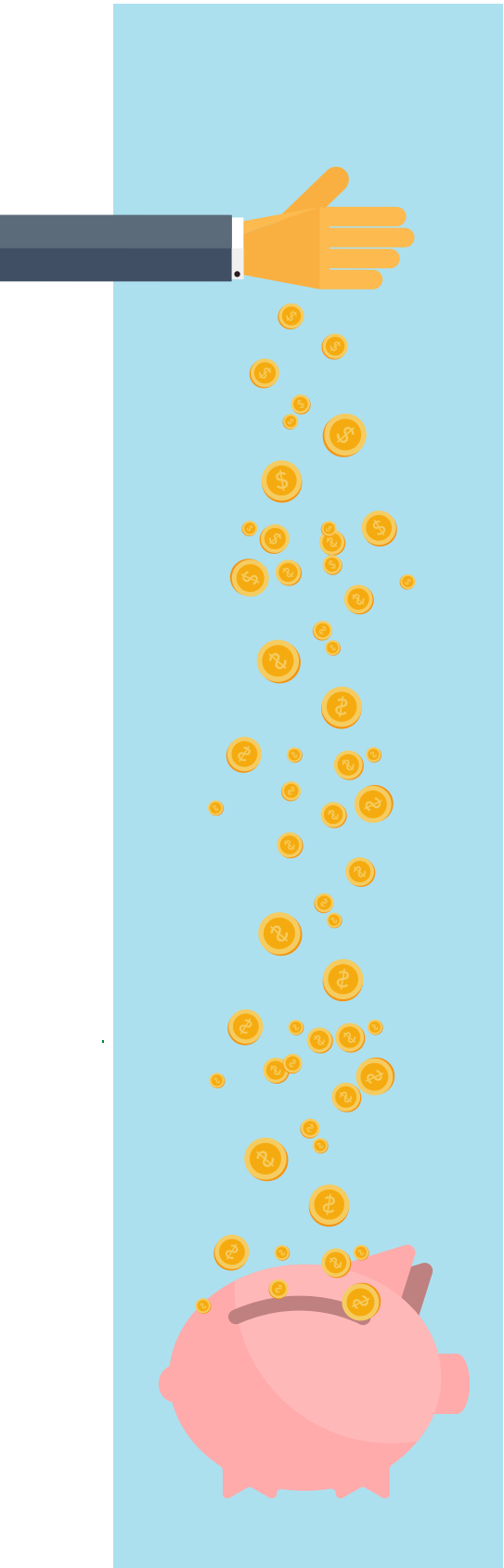
340B Program:

Mega Guidance, Mega Change



For many years, drug manufacturers and covered entities (as defined herein) participating in the 340B program did so with little oversight. However, amid concerns of excessive pricing, diversion, and other abuses of the program, and at the recommendation of the Government Accountability Office (GAO),[1] the Health Resources and Services Administration (HRSA) recently has stepped up its regulatory oversight of covered entities.

In addition, the Department of Health and Human Services (HHS) is attempting to address many of the concerns about the program through interpretive guidance. HHS has developed a much-anticipated proposed body of guidance (often referred to as "Mega Guidance"). While the official date of release is still unknown, the finalized Mega Guidance is anticipated to close the gap on many ambiguous interpretations of the current rule.

In light of this new scrutiny and regulatory focus, 340B participants should take steps to ensure their 340B programs are properly structured to comply with the current applicable regulations and weather any future Mega Guidance impact. Covered entities must have in place policies, procedures, processes, and controls to ensure that they are operating within the requirements and prohibitions of the program. Covered entities that are non-compliant run the risk of repayment to manufacturers, interest penalties, and possible exclusion from the program. This white paper will provide an overview of the program, identify key risk areas for 340B covered entities,[2] foreshadow operational impacts as a result of the Mega Guidance, and provide a checklist to help providers minimize the identified current and future risks.

[1] U.S. Government Accountability Office, GAO-11-836, Drug Pricing Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement 20 (2011).
[2] This white paper will not address compliance risks for manufacturers.

