

### Amount of time and effort needed to complete the quarterly process overall

Current process involves mostly manual tasks and processes which are completed using various Excel files. Manual tasks include calculations within Excel, manually identifying possible errors or anomalies by comparing data and pricing (ASP, AMP) to previous files, looking for increases/decreases, validating drug data using Compendia or Google, etc.



"If I had to vote for the first thing, I think we should do. I think we need to improve the intake. I mean just the editing, the validating on the front end, because that would ultimately cut down on the amount of time (the team) spends reaching out to manufacturers (about possible errors)."

"What we also do is we do a quality check to see, for example, if the data that is being submitted is within a reasonable range of the previous quarters data. We have to do that manually. That's actually very time consuming, and it's prone to a human error."

"Let the portal do the heavy lifting."

*Decision points in the process:*

"... if there was a WAMP substitution we're just entering in the price OIG tells us to enter. (For others) there are several decision points where the system would have to compare: is the ASP greater, or is the AMP greater? And second comparison, if the AMP substitution is potentially going to be made. Is it is that drug in shortage? If the drug is in shortage, then we don't make it. Those decision points could be done automatically. But it is not. The system is nowhere near that granular in its initial design to make those different decisions."

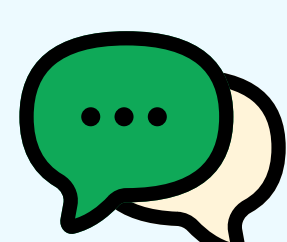
Screenshot of Input File that shows CMS users have manually flagged items to check:

Manufacturer's Name	NDC1	NDC2	NDC3	Concatenated Alternate or Alternate ID	match to previous quarter's background out file	match to previous quarter's palmetto input file	match to prior quarter input file	match to prior quarter's input file's reasons for not crosswalking	Manufacturer's Average Sales Price	Rounded ASP	Number of ASP Units	Rounded Acquistion Cost	Wholesale WAC	Check ASP-WAC	WAC Check %	WAC Check %	Potential Reason for ASP-WAC	Name of Drug or Biologic Product	Strength of the Product	Volume of Items per NDC	Number of Items per NDC
1 ACCORD HEALTHCARE INC.	18729	6250	63	18729-0250-03	#N/A	#N/A	#N/A		\$65.071	\$65.071	1,220,000	\$400,000	\$400,000	ok	-8.73%	-8.73%		BENDAMAL 25 mg	25 mg	1	1
3 ACCORD-HEALTHCARE INC.	18729	6251	50	18729-0251-00	#N/A	#N/A	#N/A		\$411.888	#####	1,380,000	\$600,000	#####	ok	-10.11%	-10.11%		BENDAMAL 100 mg	100 mg	1	1
4 A-S MEDICATION SOLUTIONS	50900	6468	50	50900-6468-00	#N/A	#N/A	#N/A		\$ 6.50	\$3.450	52,000	\$ 300	\$6.300	ok	-42.06%	-42.06%		PROMETH 25 mg	25 mg	1	1
5 A-S MEDICATION SOLUTIONS	50900	6131	00	50900-6131-00	#N/A	#N/A	#N/A		\$5.450	\$15.450	2,000	\$ 7.140	\$7.140	check	\$8.310	116.39%	generic	mi ESCITALOI 10mg	10mg	53	1
6 A-S MEDICATION SOLUTIONS	50900	6189	00	50900-6189-00	#N/A	#N/A	#N/A		\$6.020	\$16.020	2,000	\$4.100	\$14.100	check	\$1.920	13.62%	generic	mi GABAPEN 800mg	800mg	50	1
7 A-S MEDICATION SOLUTIONS	50900	6189	51	50900-6189-01	#N/A	#N/A	#N/A		\$1.150	\$21.150	20,000	\$1.150	\$21.150	ok	0.00%	0.00%		GABAPEN 800mg	800mg	50	1
8 A-S MEDICATION SOLUTIONS	50900	6190	00	50900-6190-00	#N/A	#N/A	#N/A		\$ 7.120	\$7.120	42,000	\$ 4.490	\$6.490	check	\$0.630	9.71%	generic	mi ESCITALOI 10mg	10mg	50	1
9 A-S MEDICATION SOLUTIONS	50900	6190	01	50900-6190-01	#N/A	#N/A	#N/A		\$ 3.340	\$9.340	776,000	\$9.470	\$19.470	ok	\$10.130	32.03%		ESCITALOI 10mg	10mg	90	1
10 A-S MEDICATION SOLUTIONS	50900	6188	50	50900-6188-00	#N/A	#N/A	#N/A		\$0.000	\$10.000	483,000	\$1.000	\$13.000	ok	\$5.000	33.33%		IPRATROPI 3.5mg/3ml	3.5mg/3ml	1	1
11 ASTRAZENECA	50310	6405	55	00310-6405-25	#N/A	#N/A	#N/A		\$242.888	#####	233,000	\$538.889	#####	ok	#####	-32.98%		TREMELIN 25MG V1 1.25ML	1.25ML	1	1
12 ASTRAZENECA	50310	6435	30	00310-6435-30	#N/A	#N/A	#N/A		\$8978.525	#####	566,000	\$3066.667	#####	ok	#####	-33.00%		TREMELIN 300MG V1 15ML	15ML	1	1
13 AVKARE, LLC	50268	5075	53	50268-0075-15	#N/A	#N/A	#N/A		\$6.380	\$28.380	296,000	\$4.190	\$49.190	ok	\$20.810	-41.90%		ANASTRO 1mg per 11.20 in one	11.20 in one	5	1
14 BRACCO DIAGNOSTICS	60270	7250	10	00270-7250-10	#N/A	#N/A	#N/A		\$18.101	\$18.101	5,000	\$46.390	\$864.390	ok	-\$328.289	-38.79%		ICOMEPIC/550	500	100	56

