



June 28, 2024

Duane H. Barnes
Sobi North America
President
77 4th Avenue, 3rd Floor
Waltham, MA 02451

Dear Duane:

On behalf of the National Association of Community Health Centers (NACHC), I write to highlight the significant impact an upcoming Sobi 340B restriction will have on Community Health Centers and the vulnerable patients they serve. I urge you to consider how damaging this new policy will be and exempt health centers before the effective date of July 1, 2024.

Community Health Centers are the best, most diverse, most innovative, and most resilient part of our nation's health system. For nearly sixty years, health centers have provided high-quality primary and preventive care, dental, behavioral health, pharmacy, vision, and other essential health services to America's most vulnerable, medically underserved patients in urban, rural, suburban, frontier, and island communities. In 2022, health centers reached a historic milestone of serving over 31.5 million patients, including 8.8 million children and nearly 400,000 veterans. They provide care to one in seven rural residents, one in six Medicaid beneficiaries, and one in three people experiencing poverty.¹

Access to needed pharmaceuticals is critically important to our patients, and the 340B program is a vital lifeline for health centers. By law and mission, health centers must reinvest all 340B savings into patient care to extend the reach and impact of their services. Unfortunately, since 2020, manufacturers have imposed restrictions on access to health center contract pharmacy shipments. Currently, 36 manufacturers have active restrictions, and 16 impact health centers. These restrictions have significantly hurt health center operations and are borne out of fundamental gaps within the 340B statute. Through the launch of the Alliance to Save America's 340B Program (ASAP 340B), NACHC is working in good faith with PhRMA to pursue lasting legislative solutions that will bring clarity, transparency, and accountability to the program. This reform effort is long overdue, and our combined efforts are catalyzing a broader conversation in Congress about the future of this critical program. The current and pending manufacturer restrictions on health centers complicate the legislative environment.

The recent announcement by Sobi to impose new restrictions on entity-owned health center pharmacies that are located outside of 340B OPAIS registered locations, i.e., free-standing entity-owned pharmacies, goes against the 340B statute. According to Section 340B of the Public Health Service Act, manufacturers must "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price."² Furthermore, it defines a covered entity, which includes

¹ <https://www.nachc.org/wp-content/uploads/2023/08/Americas-Health-Centers-2023.pdf>

² <https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf>

health centers, as eligible covered entities for the 340B program. A covered entity means “an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).”³

Within the Health Resources and Services Administration (HRSA), the Bureau of Primary Health Care (BPHC) uses the Electronic Handbook (EHB) Form 5B to delineate the sites that are included in the health center’s scope of grant and therefore is statutorily included in the FQHC’s 340B Program. When a pharmacy is listed as a site on EHB Form 5B by BPHC, the pharmacy is a covered entity site and statutorily included in the scope of the FQHC grant.

The EHB has fields to input information about entity-owned pharmacies, either co-located pharmacies or free-standing pharmacies. Co-located pharmacies are located in a health center clinic site and are included within the clinic site ID on EHB Form 5B. On the other hand, free-standing pharmacies are located outside of a health center’s clinic site and listed under a separate site ID on EHB Form 5B. While there are two different types of entity-owned pharmacies delineated on EHB, the location of the pharmacy is irrelevant; it is still part of the 340B covered entity when it is entity-owned. HRSA FAQ 1364 reinforces this fact.

Question: When does a pharmacy qualify as an entity-owned pharmacy?

Answer: ***An entity-owned pharmacy is owned by, and is a legal part of, the 340B entity.*** Typically, entity-owned pharmacies are listed as shipping addresses of the entity.⁴

Health centers have followed the recommendation of the Office of Pharmacy Affairs and registered their pharmacy as a shipping address on OPAIS. Therefore, refusing to ship 340B-priced medications to entity-owned pharmacies, regardless of location, goes against the 340B statute. This upcoming policy change will result in the denial of an offer to sell 340B drugs for all Sobi products to eligible entity-owned (in-house) pharmacies, which is an FQHC site included statutorily within the health center’s scope of grant, appropriately listed as a shipping address on OPAIS, based on the Office of Pharmacy Affairs registration requirements.

Again, I urge you to reconsider the substantial impact of the recent 340B restriction on Community Health Centers and their patients and exempt them before the implementation date. Thank you in advance for your consideration. If you have any questions, please contact Vacheria Keys, Associate Vice President, Policy & Regulatory Affairs, at (703) 244-3591 or vkeys@nachc.com.

Sincerely,



Kyu Rhee, MD, MPP
President and Chief Executive Officer

³ <https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf>

⁴ <https://www.340bpvp.com/hrsa-faqs/340b-eligibility/registration>