340B Overview

The Program establishes a mechanism for eligible safety-net healthcare providers to purchase drugs for certain outpatients at a significant discount. The safety-net providers get the benefit of any savings and revenues from the discount. Drugs purchased at the reduced prices may be provided only to eligible "patients" (defined later in this paper). Originally enacted in 1992,[3] the program was designed—as indicated by its legislative history—to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[4]

Critics of the program contend it is not currently serving its purpose because some of the providers who participate (and benefit from the savings and revenues) actually provide little benefit to indigent populations.[5] The program's supporters, on the other hand, generally support a tightening of program oversight, but maintain the program does in fact provide additional revenues to safety-net providers so they can better serve their communities.[6]

The safety-net healthcare providers eligible to participate in the program (covered entities) fall into two categories: (1) certain federal grantees such as hemophilia treatment centers, federally qualified health centers, and Ryan White programs; and (2) certain hospitals, including disproportionate share hospitals (DSH), children's hospitals (PED), critical access hospitals (CAH), free-standing cancer hospitals (CAN), rural referral centers (RRC), and sole community hospitals (SCH).[7]

A covered entity bears the responsibility of compliance with the myriad (and often vague) program requirements.[8] Furthermore, both HRSA and participating drug manufacturers have the right to audit covered entities for compliance.[9] The remainder of this white paper will identify program requirements that create risk for covered entities and suggest compliance strategies to address these risk areas.

Risk Areas & Compliance Tips - Current Regulation

Regulatory and interpretive guidance highlights the following key areas of compliance concern.

Covered Entity Identification & Compliance

Simply obtaining and maintaining 340B designation of a covered entity and its outpatient facilities can present compliance risk. To participate in the program, hospital-covered entities must meet certain eligibility requirements, which differ based upon the designation under which the hospital qualifies for the program. See the figure below, which outlines specific requirements for each participating hospital type, including the required disproportionate share percentage threshold.

	PED	DSH	CAH	CAN	RRC	SCH
Subject to GPO Prohibition	✓	✓		✓		
Subject to Orphan Drug Exclusion			✓	✓	✓	✓
Disproportionate Share Adjustment %	>11.75	>11.75	N/A	>11.75	≥8.0	≥8.0

[3] Public Health Service Act (PHS), 42 U.S.C. § 256b.
[4] House Energy and Commerce Report, H. Rep. No. 102-384, Pt. 2, at 12 (1992).
[5] http://www.340breform.org/page.asp?id=19
[6] http://www.aha.org/content/13/fs-340b.pdf; http://www.aha.org/content/14/ip-340b.pdf
[7] 42 U.S.C. § 256b(a)(4).
[8] 75 FR 10272, 10277 (March 5, 2010).
[9] 42 U.S.C. §256b(a)(5)(C).

In addition, entities must certify and re-certify annually through the Office of Pharmacy Affairs (OPA) database. To become and remain a covered entity, the entity must attest that:

1 | Its database entry is complete, accurate, and correct.

2 | It meets all 340B eligibility requirements, including the group purchasing organization (GPO) prohibition discussed later in this paper (if applicable).

3 | It complies with all 340B requirements and restrictions, including prohibition against diversion and duplicate discounts discussed later in this paper, and maintains auditable records demonstrating such compliance.

4 | It has systems in place to ensure ongoing compliance.

5 | If it uses a contract pharmacy, the arrangement is being performed in accordance with OPA requirements, and the covered entity obtains sufficient information from the contract pharmacy and uses an appropriate methodology (*e.g.*, independent audit) to ensure compliance with applicable legal requirements.

6 | It will notify OPA immediately of any material change or material breach of these attestations.

7 | It acknowledges that, if there is a material breach of the 340B requirements, it may be liable to the manufacturer of the drug subject to the violation, be required to pay interest, or be removed from the program.[10]

A covered entity must submit this initial certification and ongoing annual re-certification for itself and for outpatient departments that appear as reimbursable cost centers (known as child sites) on its most recently filed cost report. Outpatient clinics or departments within the four walls of a hospital need not be separately certified, but eligible outpatient facilities at another physical address must be separately registered as child sites in the OPA database. The hospital must show that the off-site facility is an integral part of the hospital and is included as reimbursable on the hospital's most recent cost report.[11]

Eligible Patients & the Risk of Diversion

The 340B discount is available only for dispensations to eligible patients. Although the Mega Guidance further addresses the definition of the "patient" for 340B purposes, current guidance comes from the HRSA guidelines published in 1996.[12] The guidelines provide that (with the exception of state-operated or funded AIDS drug purchasing assistance programs) an individual is a patient of a covered entity only if:

1 | The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's healthcare.

