

# UW Medicine

December 31, 2015

Hunter G. Goodman  
Secretary of the Senate  
417 Legislative Bldg.  
P.O. Box 40482  
Olympia WA 98504-0482

Barbara Baker  
Chief Clerk  
Washington State House of Representatives  
Legislative Building - 338B  
P.O. Box 40600  
Olympia, WA 98504-0600

Dear Chief Clerk Baker & Secretary Goodman:

I am pleased to submit the University of Washington's ("University") report in response to the Washington State Legislature's budget provision asking the University to determine the feasibility of establishing interagency agreements with the Department of Corrections and the Special Commitment Center to provide each with discounted drug pricing through the federal 340B drug discount program. The report has been reviewed by both the Department of Corrections and the Special Commitment Center.

The University welcomes the opportunity to discuss the 340B program further with the Washington State Legislature. Please let me know if you have any questions. Thank you.

Sincerely,



Paul G. Ramsey, M.D.  
CEO, UW Medicine  
Executive Vice President for Medical Affairs and  
Dean of the School of Medicine,  
University of Washington

**Paul G. Ramsey, M.D.**

C-314 Health Sciences Center University of Washington Box 356350 Seattle, WA 98195-6350  
206.543.7718 FAX 206.685.8767 pramsey@uw.edu

cc: Washington State Senate Health Care Committee  
Washington State House Health Care & Wellness Committee  
Washington State Senate Ways & Means Committee  
Washington State House Appropriations Committee  
Washington State Senate Law & Justice Committee  
Washington State House Public Safety Committee

Report to the Washington State Legislature regarding  
Possible Interagency Agreements on 340B Drug Pricing

1. **Executive Summary.** The University of Washington (“University”) was asked to determine the feasibility of establishing interagency agreements with certain state agencies to provide each with discounted drug pricing through the 340B program. The University has concluded that such an agreement would not be in compliance with 340B regulations and is not possible. However, the University has explored other options for further discussion that might have the same result. The report that follows summarizes the 340B program, the legislative request, the University’s analysis and proposed alternative options.
  
2. **Summary of 340B Program.** The 340B program, administered by the Office of Pharmacy Affairs (“OPA”) within the Health Resources and Services Administration (“HRSA”) agency of the Federal Government, allows “eligible healthcare entities” (hereinafter “Covered Entities”) to purchase drugs at discounts similar to the discounts provided to the Medicaid program. This applies generally to drugs reimbursed through the Medicaid program when a pharmaceutical manufacturer enters into a pharmaceutical pricing agreement with HRSA. The discounts provided by the 340B program allow Covered Entities to purchase drugs at reduced cost and to use the cost savings to provide additional services and drugs to patients through charity care programs, public outreach and additional support services. There are four requirements that must be met in order for 340B pricing to apply: 1) an eligible patient must receive healthcare services from a Covered Entity; 2) the site where the eligible patient seeks care must be registered for the 340B program and listed in the public 340B database; 3) the treating provider must be employed or contracted with the Covered Entity; and 4) the Covered Entity must be medically responsible for the care provided to the eligible patient. Please see **Exhibit A** for a more comprehensive summary of the 340B program. It is also important to note that HRSA recently issued proposed guidance and that to the extent the guidance is adopted, it may change the analysis contained in this report.
  
3. **Legislative Request.** On June 30, 2015, Washington State Governor Jay Inslee signed Engrossed Second Substitute Senate Bill (“SB”) 6052 into law establishing the Washington State Operating Budget for the fiscal biennium 2015 through 2017. Within Section 606, the State Legislature adopted a budget provision asking the University to determine the feasibility of establishing interagency agreements with the Department of Corrections (“DOC”) and the Special Commitment Center (“SCC”) to provide each with discounted pricing for prescription medications under section 340B of the Public Health Services Act. The University was asked to submit this report, including: (a) a description of the steps required to achieve institutional cooperation on 340B pricing; (b) identification of any barriers to achieving such an agreement; (c) possible solutions to the barriers where possible; (d) estimates of the fiscal impact of this agreement in the 2015-2017 and 2017-2019 fiscal biennia; and (e) a timeline for implementation of such an agreement. The budget provision also stated that any agreement must not jeopardize the University’s compliance with 340B program rules and regulations.

