

Comments Related to the Statutory Authority

Comment: Similar to comments made during the 60-day comment period, several commenters contended that CMS' plan to collect acquisition cost data from 340B hospitals only, and not from other providers that are paid under the OPDS, but that do not participate in the 340B program, violates section 1833(t)(14)(D)(iii) of the Social Security Act (the Act). Specifically, they stated that although the Medicare statute allows for a survey of hospitals on drug acquisition costs, the statute does not allow the Secretary to target a subset of hospitals for the survey. While commenters agreed that the Secretary has the authority to set payment rates that vary by hospital group based on relevant hospital characteristics such as volume of outpatient services, in accordance with section 1833(t)(14)(A)(iii)(I), they maintained that the Secretary is not permitted to survey only one group of hospitals for acquisition costs for purposes of setting the payment rates under the OPDS. Furthermore, commenters stated that section 1833(t)(14)(D)(iii) requires that surveys conducted by the Secretary "shall 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 (SCODs)."

Response: As stated in our response to similar comments during the original comment period, we disagree with the commenters' assertion that collection of drug and biological acquisition cost data from 340B hospitals is contrary to law. We disagree with the commenters' interpretation of section 1833(t)(14)(D)(ii) or (iii) that the survey of hospital acquisition costs for SCODs must be administered to all hospitals or all hospital types. Section 1833(t)(14)(D) does not require the Secretary to survey all hospitals, it requires Medicare to have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each SCOD. The statute does not prescribe how we develop the sampling methodology. Surveying 340B hospitals, for which average sales price (ASP) does not serve as a reliable proxy for their acquisition costs, is necessary to accurately determine payment amounts for drugs acquired under the 340B program. However, we do not believe it is necessary to survey non-340B hospitals because we already have ASP data, which are an adequate proxy of the average drug acquisition costs of such providers. Surveying non-340B hospitals would unnecessarily burden such hospitals, for which we already have an adequate proxy for drug acquisition costs.

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Unlike the reasonable proxy that exists for average acquisition drug costs for non-340B enrolled hospitals (that is, ASP), we believe that the significant drug acquisition cost discounts that 340B participating hospitals receive may vary significantly from those received by hospitals not participating in the 340B program; accordingly, 340B enrollment status is a relevant characteristic for drug acquisition costs. The statutory provision at issue – section 1833(t)(14)(A)(iii)(I) – explicitly states that the average acquisition cost for a drug for a year “at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered OPD services or other relevant characteristics).” We believe it is within the Secretary’s discretion under section 1833(t)(14)(A)(iii)(I) to choose to distinguish between hospital groups based on whether or not they are covered entities eligible to receive drugs and biologicals at discounted rates under the 340B program. We also note that section 1833(t)(14)(D)(ii) refers to use of the hospital acquisition costs for SCODs in setting payment rates under subparagraph (A), and therefore, we believe it is appropriate to read the two provisions together to permit the Secretary to survey 340B hospitals only. Conversely, no provision compels the Secretary to impose an unnecessary survey burden on non-340B hospitals, for which we have an adequate proxy for average acquisition drug costs.

Comments Related to Survey Burden

Comment: Commenters stated the survey would represent considerable burden for hospitals already operating on thin margins and the survey burden may be insurmountable. Specifically, commenters stated that the "extensive mathematical calculations, requiring analysis of tens of thousands of units of data, would bring in the risk of human error that could undermine the reliability of the data." The commenters asserted that CMS can convert NDCs to HCPCS on its own and should therefore minimize the burden of the collection by doing so. Commenters suggested that hospitals should be allowed to report their drug acquisition cost data using NDCs, rather than HCPCS codes, because several hospitals track their drug purchases by NDC. Some commenters argued that they should not have to report the "Q4 2018 Payment Rate" and "Q1 2019 Payment Rate" because providing such information would require significant time and resources and commenters state the agency already has this information. Additionally, several

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commenters expressed concern with having to convert NDCs to HCPCS codes and then to report the acquisition costs at the HCPCS unit amount (e.g., 1 mg) instead of the price per package size.

