

#### Western States Regional Hemophilia Network

cibd-ca.org/western-states-region-ix

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# WSRHN 340B FAQ

In administering a federal award, entities are required to comply with 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Award codified at 45 CFR Part 74, also known as the Uniform Guidance. The guidance was published in December 2013 and became applicable to the Regional Hemophilia Network Grant on June 1, 2015.

As recipient or sub-recipient of the Regional Hemophilia Network Grant, the Western States Hemophilia Treatment Centers (HTC) are eligible entities under the "HM" designation of the Federal 340B Program, a discount outpatient drug pricing program. Funds generated under the 340B Program are considered Program Income Per 2 CFR §200.307(e)(2), and must be used for the purposes and under the conditions of the Federal award.

The purpose of the Regional Hemophilia Network Grant is to establish an integrated and collaborative regional network to promote the comprehensive care of individuals with hemophilia and related bleeding disorders or clotting disorders such as thrombophilia. Expenses should support patient health, education, and supportive services.

To provide guidance on the use of 340B Program Income, the Western States Core Center/Grantee, the Center for Comprehensive Care and Diagnosis of Inherited Blood Disorders (CIBD), has prepared this informational document. It consists of: A) an outline of purchases and activities that require HRSA's Prior Approval; B) Areas where Use of 340B Net Program Income is Not Allowed, C) FAQ's - Using 340B Program Income, D) 340B Policies, E) 340B Operations, F) 340B Resources, and G) Publications. Please note that this document is designed to assist you in developing best practices and is not meant to be all inclusive. If legal advice or additional assistance is required, the services of a competent professional should be sought as facts and circumstance may differ.

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A. Purchases and Activities Requiring Prior Approval from HRSA Before Using 340B Net Program Income (Please refer to the Prior Approval Policy for additional information):

- Capital Expenditures, including alterations and renovations up to \$150,000 (2 CFR §200.439)
- Entertainment (2 CFR §200.438)
- Special Purpose Equipment, unit with a unit cost of \$5,000 or more (2 CFR §200.439)
- Foreign Travel
- Organization Costs (2 CFR §200.455)
- Participant Support Costs (2 CFR §200.456)
- Pre-Award Costs (2 CFR §200.458)
- Selling and Marketing (2 CFR §200.467)
- Research (2 CFR §200.87)

## B. Purchases and Activities where Use of 340B Net Program Income is Not Allowed:

- Alcoholic Beverages (2 CFR §200.423)
- Alumni/ae Activities (2 CFR §200.424)
- Bad Debts (2 CFR §200.426)
- Contributions and Donations (2 CFR §200.434)
- Goods or services for personal use (2 CFR §200.445)
- Interest (2 CFR §200.449)
- Lobbying (2 CFR §200.450)
- Losses on other awards or contracts (2 CFR §200.451)
- Major Alteration & Renovations and capital costs that exceed \$150,000 during the project period
- Student Activity Costs (2 CFR §200.469)

## C. FAQ's - Using 340B Program Income:

No.	Question	Response/Source
1	Can 340B program income be used to support <b>patient/family education</b> programs that the HTC operates?	Per 2 CFR Part 200.432, a meeting whose primary purpose is to disseminate technical information under the Federal award is allowable. Hence, the HTC may sponsor or host a meeting to support its patient/family education program. Expenses may include the rental facilities, speaker fees, and costs of meals. Allowable expenses associated with this program are only applicable to employees, not non-employees. However, if the HTC would like to support the patient/family travel or hotel rooms, then the HTC must seek and obtain prior approval. (See No. 7 below)
2	Can 340B program income be used to support <b>patient/family education</b> programs that a local or State hemophilia foundation chapter operates?	Per 2 CFR Part 200.434, contributions and donations are unallowable. However, MCHB recognizes the importance of support and has allowed agencies to support organizations that serve patients with hemophilia. Ex: Funds used to support camp must be educational in nature. Hence making a general donation to the camp, so that the association can use it as needed for camp, is not allowable under the Uniform Guidance. However, if the HTC is supporting a nurse or a social worker's time to provide educational programming at the camp, then it would be allowable. HTCs must have an

