4º Insights: Wish List

Wish List of New Functionality & Improvements from User Discovery Interviews completed March 2023

Notifications & Communication Tracking

- Ability to send submission reminders to manufacturers who have not yet submitted
- Ability to flag and then notify CMS when a manufacturer has restated or something has changed
- Ability for system to flag and send a notification when an NDC has changed manufacturers
- Ability to email to manufacturers via the portal, and to keep an on-going record of contacts made

> "If the system could generate responses like ... if their submission is late, that'd be great. Going in there, select the manufacturers, push a button that sends an email, 'Your asp submission is late. Please log into the system … blah blah blah.' That will be great."
>
> "Essentially, we're sending out, if I were to guess, thirty emails per quarter. It's hard to keep track if someone didn't respond. And then, if someone didn't respond, you have to see which email they didn't respond to because you are sending it from an email that's not from the portal."
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> "So we have manufacturers, I guess they have subsidiaries ... but it's the same submitter and certifier, and they'll report them as different entities. I'll get to a quarter, and will reach out and say, "Your asp submission is late." They send me a thing back to say, "I certified on this date." So I said,'Are you no longer reporting on the manufacturer name B?' They replied, "Oh, no. All of the 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 or the manufacturer name, or it's being reported as a different manufacturer ... that'd be great, so I know not to contact them."

Submissions Enhancements

- Ability for system to identify new drugs not previously submitted
- Ability to see, and track who submits each submission for each manufacturer
- Include a contact email for all manufacturer submissions
- Ability to flag non-reporters (new manufacturers submitting for first time)
- Additional data fields to make it easier to validate drug details such as package size, package quantity, bill units, bill units per package, link to drug data (web page or online brochure), FDA marketing date, FDA approval date, if the item was transferred to a manufacturer and when it was transferred.
  - Added after the interviews: New field for manufacturers to identify drugs as single dose, or multi dose, or type in other.
- Quality checks when data is submitted and ability for system to flag anomalies i.e. duplicated data, items that are less than/ greater than previous quarter (or above/below a set threshold), changes to volume-weighted average price (VWAP)

> "The system should be able to flag anomalies. We do that manually. We call it the HCPCS level quality check. Just for this quarter I flagged about twenty-six possible incorrect data. And out of that, six or seven of them, I was right. The companies did admit that they made mistakes and they resubmitted them. I'd like the system to flag those things right at the point of report."
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> "If there are 10 drugs in the code and there is a 10% price drop. But that volume-weighted average rate could be 10% higher than the previous year based on the number of units. If more units sold in the more expensive one, then the ASP (VWAP) goes much faster. So those things should be flagged and checked. Why is this price changing? And what could be the culprit?"
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> "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 because a lot of times, if we miss whether a manufacturer had a huge price jump, and then we publish that information ... the manufacturer may come back and say, 'Sorry, you know we made a mistake. Now we need to restate the data.' So then it kind of becomes our fault."
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> "...we'll email them and say for this NDC we noticed that there was a significant price increase. Please restate the data, if necessary, or reply with additional information. (But) when we're going through the (submission tracking report), we don't have like the emails in the files already. We have to download another file just to figure out who we need to email."
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> "So what I found a couple of manufacturers that were new into the system. They went back and reported data. This is their first time reporting for Q4 2022 but they went back and reported data for Q3 2022. Now they're showing up on the late report. They're not late reporters. They were non-reporters because they did not report at all for those."

Restatement Enhancements

- When a manufacturer reinstates, send a notification to CMS
- Flag restatements within the system
- Ability to track all restatements: who has restated, when, and how often
- Ability to see previously submitted data
- Differentiate between restatements and late submissions

> "Having notifications of whenever a manufacturer goes in there and restates data. That would be good so that we keep track of who's restating, how often, and when, to make sure that we capture everything."
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> "Manufacturers do have an obligation to report accurate information on time, but that falls into a slightly different bucket than just being late. Because if I reported 385 NDCs, and I had error in only five of them, that's not the same. I'm not late. I submitted 385 NDCs. I just found errors in five that needed to be restated."

Enhancements for CMS Users

CMS users would like the ability to:

- Create records for drugs within the portal
- Validate drugs, add notes, etc., in the portal
- Download the compliance report
- Sort and filter data
- Identify rebatable drugs
- Remove non-compliant drugs (as well as other tasks DCCA does now)
- View data that manufacturers previously submitted (they have to ask DCCA to provide that now)
- Contact manufacturers via the system
- Import HCPCS file, Compendia files, OPPS files in order to view data within the portal

> "Having a more robust way of kind of viewing the data, downloading it. It would just be very helpful. For example, in the compliance screen, once you have the data on your screen I think it only views like ten lines at a time ... and there's no option to download that, either."
>
> "And calculating the payment limits. We had that feature there, I actually tested it. We didn't push it through ... I don't think they pushed it through to the program because we didn't push like a lot of the other processes that lead up to it."
>
> "When we're calculating the bill units, bill units per package, and a lot of that ... it is a very manual process, and even having one character wrong in your excel formula control and the whole thing is off."

