

An aerial photograph of the University of California campus, showing various buildings and greenery. In the background, a city skyline is visible through a light haze. The text is overlaid on the upper portion of the image.

University of California
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Symposium

REACHING NEW HEIGHTS



Protecting the Health Care Safety Net: 340B Drug Pricing Program Compliance

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What's the 340B Program?



340B Drug Pricing Program

- Established in 1992 to help certain safety net providers (“Covered Entities”) stretch scarce federal resources as far as possible by obtaining deep discounts on covered outpatient drugs
- Manufacturers of drugs covered by state Medicaid programs must participate in 340B Program and sign “Pharmaceutical Pricing Agreement” with the Secretary of Health & Human Services
- Manufacturer must charge covered entities no more than the 340B “ceiling price” for all “covered outpatient drugs” (as defined in federal Medicaid statute)

340B Program Vocabulary

- **HRSA:** Health Resources and Services Administration; an agency within U.S. Department of Health and Human Services
- **OPA:** Office of Pharmacy Affairs; the office within HRSA responsible for administration and oversight of the 340B Program
- **Apexus:** The 340B Program Prime Vendor; a private contractor to OPA responsible for providing contracting & distribution assistance, education/training
- **Covered Outpatient Drug:** Prescription drugs approved by FDA (as well as products sold or identical, similar or related to products sold before 1962), biological products other than certain vaccines, and insulin
 - Excludes any drug, biological, or insulin provided and paid by Medicaid as part of, or as incident to and in the same setting, as certain other services such as inpatient hospital services, outpatient hospital services, physician services; **i.e., no separate reimbursement for drug**
- **Covered Entity:** One of the 17 types of safety net providers set forth in federal statute that are eligible to participate in the 340B Program
- **Contract Pharmacy:** A licensed pharmacy that has entered into a written agreement with Covered Entity to provide pharmacy services to Covered Entity patients

340B Covered Entities

Hospitals	Federal Grantees/Designees
Disproportionate share hospitals (DSH)	Federally qualified health center (FQHC)
Children's hospitals	FQHC look-alikes
Critical access hospitals	Title X family planning grantees
Free standing cancer hospitals	State AIDS drug assistance programs
Rural referral centers	Ryan White Act grantees
Sole community hospitals	Black Lung clinics
	Hemophilia treatment centers
	Native Hawaiian health centers
	Urban Indian organizations
	Sexually transmitted disease grantees
	Tuberculosis grantees

340B Hospital Eligibility Requirements

Type	Gov't/Non-profit*	DSH %	GPO Prohibition	Orphan Drug Exclusion
Disproportionate Share Hospital	Yes	> 11.75%	Yes	No
Children's Hospital	Yes	> 11.75%	Yes	No
Free-Standing Cancer	Yes	> 11.75%	Yes	Yes
Critical Access Hospital	Yes	N/A	No	Yes
Rural Referral Center	Yes	>=8%	No	Yes
Sole Community Hospital	Yes	>=8%	No	Yes

UC Covered Entities



Hospital “Child Site” Registration

- Hospital outpatient facilities located outside of the four walls of the hospital must be registered as “child sites” of the “parent” hospital to be eligible for 340B prices
- Outpatient facility must be included as a reimbursable cost center on hospital’s most recently filed Medicare Cost Report
 - Must meet Medicare’s “provider-based department” rules
 - Registrants must identify the cost center line(s) containing expenses and outpatient charges for each of the clinics, services, or facilities being registered
 - Registrants must provide the specific expenses and outpatient revenues for those clinics, services or facilities (from the working trial balance corresponding with the listed cost report)
- Facilities containing multiple clinics or services must be registered as individual child sites (i.e., for each clinic/department/service), not single registration for entire location