		agreement with a chapter (or other non-profit that serves hemophilia patients) for specific purposes. <sup>1</sup>
4	Can 340B program income be used for <b>entertainment</b> ?	Per 2 CFR Part 200.438, costs of entertainment including amusement, and social activities and any associated costs are unallowable, except where specific costs that might otherwise be considered entertainment have a programmatic purpose and are authorized under the approved budget or with prior written approval.
5	Can 340B program income be used to purchase <b>employee office furniture</b> ?	Office furniture for "general purpose" is considered an indirect cost if is used for shared common areas. As long as it is dedicated, allocated, and intended for use by the HTC staff to meet the program/project objectives then it is allowable. HTCs should maintain records specifying the number and type of items purchased and cost per item.
6	Can 340B program income be used to cover <b>co-payment bills</b> for factor and other medication?	Copayments, Charity Care, and Contributions are not an allowable use of Program Income. These types of accounts are either written off as bad debt or the organization writes them to charity care or other accounting units that an organization will absorb. Bad debt "write-offs" are unallowable expenses per OMB 2 CFR §200.426. Bad debt or uncollected billings, including losses (whether actual or estimated) from uncollectable accounts and other claims, are unallowable.
		Program income is to be used to support comprehensive care services (supportive/ancillary related). Use of 340B program income for factor product and other medications and/treatments must be consistent with co pay and financial assistance policy. When the patient's third-party insurance is utilized, the patient would be obligated to meet their responsibility of their insurance contract/benefit.
		We recommend that HTC's have a copayment policy that addresses write-offs and adjustments.
		Copayments are the responsibility of the patient. Patients agree to their financial responsibility with their insurance. Therefore, writing off copays could be viewed as an inducement if copays were automatically written off. There is a 120-day collection requirement by the Center for Medicaid and Medicare Services to attempt to collect.  HTCs should check with drug manufacturers to see if they have patient
		assistance programs. Such program may offer copay assistance and/or reduce the cost of the drug. There are also other non-manufacturer patient assistance programs that may provide various forms of assistance to patients who cannot afford their copay or the cost of the drug.
7	Can 340B program income be used to support <b>patient travel</b> to a mother/daughter educational conference on Von Willebrand Disease sponsored by a Hemophilia Treatment Center (HTC) or pharmaceutical company?	Per 2 CFR §200.75, participant support is defined as direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees in connection with conferences, or training projects. Per 2 CFR §200.456 these expenses are allowable with prior approval from HRSA.
8	Can 340B program income be used to support <b>vocational assistance</b> , e.g. to purchase a monthly bus pass for an	The use of 340B program income to support transportation assistance for the express purpose of helping unemployed patients get a job is not an allowable cost. Reducing unemployment falls outside the scope of the HRSA grant. The HRSA grant's primary purpose is improving health of our genetic blood disorders populations through increasing access

 $<sup>^{1}</sup>$  9/5/2007 email from HRSA Project Officer Michelle Puryear, MD to HTC Regional Directors and Coordinators