Furthermore, commenters noted that CMS shortened the survey response period, from approximately one month to 18 days, and pointed out that hospitals were given nearly four months to respond to the Government Accountability Office (GAO) 2004. Commenters stated that this reduced survey response period would impose a strain on hospitals' limited resources and would make it difficult for them to respond to the survey in the time allotted.

Also, a commenter indicated that in its 2004 survey, conducted in accordance with section 1833(t)(14)(D)(i), the GAO acknowledged that hospital acquisition costs and hospitals' information systems are diverse and produce acquisition cost data in different formats (<https://www.gao.gov/assets/250/249967.pdf>). The commenter further noted that in 2005, the GAO accepted data from hospitals in any format in an effort to make the task of submitting data as easy as possible for hospitals in order to encourage their cooperation. Finally, the commenter noted that, according to the GAO, the ability of hospitals to submit the data in any format was "critical to achieving good response rates." The commenter contended that "CMS is requiring hospitals to submit the data in a format that will reduce the burden on CMS as the collector of the data without regard for the burden placed on hospitals by not providing for alternative submission formats or methods." The commenter argued that, in light of the GAO findings of survey burden from the collection effort in 2004, CMS is disregarding its responsibility, under the PRA, to minimize the burden of the collection.

Commenters continued to state, as they did during the 60-day comment period, that completing the survey would drastically exceed the estimated 48 hours to complete. Further, commenters alleged that the survey constituted a Paperwork Reduction Act (PRA) violation, in part because CMS did not explain the purpose of collecting data, or how CMS intends to use this information. Commenters stated that the survey will not produce useful data or meet the "practical utility" standard required by the PRA, noting that the information taken must be useful to the government in an actual and not merely theoretical way. Commenters contended that the burden on hospitals is inconsistent with the Patients over Paperwork initiative and would take valuable time away from patient care.

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A commenter argued that a smaller, statistically valid sample size would be more appropriate than surveying all 340B-participating hospitals. The commenter asserted that actual acquisition costs for 340B drugs are largely consistent across different 340B-covered entities based on 340B statutory pricing calculations. Thus, the commenter argued, surveying all 340B-participating hospitals is unnecessary for collecting the desired information and is overly burdensome for all parties involved, including CMS.

Response: With respect to the 2004 GAO survey design, the GAO survey was limited in scope in that it was designed to collect information for only 62 SCODs; however, the GAO survey required hospitals to submit invoice pricing, which we believe would be significantly more burdensome for hospitals than the web-based survey submission we are adopting. As GAO noted, such a survey would not be practical for collecting the data needed to set and update SCOD rates routinely, but would be useful for validating, on occasion, CMS’s rate-setting data. Specifically, GAO recommended that the Secretary “seek to ensure that CMS’s SCOD payment rates are based on sufficiently reliable data by (1) validating data collected on drug prices and (2) basing payment rates for each radiopharmaceutical SCOD on the price of a ready-to-use unit dose.”

Taking into account the recommendations and lessons learned from the GAO survey, we have not imposed a survey burden at all in the years since the GAO survey was conducted, and we designed the current survey to minimize the burden on providers while seeking to collect data for all SCODs to assist us in determining more accurate pricing, which, for 340B hospitals, we believe can be confirmed somewhat by our ability to compare reported prices to ceiling prices. Because the “ceiling” price is the highest possible price that a 340B hospital would pay to acquire a 340B covered outpatient drug, we would anticipate that the acquisition prices reported to us would be no higher than the ceiling price amount. Further, we note that the GAO survey did not include 340B drugs, so this survey is unique in the respect that it only seeks acquisition costs for hospitals that enrolled in the 340B program, not all hospitals nationwide. Additionally, based on commenters’ feedback from the original comment period and 30-day comment period, we revised the survey to include prepopulated HCPCS codes for each SCOD, drug name/short

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descriptors, dosage associated with HCPCS codes, OPPS Q4 2018 payment rates, and OPPS Q1 2019 payment rates, all of which will further reduce the burden of the survey. CMS has established, through a contractor, a website for hospitals to upload the survey worksheet, whereas previously hospitals would have had to email their submissions to their individual Medicare contractors. We believe this will ease the reporting burden that many commenters shared while allowing CMS to capture the appropriate data.

