340B Characteristics Nonresponse Bias Report
(CMS-10709; 0938-1374)

HOSPITAL CHARACTERISTICS ANALYIS

We are providing this nonresponse bias report to the Office of Information and Regulatory Affairs (OIRA) prior to our utilization of the 340B drug acquisition cost data for future publications, including rulemaking, consistent with OIRA's terms of clearance of approval for the 340B survey. While OIRA used the term "nonresponse bias" we note that the survey was designed such that lack of an affirmative response to the survey in whole or in part would lead CMS to use the 340B ceiling price as a proxy for the acquisition costs of applicable drugs.

The content of this report describes the scope and characteristics of the responding hospitals such as bed count, teaching hospital status, hospital type, and geographic locality type, as well as any limitations in the generalizability of the information collected, in any publications and documents utilizing this data.

This report summarizes the survey responses by stratifying by several hospital and geographic characteristics including: bed count, teaching hospital status, hospital type, and geographic locality type. We analyzed which hospitals completed the detailed survey, opted for the quick survey, or did not respond at all.

Following the OPPS rate changes in January 2018 for drugs acquired under the 340B Drug Pricing Program and litigation brought by certain hospitals, CMS began re-evaluating the average hospital acquisition costs for 340B-acquired specified outpatient drugs and whether the agency could gather such information via a survey. To do this, a survey on acquisition drug costs was administered to 340B covered entity hospitals with the aim of using the data to ascertain these costs. CMS administered the survey to 1,422 340B entities between April 24th and May 15th, 2020. There were two survey options available to responders:

- **Detailed Survey:** Hospitals that completed the detailed survey were required to provide their average acquisition costs for each individual specified covered outpatient drug.
- **Quick Survey:** Hospitals that completed the quick survey opted for CMS to use the HRSA 340B ceiling prices to be reflective of their own acquisition costs.

DESCRIPTIVE STATISTICS SUMMARY

Out of the 1,422 340B covered entity hospitals that were surveyed, 100 (7.0%) completed the detailed survey, 780 (54.9%) completed the quick survey, and 542 (38.1%) did not respond. Thirty-three percent of the detailed survey responders, 25.6 percent of the quick survey responders, and 34.3 percent of the non-responders had a bed count of less than 99 beds.

Table 1.

	340B Hospitals Surveyed	Detailed Survey Responses	Quick Survey Responses	No Response
Count	1422	100	780	542
Percent	100.0%	7.0%	54.9%	38.1%

In the aggregate population of 340B hospitals, 51.3 percent are teaching hospitals and 45.5 percent are non-teaching. Fifty-two percent of the detailed survey responders, 55.5 percent of the quick survey

responders, and 45.0 percent of the non-responders were teaching hospitals. A full listing of this information is included in Appendix A.

The majority (79.0%) of 340B covered entity hospitals that were surveyed are disproportionate share (DSH) hospitals. Of the detailed responders, 67.0 percent were DSH hospitals, 23.0 percent were sole community hospitals (SCH), 8.0 percent were rural referral center (RRC) hospitals, and 1.0 percent were children's hospitals. Of the quick responders, 80.3 percent were DSH, 9.5 percent were SCH, and 5 percent were RRC. Seventy-nine point five percent of the entities that did not respond to the survey were DSH, and 10.7 percent were SCH.

The aggregate population of 340B covered entity hospitals, all of which were surveyed, is located primarily in urban areas and has concentrations in the East North Central, South Atlantic, and Pacific regions[1]. Fifty-nine percent of the detailed responders were hospitals from urban areas, and 35 percent were from the East North Central region. Seventy-five percent of the quick responders were from urban areas, and 20.4 percent from the East North Central region. The majority of detailed responses were from Michigan, Ohio, and California, while the majority of quick responses were from New York, California, and Illinois. With 89 entities that did not complete the survey, California also had the highest non-response rate.

STATISTICAL ANALYSIS

Using a chi-squared test, the aggregate detailed and quick survey responders is not statistically significantly different from the overall population of 340B hospitals for the majority of characteristics with a 95% confidence level (i.e., bed count, teaching hospital status, entity type, and urban/rural location). However, the survey responders differ in terms of geographic region from the overall population. Additionally, the population of survey responders is statistically significantly different from the overall population of 340B hospitals in terms of 340B drug claim line volume at a 95% confidence level but not at a 99% confidence level (p-value = 0.0121). Please see Appendix B, Table 4.

The chi-squared summaries for the detailed and quick survey responders are available in Appendix B, Tables 5 and 6, respectively.

