns should also be removed from the total net acquisition costs. The commenter alleged that the proposed instructions do not address returned units, and the commenter recommended clarifying that returned units are removed from the total units purchased and from the total net acquisition cost when finalizing the survey. The commenter contended that "it would be particularly inappropriate to retain returned units in the total unit count but then apply the manufacturer's refund for those units to reduce the net acquisition cost for those drugs. Rather, the data for returned units should be removed from both data points."

Response: We refer this reader to the Draft Survey Template[3], where the draft instructions address this scenario. Specifically, the draft instructions stated for "Total Units Purchased – Non-340B" to exclude the following: "Exclude purchases intended only for inpatient use; Exclude purchases that were returned; Exclude purchases made under the 340B Program."

[3] *https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing/cms-10931.*

Comment: Several commenters requested that in the final rule CMS provide transparency regarding survey methodology, intended use of data, and potential impacts on policymaking. The commenters stated that this approach will give interested parties additional insight into the survey and may also encourage broader participation by hospitals. One commenter encouraged CMS to ensure that any survey findings are applied in a manner that is transparent, methodologically sound and reflective of the real-world costs of acquiring and delivering oncology drugs.

Response: We agree with commenters about the importance of providing transparency regarding survey methodology, intended use of data, and potential impacts on policymaking in the final rule. With respect to our survey methodology, as we explained in the CY 2026 OPPS/ASC proposed rule, we will be conducting a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including SCODs, and drugs and biologicals CMS historically treats as SCODs. With respect to the intended use of data and potential impacts on policy making, as we stated in the CY 2026 OPPS/ASC proposed rule, we intend for the survey to be completed in time for the survey results to be used to inform policymaking beginning with the CY 2027 OPPS/ASC proposed rule. Any policy that is informed by the survey data will be subject to notice and comment rulemaking. We also appreciate the commenter's suggestion to apply survey findings in a manner that is transparent, methodologically sound and reflective of the real-world costs of acquiring and delivering oncology drugs.

Comment: Several commenters requested that CMS make the survey findings public to provide transparency for policymakers, taxpayers, and providers across care settings. Other commenters

requested that time be allowed for commentary by interested parties to review the survey data prior to implementation in CY 2027.

Response: As we indicated in section 10 of Supporting Statement A[4] to our Information Collection Request under the Paperwork Reduction Act (PRA), the proposed payment rates and calculations with aggregate data could appear in future notice and comment rulemaking; however, the confidentiality of individual hospitals and proprietary information would be maintained to the extent permitted by law.

Comment: One commenter urged CMS to revise the proposed survey design to capture other hospital characteristics that might influence drug acquisition costs, rather than the singular focus on the difference between 340B and non-340B acquired drug costs.

Response: We thank the commenter for their suggestion, and we intend to consider many different hospital characteristics when analyzing the results of the data, such as hospital size, location, urban vs rural status, teaching hospital status, etc. These are all hospital characteristics that we routinely consider and analyze for various policies under the OPPS. As such, these hospital characteristics are already known; therefore, to reduce burden on hospitals submitting data, we are not asking them to submit information we already have.

Comment: Another commenter suggested that to improve transparency, hospitals should be required to submit claims data that identifies when 340B-purchased drugs are administered to Medicare patients. A commenter suggested that CMS require either a 340B or non-340B modifier to be appended to a claim in order for it to be considered complete and eligible for

[4] *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=202507-0938-017*.

payment. They recommended that CMS require this in both the OPPS and PFS and that CMS create a clearinghouse to validate 340B units.

Response: We note that based on the CY 2024 OPPS/ASC final rule with comment period, we require that all 340B covered entity hospitals paid under the OPPS report the ‘‘TB’’ modifier effective January 1, 2025, for 340B-acquired drugs and biologicals (88 FR 81791 through 81792). We may consider modifications to this policy in future rulemaking.

