

Centers for Medicare & Medicaid Services (CMS) Hospital Survey for Specified Covered Outpatient Drugs (SCODs) Average Acquisition Cost – Instruction Sheet

PURPOSE: The results of this survey will be used in part to evaluate the average acquisition costs for specified covered outpatient drugs (SCODs) purchased by hospitals under the 340B Program.

AUTHORITY: Section 1833(t)(14)(D)(ii) of the Social Security Act.

Survey Response Period: April XX, 2020 through May 15, 2020.

WHO SHOULD FILL OUT THIS FORM?

Hospitals that purchase drugs through the 340B Program, a federal government program that requires certain drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced cost, may also receive payment for items and services furnished to Medicare beneficiaries, including 340B-acquired drugs. Any hospital that was enrolled in the 340B program as a covered entity, excluding Critical Access Hospitals (CAHs), in the last quarter of 2018 and/or the first quarter of 2019 is required to complete the survey.

Please note that we are only requesting acquisition cost data for drugs acquired through the 340B Drug Pricing program and not any other program. We understand that as a requirement of participating in the 340B Drug Pricing Program, covered entities are required to maintain accurate records documenting compliance with all 340B Program requirements, including only providing 340B Drugs to patients of the eligible entity. Accordingly, each hospital should have readily available access to the data that is being requested via this survey.

WHAT INFORMATION IS REQUESTED?

For each applicable hospital, the survey shall reflect the net acquisition cost for **each** SCOD acquired under the 340B program (that is, the sub-ceiling price after all applicable discounts). Acquisition cost refers to the price that hospitals pay upon receiving the product (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. Applicable discounts are any discounts below the discounted ceiling price. The 340B drug acquisition cost should be reported regardless of whether or not the drug was dispensed at all, or whether the drug was dispensed in multiple settings. We are only requesting the acquisition cost of the drugs acquired under the 340B program during the specified timeframe listed below. Acquisition costs for drugs acquired by 340 hospitals outside of the 340B drug program should not be included on the survey.

CONFIDENTIALITY

CMS pledges to maintain confidentiality of individual responses that include acquisition cost for each SCOD to the extent provided by law. However, CMS may make public average acquisition cost reported for each SCOD. To the extent that acquisition costs for certain SCODs are deemed sensitive and/or confidential, we do not intend to make such cost available in an individually identifiable manner.

Form CMS-10709 (Exp. TBD)

OMB control number: 0938-New

“The survey is an Excel spreadsheet that will be available for download after the 340B entity logs into the 340B Survey Gateway (<https://www.340bsurvey.com/survey>).”

INSTRUCTIONS FOR FILLING OUT SURVEY

Please utilize the following instructions below to assist with completing the drug acquisition cost survey. After logging into the 340B Drug Survey Gateway, you will be presented with the following two methods for completing the survey. Please note only the Detailed Survey OR the Quick Survey needs to be completed.

- 1.) Detailed Survey: Please use this option to provide your acquisition costs for each individual SCOD

OR

- 2.) Quick Survey: Please use this option to indicate that you prefer that CMS utilize the 340B ceiling prices obtained from Health Resources and Services Administration (HRSA) as reflective of your hospital acquisition costs. After selecting this option, the survey is complete.

1. Provider Hospital Information (Must be entered or verified for both Detailed and Quick Survey options):

- a. Enter the hospital name:
- b. Enter the hospital’s Medicare CMS Certification Number (CCN):
- c. Enter the National Provider Identifier (NPI):
- d. Enter the Tax ID Number:
- e. Enter the Contact Name:
- f. Enter the Contact Phone:
- g. Enter the Contact Email:
- h. Enter the Hospital Address:

Continued instructions for the Detailed Survey: Please complete the Excel spreadsheet as detailed below. In the spreadsheet tab entitled "Survey Worksheet," please provide the following information:

2. HCPCS code for each Drug (Pre-populated)

- a. For each SCOD HCPCS code assigned to status indicator “K” or “G” on the files listed below, list the healthcare common procedure coding system (HCPCS) code.
- b. For 2018, the applicable HCPCS code for each SCOD may be found in the October 2018 Addendum B on the CMS website:
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service->

[Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html).

- c. For 2019, the applicable HCPCS codes for each SCOD may be found in the January 2019 Addendum B on the CMS website:

<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates.html>.