2 | The individual receives healthcare services from a healthcare professional who is either employed by the covered entity or provides healthcare under contractual or other arrangements (*e.g.*, referral for consultation) such that responsibility for the care provided remains with the covered entity.

3 | The individual receives from the covered entity a healthcare service or range of services which is consistent with the service or range of services for which grant funding or federally qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a patient of the entity for purposes of 340B if the only healthcare service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.[13]

Certain ambiguities of this definition create the risk of diversion (intentional or unintentional)—particularly in mixed-use settings where both inpatient and outpatient drugs are dispensed. Diversion occurs when 340B

[10] See Apexus, 340B University Notes, 40 – 41 (May 2014), at https://docs.340bpvp.com/documents/public/resourcecenter/340B_University_Notes.pdf
[11] 59 FR 47884, 47886 (Sept. 19, 1994).
[12] 61 FR 55156 (October 24, 1996).
[13] *Id. at 55157 – 55158*. An individual registered in a state-operated or funded AIDS drug-purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a patient of the covered entity for purposes of this definition if so registered as eligible by the state program.

drugs are dispensed to individuals who do not meet the definition of an eligible patient. In a mixed-use setting such as a hospital emergency room, infusion center, cardiac catheterization lab, or in-house pharmacy, covered entities must have controls in place to ensure that they dispense 340B drugs only to outpatients who meet the eligible patient definition.

Accordingly, covered entities should review policies, procedures, and practices to assess whether they have effective controls to ensure eligible patients are correctly identified, and the dispensing of 340B drugs is limited to the identified eligible patients. This will necessitate tracking all requirements for an eligible patient, including outpatient status and the covered entity's relationship with the patient—*i.e.*, the relationship entails more than simple dispensing of drugs; the entity maintains a medical record for the patient; and an appropriate relationship (*e.g.*, contract) exists with the healthcare provider. The covered entity should maintain auditable records of its compliance efforts.

Medicaid Duplicate Discounts & State-Specific Rules

If a covered entity participates in the program and also treats Medicaid beneficiaries, it must determine whether it will dispense 340B drugs to Medicaid patients (carve in)[14] or use other drug sources for Medicaid patients (carve out). This protects manufacturers from having to provide duplicate discounts—*i.e.*, a discounted 340B price and a Medicaid rebate—for the same drug.

To facilitate compliance with this requirement, HRSA has established the Medicaid Exclusion File. Covered entities must report their election (by National Provider Identifier [NPI]) at the time of enrollment for listing in the Medicaid Exclusion File. State Medicaid agencies can then access the information and determine which drugs are purchased through 340B and, therefore, also are not eligible for the Medicaid rebate. The Medicaid Exclusion File is updated quarterly. If a covered entity's information in the Medicaid Exclusion File is inaccurate, the covered entity may be required to repay the manufacturer for any duplicate discounts incurred.[15]

In addition to the program requirements for Medicaid, each state's Medicaid program may have other restrictions or requirements. For example, some states require covered entities to bill Medicaid at actual acquisition cost, or have proposed or implemented initiatives to require that covered entities provide drugs to Medicaid patients at the 340B discounted rate.[16]

Medicaid regulation of the program is an evolving area. Each covered entity should check with its state Medicaid agency to determine its current policies regarding 340B. Covered entities regularly should review their billing practices and enrollment information with respect to each NPI to ensure consistency. Any change in status should be immediately updated in the Medicaid Exclusion File.

Contract Pharmacies

HRSA guidelines issued in 2010 permit covered entities to contract with multiple outside pharmacies to dispense 340B drugs.[17] These guidelines list 12 "essential elements" for covered entities' contracts with pharmacies. Some of those requirements include:

1 | A written contract.

2 | A full listing of pharmacy locations that will be used.

3 | Drug delivery using a "ship to, bill to" arrangement in which the covered entity purchases the drug and the manufacturer bills the covered entity, but ships the drug to the contract pharmacy.

4 | Specification that it is the responsibility of both parties to provide comprehensive pharmacy services.

5 | The covered entity's obligation to inform the patient of his or her freedom to choose a pharmacy provider.