Comment: One commenter suggested that CMS (1) use a stratified approach with separate, volume-weighted averages for different types of hospitals when analyzing cost data to ensure payment adjustments reflect actual cost differences and do not rely on broad averages; (2) consider implementing blended or graduate payment adjustments rather than applying uniform reductions across all hospitals; and (3) establish mechanisms to monitor how payment changes affect patient access and hospital financial stability, particularly for those serving vulnerable populations.

Response: We thank the commenter for their suggestions. We'll take this feedback into consideration when analyzing and implementing future payment policy informed by the results of the survey.

Comment: One commenter suggested that CMS should further consider and address the methodology recommendations and challenges identified by the Comptroller General. The commenter maintains that while CMS claims to have "reviewed and taken into account the Comptroller General's recommendations regarding the frequency and methodology of these surveys in developing [its] proposed survey," "[s]uch consideration is not reflected in the

proposed OPPS rule." The commenter stated that when GAO conducted the survey it did not require 340B costs to be reported separately. According to the commenter, GAO identified several relevant characteristics that impacted acquisition costs, and 340B status was not included in that list. The commenter opined that "[a] large number of factors outside of covered entity status implicate drug acquisition costs; it's unreasonable to base payments on 340B status alone". The commenter also contended that CMS fails to address a critical flaw in the GAO survey that would undermine the accuracy of results and misleadingly inflate the difference in relative acquisition cost between 340B and non-340B hospitals. The commenter stated that CMS proposes that hospitals would be required to report the total acquisition cost of each drug, net of rebates and discounts but that in its report GAO stated "we found that we could not obtain data that would permit calculation of hospitals' acquisition costs, because, in general, hospitals were unable to report accurately or comprehensively on rebates". The commenter stated that CMS does not acknowledge this issue or address how it proposes to assist hospitals in more accurately reporting on rebates. To the extent non-340B hospitals are more likely to receive discounts through rebates, the survey results will reflect higher than actual acquisition costs for this group as well as an overestimate of the difference from 340B hospital acquisition costs. A survey that does not address this flaw should be questioned by policymakers as a basis for rate setting. The GAO also recommended that the survey be conducted only once or twice per decade and be used only to validate "ASP data that manufacturers report to CMS for developing SCOD rates". The commenter remarked it appears that CMS' intention is to conduct the survey periodically and use the hospital acquisition cost data on its own to set payment rates rather than use the survey to validate ASP data that is already used for payments. One commenter indicated that the rebates

component of the survey would be challenging to report, ensuring only rebates that were actually paid are considered.

Response: We disagree with the commenter's contention that we have failed to review or take into account the Comptroller General's recommendations regarding the frequency and methodology of these surveys in developing our proposed survey. With respect to methodology, we agree with the commenter that factors other than 340B covered entity status can affect drug acquisition costs and our intent in conducting the survey is to collect drug acquisition cost data which reflects those other factors. We disagree with the commenter's allegation that we are proposing to base future drug payments on 340B status alone. As we have said throughout this rule, the results of the survey will be used to inform future payment policy. We are not prejudging the results of the survey or what we may do with the results of the survey. We are asking hospitals to incorporate all rebates and discounts in their acquisition cost for each NDC – including discounts directly applicable to an individual NDC – but also those discounts that are not necessarily linked to a single NDC. That discount could be one linked to a certain invoice, or discounts linked to purchases made over a certain time period such as prompt pay discounts, wholesaler discounts, or other discounts. With respect to discounts not linked to an individual NDC, we expect hospitals to report these discounts to us as part of this survey. Hospitals are most familiar with their acquisition costs and business practices and are best positioned to determine the method of incorporating discounts received into their NDC specific acquisition costs. However, if hospitals are unable to reasonably incorporate these non-NDC based discounts, rebates, and price concessions, such as those received through a GPO, we are asking hospitals to (1) indicate whether they have such discounts for the reporting time period and, if so, (2) identify what Group Purchasing Organization (GPO) they are a member of and (3) provide

