

#	Form	Change
1	Supporting Document A	Added bullet "A" to Background
2	Supporting Document A	added "Calendar Year"
3	Supporting Document A	added "Hospital Outpatient Prospective Payment and Ambulatory Surgical Center
4	Supporting Document A	added "the Centers for Medicare & Medicaid Services"
5	Supporting Document A	added "Health Resources & Services Administration"
6	Supporting Document A	deleted "Hospital Outpatient Prospective Payment System"
7	Supporting Document A	deleted "certain" covered entity hospitals
8	Supporting Document A	changed Justification Section to bullet B from A
9	Supporting Document A	replaced "used does" with "did" not fully..
10	Supporting Document A	deleted "Therefore, CMS did not use the GAO data, which did not take all of the discounts into consideration when conducting the survey. ³ "
11	Supporting Document A	deleted footnote "3 https://www.govinfo.gov/content/pkg/FR-2005-11-11
12	Supporting Document A	added "ceiling price" in "As noted previously, 340B entities receive these drugs at a discount and are charged a maximum price, ceiling price, for these drugs because of their participation.
13	Supporting Document A	deleted "also" in We also note that these covered entities also have access to..
14	Supporting Document A	replaced "Health Resources and Services Administration's" with HRSA
15	Supporting Document A	deleted "Average Sale Price" and "plus"
16	Supporting Document A	added "340B" ceiling price
17	Supporting Document A	added "either of"
18	Supporting Document A	replaced "In addition, we are only asking for data on the acquisition price for two quarters for separately payable drugs identified in Addendum B on the CMS Website." with "In addition, we are only asking for data on the acquisition price at the hospital level for two quarters. We are requesting for the separately payable drugs identified in Addendum B on the CMS Website."
19	Supporting Document A	Substituted "The practical utility of the 340B drug acquisition cost survey is that CMS is exercising the explicit statutory authority to obtain drug acquisition cost per section 1833(t)(14)(D) and the agency may use the information collected to set payment rates for drugs purchased under the 340B Program." for "This is a new collection and the agency may use the information collected to set payment rates for drugs purchased under the 340B Program."

20	Supporting Document A	replaced "However, often time" with "Often time, however,"
21	Supporting Document A	inserted 84 FR 51590
22	Supporting Document A	replaced "assuming" with "we assumed"
23	Supporting Document A	inserted "such" as postage or copying
24	Supporting Document A	substituted "analysts" for "analyses"
25	Supporting Document A	inserted "we" and "figure" in "we used this figure to derive the following"
26	Supporting Document A	moved last paragraph from the background section into section 2
27	Supporting Document A	deleted "in part"
28	Supporting Document A	inserted "the"
29	Supporting Document A	substituted "via" for "in response to"
30	Supporting Document A	inserted "or"
31	Supporting Document A	deleted underline from "See"
32	Supporting Document A	deleted "for"
33	Supporting Document A	inserted "or where a hospital does not respond to the survey"
34	Supporting Document A	deleted "include" inserted "use"
35	Supporting Document A	deleted "are shared"
36	Supporting Document A	deleted "privacy" inserted "confidentiality"
37	Supporting Document A	deleted "provided" inserted "required"
38	Supporting Document A	deleted "privacy" inserted "confidentiality"
39	Supporting Document A	deleted "provided" inserted "required"
40	Supporting Document A	deleted page break

Current Location	Reason
Page 1 - 1st paragraph	to organize the Background section under bullet A
Page 1 - 1st paragraph	to define acronym CY
Page 1 - 1st paragraph	to define acronym OPPS/ASC
Page 1 - 1st paragraph	to define acronym CMS
Page 1 - 1st paragraph	to define acronym HRSA
Page 1 - 2nd paragraph	reduntant with OPPS
Page 1 - 2nd paragraph	to clarify that it covers not certain but all covered entity hospitals
Page 1 - 2nd section	to follow the bullet A for the next section.
Page 2 - 3rd paragraph	to correct grammer and for clarity
Page 2 - 3rd paragraph	Not pertinent to the narrative
Page 2 - footnote	since the sentence was deleted, the footnote is no longer needed
Page 2 - 3.	added for clarity
Page 3 - top paragraph, 2nd sentence	deleted for clarity
Page 3 - 2nd paragraph	to use the acronym HRSA
Page 3 - 2nd paragraph	to use acronym ASP and the commonly accepted "ASP+6" language
Page 4 - top paragraph	to clarify that we are referring to the 340B ceiling price
Page 4 - 2nd paragraph	to clarify that we are referring to either of quarters
Page 4 - 3rd paragraph	to provide clarity that CMS is only requesting information at the hospital level, not at the Provider Based Department level that we had initially proposed.
Page 4 - under bullet 2. Information Users	to discuss the practical utility per the public comments received that CMS did not discuss a practical utility for the survey.

