

DRAFT

[Letterhead]

[Date]

Wayne Hartzell
Public Health Analyst
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Room 08W13C
Rockville, MD 20857

Re: Request for Use of Combined Purchasing and Distribution Model

Dear Mr. Hartzell:

Pursuant to guidance issued by the Health Resources and Services Administration (HRSA) addressing requirements for a “Grantee Combined Purchasing and Distribution Request,” this letter is to ask that HRSA approve use of a Combined Purchasing and Distribution Model for the covered entities listed below in Addendum I.

- I. Entity Information - The covered entities listed in Addendum I (Covered Entities) will participate in the Combined Purchasing and Distribution Model.
- II. Applicable Sites - Each of the Covered Entities is part of the same legal entity and uses funding under the same Ryan White grant(s) [or sub-grant(s)] for its operations. Each employee that works at any of the Covered Entities is employed by the same corporation under the same Federal Employee Identification Number. [Insert name of corporation and FEIN. If applicable, include a more detailed description of the relationship of the purchasing and receiving locations, i.e., are they owned or contracted?]

Each of the Covered Entities has been evaluated for its ability to participate in the Combined Purchasing and Distribution Model. Specifically, Covered Entities will maintain and comply with the Combined Purchasing and Distribution Policy attached at Addendum III. If a Covered Entity is not able to comply with this Combined Purchasing Distribution Policy, it will not be permitted to participate.

- III. Policies and Procedures – The Covered Entities adhere to Policies and Procedures that ensure compliance with 340B program requirements, including a schedule of periodic audits to check for compliance with the prohibitions on diversion and duplicate discounts, maintenance of accurate information in the Office of Pharmacy

Affairs Information System (OPAIS) and maintenance of auditable records. Each of the Covered Entities also will adopt the Combined Purchasing and Distribution Model Policy (Addendum III). This policy addresses inventory management, purchasing compliance and maintenance of auditable records. Each Covered Entity will cooperate with the others to ensure compliance with 340B program requirements within this Combined Purchasing and Distribution Model, including making records readily available for internal audits or audits by the Health Resources and Services Administration (HRSA).

This policy will be reviewed at least annually and more often if required by a change in HRSA policy. All staff of the Covered Entities listed in Addendum I who are involved in procurement and use of 340B drugs, as well as any staff responsible for 340B program compliance, are required to review and adhere to this policy.

Covered Entity staff responsible for overseeing the Combined Purchasing and Distribution Model, as well as ensuring continued compliance with 340B program requirements. Staff responsible for overseeing the Combined Purchasing and Distribution Model will complete annual training and receive education on any changes in HRSA policy that would affect the Combined Purchasing and Distribution Model. [Insert information about educational programs that Covered Entity staff participates in, such as 340B University, 340B Coalition conferences, and continuing education webinars sponsored by HRSA.]

Covered Entities will maintain compliance with all applicable federal, state and local laws and regulations.

- IV. The Covered Entities request permission to use the Combined Purchasing and Distribution Model for 340B drugs dispensed by their contract pharmacies listed in Addendum II. The attached Combined Purchasing and Distribution Policy addresses compliance at Covered Entities' contract pharmacies.

As the Authorizing Official for each of the Covered Entities listed above, I attest to the accuracy of the summary of the Combined Purchasing and Distribution Model described in this letter and the ability of each of the Covered Entities listed above to comply with the attached policies and procedures. I also will ensure that, upon receiving approval of the proposed arrangement, the Covered Entities will notify HRSA of any changes to the Combined Purchasing and Distribution Model.

Sincerely,

Wayne Hartzell

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[Insert Name]

340B Authorizing Official

ADDENDUM I

SITES PARTICIPATING IN COMBINED PURCHASING AND DISTRIBUTION MODEL

Covered Entity Combined Inventory Purchasing Location						
340B ID	Covered Entity Name	Grant Number	Physical Address	Shipping Address	Role of Entity (Purchaser or Receiver)	Signed Attestation from AO
					Purchaser	✓
					Receiver	✓

ADDENDUM II

CONTRACT PHARMACIES PARTICIPATING IN COMBINED PURCHASING AND DISTRIBUTION MODEL

Contract Pharmacies						
Pharmacy DEA #	Pharmacy Name	Pharmacy Address		List information for each site for which this contract pharmacy is listed in 340B OPAIS and will be combining purchasing to a single account		
				340B IDs	Entity Names	Grant Number

ADDENDUM III

Combined Purchasing and Distribution Policy

The purpose of this policy is to establish procedures for 340B inventory management, purchasing and maintenance of auditable records through a Combined Purchasing and Distribution Model that has been approved by the Health Resources and Services Administration (HRSA). This policy is adopted by all of the covered entities listed in Addendum I (Covered Entities) that have received approval from HRSA to implement the Combined Purchasing and Distribution Model. Addendum I identifies one Covered Entity as the “Purchaser” organization and any other Covered Entity as the “Receiver” organization.