the total dollar amount of all non-NDC based discounts for the reporting time period, which will then allow CMS to best determine how to incorporate these non-NDC based discounts We acknowledge that the GAO was unable to obtain data that would permit calculation of hospitals' acquisition costs because, in general, hospitals were unable to report accurately or comprehensively on rebates at that time. However, we believe all of these discounts should be readily available in hospitals' purchasing systems, and with technology advancing considerably in the 20 plus years since the GAO survey we believe it is reasonable for hospitals to determine these types of discounts. Similarly to how there have been significant advances in technology over the past 20 years, there has also been an explosion in 340B drug utilization and spending. When the GAO conducted this survey this type of discount may not have been as prevalent; however, now that the prevalence has increased over the years we believe 340B discounts are required to be tracked similar to other discounts, rebates, and price concessions. With respect to frequency, our proposal to conduct the survey every 4 years is consistent with the GAO's recommendation that the Secretary validate, "on an occasional basis—possibly every 5 or 10 years—average sales price (ASP) data that manufacturers report to CMS for developing SCOD payment rates."[5] Finally, with respect to the commenter's allegation that we might use the hospital acquisition cost data on its own to set payment rates rather than use the survey to validate ASP data that is already used for payments, we emphasize that were we to use survey data to set payment rates in future rulemaking, doing so would be consistent with section 1833(t)(14)(D)(ii) of the Act which requires "the Secretary to conduct periodic…surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates."

[5] *https://www.gao.gov/assets/gao-06-372.pdf*.

Comment: Many commenters opposed our intent to propose and seek comment on any payment rates for SCODs based on the survey results in CY 2027 rulemaking. These commenters expressed concern about future payment reductions based on the results of the survey and urged CMS to abandon the survey to avoid its results being used to reduce Medicare reimbursements in 2027 and beyond. In these commenters' view, Medicare payment is already too low and further reductions resulting from the survey would be unsustainable. Many commenters expressed concern that future payment reductions would come at the expense of services provided to patients.

Response: We thank the commenters for their input. It is premature to consider the payment consequences of a survey we have not yet completed, and commenters' policy concerns of those payment consequences are therefore out of scope for purposes of this final rule with comment period regarding CY 2026.

Comment: Many commenters expressed concern about the disproportionate effect future payment reductions resulting from the survey would have on safety-net hospitals and rural providers. Some of these commenters asked CMS to exempt all rural hospitals, including SCHs, MDHs, Low-Volume Hospitals (LVHs), Rural Emergency Hospitals (REHs) and small rural hospitals with 100 beds or less from any such reductions. One commenter requested an exemption from any payment reductions resulting from the survey for the three freestanding cancer centers that currently participate in the 340B program.

Response: We thank the commenters for their input. It is premature to consider the payment consequences of a survey we have not yet completed, and commenters' policy concerns of those

payment consequences are therefore out of scope for purposes of this final rule with comment period regarding payment amounts for CY 2026.

Comment: One commenter stated that CMS should not use the proposed survey to set OPPS rates because the CY 2026 OPPS/ASC proposed rule discusses use of the survey results in future rate-setting in ways that could be inconsistent with the OPPS statute. The commenter states that while CMS acknowledges the statutory requirement to conduct a survey of acquisition costs on a periodic basis, CMS does not clarify how it would adjust payments outside of survey periods. By contrast, current policy updates payments quarterly based on Medicare's ASP, ensuring payment rates reflect current market drug costs. The CY 2026 OPPS/ASC proposed rule includes no such similar adjustment for routine adjustments to costs. The commenter states that section 1833(t)(14)(A)(iii)(I) of the Act requires that the payment for a specified covered outpatient drug should be equal to the average acquisition cost for the drug for that year. Given the significant changes being implemented by and further proposed by this Administration— such as changes resulting from proposed Pharmacy Benefit Manager (PBM) reform, Medicare fair price negotiations, and international price matching, as noted above — a survey fielded at the start of CY 2026 is unlikely to reflect the acquisition cost even in CY2027, never mind future years.