### Amount of time and effort needed to manually validate drug data

Pharmacists must manually verify:

- Drug data that manufacturers submit for new drugs (NDCs and skin substitutes).
- New drugs identified by Palmetto as Part B.



"... why can't (manufacturers) submit the information in the portal. And then we kind of just validate the information rather than doing the digging from square one."

"So I feel like a lot of the work is where we kind of have to go back and find information which really should be available easily."

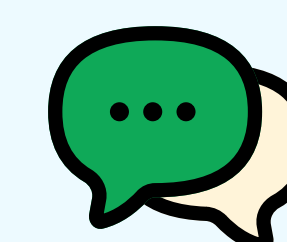
*Skin substitute research:*

"It's a very manual process. It's very time consuming and it takes quite a bit of manual effort just to make sure what they're submitting to us is accurate, because you know it's really the burden of responsibility. If we're publishing files, and their information is on our file, yes, they have responsibility to make sure what they're sending us is right, but we have also a responsibility to make sure what we're publishing is also correct."

"We really want to validate it in a publicly available source in order to ensure that the information that they are submitting to us is actually accurate information. With NDCs we can validate from, like, you know the Red Book, Daily Med, whatever. For skin substitutes they don't have NDCs, and they're not in any of the compendia. So, this is what they do (referring to using Google to search for drug data for skin substitutes).

### Data that contains errors, or is inaccurate, or anomalies in data

CMS staff uses the "Input" Excel file to manually look/check for data that seems off or incorrect (i.e. ASP and WAC transposed, decimals that may be off, etc).



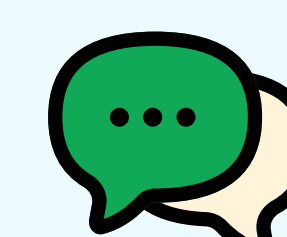
"If someone reports inaccurate data, everything from that point is false."

"For this quarter ... I checked about one hundred and thirty or then thirty-five towards, and I flagged twenty-six to make inquiries. Some companies had an explanation. Some admitted they made a mistake."

"The OIG has pointed out in multiple different times, not just here, but in descriptors of codes and that kind of thing, mistakes that maybe the manufacturer entered, and honestly, we don't look super heavily at fields that don't affect pricing, and the OIG has aligned our thinking on that one because they don't want to see errors."

### Unaware of when an NDC changes manufacturers

NDC may change to another manufacturer if that manufacturer has subsidiaries (*note: still has the same submitter and certifier*) or if an NDC is sold to another manufacturer.

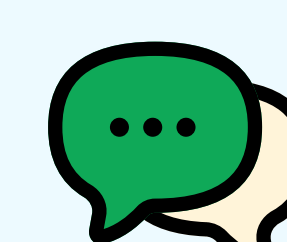


"So we have manufacturers, I guess they have subsidiaries or something, but it's the same submitter and certifier, and they'll report them as these different entities. Then I'll reach out and say your asp submission is late. (They reply) that they certified on this date. (I ask) are you no longer reporting on the manufacture name B? (They reply) that all NDCs that were reported under A, B and C are now being reported as this..."

...so maybe if the system can tell us when the NDC has changed manufacturer name, or it's being reported as a different manufacturer name that'd be great so I know not the contact them."

### Unaware of when a manufacturer has restated & unable to track restatements

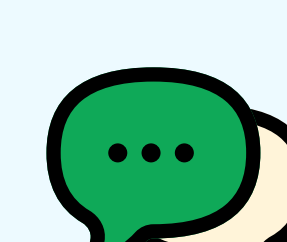
Contacts a manufacturer if there is an error in their submission but at times discovers they've already corrected it because the system does not flag or track restatements. Would also be helpful to track who is resubmitting and how often.



"When the process was manual, they came here through Cd. So if there was a change, I had a Cd. So I knew what was new. (In the current system) we don't have a notification or alert. I don't know what's there. Although I'm reaching out the manufacturers when I do some of these checks, and saying, "Hey! We noticed this." There could be another manufacturer that noticed their own stuff, and they do the resubmission. But I won't know that person did a resubmission, because I'm not getting an alert."

### Multiple names/spellings in the system for one manufacturer

Submitters enter a new name with a different spelling or abbreviation, etc. There can be multiple names in the system for one manufacturer.



(Submitters) create another manufacturer name. It's the same (company), but they put a period, a comma, or something like that. They can have two entries. One of them their name is misspelled, and they're submitting about twenty NDCs or alternate IDs under the correct one, and then about 2, 3, or 4 identifiers under the one that is spelled incorrectly.