

COVID-19: 340B UPDATE: HRSA UPDATES GUIDANCE GRANTING NEW HOPD FLEXIBILITY

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U.S. Health Care Alert

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As health care providers continue to grapple with the evolving impact of COVID-19, the Health Resources and Services Administration (HRSA) has updated its COVID-19 guidance for providers participating in the 340B Drug Pricing Program (340B Program), also known as covered entities.¹

The two key takeaways are as follow:

- New hospital outpatient departments (HOPDs) may begin using 340B drugs upon converting a location to provider-based without having to wait through the cost report filing and enrollment process (for offsite locations) before beginning to use 340B drugs as has been traditionally required. Notably, while granted as a COVID-19 flexibility, HRSA has communicated with multiple 340B Program stakeholders and directly with K&L Gates that this new flexibility is a permanent change that will apply after the end of the COVID-19 public health emergency.
- HRSA states its position that it is unable to waive statutory 340B eligibility requirements, reinforcing the need for a statutory fix to be included in the next COVID-19 relief legislation.

Immediate next steps that covered entities should take in light of the new guidance include:

- Updating their 340B Program policies and procedures to reflect the new timeline on use of 340B Program drugs at new HOPDs; and
- Considering speaking with legislators to continue to advocate for disproportionate share hospital (DSH) eligibility flexibilities as part of the next COVID-19 relief legislation in light of HRSA's stated position that it lacks authority to address facilities facing 340B Program disenrollment as a result of changes in DSH adjustment percentage driven by the COVID-19 pandemic.

BACKGROUND

Following President Trump's declaration of COVID-19 as a national emergency on March 13, 2020, HRSA issued guidance to covered entities regarding 340B Program requirements in light of the COVID-19 pandemic.² As previously reported in our client alert (here), HRSA's COVID-19 guidance touched on issues relating to the use of telehealth services, the registration of temporary sites, and Group Purchasing Organization limitations, but provided little implementation instruction for covered entities. HRSA generally advised covered entities to ensure that their handling of 340B matters as part of their emergency responses is 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.

HOSPITAL OUTPATIENT FACILITY ELIGIBILITY

Under longstanding 340B guidance, HOPDs are eligible for 340B discounts if they are a reimbursable facility included on the registered parent hospital's Medicare cost report.³ HRSA allows onsite locations that are within the four walls of the parent hospital to use 340B drugs without having to be individually registered on the 340B Office of Pharmacy Affairs Information System ("OPAIS") if they have reimbursable costs on the hospital's most recently filed cost report.⁴ In contrast, HRSA has required offsite locations to register in OPAIS in addition to having their costs and charges appear on a final filed Medicare cost report.⁵

As a result, new HOPDs are often delayed in accessing 340B discounts. New HOPDs must be operational during a cost reporting year and the hospital must have filed a final cost report for that year that reflects the new location. In addition, in the case of offsite locations, they must be registered in OPAIS during HRSA's 340B quarterly registration period, which only occurs for 15 days at the start of each quarter.⁶ Further, even if the registration is approved, the registration is not effective until the following quarter.

Notably, under HRSA's new guidance, HOPDs may begin using 340B drugs upon converting a location to provider-based without having to wait through the cost report filing and enrollment process (for offsite locations) as long as they otherwise meet 340B Program requirements. HRSA notes that, "for hospitals who are unable to register offsite HOPDs because they are not yet on the most recently filed Medicare cost report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity."⁷ As stated, HRSA's new policy would apply to prescriptions that originate at the new site as well as to drugs administered and/or dispensed at the site during patient encounters.

HRSA notes that this practice should be documented in the registered hospital's 340B policies and procedures, adding that the hospital is responsible for demonstrating compliance with 340B Program requirements and ensuring that auditable records are maintained for patients dispensed 340B drugs.⁸

Although granted as a COVID-19 flexibility, we understand HRSA plans to make this flexibility permanent. 340B Health, which represents 340B safety net hospitals, reported HRSA's HOPD guidance to its members and further noted HRSA's intent to make the flexibility permanent, which we have since confirmed with the agency.

