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Correspondence Memorandum

Date: December 17, 2019

To: Wisconsin Pharmacy Cost Study Committee

From: Renee Walk, Strategic Health Policy Advisor
Department of Employee Trust Funds

Subject: Options to Leverage 340B Pricing for State of Wisconsin Purchasers

The Pharmacy Workgroup (Workgroup) recommends that the Wisconsin Department of Corrections (DOC) enter into a cooperative agreement with the Department of Health Services' Division of Public Health as a subgrantee in order to obtain 340B pricing for eligible clients.

Background

The 340B program is a federal drug subsidy program intended to help service providers who work with certain vulnerable populations obtain prescription drugs at reduced prices. Under 340B, manufacturers must provide drugs to certain safety-net providers at reduced prices. The number and type of 340B drugs obtained by providers depends on the eligible patient mix that they serve. If a patient being seen at a 340B entity has insurance coverage, the entity can bill insurance at the market or plan-negotiated price; they are not required to pass through the 340B price to payors. 340B prices are also confidential to 340B entities.

The National Governors Association (NGA) provided a memo to the Wisconsin Pharmacy Cost Study Committee (WPCSC) at their September meeting that included three options to leverage 340B pricing. The Workgroup that supports the WPCSC met with NGA following the September meeting to further discuss how Wisconsin might implement these options and any limitations. This memo revisits those options and provides recommendations on how the Wisconsin Pharmacy Cost Study Committee (WPCSC) and its member agencies might proceed.

Hospital Centers of Excellence

The first option proposed by NGA was to create centers of excellence for certain diseases that require high-cost drugs, and to partner with 340B hospitals to treat those patients. The NGA memo acknowledges challenges for Medicaid programs in executing this option; some states have done so by obtaining freedom of choice waivers from the

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Centers for Medicare and Medicaid Services (CMS). To date, Wisconsin's Medicaid program has not sought this type of waiver, and access concerns between the rural and urban parts of the state may pose challenges to successfully implementing a freedom of choice waiver in Wisconsin. The memo also mentions the possibility of the Wisconsin state employee programs creating similar centers of excellence. As noted above, however, 340B entities are not required to pass through 340B pricing to insured patients. The 340B confidentiality requirement also means that prices could not be shared in a way that complies with Wisconsin Department of Employee Trust Funds' (ETF) fully-transparent pharmacy program model.

DOC has an existing contract relationship for some services with the University of Wisconsin Hospitals and Clinics (UWHC), and that contract includes the ability to share access to 340B pricing for clients who meet the definition of a "patient of the provider." In the case of DOC, the majority of care is provided by in-house medical staff, albeit some conditions require that a client be transported from a correctional facility to a hospital for care. It appears that the current language of the DOC and UWHC contract allows for this pricing to be shared in these situations.

Per UWHC correspondence, UWHC's access to 340B pricing is limited to certain conditions; their patient mix does not make them eligible for full 340B pricing. UWHC and DOC have investigated expanded both service and 340B pricing access in the past, but this poses logistical challenges for both parties. For UWHC, they must hold a separate, secure wing of the hospital solely for DOC clients. Finding beds is a challenge for all hospitals and cordoning off an entire segment of a hospital means that other patients may lose access, and beds cannot be re-allocated for other patients if DOC clients don't need enough services to fill them. For DOC, the costs of transporting a client from correctional facility to hospital is substantial, due to travel costs and staffing requirements. The map of DOC institutions included as Attachment A to this memo shows that the majority of facilities operated by DOC are not in Dane County, where UWHC has the most substantial footprint. Therefore, the value of transporting patients to UWHC to increase access to a limited set of 340B drugs may be less than the cost of facilitating this transfer.