Response: We thank the commenters for their input. It is premature to consider the payment consequences of a survey we have not yet completed, and commenters' policy concerns of those payment consequences are therefore out of scope for purposes of this final rule with comment period regarding payment amounts for CY 2026.

Comment: Several commenters stated that their experience from the 2018-2022 period demonstrated that reducing 340B payment rates set a dangerous precedent as private pharmacy benefit managers and third-party payers could use such a reduction to justify additional reductions for 340B drugs, further weakening the healthcare safety net.

Response: We thank the commenter for their input. It is premature to consider the payment consequences of a survey we have not yet completed, and commenters' policy concerns of those payment consequences is therefore out of scope for purposes of this final rule with comment period regarding payment amounts for CY 2026.

Comment: Several commenters requested that CMS provide a clear methodology for data use and protections against retroactive payment adjustments based on survey data.

Response: We are not sure what these commenters are requesting. It is premature to speculate on how a survey we have not yet completed might best be used to set future payment policies, and so commenters' concerns about hypothetical uses of the survey is therefore out of scope for purposes of this final rule with comment period regarding payment amounts set without reference to that survey.

Comment: One commenter stated that using the results of the survey as the sole basis to set drug reimbursement rates contravenes the guidance of the U.S. Comptroller General and the GAO as stated in the GAO's 2006 report to Congress: "A key lesson for CMS that we learned from conducting the 2004 MMA-mandated hospital survey is that such a survey would not be practical for collecting the data needed to set and update SCOD rates routinely. However, it would be useful, on occasion, for CMS to survey hospitals so that the rate-setting data it obtained from

other sources could be validated by an independent source." The commenter contended that, despite refencing this report in the proposed rule, CMS provides no substantive explanation for disregarding the recommendation and appears poised to use the survey not as a validation mechanism but as the foundation for setting payment rates. The commenter alleged that CMS' failure to address or justify its departure from this key lesson raises serious questions about the methodological soundness of the proposed survey and the legality of this rulemaking exercise. This will ultimately lead to a circumvention of Congressional intent in implementing the 340B Program, which is indisputably intended to support safety net providers – not to reallocate savings intended for them to all Medicare OPPS providers. The commenter stated that other mechanisms, such as surveying wholesaler distributors or using drug manufacturer data based on chargeback and other data commonly used by these entities, should first be used to collect baseline data which should then be validated.

Response: As we note, we anticipate that the results of the survey will be used to inform future payment policy. We also note that we may not rely solely on survey data to inform our drug pricing policies. Any policy to alter OPPS payment rates for drugs informed by this survey would be included in the CY 2027 OPPS/ASC rulemaking, and would be subject to notice and comment rulemaking.

Comment: Several commenters stated that the Congress has not directed the executive branch to reduce payments to 340B providers and did not direct CMS to introduce new policies that seek to reduce the Federal government's commitment to serving low-income Americans.

Response: We thank the commenters for their input. We have not proposed reductions to 340B providers in this final rule with comment period, and so these comments are out of scope.

Comment: Many commenters implored CMS not to use the survey to lower payments to 340B hospitals. One commenter acknowledged that the CY 2026 OPPS/ASC proposed rule does not explicitly state CMS' intent to use the survey to lower payments to 340B-acquired drugs only but alleges that "the proposed structure of the survey foreshadows CMS' future actions." The commenter stated that a reduction in Medicare payment rates to 340B hospitals significantly erodes the intent of the 340B program and that the 340B program is critical to ensuring that low-income and other disadvantaged people have access to the types of services best provided by essential hospitals. The commenter alleges that hospitals participating in the 340B program operate on margins significantly narrower than margins of other hospitals, with many operating at a loss. These hospitals, the commenter contends, which serve a high number of low-income individuals, are already struggling under insufficient Medicare and Medicaid payments. Given the fragile financial position of essential hospitals, policy changes that jeopardize any piece of the patchwork of support on which they rely, including the 340B program, can threaten their ability to maintain critical services. Reducing Medicare payments for 340B hospitals would have many negative consequences for patients and providers and would not save the Medicare program any money. Any changes to OPPS must be made in a budget-neutral manner. Thus, a cut in funding for 340B hospitals does not go back to the Medicare program or directly to beneficiaries; instead, the funds would be redistributed to non-340B hospitals at the expense of 340B hospitals and their patients.