[14] HRSA (OPA) Release No. 2013-2 340B Drug Pricing Program Notice, *Clarification on Use of the Medicaid Exclusion File*, February 7, 2013.
[15] Id.
[16] *See, e.g.*, West's Ann. Cal. Welf. & Inst. Code § 14105.46(2009); *see also* https://providers.amerigroup.com/ProviderDocuments/TNTN_RateReductionLetter.pdf (provider letter from Amerigroup attaching memorandum from Tennessee Director of Managed Care Operations, Keith Gaither, describing a one-time appropriation to "buy back" the TennCare MCO contract requirement that all providers who participate in the federal 340B program give TennCare MCOs the benefit of 340B pricing).
[17] 75 FR 10272 (Mar. 5, 2010).

6 | Agreement of both parties to adhere to applicable law.

7 | Agreement to establish various reporting and tracking systems, and also systems to ensure availability of information for periodic audits by the covered entity, HRSA, and manufacturers.

8 | The contract pharmacy may not dispense 340B drugs to Medicaid patients without a specific arrangement in place between the contract pharmacy, covered entity, and state Medicaid agency.

The covered entity must provide a copy of the contract to OPA upon written request.[18]

The covered entity is responsible for ensuring that the contractual arrangement complies with statutory obligations to prevent diversion and duplicate discounts, and the covered entity remains responsible for ensuring that drugs dispensed through a contract pharmacy meet 340B eligibility requirements. The covered entity must register each contract pharmacy on the 340B database and recertify annually, providing assurance to HRSA and manufacturers that the arrangement meets the requirements described above and limits the potential for drug diversion.[19]

With the responsibility for contract pharmacy compliance falling squarely on covered entities' shoulders, covered entities should:

1 | Implement strong controls surrounding these relationships.

2 | Review existing and proposed contracts to ensure they reflect all requirements set forth in the HRSA guidelines.

3 | Consider whether the contracts should include indemnification language for scenarios in which conduct or omissions of the contract pharmacy may trigger an overpayment or loss of eligibility.

4 | Review processes, policies, and procedures to ensure the contracts are being implemented correctly.

5 | Consider whether they should conduct independent audits of contract pharmacies.

GPO Prohibition

Section 340B prohibits certain covered entities from obtaining covered outpatient drugs through a GPO. This prohibition applies to disproportionate share hospitals, pediatric hospitals, and free-standing cancer hospitals.[20]

OPA recently issued a release clarifying some aspects of this prohibition.[21] For example, OPA clarified that the prohibition applies to the identified hospitals and any departments within the four walls of the hospital. However, it does not apply to certain off-site, outpatient facilities of the hospital if:

1 | They are located at a different physical address.

2 | They are not registered in the OPA database as participating in the 340B program.

3 | They purchase drugs through a separate pharmacy wholesaler account than the hospital.

4 | The hospital maintains records that covered outpatient drugs purchased at these sites are not transferred to the hospital or its registered outpatient facilities.[22]

OPA also cautioned against reported practices by hospitals using accounting methods to recharacterize inventory, stating that entities electing to use a "replenishment" model must be able to present auditable records that demonstrate compliance with the GPO prohibition.[23]

Covered entities subject to the GPO prohibition should cease purchasing 340B drugs from a GPO upon becoming eligible for 340B. Any GPO-purchased inventory at that time only can be used as outlined by OPA guidance. To meet this requirement, and avoid the diversion and duplicate discount concerns described above, will likely require use of 340B-compliant split-billing or rules-based compliance software that

[18] *Id.* at 10277 – 10278.
[19] *Id.* at 10278 – 10279; see also, Hospital Recertification, OPA 340B Database, http://opanet.hrsa.gov/OPA/Default.aspx (last visited August 10, 2014).
[20] 42 U.S.C. 256b(a)(4)(L).
[21] HRSA, Statutory Prohibition on Group Purchasing Organization Participation (February 7, 2013), at http://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf.
[22] *Id.*
[23] *Id.*

appropriately tracks and categorizes drugs as inpatient, 340B-eligible, or non-340B-eligible outpatient.[24] Covered entities should ensure these processes are in place and periodically audit them for continued compliance.