CONCLUSION

In conclusion, about 61 percent of the 340B hospitals submitted a quick or detailed survey. The characteristics of hospitals that completed the quick or detailed survey were similar to those observed in the overall population of 340B hospitals in terms of entity type, bed size, 340B drug volume, geographic locality, and teaching hospital status. For example, survey responses were received from cancer hospitals, children's hospitals, sole community hospitals and RRCs in addition to a large number of DSH hospitals. Therefore, we do not believe there are limitations in the generalizability of the survey data to the population of 340B covered entities.

---

[1] For a detailed list of abbreviations and states assigned to regions see Appendix A, Table 3.

Appendix A.

Table 1. Hospital Characteristics - Summary of 340B Survey Responders

	# 340B Entities	% 340B Entities	# Detailed Survey	% Detailed Survey	# Quick Survey	% Quick Survey	# No Affirmative Response	% No Affirmative Response
Bed Count								
Total	*1,422*	*100.0%*	*100*	*100.0%*	*780*	*100.0%*	*542*	*100.0%*
0 - 99	419	29.5%	33	33.0%	200	25.6%	186	34.3%
100 - 199	347	24.4%	18	18.0%	178	22.8%	151	27.9%
200 - 299	214	15.0%	21	21.0%	123	15.8%	70	12.9%
300 - 499	232	16.3%	20	20.0%	132	16.9%	80	14.8%
500 +	164	11.5%	8	8.0%	115	14.7%	41	7.6%
Missing	46	3.2%	0	0.0%	32	4.1%	14	2.6%
Teaching Hospital								
Total	*1,422*	*100.0%*	*100*	*100.0%*	*780*	*100.0%*	*542*	*100.0%*
Teaching	729	51.3%	52	52.0%	433	55.5%	244	45.0%
Non-Teaching	647	45.5%	48	48.0%	315	40.4%	284	52.4%
Missing	46	3.2%	0	0.0%	32	4.1%	14	2.6%
340B Drug Claim Line Volume (CY 2018)								
Total	*1,422*	*100.0%*	*100*	*100.0%*	*780*	*100.0%*	*542*	*100.0%*
0 - 499	522	36.7%	32	32.0%	241	30.9%	249	45.9%
500 - 999	115	8.1%	10	10.0%	57	7.3%	48	8.9%
1,000 - 4,999	458	32.2%	34	34.0%	267	34.2%	157	29.0%
5,000 - 9,999	152	10.7%	14	14.0%	95	12.2%	43	7.9%
10,000 - 49,999	158	11.1%	10	10.0%	106	13.6%	42	7.7%
50,000 +	17	1.2%	0	0.0%	14	1.8%	3	0.6%
Hospital Type								
Total	*1,422*	*100.0%*	*100*	*100.0%*	*780*	*100.0%*	*542*	*100.0%*
CAN	3	0.2%	0	0.0%	2	0.3%	1	0.2%
DSH	1,124	79.0%	67	67.0%	626	80.3%	431	79.5%

PED	51	3.6%	1	1.0%	37	4.7%	13	2.4%
RRC	74	5.2%	8	8.0%	39	5.0%	27	5.0%
SCH	155	10.9%	23	23.0%	74	9.5%	58	10.7%
Missing	15	1.1%	1	1.0%	2	0.3%	12	2.2%
Geographic Locality Type								
Total	*1,422*	*100.0%*	*100*	*100.0%*	*780*	*100.0%*	*542*	*100.0%*
Rural	395	27.8%	41	41.0%	196	25.1%	158	29.2%
Urban	1027	72.2%	59	59.0%	584	74.9%	384	70.8%
Region								
Total	*1,422*	*100.0%*	*100*	*100.0%*	*780*	*100.0%*	*542*	*100.0%*
East North Central	228	16.0%	35	35.0%	159	20.4%	34	6.3%
East South Central	133	9.4%	5	5.0%	69	8.8%	59	10.9%
Middle Atlantic	171	12.0%	11	11.0%	113	14.5%	47	8.7%
Mountain	89	6.3%	3	3.0%	51	6.5%	35	6.5%
New England	61	4.3%	5	5.0%	39	5.0%	17	3.1%
Pacific	223	15.7%	10	10.0%	78	10.0%	135	24.9%
Puerto Rico	5	0.4%	0	0.0%	0	0.0%	5	0.9%
South Atlantic	227	16.0%	12	12.0%	123	15.8%	92	17.0%
West North Central	112	7.9%	7	7.0%	67	8.6%	38	7.0%
West South Central	173	12.2%	12	12.0%	81	10.4%	80	14.8%