Response: We thank the commenters for their input. We have not proposed reductions to 340B providers in this final rule with comment period, and so these comments, including speculation

about legislative intent and policies that could be enacted by future legislation are out of scope for purposes of this CY 2026 OPPS/ASC final rule with comment period.

Comment: Some commenters supported our intent to propose and seek comment on payment rates for SCODs based on survey results in CY 2027 rulemaking. One commenter encouraged CMS to ensure a transparent process in analyzing information obtained from the survey, to the extent possible, in advance of CY 2027 proposed rulemaking.

Response: We appreciate commenters' support.

We noted in the CY 2026 OPPS/ASC proposed rule that under section 1833(t)(14)(D)(iii) of the Act, the surveys must 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. Consequently, we stated that we would seek an adequate response rate to the survey and that surveyed hospitals had an obligation to respond to the survey. We indicated that hospitals had ample notice in the CY 2026 OPPS/ASC proposed rule regarding the intent and the details of the OPPS Drug Acquisition Cost Survey so we expected all hospitals would submit their acquisition costs in a timely manner to CMS. We stated that we understood that hospitals have significant drug acquisition costs, and so, consistent with the Comptroller's General experience conducting earlier drug acquisition cost surveys in which 83 percent of the hospitals surveyed provided usable data,[6] we anticipated hospitals would want to respond to the survey to demonstrate to CMS these costs. We requested comment from readers on whether we should

[6] *https://www.gao.gov/assets/gao-06-372.pdf*. Page 7.

make responding to the survey a mandatory requirement of all hospitals paid under the OPPS through 1833(t)(14)(D)(iii) of the Act.

Comment: Many commenters stated that CMS lacks the statutory authority to make the survey mandatory and requested that CMS state in the final rule that the survey is voluntary. These commenters stated that section 1833(t)(14)(D)(iii) simply sets forth the requirements for a survey and does not provide the agency with the authority to mandate hospital responses. These commenters contended that if the Congress wanted to require hospital participation in a drug acquisition cost survey or allow HHS to take action for a non-response, it would have done so, as it has in other contexts. One commenter, referencing the survey previously conducted by GAO, suggested that the level of response to that survey demonstrates that making completion of the survey mandatory is not necessary to ensure sufficient responses. The commenter stated that when GAO previously conducted the survey it provided no incentives or penalties to encourage participation. Even without any incentives in place, GAO received usable data from 83 percent of the hospitals.

Other commenters supported making the survey mandatory, arguing that doing so was critical to ensuring that the wide range of hospital acquisition costs is appropriately accounted for and reflected in the survey results and in CY 2027 OPPS rates. Several commenters stated that making the survey mandatory is the only way for CMS to ensure it collects complete and usable data.

Response: Under section 1833(t)(14) (D) of the Act, the Secretary "shall conduct periodic surveys" which "shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost" and which the Secretary shall under

section 1833(t)(140(A) of the Act "tak[e] into account" when determining the average acquisition cost of drugs for a year to set payment policy. Hospitals attempt to read a conditional into the text of the statute: the Secretary may use cost acquisition survey data to set policy "only if" that data generates a statistically significant estimate of the average hospital acquisition. But that is not what the statute says. Rather, it provides that the survey sample "shall" generate such an estimate. We read that instruction from the Congress to impose obligations on both the Secretary to design such a survey and on hospitals generally to respond the survey, just as they did when GAO conducted the survey in 2004 and 2005. We agree that section 1833(t)(14)(D) of the Act does not itself mandate specific consequences either on CMS for failing to design the survey it describes or on hospitals for failing to respond to that survey. We reiterate the reciprocal obligations imposed by section 1833(t)(14)(D) of the Act on CMS and hospitals alike, however, in light of certain comments suggesting that some hospitals might be planning to coordinate non-responses. The lack of a response to this required survey is still meaningful data to CMS which can be taken into consideration to inform future payment rates in future rulemaking.

