



October 21, 2015

Commander Krista Pedley
 Director, Office of Pharmacy Affairs (OPA)
 Health Resources and Services Administration (HRSA)
 5600 Fishers Lane, Mail Stop 08W05A
 Rockville, MD 20857

Commander Pedley:

The Communities Advocating Emergency AIDS Relief (CAEAR) Coalition respectfully submits the following comments on the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program Omnibus Guidance.

The CAEAR Coalition is a national membership organization that advocates for federal policy, legislation, regulations, and appropriations to meet the care, treatment, support, and prevention needs of people living with HIV/AIDS and the organizations that serve them. The Coalition’s members include Ryan White Program Part A, Part B, and Part C consumers, grantees, and providers, as well as the Part F AIDS Education and Training Centers.

The CAEAR Coalition applauds HRSA’s goal to increase accountability and its desire to provide additional oversight for the 340B Drug Pricing Program. CAEAR Coalition strongly believes, however, that two changes proposed in the guidance would undermine the success of the Program.

- The CAEAR Coalition is extremely concerned that the current guidance eliminates Ryan White Medical Case Management providers from participating in the 340B program.
- The CAEAR Coalition is extremely concerned that the current guidance unfairly places the burden of avoiding *duplicate discounts* on the covered entity.

The Coalition’s rationales and recommendations to address these concerns are noted below:

Current 340B Omnibus Guidance Part C[b]1: Exceptions (Federal Register/Vol.80, No. 167/Friday, August 28, 2015/Notices/page 52306)	CAEAR Coalition Recommendation
<i>AIDS Drug Assistance Programs. An individual enrolled in a Ryan White HIV/AIDS program AIDS Drug Assistance Program funded by title XXVI of the PHSA will be considered a patient of the covered entity for the purposes of this definition.</i>	Add the text that is <u>added and underlined</u> . <i>AIDS Drug Assistance Programs/<u>Ryan White Medical Case Management Providers</u>. An individual enrolled in a Ryan White HIV/AIDS program AIDS Drug Assistance Program funded by title XXVI of the PHSA <u>or receiving care through a Ryan White Medical Case Management Provider (Ryan White grantee or sub-grantee)</u> will be considered a patient of the covered entity for the purposes of this definition.</i>

Current 340B Omnibus Guidance Part D – Covered Entity Requirements: Prohibition of Duplicate Discounts	CAEAR Coalition Recommendation
In several particulars, proposed guidance creates new and exceptional burdens for avoiding duplicate discounts and places them on the covered entity.	Exclude Medicaid FFS and MCO plans from claim submissions for 340B contract pharmacies in order to eliminate duplicate discounts.

Ensure Ryan White Medical Case Management Providers Continue Participating in the 340B Program as Covered Entities

The CAEAR Coalition urges HRSA to clarify the proposed rule to ensure that Ryan White-funded Medical Case Management providers are able to access 340B as the program intended. Eliminating Ryan White Medical Case Management providers from participating in the 340B program would have severe negative impacts on healthcare utilization and health outcomes for thousands of people living with HIV/AIDS currently served by these federally funded Medical Case Management Program-covered entities.

Ryan White-funded Medical Case Management providers are currently enrolled as 340B covered entities based on their receipt of federal grants, contracts, and designations. They have a strong and successful track record of utilizing federal resources to reach eligible HIV patients, ensure their access to life-saving medications, and augment their medical treatments with comprehensive support services. **It is essential that patients of federally funded non-hospital community providers of Medical Case Management services remain eligible to receive 340B drugs.**

Data demonstrates that Ryan White Medical Case Management 340B programs fill a unique role in increasing access to life saving services for HIV-positive patients. For example, in Medical Case Management programs in New York City and Philadelphia, patients receiving both medical case management and 340B pharmacy services have over a 97% medication fill and pick-up rate, and over 80% of patients achieve an undetectable viral load within six months of enrolling in services. This outcome has a dramatic impact on both the individual and the community. For the individual patient, there is a decrease in emergency room visits and hospitalizations, reducing overall health care costs. For the community, achieving an undetectable viral load reduces the community viral load and decreases HIV transmissions.

CAEAR Coalition strongly urges HRSA to amend the pending guidance on 340B Programs to continue including individuals enrolled in a Ryan White HIV/AIDS Medical Case Management Programs. Patients who are seen by programs benefit from a comprehensive set of services designed to improve health outcomes, manage multiple chronic conditions, and ensure medication adherence. These individuals are patients of the programs by virtue of their plan of care and the services provided are within the scope of the grant. Their eligibility to be a patient is not on the prescription-by-prescription basis.