Contract Pharmacies

- Since 2010, HRSA permits Covered Entities to contract with one or more retail pharmacies to serve their patients
- Covered Entity must have written contract in place with Contract Pharmacy
- Covered Entity responsible for Contract Pharmacy compliance
 - Annual audits performed by independent outside auditor are expected
 - Covered Entity must have sufficient information re: program compliance
 - If Covered Entity identifies drug diversion or duplicate discounts, it must take immediate remedial action and notify OPA about the compliance issue and actions taken to remedy those programs
- Covered Entity must annually certify to OPA that it has signed contract pharmacy agreement in place that meets HRSA requirements
- Typically covered entities use “third-party administrator” to assist with back end claims processing/reconciliation to link 340B eligible patients with dispensed prescriptions

Contract Pharmacy Oversight

- Essential elements for contract pharmacy arrangements:
 - Covered Entity must purchase drug, maintain title and establish its price
 - Specify responsibility of parties to provide comprehensive pharmacy services
 - Covered Entity must inform patient of freedom of choice of pharmacy provider
 - Contract Pharmacy may provide other services
 - Compliance with all federal, state and local laws and requirements
 - Contract Pharmacy must provide Covered Entity with reports consistent with customary business practices
 - Contract Pharmacy, with assistance of Covered Entity, shall establish and maintain a tracking system to prevent diversion
 - Covered Entity and Contract Pharmacy will develop system to verify patient eligibility
 - No 340B drugs for **Medi-Cal FFS** prescriptions unless Covered Entity, Contract Pharmacy, and State Medicaid agency have established an arrangement to prevent duplicate discounts
 - Covered Entity and Contract Pharmacy will identify necessary information for Covered Entity to meet its ongoing responsibility of ensuring compliance
 - Both parties understand subject to audits by outside parties, including DHHS and manufacturers
 - Upon written request, copy of contract pharmacy service agreement must be provided to OPA

Key 340B Program Compliance Requirements

- GPO prohibition
- Patient definition/prohibition against “diversion”
- “Duplicate discount” prohibition
- Contract pharmacy oversight
- Audits and “good faith inquiries”

GPO Prohibition

- Certain types of hospital covered entities must not obtain Covered Outpatient Drugs through a group purchasing organization (GPO) or “other group purchasing arrangement” [42 U.S.C. 256B(a)(4)(L)(iii)]
 - **HRSA says a hospital system conducting price negotiations for covered outpatient drugs on behalf of more than one hospital (i.e., with separate 340B registrations/Program ID numbers) is a prohibited group purchasing arrangement**
- Applies to all clinics/departments within the four walls of the hospital (same physical address) and all of hospital’s registered child sites
- Does not apply to drugs that are not Covered Outpatient Drugs; covered entities must maintain policies and procedures and auditable records to demonstrate that any GPO purchases are consistent with 340B statute
- Violation of GPO prohibition (even at child site or contract pharmacy) may mean termination from the 340B Program and repayment to manufacturers

GPO Prohibition—Practical Applications

- **Hospital Pharmacy Inventory**

- Hospitals must maintain physically or virtually separate inventories for Covered Outpatient Drugs used in “mixed use” (i.e., inpatient/outpatient) areas
- Split ordering software tracks accumulation for specific accounts (e.g., GPO, 340B, WAC) and produces replenishment orders to replace physical inventory; must maintain auditable records to show virtual accumulations

- **Drug Shortages/340B Price not available**

- Covered Entity must first work with manufacturer to obtain product at 340B price; then WAC
- If product can't be purchased at WAC, may use GPO only if Covered Entity immediately notifies OPA using HRSA Template Notification Tool and document and maintain records all other options have been exhausted
- Must attempt to purchase drug at 340B price every time an order is made; can't simply rely on prior attempts

GPO Prohibition—Practical Applications

- **Drug Purchases/Discounts**

- Each Covered Entity must have an individual direct contract with manufacturer for discounted drug price (regardless of whether offered through wholesaler/other third party)
- Agreement must be produced for review during audit
- Examples of non-compliant arrangements:
 - Accessing contracts executed by an IDN in which hospital is a member;
 - Wholesaler's generic source program (unless a subcontracted solution to Apexus Generics Program)
 - Manufacturer extending discounted price to a group of Covered Entities through wholesaler, other third party or group purchasing arrangement that is not supported by individual contract between 340B covered entity and manufacturer