3. Drug Name/ Short Descriptor (Pre-populated)

- a. The Short Descriptor of the drug that corresponds to the HCPCS number identified in the previous field. The short descriptor for each SCOD is located in the column entitled "Short Descriptor" in Addendum B.

4. Dose (as reflected in HCPCS dose descriptor) (Pre-populated)

- a. This is the amount of drug to which the acquisition cost corresponds. The HCPCS dosage for each drug is reflected in the HCPCS long descriptor or the "HCPCS Dosage" identified in the crosswalk files discussed below. For example, the amount of drug used for reporting J0885, epoetin alfa, is 1,000 units.

5. Q4 2018 Payment Rate (Pre-populated)

- a. The payment rate is prepopulated using the payment rate from the OPSS Addendum B for Q4 2018.

6. Q1 2019 Payment Rate (Pre-populated)

- a. The payment rate is prepopulated using the payment rate from the OPSS Addendum B for Q1 2019.

7. Average 340B Acquisition Cost of Drugs for Q4 of CY 2018 (October 1, 2018-December 31, 2018)

- a. For each SCOD purchased under the 340B Program at any time during the 4th quarter of 2018 (October 1, 2018-December 31, 2018), enter the average acquisition cost for that SCOD as identified by the SCOD's Healthcare Common Procedure Coding System (HCPCS) code for the amount corresponding to a single billing unit of the corresponding HCPCS billing code.
- The amount of drug represented by a single billing unit of a HCPCS code, also referred to as the HCPCS code dosage, can be found in the "HCPCS Dosage" column of the NDC-HCPCS Crosswalk files mentioned above. Note, while a single billing unit of a HCPCS code is equivalent to the HCPCS code dosage, it is not equivalent to the dose received by the patient. Please see Appendix B for calculation examples.
 - To the extent the hospital purchased a drug with multiple NDCs that map to a single HCPCS code but the NDC pricing varies, the average acquisition cost submitted at the HCPCS level should reflect the volume weighted average acquisition cost.

- b. If the acquisition cost for the SCOD is unknown, you may leave this field blank and CMS will use the 340B ceiling price as a proxy for the acquisition cost for that drug.

8. Average 340B Acquisition Cost of Drugs for Q1 of CY 2019 (January 1, 2019- March 31, 2019)

- a. For each SCOD purchased under the 340B Program at any time during the first quarter of 2019 (January 1, 2019- March 30, 2019), enter the average acquisition cost for that SCOD as identified by the SCOD's Healthcare Common Procedure Coding System (HCPCS) code for the amount corresponding to a single billing unit of the corresponding HCPCS billing code.
 - The amount of drug represented by a single billing unit of a HCPCS code, also referred to as the HCPCS code dosage, can be found in the "HCPCS Dosage" column of the NDC-HCPCS Crosswalk files mentioned above. Note, while a single billing unit of a HCPCS code is equivalent to the HCPCS code dosage, it is not equivalent to the dose received by the patient. Please see Appendix B for calculation examples.
 - To the extent the hospital purchased a drug with multiple NDCs that map to a single HCPCS code but the NDC pricing varies, the average acquisition cost submitted at the HCPCS level should reflect the volume weighted average acquisition cost.
- b. If the acquisition cost for the SCOD is unknown, you may leave this field blank and CMS will use the 340B ceiling price as a proxy for the acquisition cost for that drug.

Completed surveys (either the Detailed or the Quick method) should be submitted to your MAC no later than Friday, May 15, 2020.

Appendix A

NDC-HCPCS Crosswalk

- a. Your organization may have multiple NDCs for each HCPCS code depending on the specific drugs, and associated NDCs, acquired by your institution during the designated timeframe under the 340B program. Please note that CMS publishes quarterly NDC-HCPCS Crosswalk files that are available on the CMS website. Due to an operational lag time that exists between the manufacturers' reporting of the NDCs/ASPs and their CMS publication, the October 2018 HCPCS codes do not correspond to the October 2018 ASP NDC- HCPCS Crosswalk.
 - For HCPCS codes listed in the October 2018 Addendum B, corresponding NDC crosswalk files appear under the [April 2019 ASP NDC-HCPCS Crosswalk](#).
 - For HCPCS codes listed in the January 2019 Addendum B, corresponding NDC crosswalk files appear under the [July 2019 ASP NDC-HCPCS Crosswalk](#).
 - The April 2019 and July 2019 Crosswalks appear in the Related links section for the following CMS webpage: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2019ASPFiles>
- b. The April 2019 and July 2019 crosswalk files each contain 10 files. Combining the following three files from each quarter will create a list of NDCs associated with the majority of HCPCS codes that are billed under the OPPS:
 - AWP NDC-HCPCS Crosswalk
 - ASP NDC-HCPCS Crosswalk
 - OPPS NDC-HCPCS Crosswalk