In the CY 2026 OPPS/ASC proposed rule, we welcomed comment on how we might propose to interpret non-responses to the survey. For example, since a failure on the part of a hospital to respond to the survey could suggest that the hospital has minimal acquisition costs, or has lower acquisition costs than an otherwise similar hospital that responds to the survey and so is withholding its response strategically, we stated in the CY 2026 OPPS/ASC proposed rule that we might, if the data so suggested, determine that groups of hospitals who do not respond to the survey have lower acquisition costs for SCODs than their otherwise similar counterparts under

section 1833(t)(14)(A)(iii)(I) of the Act. In such instances, we stated that we would consider various appropriate ways, taking into account the hospital acquisition cost survey data, to determine the average acquisition cost. One method we said we might consider, depending on the cost survey data, could be to use the lowest acquisition cost reported among otherwise similar responding hospitals as a proxy for the average acquisition costs for hospitals that do not respond to the survey. We also stated that we might also consider supplemental data sources to inform our determination of average acquisition costs for hospitals for whom we lacked cost acquisition survey data. For example, we said we might consider using, as available, pricing from the FSS[7]; 340B ceiling price[8]; ASP plus 6 percent, zero percent or another percentage; or other recognized drug pricing for payment of hospitals that do not respond to the survey.

We stated that we could also consider a hospital's non-response to the survey when determining how to package drug costs for particular hospital groups. We noted that under section 1833(t)(2)(B) of the Act, the OPPS establishes groups of covered HOPD services, namely APC groups, and uses them as the basic unit of payment. In the case of much of the care paid under the OPPS, we indicated that we viewed a complete service as potentially being reported by a combination of two or more HCPCS codes, rather than a single code, and establish payment policies that support this view. We stated that ideally we would consider a complete HOPD service to be the totality of care furnished in a hospital outpatient encounter or in an episode of care. We noted that we generally package payment for items and services that are typically ancillary and supportive into the payment for the primary diagnostic or therapeutic modalities in which they are used rather than pay for them separately. We indicated that as we noted previously in the CY 2026

[7] FSS pricing from the Veteran Affairs' (VA's) pharmaceutical pricing database is publicly available at the NDC level and published at *https:// www.va.gov/opal/nac/fss/pharm Prices.asp*.

[8] section 340B(a)(1) of the Public Health Service Act. *https://www.hrsa.gov/about/faqs/what-difference-between-340b-ceiling-price-package-adjusted-price-which-are-both-published-340b*.

OPPS/ASC proposed rule, if a hospital does not submit its acquisition cost data, it could suggest that the hospital has minimal acquisition costs. We also noted that if the hospital has minimal acquisition costs for drugs, that could support viewing those costs as ancillary or supportive, and we might, if the data supported it, conclude that hospitals who do not report their drug acquisition costs lack meaningful additional, marginal costs related to their acquisition of these drugs and, as such, their drugs costs should not be paid separately but rather should be packaged into the payment for the associated service.

We sought comment broadly on how to approach payment to hospitals for drugs usually paid under the OPPS absent a hospital's response to the survey.

We received many comments in response to our request for comment.