Orphan Drugs

"Orphan drugs" are drugs developed to treat rare conditions and are designated as orphan pursuant to a 1983 law[25] designed to enhance the economic feasibility of developing the drug. A provision of the Affordable Care Act[26] excluded orphan drugs from 340B pricing for certain covered entities—free-standing cancer hospitals, critical access hospitals, sole community hospitals, and rural referral centers. In an interpretive ruling effective July 21, 2014, HHS took the position that covered entities may still receive the 340B discount for these drugs when they are purchased for a "non-orphan indication," *i.e.*, used for conditions other than the rare condition for which the drug received orphan drug designation.[27]

However, on October 14, 2015, a Washington D.C. district court ruling invalidated HRSA's interpretation of the Orphan Drug Exclusion, stating that Congress intended to exclude all drugs carrying an orphan drug designation from 340B program eligibility.[28] Thus, covered entities subject to the Orphan Drug Exclusion are now prohibited from purchasing any orphan drugs through the 340B program, regardless of the use for which the drug is intended. A listing of orphan drugs can be found on the HRSA website and is updated quarterly.

Audits & Sanctions

The 340B statute requires covered entities to permit audits by the Secretary of HHS and manufacturers.[29] There have been very few manufacturers to exercise this right, but in response to the Office of Inspector General's (OIG) report, HHS (through HRSA) has recently stepped up its audit efforts.[30] Thus, the likelihood that a covered entity will be audited has increased, especially for those with a high number of outpatient facilities or contract pharmacies, a high volume of 340B purchases, or a complex 340B program.

The statute also imposes sanctions on covered entities for certain violations. If the Secretary finds, after an audit (and after notice and hearing), that a covered entity is in violation of the prohibition against duplicate discounts or has sold or transferred covered drugs to an individual who is not an eligible patient, the covered entity will be liable to the applicable manufacturer for the amount of the price reduction.[31] If the Secretary finds that a covered entity's sale or transfer of covered drugs to an ineligible patient was done "knowingly or intentionally," the covered entity also will be liable to the manufacturer for interest on the amount of the price reduction. If the Secretary finds that the sale or transfer to ineligible patients was systematic and egregious (in addition to knowing and intentional), the Secretary can remove the covered entity from the program and also is authorized to refer such violations to the U.S. Food and Drug Administration, the OIG of HHS, "or other Federal agencies for consideration of appropriate action under other Federal statutes."[32]

[24] See Apexus, 340B University Notes, 49 – 50 (May 2014), at https://docs.340bpvp.com/documents/public/resourcecenter/340B_University_Notes.pdf.
[25] 21 U.S.C. 360bb(a)(1); see 21 C.F.R. 316.24.
[26] Pub. L. 111-152 § 2302(4), codified at 42 U.S,C, §256b(e).
[27] HRSA, *Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program*, at http://www.hrsa.gov/opa/programrequirements/interpretiverule/interpretiverule.pdf. This Interpretive Rule is a re-statement of the proposed substantive rule that was vacated by the U.S. District Court for the District of Columbia on May 23, 2014. *Infra*, n. 33. The court noted that HHS's interpretation of the orphan drug exclusion was reasonable, but ruled that HHS did not have authority to issue the substantive rule.
[28] Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services, No. 14-1685 (October 14, 2015).
[29] 42 U.S.C. §256b(a)(5)(C).
[30] HRSA, *Office of Pharmacy Affairs Update* (July 3, 2014), at http://www.hrsa.gov/opa/updates/july2014.html.
[31] 42 U.S.C. § 256b(a)(5)(D).
[32] Id. § 256b(d)(2)(B)(v).

Are You Ready for the Proposed Mega Guidance?

Covered entities should closely review the proposed Mega Guidance from HRSA, as these criteria would impose more stringent eligibility guidelines, clarifying previous requirements which may have been open to interpretation. If finalized, these proposed changes would require additional revisions to existing processes surrounding patient and prescriber eligibility, record retention, Medicaid status, and independent auditing. Specifically, HRSA has recommended identifying eligible dispensations on a "prescription-by-prescription basis." Key proposed changes include:

1 | 340B prescriptions must originate from a healthcare service provided at a registered 340B facility, eliminating the "referral for consultation" exception in the current guidance. This affirms HRSA's stance that prescriptions to patients seen in a physician's private practice are ineligible.

2 | The prescribing provider must be employed or have an independent contractor relationship with the covered entity such that the covered entity may bill for services on behalf of the provider. Thus, under the proposed Mega Guidance, prescribers with medical staff privileges alone will not qualify as eligible.