Please note that although the NDC-HCPCS crosswalk files provide examples of commonly associated NDCs for the majority of the HCPCS codes, these files do not provide a complete and comprehensive list of all available NDCs for each HCPCS code. Thus, respondents may include acquisition costs for additional NDCs associated to a given HCPCS code.
- c. Please be sure to utilize the most recent versions of the crosswalk files in the hyperlinks above. Some of the crosswalk files have been updated very recently.

Appendix B Calculation Examples

1. HCPCS code J0885 (Injection, epoetin alfa, (for non-esrd use), 1000 units) include products sold under the brand names Epogen and Procrit. The drug products are sold in a variety of amounts, including vials and syringes that contain between 2000 units and 40,000 units of epoetin packaged in amounts that vary from 4 to 25 vials. On the CMS NDC-HCPCS Crosswalk files, the "HCPCS Dosage" column indicates that CMS payment of J0885 to outpatient hospitals (and other providers billing Part B by HCPCS codes) is based on 1,000 units of epoetin. Alternatively stated, a single billing unit is equivalent to 1,000 units of epoetin for HCPCS code J0885. For the survey, CMS is seeking the 340B average acquisition cost of J0885 per 1,000 units. Therefore, if the acquisition cost of a package of ten 20,000 unit epoetin vials is \$1800, the acquisition cost of each 20,000 unit epoetin vial in the 10 vial package is \$180. For reporting, the acquisition cost per 1,000 units of epoetin (corresponding to the amount in the HCPCS dosage as well as the HCPCS code dose descriptor) would be \$180 divided by 20, or \$9.00.

2. HCPCS code J0878 (Injection, daptomycin, 1mg). Daptomycin is commonly sold in 350 mg or 500 mg vials packed in quantities ranging from 1 to 10 vials. The survey is seeking the acquisition cost of daptomycin based on 1 mg of the drug. In this example, the single billing unit is equivalent to 1mg. If a package of ten 350 mg vial is acquired for \$1400, then the acquisition cost a single 350 mg vial from the package is \$140. The acquisition cost per 1 mg of daptomycin in the HCPCS dosage or dose descriptor, 1 mg, is \$0.40.

Appendix C

Medicare Administrative Contractor (MAC) websites

A/B MAC Jurisdiction Website:

1. Jurisdiction 5
Wisconsin Physicians Service Government Health Administrators
<https://www.wpsgha.com/wps/portal/mac/site/home/>
2. Jurisdiction 6
National Government Services, Inc.
<https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/entry/>
3. Jurisdiction 8
Wisconsin Physicians Service Government Health Administrators
<https://www.wpsgha.com/wps/portal/mac/site/home/>
4. Jurisdiction 15
CGS Administrators, LLC
<https://cgsmedicare.com/>
5. Jurisdiction E
Noridian Healthcare Solutions, LLC,
<https://med.noridianmedicare.com/>
6. Jurisdiction F
Noridian Healthcare Solutions, LLC
<https://med.noridianmedicare.com/>
7. Jurisdiction H
Novitas Solutions, Inc.
https://www.novitas-solutions.com/webcenter/portal/NovitasSolutions?_adf.ctrl-state=8qijpgz81_54
8. Jurisdiction J
Palmetto GBA, LLC
<https://palmettogba.com/>
9. Jurisdiction K
(National Government Services, Inc.)
<https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/entry/>
10. Jurisdiction L
Novitas Solutions, Inc.
https://www.novitas-solutions.com/webcenter/portal/NovitasSolutions?_adf.ctrl-state=8qijpgz81_4

11. Jurisdiction M

Palmetto GBA, LLC

<https://palmettogba.com/>

12. Jurisdiction N

First Coast Service Options, Inc.

<https://www.fcso.com/>

**If you have any questions regarding the survey, please contact the 340B Survey
Technical Helpdesk Hotline at 1-833-886-5682**

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this mandatory information collection is **0938-XXXX (Expires XX/XX/XXXX)**. The time required to complete this information collection is estimated to average **[Insert Time (hours or minutes)]** per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ******CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact your local Medicare Administrative Contractor.**