Therefore, we ask HRSA to modify proposed guidance to clarify that patients receiving services at Ryan White HIV/AIDS Medical Case Management Programs —and other HRSA grantees—are considered 340B

eligible patients if they are considered patients under existing HRSA grants and obligations. This will ensure consistency across HRSA and other federal programs, as well as ensure that patients receiving services are consistently 340B eligible. This could be accomplished with the following changes to the guidance:

Current 340B Omnibus Guidance	CAEAR Coalition Recommendation
<p style="text-align: center;">Part C[b]1: Exceptions</p> <p><i>AIDS Drug Assistance Programs. An individual enrolled in a Ryan White HIV/AIDS program AIDS Drug Assistance Program funded by title XXVI of the PHSA will be considered a patient of the covered entity for the purposes of this definition.</i></p>	<p>Add the text that is <u>bolded and underlined</u>.</p> <p><i>AIDS Drug Assistance Programs/<u>Ryan White Medical Case Management Providers</u>. An individual enrolled in a Ryan White HIV/AIDS program AIDS Drug Assistance Program funded by title XXVI of the PHSA <u>or receiving care through a Ryan White Medical Case Management Provider (Ryan White grantee or sub-grantee)</u> will be considered a patient of the covered entity for the purposes of this definition.</i></p>

The benefits of Medical Case Management within the 340B program are indisputable. Medical Case Management is a **core service** of the federal Ryan White HIV/AIDS Program. Medical Case Managers are **healthcare professionals**. Medical Case Management is a **proven and essential healthcare service** that significantly increases prescription fill rates, adhere to medication regimens, and patient retention in medical care. Medical Case Management provider agencies have Business Associates Agreements and Data Sharing Agreements with local hospitals and health centers. Medical Case Managers use CareWare, a HRSA-approved Electronic Medical Record.

Further, Medical Case Management services are in complete **alignment with the National HIV/AIDS Strategy**, recognized for improving health outcomes for people living with HIV/AIDS, specifically by contributing to increased viral load suppression; decreased hospitalizations and emergency room visits; and sustained engagement with primary care providers.

As 340B covered entities, Ryan White Medical Case Management provider agencies have dedicated 340B revenues to enhanced service delivery for the HIV population, increasing services in underserved neighborhoods, serving more patients, facilitating coverage of deductibles and co-pays for patients who would otherwise be unable to afford them, ensuring enhanced access to life-saving medications, and all in coordination with medical facilities.

The role and results of 340B Medical Case Management entities fulfill a main legislative intent of the 340B program—support 340B safety net providers to improve healthcare outcomes and to expand service provision to high-need, low-income individuals living with HIV/AIDS. They should not be eliminated from the 340B Program.

Part D: Prohibition of Duplicate Discounts — Exclude Medicaid FFS and MCO Plans from Claim Submissions for 340B Contract Pharmacies in Order to Eliminate Duplicate Discounts

The procedures for preventing duplicate discounts with respect to Medicaid Fee-for-Service (FFS) patients have long been established. HRSA currently requires that 340B covered entities indicate on the OPA database if they will bill Medicaid for drugs purchased under the 340B program (“carve in” or “carve out”) or not. As a result, the 340B Medicaid Exclusion File is the mechanism to prevent duplicate discounts with respect to Medicaid FFS patients.

The 340B Guidance generally allows covered entities to make their own determinations regarding "carve-in" or "carve-out" status for Medicaid Managed Care Organizations (MCO) patients, as long as the covered entities have an appropriate process to identify 340B claims. However, with the new guidance, HRSA reaches a stricter conclusion for covered entities that use contract pharmacies, noting that the "[r]isk of duplicate discounts can increase with certain drug purchasing and distribution systems." HRSA concludes that "when a contract pharmacy is listed on the public 340B database, it will be presumed that the contract pharmacy will not dispense 340B drugs to Medicaid FFS or MCO patients". If a covered entity wishes to overcome this presumption and purchase 340B drugs for its Medicaid FFS or MCO patients and dispense 340B drugs to those patients utilizing a contract pharmacy, the covered entity must "provide HHS a written agreement with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts." **This previously unrequired step is overly burdensome to the covered entity.**

CAEAR Coalition proposes that the contract pharmacy covered entity itself, regardless of whether patients are enrolled in a Medicaid FFS or MCO Plan, should maintain the right to use its 340B pharmacy program for its patients. This mechanism achieves the intended benefit that allows the covered entity to maximize its opportunities to offer and expand services to its community of patients, regardless of ability to pay.

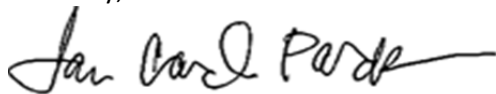
340B Omnibus Guidance Part D: Prohibition of Duplicate Discounts	CAEAR Coalition Recommendation
Proposed guidance creates new and exceptional burdens for avoiding duplicate discounts and places them on the covered entity.	Exclude Medicaid FFS and MCO plans from claim submissions for 340B contract pharmacies in order to eliminate duplicate discounts.

CAEAR Coalition respectfully urges HRSA to amend the proposed 340B guidelines to:

- **Include an exception for federally funded Ryan White HIV/AIDS Medical Case Management programs to remain active and impactful participants in the 340B program.**
- **Exclude Medicaid FFS and MCO plans from claim submissions for 340B contract pharmacies in order to eliminate duplicate discounts.**

Thank you.

Sincerely,



Jan Carl Park
Chair, Board of Directors
CAEAR Coalition