While the current survey would necessitate some basic conversions of units to report based on the HCPCS code descriptor unit amount instead of the per package amount by NDC, we do not believe that the current survey methodology imposes a significant burden on hospitals because hospitals already report drug data at the HCPCS unit level to bill Medicare. As described later, we have established a web portal to streamline reporting for hospitals (rather than hospitals having to report via email submission), and we have set up a hotline that hospitals can call should they encounter any technical issues. The 340B Survey Technical Helpdesk hotline number is 1-833-886-5682. Further, the web portal includes an option where the hospital can select the “Quick Survey” method to indicate that it would prefer not to submit any individual data and would instead prefer that we use ceiling price data for their submission because that is an adequate representation of their hospital acquisition costs. For hospitals that elect to submit individual drug acquisition cost data, we believe hospitals are very familiar with NDCs from a purchasing standpoint, and with HCPCS codes from a Medicare billing perspective. 340B hospitals have obviously been performing these calculations to bill Medicare for payment using HCPCS units. To the extent some hospitals may still have questions about converting drug purchasing units to HCPCS code units, we have included examples in the “Centers for Medicare & Medicaid Services (CMS) Hospital Survey for Specified Covered Outpatient Drugs (SCODs) Average Acquisition Cost – Instruction Sheet” under Appendix B. We note that these calculations can easily be performed in an Excel spreadsheet if hospitals do not have access to a tool that automatically converts their drug units to HCPCS. As stated previously, hospitals bill and are paid by Medicare based on reporting of HCPCS code units, so we expect that all hospitals who have billed Medicare for drugs should be very familiar with using HCPCS code unit formats.

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As stated in response to comments from the 60-day comment period, we continue to believe that the estimated 6 working days (48 total hours) is reasonable given that the requested information should be readily available to hospitals for their institutional accounting purposes. Based on commenters' feedback from the original comment period, we revised the survey to eliminate the request for information at the hospital provider-based department (PBD)-level. Instead, the survey will permit hospitals to respond at the hospital level. This obviates the need for tracking data based on which department used the drug. As noted above, we have also added an option for hospitals to use the "Quick Survey" option on the web portal indicating that the hospital would like us to use 340B ceiling prices in lieu of submitting a survey with individual drug-by-drug information because those prices reflect their hospital acquisition costs. This option should almost completely eliminate any burden associated with filling out the survey.

With respect to the comments about the practical utility standard, as we stated in response to similar comments from the original comment period, we note that the PRA seeks to:

- Minimize the paperwork burden on the public and other entities.
- Ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared, and disseminated by or for the Federal Government.
- Improve the quality and use of Federal information to strengthen decision-making, accountability, and openness in Government and society.
- Minimize the cost to the Federal Government of creating, collecting, maintaining, using, disseminating, and disposing of information.
- Ensure the integrity, quality, and utility of the Federal statistical system.¹

This information collection is in accordance with the authority granted to the Secretary under section 1833(t)(14)(D) of the Act, and may be used to inform payment rates under the Medicare program for drugs purchased under the 340B program. We are exercising explicit statutory authority under section 1833(t)(14)(D) to collect information regarding hospital acquisition costs for drugs. The acquisition cost data hospitals submit in response to this survey will be used to

¹ <https://www.opm.gov/about-us/open-government/digital-government-strategy/fitara/paperwork-reduction-act-guide.pdf>

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help determine payment amounts for drugs acquired under the 340B program, which demonstrates the practical utility of the information collection. We want to ensure that the Medicare program pays for SCODs purchased under the 340B program at amounts that more accurately reflect what hospitals actually pay to acquire the drugs. This will provide a safeguard for Medicare trust fund dollars, maintain beneficiary access to these drugs, and allow beneficiary cost-sharing to be based on the amounts hospitals actually pay to acquire the drugs.