Enhancements for ASP Portal

- Perform automated calculations and data comparisons to replace tasks that are currently performed manually
- Generate the background file
- Calculate the payment limits *(Note: This was built for current portal but is not currently used)*
- Create the crosswalk. *(Note: Was tried previously but was not successful)*
- Improve search functionality

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>
> "Even if the system could generate the background file, and I think we had gotten close to it. But then we pulled back, and we were like we'll just use it for an intake system. But even if it generated the background file. That's that would be a big, you know. That would be a big to do."

Enhanced Reporting

- Ability to track late reporters over multiple quarters
- Ability to see and compare previously submitted data
- Ability to view multiple quarters of data for one or more manufacturers
- More reports such as how many drugs are rebatable, how many were close to being rebatable (for OIG)
- Tracking/trending reports of how something has changed over multiple quarters such as how bio-similars have changed
- There will be one-time requests which do not need to be automated but CMS needs functionality to run such reports

> "We used to track ... the late reporter sheet, although Felicia says it doesn't actually track accurately track late reporters. It doesn't have all the information they're looking for. What the OIG is looking for is not the guy that was late one quarter. They want to look for the guy that's been 20 days late, four quarters in a row." *(Note: Kwan has been working on this and has talked to OIG about it.)*
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> "You know there are a lot of questions like how many drugs were almost rebatable, how many were like within one percent of being rebatable, how many drugs were rebatable, and just being able to generate these counts really, really, really, quickly."
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> "I'm assuming that we'll probably get into those (report) details as a project, but the same with biosimilars, I mean, we have to report how many bios, how it's changed over time, you know. (OIG) seems to like a lot of how something's changed across quarters."

Improve Oversight of Manufacturers & Internal Controls

Additional data needed to improve oversight and accountability

- Have system track pricing methodology used and why
- Strengthen internal controls to help reduce late submissions
- More detailed, granular reporting
- Capture and track submission details
- Who submitted and when
- Details of what they submitted
- Who certified it and when
- Close gaps in the oversight of manufacturer-reported ASP data to ensure the accuracy of ASP data and calculation of Part B drug payment amounts (implementing data checks, oversight of processes used to analyze data and calculate payment amounts. *(Noted in an OIG report.)*
- Create analytics reports to monitor ASP data quality and maximize oversight capabilities. *(Noted in an OIG report.)*

> "This (report from OIG). We need to bolster our oversight of manufacturers to ensure accurate payments ... strengthening our internal controls."
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> "...if somebody logged in with an ID there's got to be a way to track their behavior in the system."
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> *Referring to Rebatable drugs:*"We've got to be very, very, very accurate, because the minute we start billing back a manufacturer because they have wasted over ten percent of a drug, you know, or because their drug price went higher than inflation ... we're going to be in arguments about what they really submitted, because nobody's going to want to pay a rebate back to the Government."
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> *Referring to Rebatable drugs:* "I think we're just gonna have to have much better tracking. Your representative on this date, put in this data, and they certified that that was accurate. Not only did the submitter, submit it. But your CFO certified it. We've got to be able to be very, very, very accurate about what their behavior has been in the system.

Improvements for Drug Manufacturers

- Ability to add/edit points of contact (include a secondary contact)
- Ability to select items from dropdown lists to prevent errors (i.e, manufacturer names)
- Flag possible errors or anomalies in the system before they submit data
- Define CMS terms better as some drug manufacturers struggle with them e.g., Date of sales, Date of marketed, Reporting units
- Improved submission guidance such as:
  - Types of drugs they should include
  - Type of sales they should include or exclude
  - Guidance for manufacturers with multiple identifiers
  - Ensuring they know to report at NDC level unless drug appears in units other than NDC
- Add more help and guidance at the point of need: tool tips, FAQs; videos; webinars

> "I think the biggest question I see from them is, 'If I don't have this data, do I enter? Do I leave it blank or do I enter a zero?'"
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> "They need more guidance on the drugs they should include, and they need more guidance on the type of sales they should include or exclude. That part is pretty weak as of today."
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> "A study was performed last year, a market survey of some manufacturers. Eighteen items were flagged on where CMS needs to provide more guidance."
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> "But we've gotten several Inspector General findings where they're finding inconsistencies in the way that ASP is being submitted, and some of them may be deliberate inconsistencies, but some of these, I think, are also that there is not a lot of help capability. If you're a newer reporter, trying to understand like what it is you need to report ... like the ASP user guide as an example, is a collection of screenshots, and there is absolutely no information in that user guide beyond what's on the screen."
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> "I think that there are terms they have to report. You know, some volume weighted, sales, that kind of thing. I hear a lot about how they're confused on what goes into that calculation, and for some of these fields what is the difference between date of sale and date last marketed? Being very clear about what's in, and what's out. If you're reporting units, what units are you reporting ... units for an individual NDC, units for a fixed code? What is it, you know?"
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> "In the last two quarters or three quarters. We have exponentially more users. And these guys, many of them, are skin substitute manufacturers that have never reported to us. We've got a lot of newer folks that haven't already figured out a process that don't even know where to start. We're having a hard time verifying some of their data, because, some reasons that have nothing to do with the system, but some of it, because they're new..."