9	unemployed patient to job search and make it to interviews?  Can 340B program income be used to upgrade to first class for business flights exceeding six hours?	comprehensive genetic blood disorders health services. It would be allowable to use 340B program income to help needy patient's w/transportation services to enhance their access to comprehensive care services. While HTC Social Workers (SW) do provide guidance and referrals for employment or insurance problems per the SW roles and responsibilities noted in NHF's MASAC Recommendation 132, the purpose of the HRSA grant remains enhancing access to comprehensive health care services.  Per 2 CFR §200.474, airfare costs that exceed the basic, least expensive, and unrestricted accommodations class offered by commercial airlines are unallowable except when such accommodations would: (i) Require circuitous routing; (ii) Require travel during unreasonable hours; (iii) Excessively prolong travel; (iv) Result in additional costs that would offset the transportation savings; or (v) Offer accommodations not reasonably adequate for the traveler's medical needs. These conditions must be justified and documented in order for the use of first-class or
		business-class airfare to be allowable. These requests will be considered on a case-by-case basis.  "Excessively prolong travel", should not be confused with "excessively long travel".  The Uniform Guidance indicates that airfare costs that are in excess of the lowest priced fares would potentially be allowable IF the cheaper fare caused travel to be excessively longer than if the business class fare was paid. For example if the cheaper fare resulted in multiple connections and/or layovers that could be a case where the cheaper fare was a cause to, "excessively prolong travel".
11	Can we use program income to cover registration and travel costs for a conference, program or meeting occurring in another country (ex: participation in the World Federation of Haemophilia (WFH) Twinning Program, attendance at WFH or ISTH)?	HRSA has become increasingly restrictive about allowing use of program income for foreign travel. HRSA has only allowed 340B funds to support travel to meetings outside the US if the traveler is either 1) an invited speaker presenting their work (not just a poster session) and/or 2) attendance at the conference gives Continuing Medical Education credits or some other real certification or training opportunity that is not offered in the US. Both options would require documentation.  Foreign travel is allowable with prior approval. Costs must be reasonable and justifiable.  Prior Approval is not required if travel is occurring within the United States.  Foreign travel related to the WFH Twinning Program would require prior approval.
12	Can 340B program income be used to support international fellows, such as visa sponsorship, etc.	Per 2 CFR §200.466, costs of scholarships, fellowships, and other programs of student aid are allowable only when the purpose of the federal award is to provide training to selected participants and the charge is approved by HRSA. This is not the purpose of the Regional Hemophilia Network Program and therefore this would not be an allowable use of federal funds under the award.
13	Can we charge the cost of a special chair that we purchase for an employee in the Hemophilia Program with special medical requirements to	Per 2 CFR §200.437, "Costs incurred in accordance with the non-Federal entity's documented policies for the improvement of working conditions, employer-employee relations, employee health, and employee performance are allowable." Hence, if this equipment is to improve the work conditions for this particular employee, then yes, it can be charged

	the below the line Hemophilia Program account?	below the line. Note that "below the line" refers to allowable items of cost that were NOT incurred in the generation of program income.
14	Can program income be used to purchase <b>alcohol</b> that will be served during an educational event or training?	Per 2 CFR §200.423 the costs of alcoholic beverages are unallowable.
15	Can 340B program income be used to support dental care?	Yes, as long as it meets the program/project objectives then it is allowable. HTCs can contract with individual dentists and/or dental clinics. This must be available to all patients regardless of their participation in the 340B Program.
16	Can we use program income to pay for construction, major alterations, or renovation costs for our HTC that exceed \$150,000?	No. Unless specifically authorized by law, award funds, and program income generated from award funds, may not be used to fund construction or the acquisition of title to real property. The HTC authorizing statute, 42 U.S.C. § 701(a)(2), does not provide sufficient legal authority for construction or major renovations.
		45 C.F.R. § 75.307 states that program income must be used for the same objectives/purposes/goals of the hemophilia program that are stated in the Notice of Funding Opportunity (NOFO). The NOFO contains no requirement, goal, or objective regarding construction. Therefore, using program income for these purposes is not allowable under the current award.
		For the purposes of the Regional Hemophilia Network program, minor Alteration & Renovations are allowable with prior approval and should not exceed \$150,000.
		Major Alteration & Renovation (A&R) projects exceeding \$150,000 are unallowable. Major A&R consists of a structural change (e.g., to the foundation, roof, floor, or exterior or load-bearing walls of a facility or extension of an existing facility) to achieve the following: Increase the floor area; and/or, change function and purpose of the facility.
17	Can we use 340B program income to pay for <b>meals</b> for our staff and patients?	<ul> <li>Generally unallowable except for the following:</li> <li>Subjects and patients under study</li> <li>Where specifically approved as part of the project or program activity</li> <li>When an organization customarily provides meals to employees working beyond the normal workday, as a part of a formal compensation arrangement</li> <li>As part of a per diem or subsistence allowance provided in conjunction with allowable travel</li> <li>Under a conference grant, when meals are a necessary and integral part of a conference, provided that meal costs are not duplicated in participants' per diem or subsistence allowances.</li> <li>Guest meals are not allowable.</li> </ul>
18	What documentation do we need if we want to purchase a piece of equipment for \$11,000?	Due to the fact that the item in question exceeds the micro-purchase threshold of \$10,000, the HTC would be required to abide by Small Purchase procedures and ensure price or rate quotes are obtained from an adequate number of sources. While HRSA does not define what an "adequate number of sources," consists of; bidding procedures should be aligned with the site's internal purchasing procedures. As a general practice, we recommend quotes from three different agencies. The micropurchase threshold was updated per OMB memo M-18-18

