

William H. von Oehsen  
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May 12, 2023

*Via Email*

Carole Johnson  
Administrator  
Health Resources and Services Administration  
U.S. Department of Health and Human Services  
Parklawn Building  
Room 13N188  
Rockville, MD 20857

**Re: 340B Eligibility of Unregistered Hospital Outpatient Department Patients**

Dear Administrator Johnson:

Our law firm represents numerous hospitals participating in the 340B drug pricing program (340B program). We also serve as counsel to 340B Health whose members include more than 1,400 340B hospitals. I am following up 340B Health's letter to you dated May 9, 2023 requesting clarification that hospitals may continue to use 340B for 340B-eligible patients in hospital outpatient departments (HOPDs) that are not registered in the 340B database because the costs of the HOPDs have not yet appeared on a filed Medicare cost report. In particular, we wanted to share the attached email exchange we had with Apexus in May 2020 regarding HRSA's FAQ acknowledging for the first time that individuals receiving services in unregistered HOPDs may still be 340B eligible if they meet HRSA's 1996 patient definition guidance. Apexus made clear in that email exchange that the 340B eligibility of patients at unregistered HOPDs was not a temporary policy adopted in connection with the COVID-19 public health emergency (PHE). Rather, in Apexus's own words, the policy "is applicable regardless of COVID-19." We therefore share the confusion expressed by 340B Health over HRSA's apparent withdrawal of this policy on the grounds that it only applied during the PHE.

Sincerely,



William von Oehsen  
Principal

cc: Rear Admiral Krista M. Pedley, Director, Office of Special Health Initiatives, Health Resources and Services Administration

Dr. Emeka Egwim, Director, Office of Pharmacy Affairs, Health Resources and Services Administration

Maureen Testoni, President and Chief Executive Officer, 340B Health

# Attachment

**From:** von Oehsen, William  
**Sent:** Monday, May 18, 2020 5:31 PM  
**To:** 'Richardson,Katheryne' <katheryne.richardson@apexus.com>  
**Subject:** RE: Follow-Up 340B Registration Question

Katheryne: Wow! I guess I had assumed that using 340B for infusions at an unregistered site would normally be considered diversion and is only being tolerated by HRSA right now because of the COVID-19 public health emergency. But a permanent change in position makes a lot of sense to me because the only obstacle to registration is the lag time involved in filing a new Medicare cost report. It seems to me that an individual's status as a "patient" should not depend on the timing of when a cost report is filed. Good to see the agency coming around on this point. Bill

**From:** Richardson,Katheryne [<mailto:katheryne.richardson@apexus.com>]  
**Sent:** Monday, May 18, 2020 2:16 PM  
**To:** von Oehsen, William  
**Subject:** RE: Follow-Up 340B Registration Question

Thanks for reaching out, Bill. The highlighted advice in yellow is applicable regardless of COVID-19.  
Katheryne

**From:** von Oehsen, William  
**Sent:** Monday, May 18, 2020 9:49 AM  
**To:** Richardson,Katheryne  
**Subject:** Follow-Up 340B Registration Question

Katheryne:

Am I right that your advice highlighted in yellow is applicable only during the COVID-19 public health emergency? You cite the 1996 patient definition guidance in support of the highlighted statement, which could suggest that the policy is applicable regardless of COVID-19. I ask because covered entities are asking what happens when the public health emergency ends.

Thanks, Bill

**From:** Richardson,Katheryne [<mailto:katheryne.richardson@apexus.com>]  
**Sent:** Tuesday, April 21, 2020 4:38 PM  
**To:** von Oehsen, William  
**Subject:** RE: 340B Registration Question

Hi Bill,  
Thank you for reaching out. I hope you are adjusting to the work from home situation without any issues on your team.

Your question is similar to others that we've seen, and HRSA has responded consistently to it, so I will share that response below. I am confident it applies to your situation. If you'd like to call me for clarity, I am available at the number below.

Response:

HRSA is unable to register a site not on the Medicare cost report. In order to be registered and listed on the 340B Office of Pharmacy Affairs Information System (OPAIS), the site must have reimbursable outpatient costs and charges on the most recently filed Medicare cost report.

However, until such time the site is listed on the cost report, we would note that patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity. These situations should be clearly auditable and documented in policies and procedures. More information on HRSA's patient definition guidance can be found at <https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf>.

In addition, information regarding flexibilities during this time can be found at <https://www.hrsa.gov/opa/COVID-19-resources>.

Katheryne  
Katheryne Richardson, PharmD  
Vice President, 340B Compliance

469.299.7303

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**From:** von Oehsen, William [<mailto:William.vonOehsen@PowersLaw.com>]  
**Sent:** Monday, April 20, 2020 5:50 PM  
**To:** Richardson,Katheryne <[katheryne.richardson@apexus.com](mailto:katheryne.richardson@apexus.com)>  
**Subject:** 340B Registration Question

Katheryne:

I hope you and your family are safe and healthy. My guess is that you're getting a lot of "family time".

I'm reaching out with respect to a question I received today from a 340B DSH hospital that is seeking regulatory relief to help register a new child site that has been adversely affected by the coronavirus. I read a statement from OPA that appeared in last week's 340B Report. The statement seems to indicate that OPA can help expedite enrollment of hospital facilities in the 340B program if there are compelling reasons attributable to the covid-19 pandemic. Here's the statement:

"HRSA understands the critical role that covered entities are playing at this time more than ever. We have worked with each entity that has contacted us and we are evaluating each circumstance situation based on the unique circumstances they present. To the extent we can provide an immediate enrollment into the 340B Program, we will work with the entity to do so. Otherwise, we are providing targeted technical assistance that supports the entity to ensure

they are maximizing all possible opportunities to participate in the Program. HRSA encourages entities with questions to first contact the 340B Prime Vendor Program (1-888-340-2787 or [apexusanswers@340bpvp.com](mailto:apexusanswers@340bpvp.com)) and they will coordinate technical assistance with HRSA. In addition, covered entities are also encouraged to visit the 340B Program COVID-19 webpage for other flexibilities during this time.”

This statement gives me hope that maybe the agency would help be willing to help register the hospital’s new child site on an accelerated timeframe.

Here are the facts. The hospital was planning on opening up a new site, including an infusion center, in a covid-19 hotspot before June 30 which is the end of its fiscal year. That would have allowed it to include the new site on its next Medicare cost report in time to register the site in OPAIS in October for a January 1, 2021 start date. The hospital just learned that, due to the coronavirus, the state will not be able to perform the provider-based occupancy survey that the hospital needs in order to include the new site on the cost report. That’s because all of the state board inspectors are being furloughed as a result of the virus. The hospital doesn’t want to wait a whole additional year to start using 340B for infusions at the new site. Do you think HRSA would register the site during the October registration period given the circumstances? Might it even be willing to register it during the July window? If you think this is a reasonable request, what is the process that the hospital should follow?

I’m not sure if it’s relevant or not but the new site will be highly integrated with the hospital – shared EHR, all doctors employed by the hospital, all doctors credentialed at the hospital, etc. And the infusion center would only use 340B for infusions ordered by the hospital (no outside orders). We know that HRSA has recently be willing to recognize the 340B eligibility of prescriptions written at unregistered sites on a case-by-case basis. Maybe HRSA would be more willing to grant the request for expedited enrollment knowing these additional facts.

Thanks, Bill

William H. von Oehsen

## **POWERS**

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