“Patient” of the Covered Entity

- Covered Entity shall not resell or otherwise transfer Covered Outpatient Drug to a person who is not a patient of the Covered Entity [42 U.S.C. 256B(a)(5)(B)]
- Covered Entity must have established relationship with individual; maintain records of individual’s health care
- Individual receives health care services from health care professional employed by Covered Entity or who provides services under contractual or other arrangements (e.g., referral for consultation)
 - Services must be more than dispensing of drug for subsequent self-administration or administration in home setting
- Responsibility for individual’s care remains with covered entity

Duplicate Discount Prohibition

- Covered Entity shall not request payment from Medicaid (Medi-Cal) for a 340B drug if the drug is subject to rebate to State under Medicaid Drug Rebate Program [42 U.S.C. 256B(a)(5)(A)]
- California law requires Covered Entities to “carve-in” –i.e., use 340B drugs to treat Medi-Cal patients [Cal. Welf. & Inst. 14105.6(b)]
 - Unless 340B drug is not available
 - Covered Entity shall bill Medi-Cal FFS drug’s actual acquisition cost, plus professional fee or dispensing fee
 - If 340B drug is not available, Covered Entity shall bill Medi-Cal at the Usual and Customary charge
 - Covered Entity shall identify 340B drug on claim submitted to Medi-Cal for reimbursement

Preventing Duplicate Discounts: Medi-Cal FFS

- HRSA Medicaid Exclusion [File](#) lists all Covered Entities that bill Medicaid for 340B drugs used for Medicaid patients (“carve-in”)
 - Must include any Medicaid provider number and NPI used to bill Medicaid FFS **in any state**
 - **Must obtain separate Medicaid provider numbers and NPIs for 340B eligible clinics**
 - Quarterly changes/updates must be received, approved and processed by OPA by 15th day of month prior to start of quarter
- Covered Entity shall identify 340B drug on claims submitted to Medi-Cal
- Medicaid Exclusion File does not apply to Medicaid managed care

Preventing Duplicate Discounts: Medi-Cal Managed Care

- CMS requires state Medicaid agencies, Medicaid managed care organizations, and covered entities to put mechanisms in place to prevent duplicate discounts
- Covered Entity shall identify 340B drug on claims submitted to Medi-Cal managed care plans
 - Medicare crossover claims;
- Draft All-Plan Letter and Provider Bulletin in 2018 not finalized

Duplicate Discount Prohibition—Contract Pharmacy

- Contract Pharmacies may not use 340B drugs to dispense Medi-Cal FFS prescriptions unless:
 - Covered Entity, Contract Pharmacy and State Medicaid agency have established an arrangement to prevent duplicate discounts
 - Arrangement has been reported to HRSA
- Contract Pharmacies may use 340B drugs to dispense to Medi-Cal managed care prescriptions BUT:
 - Required modifiers not added at point-of-sale/dispensing → must be added later

Audits and Good Faith Inquiries

- HRSA must audit Covered Entities and manufacturers
 - Historically, HRSA has audited many more Covered Entities than manufacturers
- Manufacturers may audit Covered Entities to ensure compliance with the drug diversion and duplicate discount prohibitions
 - Must first attempt to resolve issues with covered entities in good faith
 - Must submit work plans to HRSA at least 45 days in advance
- Covered entities must cooperate in good faith with manufacturer “inquiries”

Hot Topics in the 340B Program

- Congressional and other government scrutiny
- AHA Good Stewardship Principles
- Medicare reimbursement
- Commercial reimbursement
- California/Medi-Cal pharmacy cost initiatives
- Federal Prescription Drug Cost proposed legislation

Federal Government Oversight

- Throughout 2017, numerous Congressional hearings and federal bills introduced, focused on:
 - Transparency
 - Child sites
 - Use of 340B “savings”
 - Charity care provided
 - Contract pharmacy oversight
- GAO Report on Contract Pharmacy Oversight (2018)
- 2018 change in control in U.S. House of Representatives means legislative change is unlikely
- But some changes to 340B Program within HRSA’s authority and could be addressed via guidance
 - GPO prohibition
 - Definition of eligible “patient”