4. **Institutional Cooperation Agreement.** Within UW Medicine, three hospitals are Covered Entities: UW Medical Center, Harborview Medical Center and King County Public Hospital District No. 1 d/b/a Valley Medical Center (collectively referred to as “UW Medicine Covered Entities”). The Legislature asked the University to determine the feasibility of establishing interagency agreements to provide DOC and SCC with discount pricing pursuant to the 340B program.
  - 4.1 **Requirements.** An institutional cooperation agreement with any of the UW Medicine Covered Entities would need to meet the requirements of the 340B program. Specifically, a 340B eligible patient must receive healthcare services from the Covered Entity; the site where the eligible patient seeks care must be registered for the 340B program and listed in the public 340B database; the treating provider must be employed or contracted with the Covered Entity; and the Covered Entity must be medically responsible for the care provided to the patient. An individual who sees a physician in that physician’s private practice or any other non-340B site, even as follow-up to care at a 340B registered site, is not eligible to receive 340B drugs for the services provided at those non-340B eligible sites. Similarly, an individual will not be considered a patient of the Covered Entity if the individual’s healthcare is provided by another healthcare organization that only has an affiliation arrangement with the Covered Entity, even if the Covered Entity has access to the affiliated organization’s medical records.
  - 4.2 **Description of DOC facilities.** DOC manages all state-operated adult prisons and is required to provide access to a healthcare infrastructure for individuals in custody (hereinafter “Custodial Population”) at all times. This includes care for acute and chronic diseases. When the healthcare provided to a patient is eligible as an inpatient hospital service, DOC enrolls the individual in the Medicaid program, allowing the State to access federal funding for qualifying in-patient hospital costs. In addition, DOC participates in the Health Care Authority (“HCA”) Pharmacy Consortium to maximize its pharmaceutical purchasing power. DOC continues to have within its facilities an increasing number of individuals with serious and chronic medical, mental health and dental conditions. To maximize efficiency, DOC attempts to provide specialized, high-cost health services, such as kidney dialysis and blood products, at specific locations, though there are constraints including differing offender classification, lack of bed availability and offender needs.
  - 4.3 **Description of SCC facilities.** SCC provides general healthcare and specialized mental health treatment for individuals who are sexually violent predators that are civilly committed (hereinafter also “Custodial Population”). Significantly, SCC averages two to three Hepatitis C patients per year. At present, required hospital care is provided by transporting individuals to a nearby hospital for treatment.
5. **Feasibility of an Institutional Cooperation Agreement.** It is not possible to simply enter into an agreement between a UW Medicine Covered Entity and DOC or SCC that extends 340B discounted drug pricing to those entities while maintaining compliance with the 340B program requirements. It might be possible to structure an arrangement that achieves SB 6052’s stated

objectives, but only if there are significant changes in the delivery of care to the Custodial Population as described below.

6. Options evaluated to address Barriers.

6.1 Treatment of Custodial Population within Existing UW Medicine Covered Entity Locations or Other Eligible 340B Facilities. If a UW Medicine Covered Entity or other eligible Covered Entity, meeting all the eligibility requirements described previously, were the treating provider for the Custodial Population, the Custodial Population might be eligible for discounted 340B pricing. Under this approach, the Custodial Population would need to be treated by Covered Entity healthcare professionals in an eligible location that is registered as a 340B location with reimbursement for the care delivered through a written contract with DOC and SCC, setting the terms and conditions for reimbursement pursuant to RCW 72.10.030 as applicable. Such an agreement could be with or without the development of a contract pharmacy relationship for the dispensing of medication, but the less expensive and more straightforward approach is for the Covered Entity to dispense the drug directly. If the pharmacy dispensing the drugs is neither the Covered Entity nor the contract pharmacy, 340B pricing is not available. This approach would require the Custodial Population to be transported, under continuous custodial control, to the Covered Entity. As discussed below, it is not clear that remote care through telehealth is a viable option under the current legal framework. In addition, the scope of eligible prescriptions is limited to those prescriptions written pursuant to the care delivered at Covered Entities.

6.1.1 Other DSH 340B Hospitals. There are 27 Disproportionate Share Hospital (“DSH”) program hospitals in the state of Washington that qualify for 340B participation. The potential solutions described herein could also be applied at those facilities. Such an approach could take into account the complex logistics involved in transporting the Custodial Population whenever care at a Covered Entity is necessary. Please see **Exhibit B** for a list of the hospitals currently registered for the 340B program.