3 | Eligible prescriptions must be ordered pursuant to an outpatient service, which is determined based upon how the clinical service is billed to the patient's insurance. For example, a discharge prescription written to a patient after an inpatient hospital stay would no longer qualify as eligible, even though the individual would not be an inpatient at the time the prescription is dispensed.

4 | Eligible patients must receive a drug that is ordered and prescribed by an eligible prescriber. Thus, an individual is not considered a patient if the only relationship with the covered entity is the dispensing or infusion of a drug. This will have implications on the processes for 340B eligibility determination related to cancer care and chemotherapy administration.

5 | Covered entities would be required to obtain annual independent audits of contract pharmacy arrangements, to make a determination regarding inclusion or exclusion of Medicaid Managed Care payers, and to maintain 340B program records for a minimum of five years.

Your Prescription for 340B Compliance

Many covered entities utilize a split-billing software solution to track and identify 340B-eligible dispensations through a set of rules or filters. Covered entities should have multiple criteria in place to identify eligibility at the prescription level. Otherwise, covered entities risk qualifying all prescriptions that meet one condition as eligible without considering other factors that may render some ineligible.

The below considerations provide a conservative approach to determining 340B eligibility on a prescription-by-prescription basis determined by the current guidance. However, this represents a general guideline, and each covered entity should independently assess 340B eligibility based upon the specific details of its program participation.

Prescriber Eligibility

- CE's definition of eligible prescriber should meet current HRSA guidance.
- All prescriptions purchased under 340B should be ordered by prescriber on CE's eligible listing.

Patient Eligibility

- Does the CE maintain records for the patient's care?
- Did the patient receive a healthcare service other than the dispensing of a drug?

Location of Prescription Origination

- Was the patient seen within the four walls of the hospital or at an eligible child site?
- Confirm that encounter where drug was prescribed is not related to a visit to the private practice of an eligible prescriber.

Drug Eligibility

- Does the patient's diagnosis for the qualifying encounter correspond to the drug dispensed?
- Is the CE subject to the Orphan Drug Exclusion? If so, how were processes updated since HRSA's Interpretative Rule was overturned?

Patient Status

- Was the prescription dispensed while the patient was in outpatient or observation status?
- Confirm that an order to admit to inpatient status was not entered prior to drug dispensation.

Payer Status

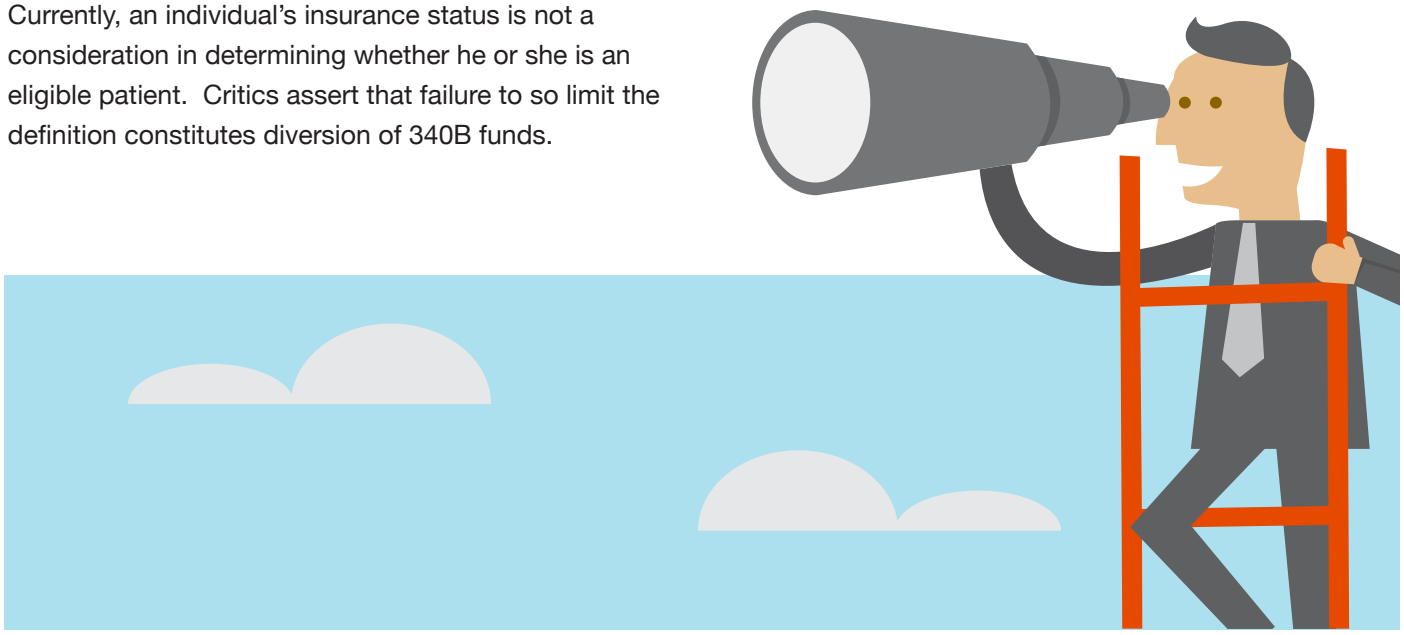
- Medicaid Carve-Out: Establish controls to exclude patients with a Medicaid payer type from 340B accumulations.
- Medicaid Carve-In: List NPIs of each participating location on Medicaid Exclusion File, and update appropriately as changes occur. Confirm accuracy on a regular basis.