		If the item is greater than or equal to \$5,000.00, prior approval is required.
19	We invest unexpended program income into money markets, etc. Is interest earned on the investment of 340B program income considered program income? How do we report interest accrued on our Factor Replacement Program Report?	Per our HRSA Grants Management Specialist on September 14, 2017, the Division of Financial Integrity stated that the "interest earned on the program income is also program income. The program income, i.e. the interest, must be allocated to the federal grant that generated it, and used for the purposes and under the conditions of the award."  We recommend that HTC's report interest earned on the investment of unexpended program income in Section C, "Other Income", of the Factor Replacement Program report.
20	Can an HTC can give priority in the level of transportation assistance that it offers to patients who are enrolled in the HTC's 340B program?	No, services that an HTC is providing to its patients should not be tied to participation in the 340B Program. By keeping the service separate from 340B participation, the HTC is making it clear that the particular service is not an inducement for patients to participate in the 340B Program.
21	The total cost of a service agreement for a piece of equipment is \$6700. The expense is related to maintenance of the equipment NOT the purchase of the equipment. Can an HTC use program income to cover the cost of equipment maintenance expenses?	Per an email dated October 18, 2019 from our program officer, an HTC does not need to submit a prior approval request since the cost is not for physical equipment (that could be resold, which is the reason HRSA tracks purchases over \$5,000).
22	If an HTC is interested in conducting an external audit of their 340B program. The estimated cost is \$18,000. Is prior approval required?	Per an email dated October 18, 2019 from our program officer, an HTC would not need to submit a prior approval for an audit of the HTC's 340B program, since it's a requirement of the grant to ensure that all rules and regulations of the 340B program are being followed. However, if the audit is broader than the HTC grant activities, such as an audit for a system's entire 340B program (e.g., the site has multiple 340B designations and want to use HM program income to audit other covered entities within the sponsoring organization), that would not be allowable. The site would have to chip in funds from other sources for that activity, similar to only being allowed to charge partial FTE salaries to the grant based on their percent of assigned grant responsibilities.  NOTE: This concept is applicable to most activities. An HTC cannot use HTC program income to cover other activities in sponsoring organizations, even if it's the same activity across different covered 340B populations. But, a sponsoring organization can use their DSH or Children's Hospital 340B program income to support the HTC, because
23	An HTC has service sites in multiple locations. They provide care at these service sites, sometimes on a monthly or annual basis. For one of these locations, they do write prescriptions with the address of that particular site. Is it accurate to say that each site, where a prescription originates from,	those types of covered entities have a much larger umbrella of allowable patients.  If 340B prescriptions are written from an address, that should be registered in OPAIS as a site. An HTC can have the same Authorized Official and Point of Contact registered for these "outreach" sites, and they don't have to use the purchasing number from the "outreach" sites.

