

MEMORANDUM

June 18, 2018

To: Senator Bill Cassidy, M.D.
Attention: Jeff Lucas, Health Policy Advisor

From: Cliff Binder, Health Care Financing Analyst, x 7-7965

Subject: **Public Health Service Act Section 340B Drug Pricing Program Questions on Cosmetic Drugs and Movie Stars from Hollywood**

Per your request, this memorandum on the Public Health Service Act (PHSA) Section 340B Drug Pricing Program (340B program) responds to the following questions you asked concerning 340B program covered entity authority to purchase covered outpatient drugs approved by the Food and Drug Administration (FDA) for cosmetic purposes at the 340B discounted ceiling price and dispense them to their patients. Specifically, your questions are with regard to the ability of covered entities to provide those discounted drugs to patients who are movie stars from Hollywood.

1. Under the 340B program, are there covered entities, including hospitals, in or around Hollywood and Beverly Hills (CA) that participate in the 340B program?
2. If a movie star from Hollywood were to receive a covered outpatient drug at a hospital that is a CE, can the covered entity legally receive a 340B discount for this drug?
3. If a movie star from Hollywood were to receive a covered outpatient drug at a hospital that is a CE, would such a hospital be legally prohibited from claiming the 340B discount for drugs used for outpatient cosmetic purposes?

The memorandum will respond to each of these questions.

In summary, all 340B covered entities may purchase any 340B program covered drugs, including drugs approved by the FDA for cosmetic purposes, at the 340B program discounted ceiling price and dispense those drugs to their patients who meet the 340B program patient definition. There are 24 covered entity sites in and around Hollywood and Beverly Hills, CA that participate in the 340B program including the following: three disproportionate share hospitals (DSHs), one children's hospital, 12 federally qualified health centers (FQHCs) or FQHC look-alikes, three Ryan White HIV/AIDS programs, and five specialized clinics.

This memorandum and your request are confidential, although because of general interest in the 340B program by other Members, their staff, or Committees, general 340B program material may be used in other CRS products.

Senator Cassidy's Questions

The questions are shown in bold type, responses in normal type.

Question 1: Under the 340B program, are there covered entities, including hospitals, [in or around Hollywood](#) and Beverly Hills (CA) that participate in the 340B program? (Yes: <https://opanet.hrsa.gov/340B/Views/CoveredEntity/CESearch>, for just one example, in ZIP code 90048).

Only nonprofit health care organizations that have certain federal designations or receive federal program funding are eligible to register and be enrolled as covered entities and purchase drugs at 340B program ceiling prices.¹ Covered entities eligible to participate in the 340B program are identified in statute and, as shown in **Table 1**, include a number of public health service grantees such as health centers, Ryan White HIV program grantees, certain hospital types, and specialized clinics.

Table 1. 340B Program Covered Entities

Covered Entities
Health Centers ^a
<ul style="list-style-type: none"> • Federally Qualified Health Centers • Federally Qualified Health Center Look-alikes • Native Hawaiian Health Centers • Tribal/Urban Indian Health Centers
Ryan White HIV Program Grantees ^b
Hospitals
<ul style="list-style-type: none"> • Children’s Hospitals • Critical Access Hospitals • Disproportionate Share Hospitals • Freestanding Cancer Hospitals • Rural Referral Centers • Sole Community Hospitals
Specialized Clinics
<ul style="list-style-type: none"> • Black Lung Clinics • Comprehensive Hemophilia Treatment Centers • Title X Family Planning Clinics^c • Sexually Transmitted Disease Clinics • Tuberculosis Clinics

Source: CRS summary of information from the HRSA 340B website and OPA Information System (OPAIS).

Notes:

- a. For more information, see CRS Report R43937, *Federal Health Centers: An Overview*, by Elayne J. Heisler.
- b. For more information, see CRS Report R44282, *The Ryan White HIV/AIDS Program: Overview and Impact of the Affordable Care Act*, by Judith A. Johnson and Elayne J. Heisler.
- c. For more information, see CRS Report RL33644, *Title X (Public Health Service Act) Family Planning Program*, by Angela Napili.

¹ Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) website, <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

Covered entities must register and recertify annually by submitting certain information to the Health Resources and Services Administration's (HRSA's) Office of Pharmacy Affairs (OPA), the federal agency that administers the 340B program.² HRSA adds approved covered entities to the OPA Information System (OPAIS) – a public database – which then makes the entity eligible to receive 340B program discounts and enables drug manufacturers to verify that a covered entity is eligible to receive 340B program discounts.³ Often 340B program covered entities consist of a parent organization that has a number of associated child sites. Child sites can include satellite clinics or facilities, hospital departments, outpatient treatment units, and other facilities. HRSA indicated that as of January 1, 2018, there were a total of 42,486 registered sites, including both parent organizations and associated child sites.⁴ Nationally, there were approximately 12,823 unique 340B program covered entity organizations on January 1, 2018.⁵

As requested by Senator Cassidy, CRS identified 26 ZIP codes in or around Hollywood and Beverly Hills, California (Hollywood, California-area), which included parts of Los Angeles (18 Zip Codes), North Hollywood (6 ZIP Codes), Beverly Hills (1 ZIP code), and Burbank (1 ZIP Code).⁶ **Table 2** displays a summary of the types of 340B covered entities operating in the 26 Hollywood, California-area ZIP codes in March 2017.⁷ Throughout the remainder of this memorandum, the area in or around Hollywood and Beverly Hills California will be referred to as the Hollywood, California-area.