AHA 340B Good Stewardship Principles

- All six UC disproportionate share hospitals (DSH) have voluntarily committed to three principles (along with hundreds of other hospitals):
 - **Communicate** the value of the 340B Program
 - Narrative description of how hospital uses the 340B program to benefit its community (e.g., programs and services funded in whole or in part by 340B savings)
 - Published on an annual basis
 - **Disclose** the hospital's 340B estimated savings
 - Published on an annual basis using a standardized method to compare the acquisition cost of 340B drugs to GPO pricing
 - Continue rigorous **internal oversight**
 - Including regular and periodic training for hospital's interdisciplinary 340B teams

Medicare Reimbursement for 340B Drugs

- Starting in CY2018, CMS cut Medicare Part B reimbursement for 340B drugs by nearly 30 percent
 - **New modifier required for drugs separately paid under Part B**
- American Hospital Association, America's Essential Hospitals and others sued
- In December 2018, federal district judge ruled in favor of hospitals, but asked for supplemental briefing on remedy
- In May 2019, federal district judge instructed CMS to develop appropriate remedy for CY2018 and CY2019 and propose to court by **August 5**
- In July 2019, CMS proposed rule in July seeking input on potential remedies in the event ruling is upheld
 - CMS says a decision from Court of Appeals by March 1, 2020 needed in order for CMS to propose and finalize an appropriate remedy and budget neutrality adjustments in the CY 2021 rulemaking
- CMS appealed; federal appeals court scheduled to hear arguments in case in **late fall 2019**

Commercial Payor Reimbursement for 340B Drugs

- Commercial payors and pharmacy benefit managers have been reducing payment rates for network Covered Entity owned pharmacies or 340B drugs
 - CVS Caremark
 - Based on feedback from providers and 340B Health; reimbursement rate reduction not implemented
 - Humana

California Pharmacy Cost Initiatives

- Governor Newsome's first Executive Order in office targeted rising prescription drug costs
 - Ordered Department of Health Care Services to take all necessary steps to transition pharmacy services for Medi-Cal managed care to a fee-for-service benefit by January 2021
 - Ordered Department of General Services, in consultation with California Pharmaceutical Collaborative to develop a list of prescription drugs to prioritize for future bulk purchasing initiatives
- Likely means change in Medi-Cal reimbursement for prescription drugs from contracted rates to "actual acquisition cost" (i.e., 340B price)

References

- Section 340B of the Public Health Service Act, 42 U.S.C. 256B
- Section 1927(k) of the Social Security Act, 42 U.S.C. 1396r-8(k)(2)—(3)
- HRSA Final Notice, Definition of Covered Entity “Patient”, 61 Fed. Reg. 55,156 (Oct. 24, 1996)
- HRSA Final Notice, Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010)
- Government Accountability Office, Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement (June 2018), available at <https://www.gao.gov/assets/700/692697.pdf>
- HRSA 340B Drug Pricing Program, <https://www.hrsa.gov/opa/index.html>
- HRSA OPA FAQs, <https://www.hrsa.gov/opa/faqs/index.html>
- Apexus FAQs, <https://www.340bpvp.com/controller.html>
- Executive Order N-01-19, <https://www.gov.ca.gov/wp-content/uploads/2019/01/EO-N-01-19-Attested-01.07.19.pdf>

UC Covered Entities 340B Program Websites

- UCSD: <https://health.ucsd.edu/about/Documents/Value-of-340B-Program-UCSD.pdf>
- UCD: <https://health.ucdavis.edu/newsroom/public-reporting/340b-program.html>
- UCSF: <https://www.ucsfhealth.org/about/340b-program/>
- UCLA: <https://www.uclahealth.org/340b-program>
- UCI: <http://www.ucihealth.org/340b-program>