	should be registered in the <b>OPA</b>	
	database.	
24	An HTC is establishing a maintenance contract for their Compact Coagulation Analyzer for their Hemophilia Clinic. The total cost of the 12 month service agreement exceeds \$5,000. The expense is related to maintenance of the equipment NOT the purchase of the equipment. Is prior approval needed to use program income for this expense (eg: maintenance)?	No, the HTC will not need to submit a PA request since the cost is not for physical equipment (that could be resold, which is the reason HRSA tracks purchases over \$5000).
25	HTC is interested in performing an <b>external audit</b> of the 340b program. Does this expense need prior approval from HRSA?	Per our program officer, the HTC does not need to submit a prior approval for an audit of the HTC's 340B program, since it's a requirement of the grant to ensure that all rules and regulations of the 340B program are being followed. However, if the audit is broader than the HTC grant activities, such as an audit for a healthcare system's entire 340B program (e.g., the healthcare system has multiple 340B designations and wants to use HM program income to audit other covered entities within the healthcare system), that wouldn't be allowable. The healthcare system would have to chip in funds from other sources for that activity, similar to only being allowed to charge partial FTE salaries to the HRSA Regional Hemophilia grant based on the percent of assigned HRSA grant responsibilities
26	Can we use 340B funds for advertising?	Per CFR §200.421(b)(4): Advertising and public relations - there are only a few allowable advertising costs, one of which is "Program outreach and other specific purposes necessary to meet the requirements of the Federal award."  An HTC can use program income to advertise the availability of the 340B program, but it should be done in conjunction with messaging that promotes access to care. Increasing awareness of the availability of the 340B program may enable the HTC to enhance patients access to therapeutics, thus positively impacting their health outcomes, but any "advertisements," should ensure that messaging is clear and does not require or pose pressure on individuals to participate in the 340B program in order to access care at the HTC.
27	One of our patients has been unsuccessful in administering his/her self-home infusions and has missed around 2-3 months' worth of medication. We will be paying around \$1,200 a month for a third-party nursing agency to go to his home and administer the medication. Are these charges allowable?	Yes, this would be an allowable use of program income as long as services are provided in alignment with the HTC's policies and procedures on provision of home infusions.
28	We had a patient come in to receive clinical services and their healthcare provider ordered labs that he felt were necessary in order to determine what medications he should prescribe. While the patient had received a	The Uniform Guidance provides little information on the use of program income, providing only that "program income must be used for the purposes and under the conditions of the Federal award." (See 2 CFR 200.307(e)(2)/45 CFR 75.307(e)(2)). The purposes of the program are, in part,to "Improve access to coordinated and comprehensive systems of care for patients with hemophilia and related blood or clotting disorders, strengthen hemophilia treatment centers' (HTC) integrated care teams, and

pre-authorization for their clinical visit, there was no authorization to do labs at the HTC. The patient's insurance company is now denying payment for the cost of the labs. The entity under which the HTC is housed is not waiving the cost. The insurance company has stated two reasons for not covering the cost of the labs: 1) labs were not done on the same day of the visit and 2) there was no authorization to do labs at the HTC.

improve the health and well-being for children, youth and adults with hemophilia and related bleeding and clotting disorders."

CIBD has not seen anything in the general rules for all costs (allocable, allowable) or the rules for specific costs that prohibits this use. HRSA guidance for use of program income provides that it is to be used to "further eligible project and program objectives. Therefore, the program income is to be used for patient care and supportive services necessary to provide comprehensive care to patients." (See Hemophilia Treatment Center Manual for Participating in the Drug Price Program Established by Section 340B of the Public Health Service Act).

The proposed use is to pay for patient care for an underinsured patient. This is consistent with the above and, therefore, an allowable use of program income.

Can program income be used to cover the cost of the patient's labs?

30 We are looking at a professional online subscription to the Anatomy App/\$99/year. This subscription will be an opportunity to support clinic patient centered care with knowledgeable professional staff.

Per 2 CFR 200.454 (b) Costs of the non-Federal entity's subscriptions to business, professional, and technical periodicals are allowable.

The app can be uploaded on all available devices. Some subscription features include muscle function, innervation, and even a "Lean Physiology Course: Haematology Practical Course and a blood and blood vessel microanatomy. Physical Therapist uses: Patient education on anatomy, review of anatomy, assistance with teaching other professionals about anatomy as it relates to MSKUS.

## D. PRIOR APPROVAL Policies

Please refer to the attached WSRHN Prior Approval policies: prior approval (general) and prior approval for research.