Page 5 - "Duplication of efforts"	edited to correct sentence flow
Page 5 - "Federal Register/Outside Consulation"	inserted since it was TBD
Page 6 - Burden Estimates (Hours & Wages)	edited for grammatical correction
Page 6 - Burden Estimates (Hours & Wages)	inserted for clarity
Page 6 - Cost to Federal Government	corrected for clarity
Page 6 - Burden Estimates (Hours & Wages)	inserted for clarity
Page 5 - Information Users	inserted paragraph for clarity
Page 2 - Need and Legal Basis	deleted for clarity
Page 3 - Need and Legal Basis	inserted for clarity
Page 4 - Need and Legal Basis	corrected for clarity
Page 4 - Need and Legal Basis	inserted for clarity
Page 4 - Need and Legal Basis	deleted for clarity
Page 4 - Need and Legal Basis	deleted for clarity
Page 4 - Need and Legal Basis	inserted for clarity
Page 4 - Need and Legal Basis	corrected for clarity
Page 5 - Duplication of efforts	deleted for clarity
Page 6 - Confidentiality	corrected for clarity
Page 6 - Confidentiality	corrected for clarity
Page 6 - Sensitive Questions	corrected for clarity
Page 6 - Sensitive Questions	corrected for clarity
Page 7 - Cost to Federal Government	corrected for clarity

#	Form	Change
1	Supporting Document B	changed to "CMS contractors will make survey information available to all hospitals that purchase drugs through the 340B Program." from "CMS shall disseminate (via the Medicare Administrative Contractors (MACs)) the survey to all hospitals paid under the OPPS that purchase drugs through the 340B Program."
2	Supporting Document B	changed to "1,384 responses" from "1,338 responses"
3	Supporting Document B	changed to "Each hospital that acquired drugs under the 340B program in the fourth quarter of 2018 and/or first quarter of 2019 is required to complete one survey that includes acquisition costs for each of the two quarters." from "Each hospital is required to complete one survey that includes acquisition costs for each SCOD for two quarters (Quarter 4 of 2018 and Quarter 1 of 2019)."
4	Supporting Document B	deleted "the authority" Section 1833..
5	Supporting Document B	added "which" and deleted "part"
6	Supporting Document B	added "CMS is surveying the complete universe of 340B covered hospitals for the survey period" and deleted "NA"
7	Supporting Document B	substituted "CMS contractors will make available notice of the surveys and receive the survey responses." for "the MACs shall disseminate and receive the survey data. The MACs shall follow up with each hospital that has not responded to the survey or sent in incomplete data approximately two weeks after survey is distributed."
8	Supporting Document B	corrected "price" to "prices"
9	Supporting Document B	substituted "rate" for "amount"
10	Supporting Document B	substituted "Not applicable since CMS is not using a sampling methodology." for "CMS shall not undertake any methods or tests of procedures."
11	Supporting Document B	inserted "the"
12	Supporting Document B	deleted "make available notice" inserted "announce the availability"
13	Supporting Document B	inserted "CMS will also uses 340B ceiling prices as proxies for the acquisition costs of drugs where a hospital fails to respond to the survey."

Current Location	Reason
Page 1 - 2nd paragraph	changed to clarify the method of making the survey available to respondents and that the respondents are not limited to OPPS.
Page 1 - 2nd paragraph	updated database indicate updated numbers.
Page 1 - 2nd paragraph	to clarify and refine the sentence for better flow
Page 1 - 2nd paragraph	deleted since it is implied
Page 1 - 2nd paragraph	corrected typo error from earlier version
Page 1 - bullet 2	to clarify that this suvey represent the universe of the study subject so there is no need for statistical validity
Page 1 - bullet 3	changed to clarify the method of making the survey available to respondents
Page 1 - bullet 3	plurality correction
Page 2 - top	changed to correct meaning
Page 1 - bullet 4	reworded for clarity
Page 1 - bullet 1	inserted for clarity
Page 1 - bullet 3	reworded for clarity
Page 1 - bullet 4	reworded for clarity