Table 2: State Summary of Survey Responses

State	# 340B Entities	% 340B Entities	# Full Survey	% Full Survey	# Quick Survey	% Quick Survey	# No Response	% No Response
Total	1,422	100%	100	100%	780	100%	542	100%
California	150	10.5%	7	7.0%	54	6.9%	89	16.4%
New York	95	6.7%	5	5.0%	72	9.2%	18	3.3%
Texas	83	5.8%	6	6.0%	40	5.1%	37	6.8%
Illinois	63	4.4%	5	5.0%	46	5.9%	12	2.2%
Ohio	61	4.3%	11	11.0%	38	4.9%	12	2.2%
Pennsylvania	54	3.8%	5	5.0%	30	3.8%	19	3.5%
Georgia	53	3.7%	5	5.0%	26	3.3%	22	4.1%
Michigan	51	3.6%	11	11.0%	35	4.5%	5	0.9%
North Carolina	51	3.6%	0	0.0%	33	4.2%	18	3.3%
Louisiana	47	3.3%	3	3.0%	18	2.3%	26	4.8%
Kentucky	44	3.1%	1	1.0%	30	3.8%	13	2.4%
Florida	39	2.7%	1	1.0%	30	3.8%	8	1.5%
Missouri	35	2.5%	3	3.0%	23	2.9%	9	1.7%
Washington	35	2.5%	1	1.0%	13	1.7%	21	3.9%
Indiana	32	2.3%	6	6.0%	24	3.1%	2	0.4%
Alabama	32	2.3%	1	1.0%	13	1.7%	18	3.3%
Mississippi	31	2.2%	2	2.0%	10	1.3%	19	3.5%
Colorado	29	2.0%	0	0.0%	21	2.7%	8	1.5%
Minnesota	27	1.9%	0	0.0%	20	2.6%	7	1.3%
Maryland	26	1.8%	2	2.0%	4	0.5%	20	3.7%
Tennessee	26	1.8%	1	1.0%	16	2.1%	9	1.7%
Massachusetts	26	1.8%	1	1.0%	18	2.3%	7	1.3%
Oregon	25	1.8%	2	2.0%	4	0.5%	19	3.5%
Arizona	25	1.8%	1	1.0%	11	1.4%	13	2.4%
Iowa	22	1.5%	4	4.0%	8	1.0%	10	1.8%

Arkansas	22	1.5%	3	3.0%	10	1.3%	9	1.7%
New Jersey	22	1.5%	1	1.0%	11	1.4%	10	1.8%
Wisconsin	21	1.5%	2	2.0%	16	2.1%	3	0.6%
Oklahoma	21	1.5%	0	0.0%	13	1.7%	8	1.5%
South Carolina	17	1.2%	1	1.0%	10	1.3%	6	1.1%
Virginia	17	1.2%	0	0.0%	14	1.8%	3	0.6%
West Virginia	14	1.0%	2	2.0%	2	0.3%	10	1.8%
Connecticut	12	0.8%	2	2.0%	10	1.3%	0	0.0%
Kansas	12	0.8%	0	0.0%	5	0.6%	7	1.3%
New Mexico	11	0.8%	0	0.0%	7	0.9%	4	0.7%
Maine	10	0.7%	2	2.0%	7	0.9%	1	0.2%
Hawaii	9	0.6%	0	0.0%	6	0.8%	3	0.6%
Montana	8	0.6%	0	0.0%	2	0.3%	6	1.1%
Utah	7	0.5%	0	0.0%	5	0.6%	2	0.4%
Idaho	6	0.4%	2	2.0%	4	0.5%	0	0.0%
Delaware	6	0.4%	1	1.0%	2	0.3%	3	0.6%
Nebraska	6	0.4%	0	0.0%	2	0.3%	4	0.7%
Vermont	6	0.4%	0	0.0%	3	0.4%	3	0.6%
South Dakota	6	0.4%	0	0.0%	6	0.8%	0	0.0%
Puerto Rico	5	0.4%	0	0.0%	0	0.0%	5	0.9%
Rhode Island	4	0.3%	0	0.0%	0	0.0%	4	0.7%
Alaska	4	0.3%	0	0.0%	1	0.1%	3	0.6%
District of Columbia	4	0.3%	0	0.0%	2	0.3%	2	0.4%
North Dakota	4	0.3%	0	0.0%	3	0.4%	1	0.2%
New Hampshire	3	0.2%	0	0.0%	1	0.1%	2	0.4%
Nevada	2	0.1%	0	0.0%	1	0.1%	1	0.2%
Wyoming	1	0.1%	0	0.0%	0	0.0%	1	0.2%

