Ryan White Clinics for 340B Access

	ASAP 340B PRINCIPLES *March 2023*	ASAP 340B DRAFT DOCUMENT changes from original principles *November 2023*	RWC-340B PRINCIPLES *March 2023*	RWC-340B COMMENTS ON DRAFT *December 2023*
Intent	• Make 340B a true safety-net program for patients by structuring the program to enable true safety-net providers to help low income and other vulnerable populations.	• Help support safety net providers serving low-income and vulnerable patients. • The 340B program should be structured to enable true safety-net providers to better reach communities that otherwise would not have access to affordable health care services and medications they depend on.	• Keep legislative intent of 340B the same – enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.	• **Contrary to recent ruling in *Genesis* case where court validated the intent of the program to serve more people with more services.** • **Could limit populations served by 340B, starkly reducing savings that help care for the underserved, threatening public health provided through 340B.**
Use of Savings	• Mandatory sliding fee scale approach for hospitals for up to 200 percent FPL. • Grantees' sliding fee scale for prescriptions must be as generous as the scale for medical care.	• Mandatory sliding fee scale approach for hospitals for up to 200 percent FPL. • Grantees' sliding fee scale for prescriptions must be as generous as the scale for medical care. • Covered entities must offer prescription drug discount programs through contract pharmacy arrangements. • OIG should audit adherence to above.	• 340B allows entities to provide more comprehensive services. • The 340B program should not be structured as solely a patient drug assistance program.	• **Overly prescriptive sliding fee scale and mandatory patient drug assistance programs takes away safety net providers flexibility to best serve their communities.** • **Drug companies are already able to offer drug discount programs to patients.** • **340B should not be re-envisioned as a drug assistance program.**
Patient Definition	• Narrows 340B patient definition, including requiring periodic in-person visits to the covered entity by the patient. • Covered entity should be required to maintain	• Eligible patient should be established on a prescription-by-prescription basis. • Only prescriptions directly related to a medical condition that patient sought care for from covered entity should be covered.	• 340B program should not focus solely on low-income and uninsured patients.	• **Proposed patient definition is contrary to *Genesis* decision which rejected prescription-by-prescription eligibility.** • **Limiting eligibility = limiting vulnerable populations' access to 340B savings.**

	consistent responsibility for care. • Require direct connection between prescription, the patient's medical condition, and the services provided by the covered entity.	• Covered entity must maintain a consistent responsibility for care of a patient. • Provider must be employed by or independent contractor of the covered entity. • Telehealth prescriptions covered only when telehealth is within the scope of the covered entity's grant. • Patient's health care service must be within the scope of the covered entity's grant and patient must have an in-person visit periodically.		**Proposed additions are problematic:** • **Limit eligibility to only certain medical conditions.** • **Create new legal relationship requirements for providers.** • **Greatly limit use of telehealth.**
Limitations by Disease State or Condition	• Principles are silent on limitations by disease state or condition but often noted by PhRMA-friendly surrogates.	• Only prescriptions directly related to a medical condition that the patient sought care for from a covered entity should be covered.	• Any proposals creating narrowly defined limits on access to 340B drugs, by disease state or condition, would seriously undermine 340B program.	• **Proposed limit would reduce patient access to care by only allowing use for drugs related to the patient's original medical condition.** • **Defies program intent: providing more COMPREHENSIVE services to patients.**
Contract Pharmacy	• Establish clear criteria for 340B contract pharmacy arrangements, including limiting contract pharmacies to MUA/MUPs, or grantees proving care to a specific population, such as HIV or chronic disease. • Contract pharmacies must be near covered entity. Contract pharmacies should provide same affordability assistance as the covered entity.	• Contract pharmacies should be limited to an MUA/MUP, or qualified prescriptions provided within the scope of a Federal grant for a specific population, such as HIV or chronic disease. • Contract pharmacies should be located near the service area where the covered entity provides care. • New restrictions on use of specialty and mail order pharmacies.	• Contract pharmacy arrangements must not be limited in number, by geography or to certain service areas or populations.	• **New limitations on specialty and mail order pharmacies would seriously limit patient access to care, especially for patients living in rural areas and/or needing specialty medications.** • **Contract pharmacy use is integral to giving patients of safety net providers convenient access to drugs and pharmacy services.**