#### E. 340B OPERATIONS

- 1. COMPLAINTS: Where to file complaints about homecare/Specialty Pharmacy factor and home nursing services?
  - a. Nursing Services:
    - The CA Department of Licensing and Certification: <a href="https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LandCProgramHome.aspx">https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/LandCProgramHome.aspx</a>
    - ii. Nationally: The National Association of Homecare and Hospice: www.nahc.org/
  - b. Pharmacy California has two state agencies
    - CA Department of Consumer Affairs:
       <a href="https://www.dca.ca.gov/consumers/complaints/index.shtml">https://www.dca.ca.gov/consumers/complaints/index.shtml</a>
       This agency is responsible for implementing/monitoring the CA Standards of Service for Providers of Blood Clotting Products for Home Use Act. <a href="http://codes.lp.findlaw.com/cacode/HSC/1/d106/5/2/5">http://codes.lp.findlaw.com/cacode/HSC/1/d106/5/2/5</a>
    - ii. CA Board of Pharmacy: http://www.pharmacy.ca.gov/consumers/complaint\_info.shtml
  - c. Pharmacy Nevada
    - i. http://bop.nv.gov/services/Complaint/
  - d. Pharmacy Hawaii
    - i. Board of Pharmacy http://cca.hawaii.gov/pvl/boards/pharmacy/
    - ii. Complaint filing w/Regulated Industries Complaints Office : <a href="http://cca.hawaii.gov/rico/">http://cca.hawaii.gov/rico/</a>
  - e. Pharmacy Guam
    - i. Department of Public Health and Social Services Guam Board of Examiners for Pharmacy: https://nabp.pharmacy/bop\_members/guam/

#### 2. MEDICATION AND INFUSION ADMINISTRATION LOCATION

- a. Where can medication and infusions that are provided by 340B pharmacy be administered? Can it be administered in the inpatient setting? Hospital Emergency Department? In the outpatient infusion center? What about in the day hospital for an outpatient procedure?
  - i. Outpatient is allowable. Inpatient and hospital locations are unallowable unless there is a hospital policy that allows patient to bring drugs from home. [HTC Manual p.46]

## 3. FREEDOM OF CHOICE POLICIES

- a. What are the current policies?
  - i. The Federal Register "Notice 3/10/14 Regarding 340B Drug Pricing Program Services —Contract Pharmacy" under the section: "Essential Covered Entity Compliance Elements" at item 3c states, "The covered

entity will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice." The HRSA National Hemophilia Program also requires that... "all HRSA funded HTCs have a "Freedom of Choice" policy where patients are informed of choices they have regarding factor replacement products and where these products might be purchased." Many HTCs have 'Choice' policies that are signed by patients on a regular schedule, and kept in the EMR. We recommend that HTCs have a policy/procedure which indicates when and how they document giving patients 'choice' of pharmacy provider, and which indicates frequency with which these policies are reviewed and updated as needed.

#### 4. PHARMACY COSTS

- a. What pharmacy costs can be charged to program income?
  - i. Pharmacy costs which are Allowable, Allocable & Reasonable can be charged to program income.

## 5. POLICY AND PROCEDURES

- a. Are there regional templates?
  - i. The Hemophilia Alliance has developed a policy and procedure manual September 2017, which can be used as a template to develop your own 340B policies. It is available on the members section of their website.

## F. RESOURCES

- 1. Where can I find all the 340B laws, guidance, rules and regulations?
  - a. The Federal government is the official source for all 340B laws, guidance, rules and regulations.
  - b. HRSA: http://www.hrsa.gov/opa/ where you can sign up for 340B updates
  - c. APEXUS: serves as HRSA's 340B prime vendor and staffs HRSA's 340B Technical Assistance Center http://www.340bpvp.com/
  - d. 340B Peer to Peer Network: http://www.hrsa.gov/opa/peertopeer/webinars.html
  - e. Notice of Award (a copy is included in your sub award agreement)
  - f. HRSA's Notice Of Funding Opportunity: https://www.hrsa.gov/grants/find-funding/hrsa-22-068
- 2. Other Reliable resources are:
  - a. Health Resources & Services Administration, Office of Pharmacy Affairs: <a href="https://www.hrsa.gov/opa/">https://www.hrsa.gov/opa/</a>
  - b. The Hemophilia Alliance: <a href="http://hemoalliance.org/">http://hemoalliance.org/</a>
  - c. Private Consultants. There are many consultants in the 340B space, make sure you vet consultants carefully