Table 2. Covered Entity Types Operating In the Hollywood, California-Area
Participating 340B Covered Entity Organizations in March 2017

Covered Entities	Number of 340B Covered Entity Organizations in the Hollywood, California-area
Children's Hospital	1
Comprehensive Hemophilia Center	1
Disproportionate Share Hospital	3
Family Planning	1
Health Center	11
Health Center Lookalike	1
Ryan White HIV Programs	3
Sexually Transmitted Disease Clinic	2
Tuberculosis Clinic	1
Total	24

Source: CRS analysis of USPS ZIP codes in the Hollywood, California- area and the HRSA OPAIS covered entity database.

² 42 U.S.C. § 256b(d)(2)(B)(i), Covered Entity Compliance.

³ OPA maintains a public database that lists participating covered entities, drug manufacturers, and contract pharmacies, <https://opanet.hrsa.gov/340B/Default>.

⁴ Department of Health and Human Services, FY2019 Health Resources and Services Administration, Justification of Estimates for Appropriations Committees.

⁵ Ibid.

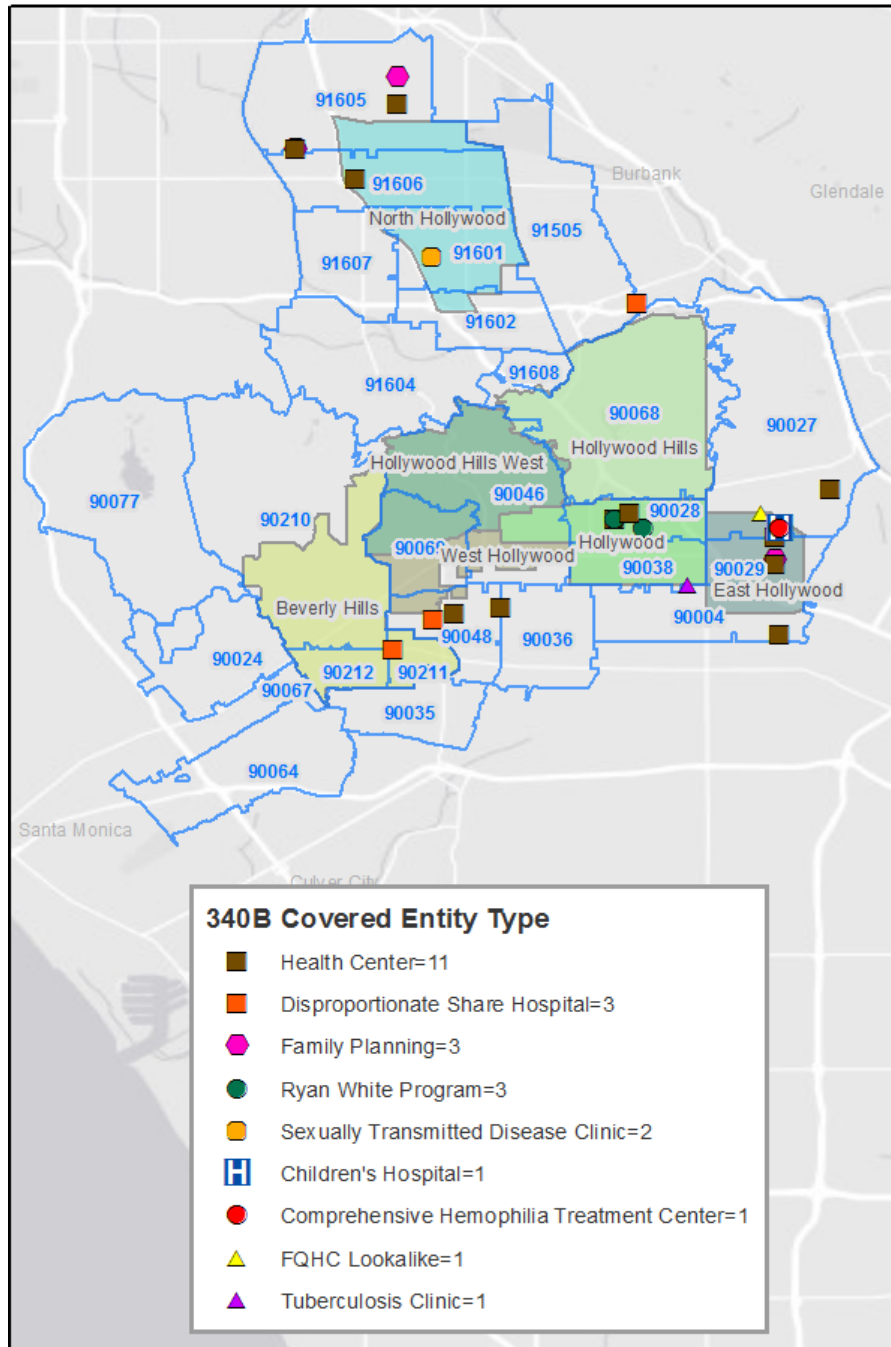
⁶ CRS identified ZIP codes in the Hollywood, California-area using data from the U.S. Bureau of the Census and the U.S. Postal Service (USPS) Zone Improvement Plan (ZIP) code boundary file.