The Workgroup's research has found that there are several other 340B hospital entities in the state of Wisconsin, some of which with more expansive access to 340B pricing than UWHC. Some of these entities may also be closer to DOC facilities. While the same challenges remain regarding hospital build-outs to accommodate correctional clients, DOC may wish in the future to explore options for expanding partnerships with these entities to pass through 340B pricing. Establishing such partnerships could also impact client relationships with local providers and may encourage post-incarceration continuity of care for clients who continue living in a region once released. Creating multiple contracts with local providers will likely be administratively burdensome for DOC, however, and so the Workgroup does not recommend that DOC pursue this option as its first approach.

340B Entity Billing
The second recommendation provided by NGA was to ensure that 340B entities are billing state programs at acquisition cost for 340B drugs. Once again, 340B pricing confidentiality presents a challenge to DOC, Medicaid, and ETF in determining what the true acquisition cost is. In addition, ETF's fully-transparent pharmacy model would require that these prices be available to ETF's auditor in order to verify correct claims payment, an arrangement that likely violates the 340B confidentiality rule. For Medicaid, the Medicaid Average Manufacturer Price (AMP) is confidential to Medicaid, and cannot be shared, further complicating a lower-of pricing requirement. Given the limitations surrounding price-sharing, the Workgroup does not recommend that the agencies pursue this option at this time.

Public Health and Corrections Partnership
The final option provided by NGA was to investigate partnerships where DOC could access 340B pricing. Similar to options described in the hospital centers of excellence model above, the paper laid out different methods that other state correctional departments have used to access 340B pricing. Most other states use some type of partnership with a 340B eligible hospital, but some states have begun to work more closely with departments of health to access 340B drugs for some populations.

340B statutes allow entities receiving funding under Section 318 of the Public Health Service Act (PHSA) for treatment of sexually-transmitted diseases (STDs) and under Section 317 for tuberculosis are considered 340B covered entities if certified by the Secretary of the federal Department of Health and Human Services (HHS). According to CMS, STDs include HIV and Hepatitis C treatments, which include very high cost drugs. In order to be a subgrantee of a public health entity, a provider would need to establish a treatment relationship with the public health entity. This can be as broad as full health care provision by the public health entity or as narrow as receiving in-kind materials from the agency related to STD treatment (e.g. test kits). Wisconsin DOC currently receives STD testing kits from the Wisconsin Department of Health Services' Division of Public Health (DPH). DOC pays for these kits currently, but the Health Resources and Services Administration (HRSA), the arm of HHS that administers 340B certification, has indicated that even a discounted payment rate for STD kits can be treated as an in-kind arrangement.

To initiate the subgrantee arrangement, DOC should make its intentions known to DPH and document the nature of their current partnership, adjusting the in-kind relationship if needed. DOC can then apply directly to HRSA for subgrantee status. HRSA will contact DPH to verify the relationship and that DPH is receiving funds under Section 317 and 318.

Once awarded the subgrantee status, DOC is able to enroll as a 340B entity and use 340B drugs to fill client prescriptions as long as the client is receiving services that are within the scope of STD or tuberculosis treatments. DOC would need to be able to

separately account for drugs that are provided under 340B, either through a separate physical inventory or through software solutions. According to an analysis provided to the state of North Carolina, who like DOC purchases drugs through the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), enrolling in 340B will not impact the volume discounts received from purchasing through MMCAP. In the same North Carolina analysis, HRSA's vendor, Apexus, indicated that Section 318 grantees can dispense any 340B drug to an individual who is eligible. This means that a client who has both an STD and another condition can receive drugs at 340B prices.[1]

The Workgroup agrees that this option will likely provide substantial savings to DOC, even if technological solutions are needed to manage inventory. If the WPCSC agrees to recommend DOC pursue this approach, the Workgroup suggests completing a cost savings analysis to determine more specifically what the impact of 340B partnership would be.

(Attachment)

[1]Powers Pyles Sutter & Verville PC (2019). *Recommendations for a 340B Correctional partnership in North Carolina.* Washington, DC. Pp. 12-13.