



September 11, 2020

(VIA ELECTRONIC MAIL: KPedley@hrsa.gov)

Krista Pedley, RADM
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 8W05A
Rockville, MD 20857

Re: 340B Drug Pricing Program Telehealth Policies Beyond COVID-19 Pandemic

Dear Admiral Pedley:

Members of RWC-340B are reaching out to the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA) in response to the President's Executive Order directing federal agencies to review the regulatory standards that have been temporarily waived during the COVID-19 public health emergency (PHE) and consider making these waivers permanent in an effort to promote economic recovery.¹ In the spirit of that Executive Order, we are requesting that OPA clarify: 1) that the telehealth guidance that is currently published on the OPA Drug Pricing COVID-19 Resources Page is permanent guidance and will not expire at the end of the PHE; and 2) any details related to meeting patient definition requirements for telehealth services.

RWC-340B is an association of HIV/AIDS health care clinics and service providers that receive funding under the Ryan White CARE Act, either through a primary grant or subgrant, and participate as covered entities in the federal 340B Drug Pricing Program. Ryan White clinics (RWCs) are dedicated to caring for low-income and vulnerable patients living with HIV/AIDS and, according to the Secretary of Health and Human Services, "are serving on the frontlines of this pandemic, supporting clients and communities at higher risk from COVID-19."² Ryan White clinics achieve viral suppression rates far above the average national viral suppression rate. This success in viral suppression rates results in fewer transmissions of the HIV/AIDS virus and is instrumental in helping to achieve the goal of the Trump Administration to end the HIV/AIDS epidemic by 2030.

¹ Exec. Order No. 13924, 85 Fed. Reg. 31,353, *Executive Order on Regulatory Relief to Support Economic Recovery* (May 19, 2020), available at <https://www.whitehouse.gov/presidential-actions/executive-order-regulatory-relief-support-economic-recovery/>.

² Health and Human Services (HHS) Secretary Alex Azar, HHS Awards \$90 Million to Ryan White HIV/AIDS Program Recipients for COVID-19 Response, April 15, 2020, available at <https://www.hhs.gov/about/news/2020/04/15/hhs-awards-90-million-ryan-white-hiv-aids-program-recipients-for-covid-19-response.html>.

RWC-340B appreciates that OPA has acknowledged on its COVID-19 Resources Page that “telemedicine is merely a mode by which the health care service is delivered”.³ RWC-340B has heard from members that these new telehealth flexibilities have been a key factor in their COVID-19 response. Our members have reported that younger patients in particular have been more willing to seek treatment, including case management and mental health services, if those services are provided through telehealth. The development and implementation of telehealth capabilities have required significant financial investments and staff training time. RWC-340B is concerned about the consequences for our members and their patients if OPA’s telehealth policy is in place only during the COVID-19 PHE and our members are required to end their current telehealth practices when the PHE is over. The fact that OPA’s telehealth policy is published on the COVID-19 Resource Page, and there is no other guidance on the OPA website or the Apexus website regarding telehealth services, could suggest that the guidance is only applicable during the COVID-19 PHE. We believe that OPA intends for the guidance to be applicable after the COVID-19 PHE is over. **Therefore, RWC-340B requests that HRSA make clear that its guidance on telehealth is not related solely to the COVID-19 PHE.**

Our members understand that they must meet HRSA’s long-standing patient definition guidance in order to qualify any prescription for 340B.⁴ In addition to its three-prong patient definition guidance, HRSA has taken the position in covered entity audits that the health care service that results in a 340B-eligible prescription must take place within the covered entity facility, absent some limited exceptions. This “location test” does not work well in the context of telehealth services, which may be furnished by a prescriber who is working from his or her home and to a patient who is also at home. This scenario has become quite common during the COVID-19 PHE given that Governors in most states have issued orders for residents to stay at home to the extent possible in order to prevent the spread of COVID-19.

Members of RWC-340B have received informal guidance from Apexus that the location test does not have to be met if the telehealth service is recorded in the covered entity’s medical records as a health care visit. That informal guidance, however, is not posted on either the OPA or Apexus websites. **Therefore, RWC-340B requests that HRSA formally state how the patient definition requirements apply in the context of a telehealth service and, in particular, confirm that neither the prescriber nor the patient are required to be located at the 340B covered entity facility in order to establish a relationship that meets the HRSA patient definition guidance.**

RWCs have played an important role in preventing the spread of COVID-19 because the expertise and programmatic infrastructure that they have developed in addressing HIV/AIDS are exactly the type of resources needed to address this unprecedented pandemic. It is important that RWCs have uninterrupted access to 340B when prescribed via telehealth services when the pandemic is declared over.

³ HRSA, OPA, COVID-19 Resources, available at <https://www.hrsa.gov/opa/COVID-19-resources> (last updated June 2020).

⁴ Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156-01 (Oct. 24, 1996).

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We appreciate your attention to this important matter. RWC-340B looks forward to working with HRSA and Congress to ensure that our country's most vulnerable population continues to have continued access to telehealth services.

Sincerely,

A handwritten signature in black ink that reads "Shannon Stephenson". The signature is written in a cursive, flowing style.

Shannon Stephenson
President

cc: Thomas J. Engels, Administrator
Health Resources and Services Administration
Thomas.Engels@hrsa.hhs.gov