Table 3: Key

Region Abbreviations

ESC = East South Central
MA = Middle Atlantic
SA = South Atlantic
WSC = West South Central
WNC = West North Central
MNT = Mountain
ENC = East North Central
PAC = Pacific
NE = New England
PR = Puerto Rico

STATE	REGION
ALABAMA	ESC
ALASKA	PAC
ARIZONA	MNT
ARKANSAS	WSC
CALIFORNIA	PAC
COLORADO	MNT
CONNECTICUT	NE
DELAWARE	SA
DISTRICT OF COLUMBIA	SA
FLORIDA	SA
GEORGIA	SA
HAWAII	PAC
IDAHO	MNT
ILLINOIS	ENC
INDIANA	ENC
IOWA	WNC
KANSAS	WNC
KENTUCKY	ESC
LOUISIANA	WSC
MAINE	NE

MARYLAND	SA
MASSACHUSETTS	NE
MICHIGAN	ENC
MINNESOTA	WNC
MISSISSIPPI	ESC
MISSOURI	WNC
MONTANA	MNT
NEBRASKA	WNC
NEVADA	MNT
NEW HAMPSHIRE	NE
NEW JERSEY	MA
NEW MEXICO	MNT
NEW YORK	MA
NORTH CAROLINA	SA
NORTH DAKOTA	WNC
OHIO	ENC
OKLAHOMA	WSC
OREGON	PAC
PENNSYLVANIA	MA
PUERTO RICO	PR
RHODE ISLAND	NE
SOUTH CAROLINA	SA
SOUTH DAKOTA	WNC
TENNESSEE	ESC
TEXAS	WSC
UTAH	MNT
VERMONT	NE
VIRGIN ISLANDS	#N/A
VIRGINIA	SA
WASHINGTON	PAC
WEST VIRGINIA	SA
WISCONSIN	ENC

WYOMING	MNT
CALIFORNIA	PAC
AMERICAN SAMOA	
GUAM	
NORTHERN MARIANAS ISLANDS	
TEXAS	WSC
FLORIDA	SA
FLORIDA	SA
KANSAS	WNC
LOUISIANA	WSC
OHIO	ENC
PENNSYLVANIA	MA
TEXAS	WSC
MARYLAND	SA

Appendix B.

Table 4. Chi-Square Summary of Aggregate 340B Survey Responders

	% Responders	% 340B Hospitals	Chi-Square p-value	Chi-Square Interpretation
Bed Count				
0 - 99	26.5%	29.5%	0.2584	The population of responders is not statistically significantly different from the overall population of 340B hospitals.
100 - 199	22.3%	24.4%		
200 - 299	16.3%	15.0%		
300 - 499	17.3%	16.3%		
500 +	14.0%	11.5%		
Missing	3.6%	3.2%		
Teaching Hospital				
Teaching	55.1%	51.3%	0.1339	The population of responders is not statistically significantly different from the overall population of 340B hospitals.
Non-Teaching	41.3%	45.5%		
Missing	3.6%	3.2%		
340B Drug Claim Line Volume (CY 2018)				
0 - 499	35.0%	41.6%	0.0121	The population of responders is statistically significantly different from the overall population of 340B hospitals at the 0.05 level. However, the population of responders is not statistically significantly different from the overall population of 340B hospitals at the 0.01 level.
500 - 999	8.5%	9.3%		
1,000 - 4,999	35.9%	32.3%		
5,000 - 9,999	11.4%	9.8%		
10,000 - 49,999	9.2%	7.1%		
Hospital Type				
CAN	0.2%	0.2%	0.5022	The population of responders is not statistically significantly different from the overall population of 340B hospitals.
DSH	78.8%	79.0%		
PED	4.3%	3.6%		
RRC	5.3%	5.2%		
SCH	11.0%	10.9%		
Missing	0.3%	1.1%		

Geographic Locality Type				
Rural	26.9%	27.8%	0.6585	The population of responders is <u>not</u> statistically significantly different from the overall population of 340B hospitals.
Urban	73.1%	72.2%		
Region				
East North Central	22.1%	16.0%	0.0003	The population of responders <u>is</u> statistically different from the overall population of 340B hospitals.
East South Central	8.4%	9.4%		
Middle Atlantic	14.1%	12.0%		
Mountain	6.1%	6.3%		
New England	5.0%	4.3%		
Pacific	10.0%	15.7%		
Puerto Rico	0.0%	0.4%		
South Atlantic	15.3%	16.0%		
West North Central	8.4%	7.9%		
West South Central	10.6%	12.2%		

