As U.S. hospitals and health clinics continue preparing for novel coronavirus (COVID-19) patient surges, federal regulatory agencies are developing resources to help health care providers comply with myriad regulatory requirements. In this context, the U.S. Health Resources and Services Administration (HRSA) recently issued a number of COVID-19 resources aimed at assisting Federal 340B Drug Discount Program (340B Program) covered entities in maintaining 340B Program compliance throughout the COVID-19 outbreak.

The latest HRSA COVID-19 resources address a number of issues, including recordkeeping requirements, registration of additional covered entity sites, relaxation of the Group Purchasing Organization (GPO) prohibition, and the delivery of services through telehealth platforms. Further, the COVID-19 resources state HRSA will continue auditing covered entities for 340B Program requirements. However, 340B Program audits will be performed remotely for at least the next several months.

In order to assist covered entities in quickly understanding HRSA COVID-19 resources changes, we have broken them down here:

- **Use of Abbreviated Health Records:**
The 340B Program prohibits covered entities from reselling or otherwise transferring 340B Program discounted drugs to a person who is not a patient of the covered entity. Typically, covered entities document a person’s patient status by maintaining responsibility for (and records of) the individual’s health care. Common records may include detailed medical histories, identification information, and insurance payment information. While HRSA has not waived this health record maintenance requirement, its COVID-19 resources now permit covered entities to utilize an “abbreviated health record” for 340B Program purposes.

The abbreviated health record may consist of a single note or page, but must: (i) include the patient’s identity; (ii) record the medical evaluation (i.e., any testing, diagnosis or clinical impressions); and (iii) the treatment provided or prescribed. Further, HRSA COVID-19 resources state, “Self-reporting of identity, condition, and history are adequate for purposes of 340B recordkeeping requirements.” Lastly, where care is delivered by a volunteer health provider to a 340B-eligible patient, covered entities must clearly document their responsibility for the patient’s care in order to maintain 340B Program compliance.

- **Child Site Eligibility:**

The 340B Program allows covered entities to add additional health care delivery sites (i.e., child sites) to participate in the 340B Program under the covered entities’ 340B Program registration. Hospitals may add child sites to their 340B Program participation if the site appears as a reimbursable facility on the hospital’s more recently filed Medicare cost report and has associated outpatient costs and charges. Comparatively, non-hospital covered entities may add a child site if the site is listed in the covered entity’s scope of grant, project, or contract.

However, due to possible surges in COVID-19 patient volumes, covered entities may wish to more quickly expand services to additional 340B Program-eligible child sites. In these circumstances, HRSA COVID-19 resources direct covered entities to contact the 340B Prime Vendor Program to evaluate additional site requests on a case-by-case basis.

- **Relaxation of GPO Prohibition:**

The 340B Program prohibits Disproportionate Share Hospitals (DSH), Children’s Hospitals (PED) and Free-Standing Cancer Hospitals (CAN) from acquiring covered outpatient drugs through Group Purchasing Organizations (GPO). While the HRSA COVID-19 resources document does not waive the GPO prohibition, it states DSH, PED, and CAN hospitals may purchase covered outpatient drugs through a GPO where the hospital is unable to purchase the drug due to shortages under its 340B and general wholesale (i.e., WAC) contracts.

- **Use of Telemedicine Platforms:**

Although covered entities have delivered health care services through telemedicine platforms for years, using such services for patients who receive 340B Program-discounted drugs is relatively complex. Historically, HRSA has advised covered
entities telemedicine-based services may be used in relation to the 340B Program, only if authorized under applicable federal, state, and local law and if the purchase of the drug complies with 340B Program requirements.

While the recent HRSA COVID-19 resources document does not waive these legal compliance requirements, it acknowledges the use of telemedicine is critical in treating COVID-19 patients. As such, HRSA has recommended covered entities outline the use of telemedicine platforms in their 340B Program policies and procedures and continue to maintain auditable records.

As the COVID-19 outbreak continues to evolve, 340B Program covered entities are reminded the regulatory flexibility incorporated into HRSA COVID-19 resources is likely temporary and should be implemented in a clear and auditable manner.

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