Regarding the survey response timeframe of 18 days, CMS believes this is an adequate timeframe to complete this survey; however, we are revising the timeframe to **about** 3 weeks in order to allow hospitals adequate time to complete the survey, and we further note that hospitals are welcome to use the Quick Survey submission if they so choose and there should be very little time and effort involved with that option.

We appreciate the comment that acquisition costs for 340B drugs are largely consistent across different 340B-covered entities based on 340B statutory pricing calculations, however, we disagree that a smaller sample would be a better approach or yield more accurate results. We note that the statute permits, but does not require, sampling, and that as shown above sampling is unnecessary here because we can survey all 340B hospitals without creating unnecessary burdens. We believe that the commenter may have been concerned about burden associated with all 340B-enrolled hospitals submitting the survey, and note that we have already taken steps to reduce survey burden by allowing reporting at the hospital CCN-level rather than requiring each hospital provider-based department to report individually; establishing a web portal to streamline survey submission; and, importantly, making a “Quick Survey” option available under which hospitals would not be required to fill out any specific drug acquisition cost data (340B ceiling price data is being used for hospitals that select this option).

Comment: Commenters requested, as they did during the 60-day comment period, that in an effort to reduce burden, rural hospitals, including rural referral centers (RRCs), and children's hospitals, be excluded from the survey population. One commenter cited that rural hospitals have considerably fewer resources than others in the 340B community. Another commenter cited that children's hospitals provide care to only a small number of Medicare beneficiaries. The

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commenter stated the information from children's hospitals would not improve the information collection request, but would significantly increase the administrative burden on children's hospitals. Furthermore, the commenter contended that the marginal utility of additional data from a small number of children's hospitals outweigh the burden this survey would impose. In addition, another commenter argued that critical access hospitals (CAHs) should be excluded from the information collection because CAHs are not paid under the OPSS.

Response: As stated in response to comments from the 60-day comment period, while current 340B payment policy exempts rural sole community hospitals, Medicare prospective payment system-exempt cancer hospitals and children's hospitals from the payment reduction, CMS is seeking to acquire data from all 340B-participating hospitals paid under the OPSS for drugs acquired under the 340B program for the last quarter of 2018 and the first quarter of 2019 so that we may appropriately capture acquisition costs from all providers participating in the 340B program. CAHs are not paid under the OPSS at section 1833(t) of the Act, and this is codified in the regulations at 42 CFR § 419.20(b)(2). Accordingly, since CAHs are not paid under the OPSS, they are therefore not required to submit the survey. The survey instructions were updated to provide additional clarity. As previously discussed, the survey was designed for ease of stakeholder completion and to reduce unnecessary burden. And, again, 340B hospitals will have the option to use the “Quick Survey” method to indicate that the 340B ceiling price is an accurate representation of their acquisition costs.

Comments Related to the Survey Methodology and Non-Disclosure Provision

Comment: Commenters contended the survey is fatally flawed and will not produce useful data to calculate 340B hospitals’ average drug acquisition costs. Commenters alleged the average pricing data reported by HCPCS codes do not identify average acquisition costs because hospitals use multiple NDCs under a given HCPCS code and each NDC could be priced higher or lower than other NDCs used under the same HCPCS code. The commenter provided an example of a hospital using high-priced NDCs for part of a quarter and then a lower-priced NDC for the rest of the quarter. The commenter alleged that reporting the price of each of the two

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NDCs does not identify the average acquisition cost of the drugs used under that HCPCS code for that quarter because it does not account for the different quantities of hospital drug purchases at these different prices. Even if hospitals choose to provide CMS with the price per individual NDC rather than the price per HCPCS code, the commenter stated that CMS will not be able to calculate hospitals' average acquisition costs, as CMS asks hospitals to report only the price, but not the volume. Commenters alleged the lack of volume renders the data meaningless.