6.2 Treatment of Custodial Population by Telehealth. The proposed 340B guidance leaves open the possibility of using telehealth, telepharmacy or other remote arrangements as a method to access patients in rural areas and provide access to 340B priced medications. At present, the proposed 340B guidance proposes to defer to state law to determine whether a prescription will be deemed 340B eligible in a telehealth encounter. In Washington State, third party reimbursement for a telehealth encounter is based on where the patient is located. If telehealth was utilized to provide care to Custodial Populations, under the current telehealth regulations, the site of service, or “originating site,” would be the DOC or SCC correctional facility. If a regulator took this view, consistent with existing state law, the location would not be a 340B eligible clinic. Any prescription that was written as a result of that telehealth encounter would not be a 340B eligible prescription since it did not generate from a 340B eligible clinic location.

- 6.2.1 State Legislative Amendment. One possible solution might be to enact a limited exception and change the site of service for purposes of telehealth services delivered to Custodial Populations, thus making such services eligible under federal law for 340B purposes. It would, however, be critical to seek guidance from HRSA as to whether such an approach is compliant with the intent and plain language of the 340B regulations. In light of the regulatory trend of narrowing the scope of the 340B program, it is unclear how such a legislative change would be perceived under federal law.
- 6.3 New UW Medicine Covered Entity Location. In addition to the options described in Sections 6.1 and 6.2, the University considered whether it was possible to create a new UW Medicine 340B eligible off-site clinic staffed with UW Medicine employed or contracted healthcare professionals at or near SCC or high-volume DOC locations. This option was determined not to be viable for the reasons described below.
- 6.3.1 Medicare Cost Report. A newly formed off-site clinic would only be 340B eligible once the location was included on a filed Medicare Cost Report. As a result of this requirement, there could be as much as a two year wait before eligibility is achieved. In addition, a 340B eligible clinic must have costs and charges. Under the proposed guidance, it would be for *Medicare* costs and charges. A clinic opened solely to serve the Custodial Population, and not indigent or non-Medicare patients, would not be able to meet this requirement.
- 6.3.2 Off-Site Locations. Hospital-based clinics in off-site locations must meet detailed rules for integration into the operation of the Covered Entity as described above. An off-site location must be hospital-based to be 340B eligible. In particular, the requirement that any off-site clinic must be within thirty-five (35) miles of the main hospital campus would only enable access to a handful of custodial facilities, absent relocating the Custodial Population.
- 6.3.3 Scope of 340B drugs. As noted above, 340B prescriptions would have to relate to the care that a Custodial Population patient received at the 340B eligible clinic. For example, if a patient received cardiovascular care, only the prescriptions relating to that cardiovascular care would be 340B eligible. This could leave gaps in DOC's and SCC's ability to access 340B eligible drugs.
- 6.4 Group Purchasing Organizations. UW Medicine participates in a group purchasing organization ("GPO") called Vizient to obtain discounted pricing on drugs, separate and distinct from participation in the 340B program. DOC and SCC also participate in a GPO called Premier through the Northwest Drug Consortium. In 2013, the Northwest Drug Consortium partnered with PeaceHealth, a multi-hospital system and member of Premier. It is our understanding that DOC also benefits from an additional discount offered to criminal justice-based organizations.

## 7. Other Potential Barriers.

7.1 Changing Federal Rules. On Aug. 27, 2015, HRSA issued long-awaited draft guidance proposing changes to the 340B program. The public comment period ended Oct. 27, 2015. Until finalized, Covered Entities are working in an ambiguous regulatory environment as they look to the future. The draft guidance sought to respond to concerns primarily among drug manufacturers that the 340B program is being used to create additional revenue for hospitals rather than furthering scarce resources as Congress intended. Drug manufacturers advocate that 340B drugs should only be provided to those patients who are uninsured or underinsured, and not to those patients who have commercial or other coverage. There has been considerable feedback from all segments of the market to the proposed guidance.

In the proposed guidance, Health and Human Services (“HHS”) suggests replacing the current four-part test for determining patient eligibility with a new six-part test that requires a prescription-by-prescription or order-by-order determination that an individual meets all of the following conditions:

- The individual receives a healthcare service at a facility or clinic site that is registered for the 340B program and is listed on the public 340B program database.
- The individual receives a healthcare service provided by a Covered Entity provider who is either an employee or independent contractor of the Covered Entity, such that the Covered Entity may bill for services on behalf of the provider.
- The individual receives a drug that is ordered or prescribed by the Covered Entity provider as a result of the healthcare service.
- The individual’s healthcare is consistent with the scope of the federal grant, project, designation or contract.
- The individual’s drug is ordered or prescribed pursuant to a healthcare service that is classified as outpatient.
- The individual’s patient records are accessible to the Covered Entity and demonstrate that the Covered Entity is responsible for that care.

