**Purpose:** This tool is intended to help all types of 340B covered entities understand their 340B net financial impact and document their use of 340B savings. It gives guidance on how to calculate net financial impact as well as articulate benefits provided to the community based on total expense for a variety of services. This tool has been developed based on best practices from informed stakeholders and was validated with covered entities (DSH, FQHC, and other grantees). This tool does not represent a HRSA requirement for 340B Program compliance.

**Background:** Although the 340B statute does not require covered entities to document what their 340B net financial impact is or how those savings are used, doing so is considered a best practice to demonstrate how the 340B Program expands access to underserved patient populations. This can also help internal stakeholders better understand what services would be directly affected if there is a loss of program savings for any reason.

**Instructions, Table 1: Calculating 340B Net Financial Impact**

1. **340B Benefits:**

**Physician-administered/clinics, entity-owned retail pharmacies:** There are several ways to calculate 340B savings. The following is an example:

* For hospitals subject to the GPO Prohibition and entity-owned retail pharmacies subject to the GPO Prohibition:

**Step 1:** Calculate 340B savings by reviewing the purchase history report from the 340B account and identify the unit price for each NDC when purchasing those NDCs at 340B price and GPO price. 340B savings will be equal to the GPO total minus the 340B total.

**Step 2:** Calculate WAC variance by identifying purchase history in the non-GPO/WAC account and what those purchases would have cost at GPO pricing. WAC variance will be equal to the non-GPO/WAC total minus the GPO total.

**Step 3:** Calculate net savings. The net savings is equal to 340B savings calculated in Step 1 minus the WAC variance calculated in Step 2.

* All other entities and entity-owned retail pharmacies not subject to the GPO Prohibition: 340B savings may be calculated by looking at the difference between 340B pricing and customary pricing for all outpatient purchases.

**Contract pharmacy:** Reimbursement received – (drug actual acquisition cost [AAC] + dispensing fees to contract pharmacies + administrative fees to vendor + DIR fees charged by PBMs + entity costs of sliding fee subsidization)

1. **340B Compliance Maintenance Costs:** Sum of all costs incurred to support program compliance
   1. External resources: split-billing software fees, legal fees, external auditor fees, consultant fees
   2. Internal resources: education, dedicated FTE time (whole or partial FTEs)
   3. Lost revenue: net revenue lost by receiving decreased reimbursement due to 340B status (examples: Medicaid MCO, Medicare OPPS, private payers identifying 340B claims)
      * NOTE: This should be the difference between what was net revenue as a 340B entity and what would have been net revenue as a non-340B entity (this would include non-340B reimbursement, but also non-340B drug cost); many sites find this very difficult, if not impossible, to calculate.

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| TABLE 1: 340B NET FINANCIAL IMPACT | | | | | |
| 340B Benefits  *Add the following three metrics together for total 340B benefit.*  TOTAL: $ | | MINUS  **–** | **340B Compliance Maintenance Costs**  **TOTAL: $** | EQUALS  **=** | **340B Net Financial Impact**  **$** |
| Physician-administered/clinics | $ | **–** |  | **=** |  |
| Entity-owned retail pharmacy | $ |
| Contract pharmacy | $ |

**Instructions, Table 2: Documenting Use of 340B Savings**

It is not standard practice in health care accounting to link a dollar amount saved on an expense line with direct funding to a program or service. For this reason, many covered entities consider aggregate areas of community benefit and charity care. This tool provides space for covered entities to have flexibility in their approach, and it lists additional areas that may not be captured in a community benefit calculation, such as services targeted to vulnerable populations. A few best practices for using this tool include:

1. Working with reimbursement or finance departments to gain access to the listed resources
2. Reviewing financial information and evaluating whether the numbers represent actual costs or charges
   1. A cost-to-charge ratio may be helpful in standardizing all information into actual costs.

Although it is a best practice to align savings from the 340B Program directly to the cost of caring for the underserved, each covered entity may make its own determination as to which areas of benefit apply directly to its 340B Program. Because many covered entity types report care to underserved populations differently, not every part of this tool will apply to all entity types. Examples are given in each of the lists that follow as demonstrations of possible areas that may align with the 340B Program depending on the covered entity’s interpretation of 340B intent.

If you have never completed this type of exercise before and would like more detailed instruction on where to look for these numbers, a detailed explanation can be found in the [340B Health Impact Profile Guidebook](https://www.340bhealth.org/files/340B_ImpactProfileGuidebook_.pdf).

**Reported Community Benefit**

Community benefit is often reported through a variety of established mechanisms. The following forms are routinely used to report community benefit activities:

* Medicare Cost Report, Worksheet S10
* Schedule H, IRS Form 990
* Grant reporting documents

*Examples*

* *Cost of treating uninsured patients (may be referred to as indigent or charity care)*
* *Unreimbursed cost of treating Medicaid patients*
* *Bad debt*
* *Community health improvement services*
* *Subsidized health services*
* *Unreimbursed cost of treating Medicare patients*
* *Unreimbursed cost of treating other government plan patients*

**Non-Reported Community Benefit**

Many nonprofit health care organizations also provide unreported care to underserved populations, which can be highlighted in Table 2. Entities that provide these services to both insured and uninsured populations may need to further break down the service costs based on program intent.

*Examples*

* *Other uncompensated care*
* *Free vaccinations*
* *Free medication delivery to rural areas*
* *Free pharmacy medication therapy management (MTM) services*
* *FTE helping connect patients to manufacturer drug programs*
* *FTE to increase outreach and enrollment of underserved patients to care or services*
* *Transition-of-care teams*
* *Capital building projects focused on low-income populations*

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| TABLE 2: USE OF 340B SAVINGS | | |
| Program or Service Provided | **Total Expense** | **Description**  (how this aligns with 340B Program intent) |
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| *Total expenses aligned with intent of 340B Program:* | **$\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |  |

*This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages all stakeholders to include legal counsel as part of their program integrity efforts.*

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