Comment: Most commenters opposed CMS modifying its payment approach based on non-responses to the survey. Many of these commenters stated that CMS lacks the statutory authority to do so. One commenter stated that the statute does not contemplate CMS "filling in gaps from non-responses". In the commenter's view, the statute instructs the agency to collect data from "a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered drug". The commenter stated that CMS cannot "manipulate an otherwise insufficient sample by using other hospitals' proxy data for hospitals that do not respond". The commenter also stated that the methodology CMS posits to interpret non-responses lacks reasoning. The commenter alleged that CMS points to no evidence for any conclusion that groups of hospitals that do not respond to the survey have lower acquisition costs, and certainly no justification for why "us[ing] the lowest acquisition cost reported among otherwise similar responding hospitals as a proxy" would be a remotely accurate methodology. The commenter concludes that the Congress, in section 1833(t)(14)(A)(iii) of the

Act, dictates drug reimbursement be based on either hospital acquisition cost data, or the average price of the drug. The commenter contends that substituting data such as "pricing from the FSS; 340B ceiling price; ASP plus 6 percent, zero percent or another percentage; or other recognized drug pricing for payment of hospitals" would contravene explicit congressional intent.

Another commenter stated that the statute authorizes CMS to conduct surveys to inform payment rates for specified covered outpatient drugs, but it does not authorize CMS to "penalize" hospitals by reducing reimbursement or applying alternative payment methodologies based solely on survey non-participation." The commenter claimed that CMS' suggestion that it may pay non-responding hospitals at rates below ASP plus 6 percent or exclude them from future rate-setting processes is not supported by the statutory text and represents an overreach of administrative authority. The commenter explained that hospitals may have legitimate operational, legal, or resource-based reasons for being unable to complete the survey within the prescribed timeframe and that "imposing financial penalties in response to non-compliance with a voluntary or burdensome survey process, particularly one that lacks finalized rulemaking and OMB approval, would be both unlawful and inequitable." The commenter urged CMS to clarify that survey participation would not be used as a basis for punitive reimbursement decisions and to ensure that any future payment methodologies are grounded in statutory authority and fair process. Many other commenters also claimed that CMS' imputing data to a non-response would unfairly penalize hospitals for simply lacking the resources to complete the survey. These commenters pointed out that a non-response is not necessarily indicative of lower acquisition costs as it could reflect data collection challenges or unclear instructions rather than lower costs. One commenter alleged that CMS does not cite any evidence that non-response means minimal acquisition costs. The commenter stated that both GAO and CMS acknowledge the burden of

this survey, which could clearly be a reason for non-response. In the commenter's view, interpreting non-responses is an attempt to make the survey effectively mandatory, even though the commenter does not believe CMS has the authority to make the survey mandatory. The commenter contended that CMS is aware that the drugs at issue can be prohibitively expensive, particularly for hospitals serving disproportionate shares of low income individuals, and that if CMS does not pay adequately for hospitals' drug costs it will not only undermine the financial stability of hospitals but will impact Medicare patients' access to critical medications. Moreover, the OPPS statute requires CMS to pay for these drugs either based on the survey or based on ASP; CMS does not have the authority to eliminate payment for these drugs.

Many commenters stated that CMS' imputing data to a non-response would result in a survey that would fail to satisfy the requirement under section 1833(t)(14)(D)(iii) of the Act that the survey "…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". Several commenters stated that absent a statistically significant number of responses, CMS cannot implement changes to reimbursement rates that vary by groups of hospitals for separately payable drugs under the OPPS.

One commenter noted that section 1833(t)(14)(D)(i)(II) of the Act requires the Secretary to take into account recommendations from the Comptroller General regarding the methodology of the survey and that when the GAO conducted its survey, it explicitly excluded non-responses from its price calculations stating it was "not appropriate for [its] purpose." Several commenters requested that non-responding hospitals be excluded from the survey dataset.

One commenter supported using the FSS and other information as a mechanism of determining hospital costs for drugs. Another expressed support for the proposal to use the lowest reported acquisition cost as a proxy for non-responding hospitals.

Several commenters suggested that in instances where hospital pricing information is not sufficiently provided, CMS should (1) for non-responsive 340B hospitals, assume the price of the drug to be the 340B ceiling price and (2) for non-responsive non-340B hospitals, assume the price of the drug to be the average acquisition cost from a similarly situated non-340B hospital (similar size, location, etc.) that responded to the survey. Other commenters suggested that for non-responding non-340B covered entities, CMS should assume the lesser of the median cost or mean cost of similarly situated non-340B hospitals.