Response: We disagree that the information collection is flawed by not taking into account the purchase volume. An average acquisition cost is just that—an average. Nevertheless, to the extent that a hospital believes that its purchasing patterns of drugs by NDCs with different price points that map to the same HCPCS code need to be case-weighted in order to appropriately reflect an average, hospitals should reflect the weighted average in their survey submission. However, volume purchasing of any drug is only relevant to the extent there is pricing variation among NDCs that map to a *single* HCPCS code. So while significant volume differences in NDCs mapping to a single HCPCS could theoretically lead to a weighted average result that differs from a non-weighted result, we do not have evidence to suggest significant variation in prices for NDCs mapping to a *single* HCPCS code across the board, nor do we have evidence that a lack of case-weighting would lead to an inaccurate “average.” Further, we believe that pricing variation among NDCs for a *single* HCPCS code would likely be more of an issue for, drugs sold by multiple manufacturers, however, the majority of SCODs paid under the OPPS are sold only by one manufacturer so we think that pricing variation among NDCs for SCODs is less variable than for NDCs as a whole. As noted by a comment reflected earlier in this document, 340B drug acquisition costs do not vary much by provider, so while it may be possible that a provider could use a lower-priced NDC drug more than a higher priced NDC for a particular quarter, or that a provider may use more of a drug at that price than its neighboring hospital for a particular quarter, we believe that such practices would be mitigated and would not distort the “average” acquisition cost because we are surveying all 340B hospitals, for 6 months' worth of data, and for all SCODs. Accordingly, we do not believe that the unlikely potential of hospitals using significantly differently priced NDCs that map to a *single* HCPCS for one quarter would skew the overall averaging of the data for all 340B hospitals, and we do not believe that the

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burden of requesting substantial additional data on volume is justified or necessary. This balance is particularly appropriate in light of the public comments we received on the other side of this issue – that the survey, as designed, is burdensome as-is – so we are not inclined to make it significantly harder to complete without more compelling substantive reasons.

Comment: Commenters stated that drugs with 340B "penny pricing" during one of the quarters included in the survey could artificially deflate actual drug costs for that drug. They argued that the survey made no mention of "penny pricing," in either the prior proposed survey or the current version of the survey on which they were commenting. They contended that 340B ceiling prices are calculated quarterly using a regulatory formula based on a variety of pricing and inflationary factors. This formula occasionally leads to a 340B ceiling price of \$0.00 for some drugs, which is increased to \$.01 per package for the quarter. They asserted that penny pricing typically only lasts one quarter for a given drug, and the drug's 340B price could significantly increase during the next quarter when the 340B ceiling price formula is recalculated. Therefore, costs for some drugs with "penny pricing" during the survey period may not accurately reflect the actual higher drug cost for those drugs in following quarters.

Response: We acknowledge "penny pricing" for drugs in the 340B program and that the penny pricing duration may be one a quarter, or more, depending on multiple factors. We also understand penny pricing for any particular drug is not necessarily a permanent price point for 340B hospitals. We believe the averaging of acquisition costs would sufficiently mitigate any pricing distortion that may otherwise occur due to penny pricing. Further, to the extent that penny pricing does reflect the acquisition cost for a particular drug, it is important that such acquisition cost is appropriately reflected in the survey data. We are seeking this drug acquisition information to estimate the average minimum discount that 340B entities receive when purchasing 340B drugs. However, we will take this feedback into account should these data be used for Medicare rate setting for 340B drugs under the OPSS in the future. We note that any methodology that takes into account penny pricing in our Medicare payment policy would be adopted through notice and comment rulemaking, and we will keep this issue in mind as we receive the survey results.