#	Form	Change
1	Instruction Sheet	changed "Collection Period" to "Survey Response Period"
2	Instruction Sheet	changed from "February 23, 2020 to March 6, 2020" to "March 23, 2020 to April 10, 2020"
3	Instruction Sheet	deleted "under the hospital outpatient prospective payment system"
4	Instruction Sheet	added new section "WHAT INFORMATION IS REQUIRED? 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/rebates). The acquisition cost should be reported regardless of whether or not the drug was dispensed or whether the drug was dispensed in multiple settings and regardless of how it was purchased (such as in a replenishment model under the 340B program). We are only requesting the acquisition cost of the drugs under the 340B program during the specified timeframe listed below. Drugs acquired outside of the 340B program should not be included on the survey."
5	Instruction Sheet	added "Please fill out the attached Excel spreadsheet. In the spreadsheet tab "Hospital Information," please provide the following information:"
6	Instruction Sheet	inserted "CONFIDENTIALITY CMS pledges to maintain confidentiality of individual responses that include acquisition prices for each SCOD to the extent provided by law. However, CMS may make public average acquisition prices reported for each SCOD. To the extent that acquisition prices for certain SCODs are deemed sensitive and/or confidential, we do not intend to make such prices available in
7	Instruction Sheet	inserted "The survey is an Excel spreadsheet that will be available for download from each Medicare Administrative Contractor (MAC) website(s) that are listed at the end of the Instruction Sheet."
8		added "In the spreadsheet tab "Hospital Information," please provide the following information:"
9	Instruction Sheet	inserted Contact "Name"
10	Instruction Sheet	inserted "Hospital Address, Email, Phone Number"
11	Instruction Sheet	substituted "Please complete the Excel spreadsheet. In the spreadsheet tab entitled "Survey", please provide the following information:" for "Please fill out the attached Excel spreadsheet. In this spreadsheet, please provide the following information:"

12	Instruction Sheet	deleted "2. Provider Based Department Name List each provider based department of the hospital that is enrolled in the 340B program and is paid under the Medicare Hospital Outpatient Prospective Payment System (OPPS). For example, oncology department A, oncology department B."
13	Instruction Sheet	Renumbered HCPCS code for each Drug to 2.
14	Instruction Sheet	replaced "For each SCOD identified with status indicator "K" or "G", list the healthcare common procedure coding system code (HCPCS). For example "J1234." with "a. For each SCOD HCPCS code associated with status indicator "K" or "G," list the healthcare common procedure coding system code (HCPCS). • Examples: • "J0885" represents epoetin alfa. • "J0878" represents daptomycin."
15	Instruction Sheet	Inserted "a. Exclusions: Please exclude vaccines, skin substitutes with a status indicator (SI) "K" or "G" from the survey responses."
16	Instruction Sheet	re-ordered the bullets "c" "d" bullets under the HCPCS code for each Drug
17	Instruction Sheet	Tip: To narrow the selection, filter Addendum B, column C "SI", for "K" and "G" only. This will help narrow the search.
18	Instruction Sheet	re-ordered the bullet 3 for Drug Name/Short Descriptor
19	Instruction Sheet	replace name with Short Descriptor
20	Instruction Sheet	deleted "Enter National Drug Code (NDC)."
21	Instruction Sheet	added "The short descriptor for each SCOD is located in the column entitled "Short Descriptor" in Addendum B." under bullet a
22	Instruction Sheet	added "Tip: Copy the short descriptor in Column B of Addendum B and paste into column C of the drug survey."
23	Instruction Sheet	re-ordered Dose under bullet 4.
24	Instruction Sheet	added "HCPCS dose" in Dose

25	Instruction Sheet	substituted "a. This is the amount of drug to which the acquisition cost corresponds. List the HCPCS dosage for each drug as 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." for "List the dosage unit for each drug as reflected in the HCPCS descriptor. For example 1mg or 1 vial."
26	Instruction Sheet	<p>a. You may choose to include the National Drug Code (NDC), but doing so is optional. Your organization may have multiple NDCs for each HCPCS code depending on your acquisition. Please note that CMS publishes quarterly NDC-HCPCS Crosswalk files that are available on the CMS website. Due to an operational lag time that exist 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.</p> <ul style="list-style-type: none"> • 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. <p>b. The April 2019 and July 2019 crosswalk files each contain 10 files. Combining the following three files from each quarter's will create a list of NDCs associated with the majority of HCPCS codes that are billed under OPPS:</p> <ul style="list-style-type: none"> • AWP NDC-HCPCS Crosswalk • ASP NDC-HCPCS Crosswalk • OPPS NDC-HCPCS Crosswalk <p>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.</p> <p>c. Please be sure to utilize the most recent versions of the crosswalk</p>
27	Instruction Sheet	<p>added "6. Q4 2018 Payment Rate</p> <p>a. The payment rate may be obtained from the OPPS Addendum B for Q4 2018"</p>
28	Instruction Sheet	<p>added "7. Q1 2019 Payment Rate</p> <p>a. The payment rate may be obtained from the OPPS Addendum B for Q1 2019"</p>
29	Instruction Sheet	re-ordered the bullet 8.
30	Instruction Sheet	added "under the 340B program" following For each SCOD purchased