The HRSA guidelines for applying for a Combined Purchasing and Distribution model must address: 1) Inventory Management; 2) Purchasing compliance; 3) maintenance of auditable records; and 4) contract pharmacy if the model is going to be used by contract pharmacies. The guidelines also state that the following areas should be addressed under the Inventory Management section of the Covered Entity’s Policies and Procedures: Process for requisitioning from main site; process for requisition fulfillment; process for submitting POs to the wholesaler/manufacturer for the main site; any other relevant information about inventory management (*e.g.*, will sites still be purchasing with their own 340B ID as well?); and how this process will be maintained and updated, including approval from HRSA prior to any changes to the approved model. Covered entity inventory management systems differ and some of the elements above may not be applicable to your model. Below is a sample P&P that can be modified to address your situation:

Inventory Management – The Covered Entities will use a combined virtual inventory system to track the dispensation or administration of 340B drugs and the purchase of 340B drugs at the 11-digit NDC level. When a Covered Entity determines that a patient is eligible to receive 340B drugs, the dispensation or administration of that drug to the patient will be recorded in the virtual inventory system. Each of the Covered Entities will have access to the virtual inventory system to record administration or dispensation of outpatient drugs to an individual that meets HRSA’s patient definition guidelines. Each Covered Entity will maintain medical and other records to demonstrate that each patient that it deems eligible to receive 340B drugs is an eligible patient under HRSA’s patient definition guidelines.

In most cases, 340B drugs will be delivered by the wholesaler to each Covered Entity directly as needed. If a package of 340B drugs is going to be used by more than one Covered Entity, Purchaser will direct that the 340B drugs be delivered first to Purchaser. Purchaser will split the package and deliver it to the Receiver.

Each Covered Entity will review and inspect 340B drugs that it receives. If a package of 340B drugs is delivered by the wholesaler directly to a Receiver, the Receiver will

document that the 340B drugs in the package correspond to the order invoice in the package. On the same day that any 340B drugs are received, the Receiver will notify Purchaser of the amount of the drugs received and whether there are any discrepancies between the 340B drugs received and the amount documented on the order invoice. Purchaser will be responsible for contacting the wholesaler to resolve any discrepancies.

Purchasing Compliance – Purchaser will place orders for 340B drugs using its 340B ID number under an account in Purchaser’s name for both itself and Receivers. Purchaser will place an order when the virtual inventory system shows that 340B drugs have been administered or dispensed to 340B eligible patients in amount that equals replenishment of the drug in the full package size at the 11-digit NDC level. None of the Receivers will order 340B drugs from the wholesaler under their respective 340B ID numbers.

Auditable Records –Covered Entities will maintain auditable records to demonstrate that the Combined Purchasing and Distribution Model complies with HRSA guidelines. Each of the Covered Entities maintains auditable records to show that individuals who receive 340B drugs from the Covered Entity or through its contract pharmacy are eligible patients under HRSA’s patient definition guidelines. Each of the Covered Entities will also maintain auditable records of any drugs that it receives based on a replenishment order by the Purchaser. Purchaser will maintain auditable records of any drugs received by any of the Covered Entities based on a 340B replenishment order.

Contract Pharmacy – The Combined Purchasing and Distribution Model extends to 340B drugs dispensed by any contract pharmacy of a Covered Entity. The signed contract pharmacy services agreement complies with HRSA’s twelve essential compliance elements, as provided in 75 Fed. Reg. 20272 (March 5, 2010).

Any 340B drugs purchased by a contract pharmacy under the “ship-to, bill-to” arrangement will be purchased under the account of the Purchaser and may be dispensed to a 340B eligible patient of the Purchaser or a Receiver. Each Covered Entity is responsible for ensuring that auditable records are maintained to demonstrate that any individual that receives a 340B drug at the Covered Entity’s contract pharmacy is an eligible patient under HRSA’s patient definition guidelines.

The Covered Entities may enter into a single contract pharmacy agreement with a pharmacy that serves both the Purchaser and the Receiver, provided that each of the Covered Entities is listed in the contract pharmacy agreement. The contract pharmacy agreement will include all requirements as stated in HRSA’s contract pharmacy guidelines. The contract pharmacy agreement will be registered on OPAIS under each of the Covered Entities.

An annual, independent audit will be conducted of all contract pharmacy operations to ensure compliance with HRSA guidance and this Combined Purchasing and Distribution Model, including compliance with patient definition requirements.

Internal Audits – Each Covered Entity will be subject to internal audits to ensure compliance with 340B program requirements as well as the above requirements. Purchaser will be responsible for conducting these audits at least every six months. Any Receiver may also conduct audits of its 340B operations on a more frequent basis.