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Comment: Similar to comments made during the 60-day comment period, several commenters stated that 340B purchasing arrangements between covered entities and wholesalers or manufacturers generally require acquisition costs to be confidential. Unless the contract contains an exception for government requests, commenters surmised that the survey request may result in covered entities violating those confidentiality provisions.

Response: As stated in response to comments from the 60-day comment period, we do not intend to release an individual hospital's SCOD acquisition cost data to the public. We reiterate our pledge to maintain the confidentiality of individual responses that include acquisition prices for each SCOD to the extent required by law. However, we may make public average acquisition prices reported for SCODs across all hospitals surveyed. We believe the confidentiality of drug prices applies to individual drugs purchased by individual hospitals, which we have no intent to make public.

Comments Related to the Survey Instructions

Comment: One commenter supported the elimination of reporting acquisition cost at the provider-based department level for Covered Entities participating in the 340B program that are paid under the OPPI.

Response: We thank the commenter for their support, and this revision is reflected on the instructions document.

Comment: A commenter stated that the CMS NDC-HCPCS crosswalk that was provided in the survey instructions as a means to identify HCPCS dosage was incomplete. The commenter argued that without the complete HCPCS dosage data, it is impossible to provide the true acquisition cost of a drug because pricing must be converted to match the appropriate HCPCS dosage.

Response: In an effort to minimize error and burden imposed by the survey, Medicare revised the survey to include prepopulated fields to include the HCPCS dosage, among other fields. The

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crosswalk files are provided as a courtesy to assist stakeholders with survey completion and, as described on the instruction sheet, to the extent the commenter believes some data is not included, we advise hospitals to use the same tools they would use to convert NDCs to HCPCS for purposes of billing Medicare.

Comment: A commenter contended that the survey instrument for the information collection request is flawed because it is limited in scope to 340B acquisition costs only. The commenter stated that excluding wholesale acquisition cost (WAC) purchases from the calculation of average acquisition cost prevents the data collection from accurately calculating the cost of drugs purchased under 340B program rules. Furthermore, the commenter stated that the 340B statute prohibits DSH, children's, and cancer hospitals from obtaining covered outpatient drugs through a group purchasing organization (GPO) or group purchasing arrangement. 340B hospitals that are subject to the GPO prohibition are required to purchase certain outpatient drugs at WAC prices that are typically significantly higher than 340B prices.

Response: Similar to comments made during the 60-day comment period, we reiterate that only the net acquisition costs for each SCOD acquired under the 340B drug program should be submitted in response to the survey. We disagree with the commenter that the exclusion of WAC purchases on the survey would prevent an accurate average cost of 340B drugs because drugs purchased at WAC-based amounts are not 340B-acquired drugs. We acknowledge that under the Health Resources and Services Administration (HRSA) regulations, 340B hospitals may "carve-out" purchase their drugs at WAC for their Medicaid patients, meaning they purchase their drugs outside of the 340B drug program. These 340B carve-out hospitals do not purchase their SCODs through the 340B drug program and should not report their acquisition cost in this survey. For the purposes of this survey, we are seeking Medicare drug acquisition costs of SCODs purchased under the 340B drug program only.

We also disagree with the commenter that the exclusion of WAC purchases on the survey would produce an inaccurate average cost of 340B drugs. We believe the commenter may be concerned that our current 340B payment policy may be extended to all drugs purchased by the

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340B covered entities regardless of whether a particular drug was carved in or out under HRSA regulations. Our current Medicare OPPS 340B payment policy applies only to drugs billed with the 340B modifier, meaning the policy only applies to drugs purchased through the 340B discount program. Drugs purchased at WAC by the 340B carve-out hospitals do not report the 340B modifier "JG" on their claims and are not affected by the Medicare OPPS 340B drug payment policy. Therefore, we believe that the incorporation of WAC purchased drugs into the average acquisition cost would artificially inflate the acquisition cost of drugs purchased through the 340B drug program, and that acquisition cost data for drugs purchased at WAC amounts are appropriately excluded from the survey.