31	Instruction Sheet	substituted "4th" for "last" quarter
32	Instruction Sheet	<p>added "based on the cost report on the amount of drug in a single billing unit of the corresponding HCPCS billing code.</p> <ul style="list-style-type: none"> • 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."
33	Instruction Sheet	re-ordered the bullet 9.
34	Instruction Sheet	added "under the 340B program" following For each SCOD purchased
35	Instruction Sheet	<p>added "based on the cost report on the amount of drug in a single billing unit of the corresponding HCPCS billing code.</p> <ul style="list-style-type: none"> • 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."
36	Instruction Sheet	substituted "Completed surveys should be submitted to your MAC no l

37	Instruction Sheet	<p>added "Calculation Examples</p> <p>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. 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.</p> <p>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. 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."</p>
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38	Instruction Sheet	<p>A/B MAC Jurisdiction Website:</p> <p>1. Jurisdiction 5 Wisconsin Physicians Service Government Health Administrators https://www.wpsgha.com/wps/portal/mac/site/home/</p> <p>2. Jurisdiction 6 National Government Services, Inc. https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/entry/</p> <p>3. Jurisdiction 8 Wisconsin Physicians Service Government Health Administrators https://www.wpsgha.com/wps/portal/mac/site/home/</p> <p>4. Jurisdiction 15 CGS Administrators, LLC https://cgsmedicare.com/</p> <p>5. Jurisdiction E Noridian Healthcare Solutions, LLC, https://med.noridianmedicare.com/</p> <p>6. Jurisdiction F Noridian Healthcare Solutions, LLC https://med.noridianmedicare.com/</p> <p>7. Jurisdiction H Novitas Solutions, Inc. https://www.novitas-solutions.com/webcenter/portal/NovitasSolutions?_adf.ctrl-state=8qipjgz81_54</p> <p>8. Jurisdiction J Palmetto GBA, LLC https://palmettogba.com/</p>
39	Instruction Sheet	deleted "or submit an email to AcquisitionDrugsurvey@cms.hhs.gov."
40	Instruction Sheet	substituted "Medicare Administrative Contractor" for "Gil Ngan at 410-7
41	Instruction Sheet	deleted "drug pricing"
42	Instruction Sheet	inserted "at all"
43	Instruction Sheet	inserted "acquired"
44	Instruction Sheet	deleted "as noted in section 10 we pledge confidentiality to the extent required by law"
45	Instruction Sheet	deleted "are" and inserted "is"
46	Instruction Sheet	deleted "based on the cost report on the amount of drug" insert "for the amount corresponding"

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Instruction Sheet

deleted "based on the cost report on the amount of drug" insert "for the amount corresponding"

Current Location	Reason
Page 1 - top	change to provide clarity
Page 1 - top under Survey Response Period	timeline has changed
Page 1 - 1st paragraph under WHO SHOULD FILL OUT THIS FORM	deleted to be consistent across the supporting documents
Page 1 - new section	to provide further clarification on 340B acquisition cost of drugs per public comments
Page 1 - bottom	to provide specific Hospital information on a specific tab on the spreadsheet
Page 1 - below what information is required	added to provide respondents on the confidentiality of the data
Page 2 - top of page	added to provide additional instructions on spreadseet
	added to provide point to Hospital Information tab
Page 2 - top	to clarify we are asking for contact name
Page 2 - under Hospital Information section	added to include contact person and email, phone to reach the POC for the respondent hospital
Page 2 - top	rewrote passage to clarify for "Survey" tab