	• Contract pharmacy must take steps to prevent diversion			
PBMs and For-Profit Entities	• Prevent middlemen and for-profit entities from profiting/siphoning off the 340B program. • Limit fees pharmacies and for-profit third parties can charge.	• Pharmacies and for-profit parties should have limits on fees they can charge for 340B-related services. • PBMs and insurers cannot ban covered entities from providing 340B claims data to third parties. • PBMs cannot ban covered entities from reducing copays.	• PBMs must be prohibited from siphoning off 340B savings in any form. • Covered entities should be permitted to continue to contract with for-profit vendors to improve patient access to prescriptions.	• **Would add some new conditions on PBMs that RWC-340B supports but far from the comprehensive approach reflected in the PROTECT Act (H.R. 2534).**
Covered Entity Eligibility Requirements	• 340B hospitals must have policies that increase access to affordable health services, no aggressive debt collection. • New eligibility criteria should be added for DSH hospitals. • Eligibility requirements should be maintained for rural hospitals. • CAHs that convert to REHs should not lose eligibility.	• Greater quantifiable requirements for DSH hospitals to qualify/limit to five contract pharmacies for DSH. • Hospitals with aggressive debt collection practices cannot participate. • Adds new criteria for nongovernmental hospitals. • Require RRCs to qualify as DSH or treat reasonable share of rural patients. • REHs should qualify for 340B if they meet the same standards as CAHs.	• Covered entities are already required to make repayments to manufacturers if they discover any issue of non-compliance, which often result from a simple error or misunderstanding of complex guidance from HRSA. • Compliance with the prohibition on diversion and duplicate discount prevention should not be a condition of eligibility for the 340B program.	• **New hospital restrictions are merely meant to shrink the program to benefit the drug companies' bottom lines.** • **Would set a new arbitrary limit of 5 contract pharmacies for DSH hospitals, limiting patient access to 340B drugs.** • **Would subject RRCs to DSH percentage or a "reasonable share of rural patients" – rewriting Congressionally-established criteria for RRCs to be eligible for 340B.**
Child Sites/ Subgrantee Eligibility	• Require child sites to meet same eligibility criteria as the 340B hospital. • Child site must be integral part of the hospital. • Child site must have same sliding fee scale requirement. • Child sites must do more than provide prescriptions. • Eligibility for subgrantees should be reviewed.	• Added requirements for child sites to be considered "an integral part of" a 340B hospital. • Child sites must meet same charity care requirements as parent. • Child sites must do more than just provide prescriptions. • Review eligibility criteria for subgrantees.	• Proposals to limit 340B eligibility should be weighed carefully against the detrimental impact on underserved communities.	• **Addition of new requirement of being an "integral" part of the 340B hospital would further limit DSH hospital's ability to use 340B savings to reach more patients.** • **Would shrink the 340B program further to benefit drug companies.** • **Cost of care for excluded child site patients would become responsibility of federal and state taxpayers without 340B savings.** • **Child site "integral" test is inherently**

				subjective.
Clearinghouse Establishment	• Create a neutral 340B claims data clearinghouse. • Data provided should be deidentified and subject to safeguards, applies to more than Medicaid claims – includes Medicare and commercial claims.	• Create an independent clearinghouse. • Establish requirements so only one covered entity can claim the 340B discount for eligible prescriptions. • Covered entities required to submit all relevant data regardless of payer. • Data should be HIPAA complaint. • Grantees should submit information related to the scope of their grant.	• A national clearinghouse should be established to reduce duplicate discounts, but the clearinghouse should be narrowly targeted to prohibit duplicate discounts on Medicaid claims only, as prohibited in the 340B statute, not expanded to commercial claims.	• **Would add unnecessary eligibility requirement for prescriptions, greatly increasing regulatory burden for submitting data.** • **Addition of other markets beyond Medicaid would conflict with federal law and greatly increase the likelihood that drug companies or PBMs can discriminate against 340B safety net providers.**
Reporting Requirements	• Covered entities should be required to report total acquisition cost and reimbursement; total amount spent to reduce out of pocket costs for patients. • Private non-profit hospitals must report state or local government contracts that are the basis of their eligibility.	• Covered entities must report to HHS total acquisition cost and reimbursement, payer mix, and amount spent subsidizing out of pocket costs for patients. • Child sites required to report separately on this data. • Private non-profit hospitals must make their state or local government contracts available.	• Proposals that would require additional, onerous reporting requirements are unnecessary.	• **New ASAP 340B principles would add payer mix and new child site-specific reporting requirements, creating additional unnecessary regulatory burdens.** • **Goal of such data-reporting is not transparency, but to facilitate further discrimination by drug companies and PBMs.**
Federal vs State Oversight and Governance	• Targeted rulemaking by relevant HHS agencies; 340B program should be exclusively governed by federal law and should supersede any state or local law.	• The program should be exclusively governed by federal law, no state law can grant additional rights or impose additional obligations. • HRSA and CMS should conduct rulemaking jointly to implement these provisions	• In no instance should Congress nullify state laws on 340B.	• **Would abolish PBM reform in over half of the states and stop pending legislation in dozens of states to protect contract pharmacies.** • **Joint rulemaking with CMS suggests that goal is to limit payments to safety net and further complicate agency oversight.**