TO: PCAs

FROM: Colleen Meiman, National PCA Policy Advisor

DATE: May 28, 2021

RE: **340B Data Requests from CiiTA/ Novo-Nordisk – Summary and Recommended Response**

Over the past week, many CHCs have received an email from CiiTA Inc, on behalf of drug manufacturer Novo Nordisk, asking for data on a large number of prescriptions dispensed to Medicaid patients. This memo gives an overview of these requests – including how they compare to other data requests CHCs have recently received -- and provides recommendations on how CHCs should respond.

Overview of CiiTA/Novo requests:

Here are some key points about the CiiTA/Novo requests, and how they compare to other data requests that CHCs have recently received.

* **In many ways, the CiiTA/Novo requests are similar to the “traditional” requests that Kalderos has been sending CHCs over the past few years.** By “traditional” Kalderos requests, I mean those asking for data on a limited number of drugs dispensed to Medicaid patients only. (Kalderos has been issuing many other types of requests recently, which we generally advise CHCs to not comply with.) Thus, my recommendations for responding to CiiTA/Novo largely mirror my recommendations for responding to traditional Kalderos requests.
* **Unlike Merck and Sanofi, CiiTA/Novo is asking only about Medicaid, which is an allowable area for manufacturer oversight.** CiiTA/ Novo’s requests are currently limited to drugs dispensed to Medicaid patients. As these drugs could potentially be subject to duplicate discounts *that are prohibited by Federal law* (both a 340B discount and a *Medicaid* rebate), there are 340B compliance issue involved. Thus, CHCs are expected by HRSA to make a “good faith effort” to work with manufacturers to identify potential compliance issues with Medicaid drugs – meaning that they should respond to CiiTA’s request. In contrast, Merck and Sanofi are seeking data on drugs dispensed to Medicaid, Medicare and privately insured – citing a need to avoid “duplicate discounts” on all three categories. However, for Medicare and private drugs, the second discounts that the manufacturers want to avoid paying are the rebates they voluntarily negotiated with PBMs (to encourage them to put their drugs on their formularies.) As such second discounts are allowed under 340B, CHCs are under no obligation to provide manufacturers or PBMs with data on drugs dispensed to Medicare and privately insured patients.
* **CiiTA/Novo may ask about a very large number of claims**. Some CiiTA/ Novo requests are much larger than traditional Kalderos requests; for example, CiiTA has asked one CHC for data on almost 3,500 claims.
* **CiiTA/Novo may request data beyond the three-year window that CHCs are required to retain records.** CiiTA /Novo is asking for info as far back as 2017. As [long-standing HRSA guidance](https://www.govinfo.gov/content/pkg/FR-1996-12-12/pdf/96-31541.pdf) requires CHCs to keep 340B records for only three years, CHCs may not have (or choose to provide) data on prescriptions filled more than three years ago.

Recommendations for how to respond:

In short, I recommend that CHCs make a “good faith effort” respond to these requests in a reasonably prompt manner – which may not require responding to the full request. Specifically:

* **Respond in a reasonably prompt manner**. If the CHC ignores the request, Novo could claim that the CHC is failing to act “in good faith” to ensure compliance, and use this as a justification for a full-fledged manufacturer audit.
* **If the request is for a large number of prescriptions, try:**
	+ **submitting data on only a subset of claims requests**
	+ **highlighting the pattern of compliance demonstrated by that subset**
	+ **highlighting the administrative burden of complying with the full request.**

Some CHCs have used this approach successfully with Kalderos. For example, if Kalderos requested data on 300 claims, they provided data for only the first 100. They then stated that since there were no compliance issues identified in the first 100 claims, there are unlikely to be any issues with the next 200. Finally, they outlined the administrative burden involved in responding to the full batch of claims, indicating that providing all the requested data would far exceed the “good faith effort” expected by HRSA.

* **Only respond to claims from within the past three years.** [Long-standing HRSA guidance](https://www.govinfo.gov/content/pkg/FR-1996-12-12/pdf/96-31541.pdf) requires 340B providers to maintain records for three years. (Page 65407, second column reads “Covered entities should maintain records to demonstrate the distribution and use of covered drugs for a period of not less than 3 years.”) Therefore, CHCs should feel free to indicate that they do not have records beyond that point, and reference the guidance.
* **Do not provide more information than specifically requested**. At times, Kalderos has offered to “make things easier” for CHCs by inviting them to submit large data sets, rather than just info on specific prescriptions. As providing more info than required benefits CiiTA/ Kalderos much more than the CHC, I strongly discourage CHCs from taking the so-called “easier” option.

Finally, please note that CHCs appear to be the only type of 340B provider to be receiving these requests to date. I am unsure why Novo-Nordisk would single out CHCs, as they are usually very supportive of CHCs and other 340B grantees. (For example, they currently refuse to ship 340B-priced drugs to contract pharmacies on behalf of hospitals, but place no limits on CHCs’ or other grantees’ use of contract pharmacies.) I am doing more research on this and expect to have an update next week.