Comment: A commenter contended that the survey instructions to report “net acquisition cost” for each 340B drug, which CMS indicates is the sub-ceiling price “after all applicable discounts/rebates” is confusing as it is unclear what constitutes “applicable” discounts/rebates. The commenter stated that there were inconsistent and conflicting terms such as “price” in some places, and “cost” in others, throughout the survey documents that added to the confusion. The commenter stated the revised instructions direct hospitals to report the price per each individual NDC. However, if hospitals were to provide pricing data for each NDC per row under a relevant HCPCS code, the instructions do not provide clear directions on the reporting of the “average” 340B price per HCPCS code.

Response: We disagree that the meaning of “net acquisition costs” is unclear. We provided a general definition in the “Centers for Medicare & Medicaid Services Hospital Survey for Specified Covered Outpatient Drugs Average Acquisition Cost - Instruction Sheet.” Specifically, net acquisition cost is defined as the price that hospitals pay upon receiving the SCOD acquired under the 340B program (that is, the sub-ceiling price after all applicable discounts); this includes, but is not limited to, 340B drugs purchased via a replenishment model under the 340B program, or under penny pricing. In other words, the acquisition cost refers to the amount the hospital paid to purchase the drug, after all discounts and rebates—that is, the final purchase price. While we have revised the instructions to refer only to “cost,” we note that the term was used interchangeably with “price” in the last version. We have revised the 340B survey

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instructions and worksheet to remove the NDC column for additional clarity since it was an optional reporting element.

Comments Related to the OPPS Payment Policy for 340B Drugs and Biologicals and Related Litigation

Comment: Commenters continued to express concerns, as they did during the 60-day comment period, that the proposed survey will ultimately be used by the Secretary to continue to reduce Medicare payments to 340B hospitals, thus harming these hospitals' ability to care for their patients. These commenters alleged that reducing Medicare payment to acquisition cost for 340B drugs would eliminate hospitals' ability to use the savings from purchasing drugs at a discounted 340B price to provide more care to underserved patients, and thereby undermine the intent of the 340B program. A commenter argued that Medicare has tried to reduce 340B payments to eligible hospitals three times, and federal courts have rejected the Secretary's authority to apply that reduction twice with the third calendar year of the policy currently under litigation. The commenter stated that the federal district courts' rulings in this matter have been based on several factors, including the Secretary's lack of data on providers' acquisition costs for 340B drugs. Finally, the commenter stated that CMS should not attempt to implement piecemeal responses to the court's decisions until the litigation is concluded.

Response: As stated in response to comments from the 60-day comment period, while outside the scope of this data collection effort, we note that we have not seen evidence that the current OPPS 340B drug payment policy has limited patient access to 340B drugs. Further, Medicare payments for drugs are not intended to cross-subsidize other programs. Section 1833(t)(14)(D)(ii) of the Act provides that the Secretary can conduct periodic subsequent surveys (following the surveys that the U.S. Government Accountability Office (GAO) was required to conduct in 2004 and 2005) to determine the hospital acquisition cost for SCODs for use in setting payment rates under subparagraph (A) of section 1833(t)(14). The survey that was included in the PRA package is consistent with this authority. In light of the United States District Court's decision in *American Hospital Association v. Azar*, CMS continues to believe it is important to obtain and consider hospital acquisition cost survey data for SCODs in order to have the ability to establish

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payment rates based on acquisition cost for drugs and biologicals acquired under the 340B program for potential future payment policy, as well as for consideration of any potential remedies should the Secretary not prevail in the ongoing litigation related to 2018 and 2019.

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