Several commenters recommended that just as any estimations used to address non-responses must consider 340B status, any findings derived from this survey should be stratified by whether the reporting hospital participates in the 340B Program.

Response: We thank commenters for their feedback regarding what we might do in the scenario in which we do not receive responses from all hospitals paid under the OPPS. Under section 1833(t)(14)(A)(iii)(I) of the Act, the Secretary may set average drug prices – which may vary by hospital group – by "taking into account" the results of survey. We have made no final decision on how, if at all, we will "tak[e] into account" non-responses, which is premature before we analyze the data we receive. Any policies based on this discussion will be included in future rulemaking, as soon as CY 2027, if we adopt payments rates based on the results of the survey.

Comment: Many commenters alleged that, given the complexity and scale of the required data collection and analysis, conducting the survey will impose a significant burden on hospitals and

that CMS's estimate of that burden grossly underestimates the cost, time and resources that will be necessary to complete the survey. Commenters also stated that CMS is wrong to assume that the reporting will be done by pharmacy technicians and that the survey will actually be completed by pharmacists, which will cost more. One commenter opined that completing the survey would demand the concerted effort of multi-disciplinary teams, including pharmacy, supply chain, finance, legal, and reimbursement professionals, far beyond what pharmacy technicians alone could provide. The commenter stated that CMS's own Information Collection Review document "acknowledges the breadth of the undertaking, but fails to account for the extensive coordination needed with vendors and suppliers, from whom much of the requested data must be sourced. The time and resources required to collect, clean, analyze, and accurately report thousands of distinct drug prices would divert critical personnel from patient care and other essential hospital functions". Many other commenters also emphasized the point that the cost of completing the survey would come at the expense of the hospital's ability to provide essential care to patients and quoted the GAO's 2006 report to the Congress in which the GAO concluded that the surveys it conducted "created a considerable burden for hospitals" and that to submit the required price data hospitals "had to divert staff from their normal duties, thereby incurring additional costs." Many commenters stated that the financial burden of completing the survey would be exacerbated by upcoming Medicaid and Medicare reductions under the Inflation Reduction Act.

Response: We have taken the burdens on hospitals of completing the survey and the GAO's conclusions relating to that burden very seriously in the design and implementation of the survey. We have created a survey instrument and survey process that we think will minimize, to the greatest extent possible, the staffing and financial burden on hospitals of collecting and

reporting the necessary information to CMS. The survey instrument consists of a streamlined online portal, where hospitals can either directly enter acquisition costs or download and reupload an excel template of acquisition costs. There will be technical assistance available for those with any issues that arise during the submission process. We have taken the feedback from commenters into careful consideration when finalizing the survey tool. We believe future surveys will be periodic in nature, as to limit the burden that hospitals face on a reoccurring basis.

We were persuaded that the role of the pharmacist in the data collection effort may be greater than 1 hour. Therefore, based on comments, we are now estimating 1 working day of 8 hours, for a pharmacist to assist in completing the survey. This is reflected in Table 160. Additionally, reflected in Table 160 is an updated number of total hospitals expected to respond to the survey. This number was determined by assessing which CCNs were paid under the OPPS during the survey period for a drug or biological under the OPPS. Additionally, in the rare event that a hospital is paid under the OPPS, but does not have any acquisition costs for the entire year period that is being surveyed, we'd still expect a submission by the hospital. During the CY 2026 OPPS/ASC proposed rule stage, we published a draft list of the NDCs that would be included in the survey, if finalized, so hospitals would have ample opportunity to review and prepare to report their acquisition costs for those NDCs. We noted there may be slight adjustments to this NDC list, but we expected the final list would be similar to the draft list. We have refined this list by removing certain NDCs that were not separately payable under the OPPS to ensure that we are only surveying necessary drugs.