Page 2 - top	deleted per the public comment that this would be too burdensome to collect information at the PBD level
Page 2 under HCPCS code for each Drug	edited to provide clarification
Page 2 under HCPCS code for each Drug, b.	added to provide clarification on drugs excluded on the survey
under the HCPCS code for each Drug	re-ordered the bullets since we added the new bullet b on exclusions
HCPCS code for each Drug:	added to provide a tip on narrowing the data
bottom of page 2	reorganized the bullets since we deleted PBD from earlier version
Page 2 under Drug Name/ Short Descriptor: bullet a.	edited to clarify it's the short descriptor of the drug
Page 2 under Drug Name/ Short Descriptor:	moved NDC to a new section below bullet 4. Dose
Page 2 under Drug Name/ Short Descriptor.	added to provide further clarity
Name/ Short Descriptor: below	provided tip for respondents using addendum B
Page 3 under Dose	reorganized the bullets since we deleted PBD section from earlier version
Page 3, bullet 4, Dose (as reflected in HCPCS dose descriptor)	added for clarification

Page 3, bullet a under Dose	provided clarifying instructions
bullet 5. NDC	added NDC section that provides information on HCPCS-NDC crosswalks in response to public comments. The hyperlinks point directly to the updated files on CMS.gov
bullet 6.	this column was there on the survey spreadsheet previously but was left out as an error from the previous version.
bullet 7.	this column was there on the survey spreadsheet previously but was left out as an error from the previous version.
bullet 8.	re-ordered since additions were added as discussed above
under bullet 8. Average 340B Price of Drug for Q4 of CY 2018 (October 1, 2018-December 31, 2018), bullet a.	to provide more clarification that is intended to be for the 340B program only

under bullet 8. Average 340B Price of Drug for Q4 of CY 2018 (October 1, 2018-December 31, 2018), bullet a.	to provide more clarification it is the 4th quarter of 2018
under bullet 8. Average 340B Price of Drug for Q4 of CY 2018 (October 1, 2018-December 31, 2018), bullet a.	to provide clarification on a single billing unit for 2018
bullet 9.	re-ordered since additions were added as discussed above
under bullet 9. Average 340B Price of Drug for Q1 of CY 2019 (January 1, 2019-March 31, 2019), bullet a.	to provide more clarification that is intended to be for the 340B program only
under bullet 9. Average 340B Price of Drug for Q1 of CY 2019 (January 1, 2019-March 31, 2019), bullet a.	to provide clarification on a single billing unit for 2019
bottom of page 4.	rewording and timeline changed

page 6-7	added to provide survey information on where the survey spreadsheet will be available
top of page 8	changed contact since MAC will be the primary contact to respondents.
under the PRA disclosure statement	changed contact since MAC will be the primary contact to respondents.
top of page 1	deleted for clarity
Page 1: WHAT INFORMATION IS REQUIRED?	inserted for clarity
Page 1: WHAT INFORMATION IS REQUIRED?	inserted for clarity
Page 1: Confidentiality	deleted for clarity
Page 1: Confidentiality	corrected for clarity
Page 3: 8. Average 340B Price of Drug for Q4 of CY 2018 (October 1, 2018- December 31, 2018)	corrected for clarity

Page 3: 9. 9. Average 340B Price of Drug for Q1 of CY 2019 (January 1, 2019- March 31, 2019)	corrected for clarity
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<u>#</u>	<u>Form</u>	<u>Change</u>
1	Drug Survey Spreadsheet	respondents to provide their hospital information: Hospital Name, CCN (Medicare Provider Number), Contact Name, Contact Title, Hospital Address, Email, Phone Number
2	Drug Survey Spreadsheet	deleted "Provider Based Department Name"
3	Drug Survey Spreadsheet	substituted "Drug Name/Short Descriptor" for "Drug Name/Descriptor"
4	Drug Survey Spreadsheet	substituted "Dose (as reflected in HCPCS code descriptor)" for "Dose (as reflected in descriptor)"
5	Drug Survey Spreadsheet	added new NDC (11 digit) Optional column
6	Drug Survey Spreadsheet	replaced examples with 3 rows of HCPCS with real life examples

<u>Current Location</u>	<u>Reason</u>
Information" on Drug Survey Spreadsheet	This information is need if we need the MAC to follow up with questions on the respondent.
Survey tab	CMS removed the reporting for Provider Based Department in response to public comments on burden
Survey tab, column C	edited to clarify it's the short descriptor of the drug
Survey tab, column D	edited to clarify in the HCPCS code descriptor
Survey tab, column E	added to assist respondents and it is optional
Survey tab, row 2-4	edited to help respondents understand the requested information and that there may be multiple NDCs for every HCPCS