⁷ CRS used ZIP codes in the Hollywood, California area and the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA) covered entity database to identify 340B covered entities in or around the Hollywood, California-area.

Figure 1 displays the location of the 24 340B program covered entity organizations on a ZIP code map of the Hollywood, California-area.

Figure 1. Hollywood, California-area Zip Code Map Displaying 340B Program Covered Entity Organizations

Covered Entities Participating in March 2017



Source: CRS analysis of HRSA OPAIS covered entity database, March 2017 and USPS ZIP code boundary files.

Notes: Some covered entity symbols may be obscured by other symbols.

Question 2: If a movie star from Hollywood were to receive a covered outpatient drug at a hospital that is a CE, can the covered entity legally receive a 340B discount for this drug?

The 340B program entitles covered entities to purchase covered outpatient drugs at a discounted ceiling price for patients of the covered entities. Individuals who receive health care treatment or services at 340B program covered entities are considered patients of those facilities when the following conditions are met:⁸

1. the 340B program covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
2. the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements, such as referral for consultation, so the responsibility for the care provided remains with the covered entity; and
3. the individual receives a health care service or a range of services from the covered entity consistent with the service or range of services for which grant funding or federally qualified health center lookalike status was provided to the covered entity. Disproportionate share hospitals are exempt from this requirement.

With certain exceptions, individuals are not considered covered entity patients if the only health care service they received from a covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration at home.⁹

PHSA Section 340B law specifies the types of health care organizations (covered entities) that may participate in the 340B program. Although 340B law identifies the discounted ceiling price it does not specify the amount that 340B program covered entities may charge covered entity patients for covered drugs.¹⁰ In addition, 340B program law does not specify how 340B program covered entity patients who receive covered drugs are to pay for drugs. Patients of 340B covered entities may pay for drugs they receive at those covered entities using the full range of payment methods, including using their health insurance (which might involve a cost-sharing obligation), paying cash if they don't have insurance, or, in some cases, receiving a subsidy from the 340B covered entity to cover some or all of the cost of the drugs.

Question 3: If a movie star from Hollywood were to receive a covered outpatient drug at a hospital that is a CE, would such a hospital be legally prohibited from claiming the 340B discount for drugs used for outpatient cosmetic purposes?

Under the 340B program, hospital covered entities may purchase covered outpatient drugs at the discounted 340B program ceiling price where covered outpatient drugs are defined in Medicaid law and include the following:¹¹ FDA-approved prescription drugs, over-the-counter drugs that are written on a

⁸ For more information on the definition of a 340B program covered entity patient see <https://docs.340bpvp.com/documents/public/resourcecenter/glossary.pdf>

⁹ Individuals may only receive drugs and still be considered 340B covered entity patients if they are registered with state state-operated or funded AIDS drug purchasing assistance programs, receive Ryan White Program financial assistance, and meet other 340B program patient definition requirements; Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 *Federal Register* 55158, October 24, 1996.

¹⁰ PHSA § 340B(a)(4), Covered Entity Defined.

¹¹ Social Security Act (SSA) § 1927(k)(2), Covered Outpatient Drug.

prescription, biological products that can be dispensed only by a prescription (except vaccines), and FDA-approved insulin.¹² Drugs are often approved by FDA for multiple uses and certain drugs approved for cosmetic purposes are approved for other indications.

If a 340B hospital covered entity patient received a drug FDA-approved for cosmetic purposes at a 340B covered entity, the hospital would not be prohibited from purchasing that drug at the 340B ceiling price. The 340B ceiling price discount percentage is defined in statute and is approximately equal to the percentage rebate amount states receive from drug manufacturers on a drug-by-drug basis (by drug strength and package size) under the Medicaid rebate program.¹³

¹² Public Health Service Act (PHSA) § 340B(b)(1), Other Definitions, PHSA § 340B(b)(2) Covered Drug, and Social Security Act (SSA) § 1927(k)(2), Covered Outpatient Drug.

¹³ PHSA § 340B(a)(2), Rebate Percentage Defined; and the SSA § 1927(c), Determination of Amount of Rebate.