DSH ADJUSTMENT PERCENTAGE REQUIREMENTS

To participate in the 340B Program, disproportionate share hospitals, free-standing children's and cancer hospitals, sole community hospitals, and rural referral centers, must have a minimum DSH adjustment percentage on their most recently filed Medicare cost report. Hospitals whose percentage fall below the minimum are not eligible participate in the 340B Program.⁹ The DSH percentage is a product of Medicaid and Medicare/Supplemental Security Income (SSI) inpatient days.¹⁰

As 340B hospitals respond to the COVID-19 pandemic, they have experienced changes in admissions and payer mix, which may impact their long-term 340B eligibility. Treating an increased number of non-Medicaid and non-Medicare/SSI patients could cause some hospitals to fall below the minimum threshold. As a result, 340B hospitals and various provider groups have been advocating for HRSA to waive the DSH adjustment percentage eligibility requirement for the duration of the public health emergency.¹¹

In new guidance, HRSA notes that it is "unable to waive the disproportionate share adjustment percentage requirements that are set in the 340B statute for certain hospitals seeking to participate as 340B covered

entities.”¹² The guidance comes as 340B hospitals, 340B Health, and several provider groups have been actively urging Congress to include 340B eligibility flexibilities as part of a COVID-19 relief package. In this regard, Senator Ben Sasse (R-NE) tried to incorporate an amendment to the Coronavirus Aid, Relief, and Economic Security (CARES) Act that would have paused eligibility requirements during the pandemic.¹³

Although the amendment was not incorporated into the CARES Act in part due to the urgency with which the bill was passed, stakeholders continue to work with policymakers on a statutory fix. Senator Sasse reintroduced language granting 340B eligibility flexibilities as part of a rural relief bill which he hopes to incorporate into the next comprehensive COVID-19 relief measure.¹⁴ In the House, Representatives Doris Matsui (D-CA) and Chris Stewart (R-UT), along with over 100 Members of Congress, sent a letter to Congressional leaders asking them to include 340B eligibility flexibilities in the next relief measure.¹⁵ Although timing is unclear, there is growing bicameral, bipartisan agreement that another relief measure may be needed, which Congressional leaders are hoping to act on before their scheduled August recess.

CONCLUSION

As covered entities assess the evolving impact of COVID-19 and navigate the path to recovery, they should consider their COVID-19 emergency responses in light of 340B Program requirements and HRSA'S COVID-19 guidance. In this regard, covered entities that rely on these flexibilities should ensure that they are incorporated into their 340B policies and procedures and that they maintain auditable records. Covered entities may also want to continue to work with Congress to the extent that additional flexibilities may be needed as a result of the operational and eligibility challenges they may experience in 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 Health Resources and Servs. Admin., *COVID-19 Resources, 340B DRUG PRICING PROGRAM* (June 2020), [hereinafter, HRSA 340B COVID-19 Guidance].

² *Id.*

³ 59 Fed. Reg. 47884, 47886 (“The outpatient facility is considered an integral part of the 'hospital' and therefore eligible for section 340B drug discounts if it is a reimbursable facility included on the hospital's Medicare cost report”).

⁴ See Apexus, 340B FAQ 1190 (last modified May 29, 2020).

⁵ See Apexus, 340B FAQ 1295 (last modified May 29, 2020).

⁶ See Health Resources and Servs. Admin., Registration, 340B Drug Pricing Program (August 2019).

⁷ See HRSA 340B COVID-19 Guidance.

⁸ *Id.*

⁹ 42 U.S.C. § 256b(a)(4).

¹⁰ 42 U.S.C. § 1395ww(d)(5)(F).

¹¹ See, e.g., Press Release, 340B Health, *340B Health Requests Federal Flexibility for Hospitals Amid COVID-19 Response* (March 20, 2020); see also Press Release, American Hospital Association, *AHA Urges HHS and HRSA to Provide Flexibility Administering 340B Program During COVID-19* (April 21, 2020); see also Press Release, America's Essential Hospitals, *340B Drug Pricing Program Flexibilities During COVID-19 Emergency* (April 30, 2020).

¹² See HRSA 340B COVID-19 Guidance.

¹³ See Press Release, Senator Ben Sasse, *Coronavirus Relief Can't Ignore Rural Health Providers* (March 24, 2020).

¹⁴ See Relief for Rural Providers During Emergencies Act, S. 3631, 116th Congress (2019-2020).

¹⁵ See Press Release, Representative Doris Matsui, *Matsui, Stewart Lead Bipartisan Letter Calling to Preserve 340B Eligibility for Hospitals* (May 8, 2020).

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