The proposed 340B guidance explicitly states that the prescription/order must come from an eligible provider who is seeing the patient in an eligible clinic, and the prescription must be related to care provided at this encounter.

In summary, given time sensitivities and the expenses necessary to meet the hospital-based 340B requirements, the option described in Section 6.1 appears to be the only possible option but likely has considerable increased costs for SCC and DOC depending on the location of the hospital. Further exploration of the option in Section 6.2 may be useful. Under the option described in Section 6.1, the Custodial Population patients could be transported to existing 340B eligible clinics for treatment, and prescriptions related to such encounters are likely to meet the criteria for 340B eligibility. The Covered Entity must be responsible for the care related to these prescriptions; merely writing the prescription is

insufficient. These prescriptions could be filled through a Covered Entity's mail-order pharmacy to minimize the cost of dispensing fees. Alternatively, a contract pharmacy could dispense but the dispensing fee adds to the cost for the Covered Entity. DOC or SCC would be responsible to remit to the Covered Entity the 340B acquisition cost, a minimal dispensing fee, and any required shipping or insurance costs, as required by WAC 182-530-7900.

8. **Fiscal Impact.** DOC, SCC and UW Medicine are contractually precluded from sharing the specific pricing information that is necessary to share in order to comprehensively evaluate what cost savings might be achieved. In light of the conclusions of this report, the fiscal impact of the option described in Section 6.1 would need to include the cost of care delivered outside of a DOC or SCC facility, including any associated transportation and staffing costs.
9. **Timeline for Implementation of Viable Option.** As noted above, the timeline for implementation of the option described in Section 6.1 would require further cost-benefit analysis by DOC or SCC to determine its feasibility and desirability. As such, a timeline is uncertain. Implementation and further evaluation of the option contained in Section 6.2 is also dependent upon several factors, making a timeline uncertain. Timelines for implementation may be reevaluated following input from, and discussions with, DOC and SCC.



## Exhibit A – Summary of the Existing 340B Program

Overview and Intent. The 340B program is administered by the Office of Pharmacy Affairs (“OPA”) within the Health Resources and Services Administration (“HRSA”) agency of the federal government. The 340B program allows “eligible healthcare entities” (hereinafter “Covered Entities”) to purchase drugs at a discount similar to the discounts provided to the Medicaid program by setting a 340B ceiling price for drugs reimbursed through the Medicaid program when a pharmaceutical manufacturer enters into a pharmaceutical pricing agreement with HRSA. The intent of Congress in enacting the 340B program is to permit Covered Entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”<sup>1</sup> The discounts provided by the 340B program are to allow Covered Entities to use the cost savings to provide additional services and drugs to patients through charity care programs, public outreach and additional support services.

- a. Covered Entity Defined. Eligible healthcare entities are nonprofit healthcare organizations that have certain Federal designations or receive funding from specific Federal programs. These include Federal Qualified Health Centers (“FQHC”), Ryan White Program grantees, certain types of specialized disease clinics and certain hospitals.
  - i. Eligible Hospitals. Eligible hospitals include certain Disproportionate Share Hospital (“DSH”) program hospitals, critical access hospitals, children’s hospitals or free-standing cancer hospitals. Eligible hospitals must register on the OPA website as the “parent site.” Once registered, the hospital can purchase drugs at the 340B discounted pricing. Hospitals can also register eligible outpatient facilities as “child sites” of the hospital.
  - ii. Eligible Outpatient Facilities. Eligible outpatient facilities include locations physically within the hospital that are owned by the hospital or locations physically outside of the hospital that are hospital-based (also known as “provider-based” within the healthcare community). Eligible outpatient facilities must: 1) have a DSH percentage of greater than 11.75 percent; 2) be an integral part of the hospital; and 3) be included as reimbursable on the Covered Entity’s most recently filed Medicare Cost Report. In registering an outpatient facility as a 340B child site, an authorizing official will have to certify that the site is an integral part of the hospital.
  - iii. Hospital-based. There are detailed requirements for an outpatient facility operated by a hospital to qualify as hospital-based. For example, these include criteria related to geographic location, integration with hospital operations and medical staff leadership requirements.
- b. Eligible Patients. An eligible patient is one who is seen at the Covered Entity in an eligible location within the Covered Entity. In addition, the Covered Entity must be treating the condition for which the prescription is written, and the prescription must be filled at one of the Covered Entity’s pharmacies or contracted pharmacies.
  - i. Contract Pharmacies. Covered Entities enrolled in the 340B program may contract with outside pharmacies to fill prescriptions at the 340B price. Most Covered Entities contract with an intermediary to administer the program in such situations because of the detailed