What's Ahead for the 340B Program?

Looking ahead, there are a number of unknowns related to the 340B program. Pharmaceutical manufacturers and advocacy groups are questioning whether the program, as currently structured, continues to serve its stated purpose. In addition, at the same time that HRSA has stepped up its audit activity, HHS' rule-making authority has been called into question.[33]

The proposed Mega Guidance is expected to address the risk areas identified within this white paper, and will impose more clearly defined parameters (and in some cases tighter restrictions) on participation in the program. For example, the proposed Mega Guidance more clearly defines who is an eligible patient. Some critics of the current status of the program have advocated for requirements that the definition of patient be limited to those who are medically indigent.[34] Currently, an individual's insurance status is not a consideration in determining whether he or she is an eligible patient. Critics assert that failure to so limit the definition constitutes diversion of 340B funds.

Another area of scrutiny is the determination of what entities are eligible to participate in the program. Some have suggested that hospital eligibility should be more closely tied to demonstrated community benefit—for example, as reported in a hospital's Form 990, Schedule H, or Medicare cost report worksheet S-10.[35] Others argue that none of these reports provides a sufficiently accurate measure of community benefit to serve as an appropriate gauge for participation, that the current hospital categories for covered entities are sufficient to identify eligible providers, and that the program should be expanded to inpatient services and additional categories of safety-net hospitals.[36]



[33] In Pharmaceutical Research and Manufacturers of America v. United States Department of Health and Human Services, 2014 WL 2171089 (D.D.C.). PhRMA successfully challenged the reach of HHS' rule-making authority. HHS issued a final rule on July 23, 2013, which required manufacturers to give the 340B discount for orphan drugs when they are used for purposes other than that for which they were granted orphan status. On May 23, 2014, the federal district court vacated HHS' final rule regarding the orphan drug exclusion, stating that although HHS' interpretation of the exclusion was reasonable, HHS did not have the statutory authority to promulgate regulations regarding orphan drugs. Instead, HHS' rule-making authority is limited to the areas outlined in the statute. Id. Shortly after this ruling, HHS issued a substantially similar rule as an "Interpretive Rule." HRSA, Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, at http://www.hrsa.gov/opa/programrequirements/interpretiverule/interpretiverule.pdf. On September 27, 2014, PhRMA filed suit objecting to the Interpretive Rule, as well. In addition to the confusion the PhRMA decision created regarding orphan drugs, the decision also called into question HHS' authority to promulgate the Mega Rule. On November 14, 2014, HHS announced that it was withdrawing the Mega Rule.

[34] See Press Release, AIRx340B Alliance for Integrity and Reform, At National Summit, Experts Across Key Sectors Discuss Needed Reforms of 340B Drug Discount Program (June 11, 2014), at http://340breform.org/userfiles/FINAL%20AIR%20340B%20Summit%20Press%20Release.%206.11.14.pdf.