#### G. PUBLICATIONS

- 1. Is there a bibliography on 340B programs that includes community benefit and other collaborative research?
  - a. Yes information continues to evolve. The impact of 340B programs has been assessed by several 340B covered entities. These include HRSA's Office of Pharmacy Affairs, the National Association of Community Health Centers, Safety Net Hospitals for Pharmaceutical Access, and Federal Family Planning Programs. What follows is not exhaustive.
- Ruley, M. et al. "The 340b Program, Contract Pharmacies, Hospitals, and Patients: An Evolving Relationship Impacting Health Care Delivery." Health Care Manag (Frederick). 2019 Oct/Dec;38(4):311-321. doi: 10.1097/HCM.000000000000279. https://www.ncbi.nlm.nih.gov/pubmed/31663869
- Community Access National Network. 340B Commission's Final Report on the 340B Drug Discount Program: The Issues Spurring Discussion, Stakeholder Stances, and Possible Resolutions. February 2019.
- Malouin, Rebecca A., et al. "Impact of the 340B pharmacy program on services and supports for persons served by hemophilia treatment centers in the United States."
   Maternal and child health journal 22.9 (2018): 1240-1246.
   https://link.springer.com/article/10.1007/s10995-018-2545-7
- Dobson and DaVano, July 2017. Assessing the financial impact of the 340b drug pricing. https://www.340bhealth.org/files/340B Financial Impact 7 17.pdf
- 340B Drug Pricing Program: Important Benefit, Significant Responsibility: https://www.hrsa.gov/opa/update.html
- Castellon, YM, et al. (2014). The impact of patient assistance programs and the 340B Drug Pricing Program on medication cost. The American Journal of Managed Care [01 Feb 2014, 20(2):146-150]. http://europepmc.org/abstract/med/24738532.
- Mulcahy, Andrew W., et al. (2014). The 340B Prescription Drug Discount Program: Origins, Implementation, and Post-Reform Future. Santa Monica, CA: RAND Corporation. https://www.rand.org/pubs/perspectives/PE121.html.
- America's Essential Hospitals (2014). Our view: 340B Benefits vulnerable patients, essential hospitals, taxpayers. http://2c4xez132caw2w3cpr1il98fssf-wpengine.netdnassl.com/wp-content/uploads/2016/03/Our-View-340B-March-2016.pdf
- National Association of Community Health Centers. (2014). Health Centers and the 340B Drug Discount Pricing Program: Increasing Access to Essential Medications and Services to Communities in Need. Fact Sheet #0614. http://www.nachc.org/wp-content/uploads/2016/02/340B FS 2014.pdf.
- Safety Net Hospitals for Pharmaceutical Access, Setting the Record Straight on 340B: a response to critics, July 2013.
   <a href="http://www.340bhealth.org/files/Setting">http://www.340bhealth.org/files/Setting</a> the Record Straight Report.pdf.
- Wallack MC, et al. (2011). Demonstrating the Value of the 340B Program to Safety Net
- Hospitals and the Vulnerable Patients they Serve: Perspectives from Safety Net Hospitals for Pharmacy Access Members. http://www.snhpa.org/images/uploads/340B\_Value\_Report\_06-29-11.pdf

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- The Lewin Group, et al. (2009). Analysis of the Effectiveness of Title X Family Planning Providers' Use of the 340B Drug Pricing Program Final Report. https://www.hhs.gov/opa/sites/default/files/304b-analysis-of-effectiveness.pdf.
- Schur C, et al. (2007). 340B Drug Pricing Program: Results of a Survey of Participating Hospitals. http://www.norc.org/PDFs/publications/340BReport\_May2007.pdf.
- Schmitz R, et al. (2004). [The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities: Final Report].
   https://www.researchgate.net/publication/254430113\_The\_PHS\_340B\_Drug\_Pricing\_Pr ogram\_Results\_of\_a\_Survey\_of\_Eligible\_Entities\_Cambridge\_MA\_Mathematica\_Policy Research
- HTC 340B Program Testimonials: Videos produced by The Hemophilia Alliance: https://hemoalliance.org/340b-program-testimonials/
- 340B and Hemophilia Treatment Centers: Improving Care, Reducing Costs. A 7-minute video produced in by the Western and Mountain States HTC Regions (AKA Regions VIII, IX, X) https://www.youtube.com/watch?v=9r3exlw6njw