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<sup>1</sup> H.R. Rep. No. 102-384(II), at 12 (1992)

compliance requirements. The drug is dispensed by the contract pharmacy, but then the drug is replaced in the contract pharmacy's inventory with the 340B drug purchased by the Covered Entity. The inventory control processes must document these exchanges in detail. The difference in drug cost is savings for the benefit of the Covered Entity who can then reach more underserved populations.

- c. Medicaid Exclusion. Covered Entities must determine upon enrollment whether they will use 340B drugs for Medicaid patients (carve-in) or whether they will purchase drugs for Medicaid patients through other mechanisms (carve-out). This process prevents manufacturers from being responsible to provide both 340B pricing and Medicaid rebates on 340B drugs (i.e., the duplicate discount prohibition described below).
- d. Eligible Drugs. The 340B Program is restricted to outpatient drugs and covers the following: FDA-approved prescription drugs, over-the-counter drugs written on a prescription, biological products that can only be dispensed by a prescription (other than vaccines), and FDA-approved insulin.
- e. Unique Compliance Issues.
  - i. Medicaid and Medicaid Coverage of Custodial Population & Duplicate Discount: The 340B program prohibits a duplicate discount, meaning that a drug purchased directly from the drug manufacturer or from the wholesaler must not be subject to both a 340B drug discount and a Medicaid Drug Rebate. This compliance element applies to Medicaid Fee for Services and Medicaid Managed Care coverage (as stated in the proposed 340B guidance), as both these payers are able to access the Medicaid Drug Rebate. If the Custodial Population has either type of coverage, then the Covered Entity will be required to notify HRSA to avoid duplicate discounts, which might impact revenue for other state agencies.
  - ii. GPO Prohibition and Mixed-Use Areas. Group Purchasing Organizations ("GPO") negotiate discounted prices on drugs for member hospitals. The discounted drugs are typically lower than the Wholesaler Acquisition Cost ("WAC"), but higher than 340B ceiling pricing. Mixed-use areas refers to mixed-use clinical settings, where both outpatient and inpatient medications are used. Covered Entities enrolled in the 340B program are prohibited from using GPO for outpatients, both 340B eligible and non-eligible, regardless of whether the drugs are 340B eligible. A specialized software tool referred to as "splitting software" is used in mixed-use areas to prepare and place drug orders on the various purchasing accounts based on medications dispensed to patients in 340B eligible locations.
  - iii. Detailed Record Keeping. The 340B program requires detailed record keeping to assure compliance with multiple regulatory requirements such that anyone participating in the program will need to resource this important function appropriately.
- f. Enforcement. The 340B program is enforced and audited by HRSA to ensure the intent of the program is being followed by participants. Failure to follow the rules and regulations could result in removal from the program. Most Covered Entities, including UW Medicine Covered Entities, have robust compliance programs to ensure compliance with the detailed and technical rules.

## Exhibit B - Washington DSH 340B Hospitals

- University of Washington Medical Center
- Harborview Medical Center
- Public Hospital District No. 1 of King County d/b/a Valley Medical Center
- Providence Health & Services - Washington (Everett)
- Providence Health & Services - Washington Providence (Centralia)
- Providence St. Peter Hospital (Olympia)
- Providence Health & Services - Washington (Spokane)
- Swedish Edmonds
- Swedish medical Center
- St. Clare Hospital
- St. Francis Hospital
- St. Joseph Medical Center
- Good Samaritan Hospital (Puyallup)
- Samaritan Hospital (Moses Lake)
- MultiCare Auburn Medical Center
- Tacoma General/Allenmore Hospital
- PeaceHealth St. John Medical Center
- PeaceHealth Southwest Medical Center
- Skagit Valley Hospital
- Highline Medical Center
- Yakima Valley Memorial Hospital
- Walla Walla General Hospital
- Kennewick General Hospital
- Kadlec Regional Medical Center
- Central Washington Health Services Association d/b/a Central Washington Hospital
- Legacy Salmon Creek Medical Center
- Kootenai Hospital District