COVID-19: 340B UPDATE - HRSA RELEASES COVID-19 GUIDANCE FOR 340B COVERED ENTITIES

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As the novel coronavirus (COVID-19) continues to spread in the United States, health care providers are turning to the federal government for guidance and flexibilities for them to respond to the influx of COVID-19 patients. The Health Resources and Services Administration (HRSA) recently issued guidance for covered entities participating in the 340B Drug Pricing Program (340B Program) outlining potential program flexibilities. While touching on key issues covered entities may be currently grappling with, such as the use of telehealth services or the registration of temporary sites, the guidance provides little implementation instruction. Covered entities should consider their emergency responses in light of 340B Program requirements and HRSA's guidance, particularly ensuring that their handling of 340B Program matters in atypical operational settings are incorporated into their 340B policies and procedures and that they establish a process to maintain some form of auditable records to demonstrate compliance with 340B Program requirements.

340B COVID-19 GUIDANCE

On January 31, 2020, U.S. Department of Health and Human Services Secretary Alex Azar declared COVID-19 a public health emergency.[1] With President Trump's declaration of a national emergency on 13 March 2020,[2] HRSA has now issued guidance to covered entities regarding 340B Program requirements in light of the evolving impact of COVID-19 on their operations.[3] The guidance touches on issues relating to eligible patients and Group Purchasing Organization (GPO) limitations, as well as the use of telehealth services and registration of temporary sites.

Patient Definition

Section 340B(a)(5)(B) of the Public Health Service Act prohibits covered entities from reselling or otherwise transferring a 340B covered outpatient drug to a person who is not a “patient” of the entity.[4] An individual is a “patient” of a covered entity only if: (i) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and (ii) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the covered entity.[5]

In its guidance, HRSA notes the importance of taking into account the realities of the COVID-19 pandemic in determining whether an individual is eligible to receive 340B drugs. While stressing that it is unable to waive 340B statutory requirements relating to reselling or otherwise transferring a 340B drug to a person who is not a patient

of the entity, HRSA's guidance provides certain flexibilities regarding 340B Program recordkeeping requirements and provider relationship requirements.

Specifically, HRSA is allowing covered entities to maintain an “abbreviated record” for purposes of establishing a patient relationship. HRSA notes that such abbreviated record may be a single form or note page that identifies the patient, records the medical evaluation, and indicates the treatment provided.[6] HRSA notes that, in absence of documented medical histories, covered entities may rely on self-reporting of identity, conditions, and history to fulfill recordkeeping requirements.[7]

Additionally, where volunteer health professionals provide care, HRSA recommends that covered entities document “the emergency nature of the situation, the name and address of the volunteer, and his/her relationship to the clinic” and make clear the covered entity's responsibility for the care provided.[8] In both instances, HRSA recommends that covered entities have policies that describe their procedures to address such situations and keep some form of auditable records.

GPO Prohibition

Section 340B(a)(4)(L)(iii) of the Public Health Service Act prohibits disproportionate share hospitals, children's hospitals, and freestanding cancer hospitals participating in the 340B Program from using a GPO for covered drugs at any time, including private label products.[9]

While stressing again its inability to waive 340B statutory requirements, HRSA notes in the guidance that if a hospital is unable to purchase a covered outpatient drug at the 340B ceiling price as a result of drug shortages, the covered entity should try to obtain the drug at wholesale acquisition cost (WAC).[10] To the extent the covered entity is also unable to purchase the product at WAC due to shortages, it may use “a GPO (or GPO private label products) only if it immediately notifies [HRSA's Office of Pharmacy Affairs] detailing the covered outpatient drug(s) involved, the manufacturer, and the communication between the parties as to why the product was not available at 340B or WAC.”[11]

Use of Telehealth Services

In the guidance, HRSA addresses potential flexibilities for covered entities to allow providers to offer telehealth services. In recognition that “the use of technology in health care delivery during this time is critical and that telemedicine is merely a mode by which the health care service is delivered,” HRSA notes that the use of telehealth may be permissible.[12] Nevertheless, HRSA recommends that covered entities “outline the use of these modalities in their policies and procedures and continue to ensure auditable records are maintained for each eligible patient dispensed a 340B drug."[13]

Registration of New Sites

HRSA's guidance addresses the need for certain covered entities to expand services to a new site in order to accommodate the influx of COVID-19 patients. However, HRSA only notes that covered entities that have concerns regarding the 340B eligibility of a new site should contact its 340B Prime Vendor, Apexus, for they will evaluate each circumstance on a case-by-case basis.[14] The treatment of new temporary treatment sites is often a

fact-intensive question, and thus, covered entities should consult with Apexus or legal counsel as to whether such locations can be treated as immediately eligible locations to generate 340B Program prescriptions.

340B Covered Entity Audits

Finally, HRSA notes in the guidance that it will be conducting 340B Program covered entity audits during the crisis, but it will move to conducting those audits remotely "for the next several months" while it monitors the impact of COVID-19. HRSA further notes that it will continue to monitor the COVID-19 response and provide updates accordingly.[15]

CONCLUSION

Given the rapidly changing environment, covered entities should consider their emergency responses in light of 340B Program requirements and HRSA's guidance. Covered entities that rely on flexibilities should ensure that they are incorporated into their policies and procedures and that they maintain some form of auditable records for patients dispensed 340B drugs. Given HRSA's stated inability to waive statutory requirements, covered entities may also want to consider legislative options to the extent that additional flexibilities may be needed as a result of the operation and eligibility challenges resulting from responding to the pandemic.

K&L Gates' health care and FDA practice and public policy and law practice regularly advise stakeholders on 340B Program implementation and compliance matters and facilitate stakeholder engagement with Congress and the administration on 340 Program matters and can assist in that regard.

FOOTNOTES

[1] *See* U.S. Dep't of Health and Hum. Servs., PUB. HEALTH EMERGENCY, *Determination that a Public Health Emergency Exists* (31 Jan. 2020).

[2] *See* White House, PROCLAMATIONS, *Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak* (13 Mar. 2020).

[3] *See* Health Resources and Servs. Admin., 340B DRUG PRICING PROGRAM, *COVID-19 Resources*, [hereinafter, "HRSA 340B COVID-19 Guidance"].

[4] 42 U.S.C. § 256b(a)(5)(B).

[5] 61 Fed. Reg. 55156, 55157–58 (Oct. 24, 1996).

[6] *See* HRSA 340B COVID-19 Guidance.

[7] *Id.*

[8] *Id.*

[9] 42 U.S.C. § 256b(a)(4)(L)(iii).

[10] *See* HRSA 340B COVID-19 Guidance.

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

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