Table 5. Chi-Square Summary of 340B Detailed Survey Responders

	% Full Responders	% 340B Entities	Chi-Square p-value	Chi-Square Interpretation
Bed Count				
0 - 99	33.0%	29.5%	0.1026	The population of responders is <u>not</u> statistically significantly different from the overall population of 340B hospitals.
100 - 199	18.0%	24.4%		
200 - 299	21.0%	15.0%		
300 - 499	20.0%	16.3%		
500 +	8.0%	11.5%		
Missing	0.0%	3.2%		
Teaching Hospital				
Teaching	52.0%	51.3%	0.1852	The population of responders is <u>not</u> statistically significantly different from the overall population of 340B hospitals.
Non-Teaching	48.0%	45.5%		
Missing	0.0%	3.2%		
340B Drug Claim Line Volume (CY 2018)				
0 - 499	40.0%	41.6%	0.9538	The population of responders is <u>not</u> statistically significantly different from the overall population of 340B hospitals.
500 - 999	9.0%	9.3%		
1,000 - 4,999	36.0%	32.3%		
5,000 - 9,999	9.0%	9.8%		
10,000 - 49,999	6.0%	7.1%		
Hospital Type				
CAN	0.0%	0.2%	0.0048	The population of responders is statistically different from the overall population of 340B hospitals.
DSH	67.0%	79.0%		
PED	1.0%	3.6%		Please note that the Chi-Square analysis may not be the most appropriate statistical test for this measure due to low sample size since 33% of the categories have expected counts less than 5.
RRC	8.0%	5.2%		
SCH	23.0%	10.9%		
Missing	1.0%	1.1%		
Geographic Locality Type				

Rural	41.0%	27.8%	0.0047	The population of responders is statistically different from the overall population of 340B hospitals.
Urban	59.0%	72.2%		
Region				
East North Central	35.0%	16.0%	0.0016	The population of responders is statistically different from the overall population of 340B hospitals.
East South Central	5.0%	9.4%		
Middle Atlantic	11.0%	12.0%		
Mountain	3.0%	6.3%		
New England	5.0%	4.3%		
Pacific	10.0%	15.7%		
Puerto Rico	0.0%	0.4%		
South Atlantic	12.0%	16.0%		
West North Central	7.0%	7.9%		
West South Central	12.0%	12.2%		

Table 6. Chi-Square Summary of 340B Quick Survey Responders

	% Quick Responders	% 340B Entities	Chi-Square p-value	Chi-Square Interpretation
Bed Count				
0 - 99	25.6%	29.5%	0.1261	The population of responders is not statistically significantly different from the overall population of 340B hospitals.
100 - 199	22.8%	24.4%		
200 - 299	15.8%	15.0%		
300 - 499	16.9%	16.3%		
500 +	14.7%	11.5%		
Missing	4.1%	3.2%		
Teaching Hospital				
Teaching	55.5%	51.3%	0.0548	The population of responders is not statistically significantly different from the overall population of 340B hospitals.
Non-Teaching	40.4%	45.5%		
Missing	4.1%	3.2%		
340B Drug Claim Line Volume (CY 2018)				
0 - 499	34.4%	41.6%	0.0053	The population of responders is statistically different from the overall population of 340B hospitals.
500 - 999	8.5%	9.3%		
1,000 - 4,999	35.9%	32.3%		
5,000 - 9,999	11.7%	9.8%		
10,000 - 49,999	9.6%	7.1%		
Hospital Type				
CAN	26.0%	0.2%	0.2211	The population of responders is not statistically significantly different from the overall population of 340B hospitals.
DSH	80.3%	79.0%		
PED	4.7%	3.6%		
RRC	5.0%	5.2%		
SCH	9.5%	10.9%		
Missing	0.3%	1.1%		
Geographic Locality Type				

Rural	25.1%	27.8%	0.1796	The population of responders is <u>not</u> statistically significantly different from the overall population of 340B hospitals.
Urban	74.9%	72.2%		
Region				
East North Central	20.4%	16.0%	0.0031	The population of responders <u>is</u> statistically different from the overall population of 340B hospitals.
East South Central	8.9%	9.4%		
Middle Atlantic	14.5%	12.0%		
Mountain	6.5%	6.3%		
New England	5.0%	4.3%		
Pacific	10.0%	15.7%		
Puerto Rico	0.0%	0.4%		
South Atlantic	15.8%	16.0%		
West North Central	8.6%	7.9%		
West South Central	10.4%	12.2%		