[35] See, *e.g.*, AIRx340B Alliance for Integrity and Reform, "Unfulfilled Expectations: An analysis of charity care provided by 340B hospitals," Media Q & A, at http://340breform.org/userfiles/FINAL%20Updated%20Media%20Q&A%20for%20Charity%20Care%20Paper.pdf.

[36] See American Hospital Association, 340B Program Expansion, at http://www.aha.org/advocacy-issues/rural/340B.shtml.

Why Should You Consider PYA to Assist with Your 340B Compliance?

PYA is a certified public accounting and healthcare consulting firm that provides timely insight and strategic direction, helping our clients thrive in the midst of rapid change. Since 1983, we have provided clients with world-class support, delivering comprehensive services in compliance, accounting, and healthcare consulting.

PYA is well-versed in the complex regulatory environment of the healthcare industry. As such, we have a unique understanding of the issues surrounding 340B compliance. With over 30 years of experience in advising healthcare clients, PYA's team of experts can assist covered entities in multiple areas of 340B compliance, including annual independent audits, compliance infrastructure design, policy and procedure development and testing, reimbursement and cost reporting, education and training, and corrective action plan support. If you are uncertain whether you are in compliance with the 340B program, contact us about an assessment. At the conclusion of the assessment, we can advise you as to the key risk areas that may need additional attention. PYA's services meet HRSA's recommendation for independent audit(s).

To assist covered entities, their advisors, and their counsel in navigating the myriad compliance issues associated with the 340B program, we have prepared the following checklist. This checklist is designed to assist covered entities with their compliance efforts when utilized as part of a comprehensive 340B compliance program.

For more information regarding PYA's 340B Assessment Services, contact:

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340B Program Compliance: Self-Assessment Checklist

General 340B Program Infrastructure

1. **Does the entity have current written policies and procedures for all areas of 340B compliance, including all child site locations?**

2. **Do the policies and procedures address the following areas:**

   a. Entity's 340B program eligibility requirements (patient, prescriber, location)?
   b. Auditable records demonstrating compliance with all 340B requirements?
   c. Internal controls in place to demonstrate ongoing compliance with all 340B requirements?
   d. Inclusion of 340B compliance in the annual internal audit/compliance plan?
   e. Contract Pharmacy Service Agreements compliance with the twelve (12) contract pharmacy essential compliance elements as defined by the Health Resources and Services Administration (HRSA)?
   f. Specific 340B program compliance duties, training, and development of responsible staff?
   g. 340B enrollment, recertification, and change request process?
   h. 340B procurement, inventory management, and dispensing?
   i. 340B compliance monitoring and reporting processes?

3. **At a minimum, have employees in the following areas been educated regarding 340B compliance: pharmacy, billing, information technology, finance, reimbursement, nursing, compliance, and medical records?**

4. **Has the entity's 340B compliance been audited internally (*i.e.*, corporate compliance or internal audit)? Does the scope of any audit(s) include Contract Pharmacy arrangements?**

5. **For any internal audits conducted, were action plans developed for any issues identified, and were the action plans implemented in a timely manner?**

6. **For significant findings identified, was HRSA notified along with the entity's corrective action plan?**

7. **Is the entity prepared to annually attest to the following essential 340B program compliance requirements?**

   a. Office of Pharmacy Affairs (OPA) Database entry is complete, accurate, and correct?
   b. Entity meets 340B eligibility requirements?
   c. Entity maintains auditable records?
   d. Systems/controls are in place to ensure compliance?
   e. All contract pharmacy arrangements are in compliance and entity has obtained sufficient information to confirm compliance?
   f. Entity has contacted the OPA for any breach identified?
   g. Entity acknowledges possibility of payment to manufacturers for failure to notify the OPA in a timely fashion?

8. **Has the entity practiced obtaining data to support 340B compliance in the event of an HRSA or manufacturer audit?**

   a. Cost reports and any amendments?
   b. Provider NPI listing and contractual arrangements?
   c. Dispensing records at the specific patient/drug level?
   d. Purchasing records (GPO, WAC, and 340B)?
   e. Flow charts of all 340B processes including a listing of all information systems?
   f. List of providers eligible to write 340B prescriptions (includes employed and contracted physicians)?
   g. Ability to identify any providers that could have had the ability to write 340B prescriptions during the audit time frame (*i.e.*, medical staff, rotating physicians, physicians who are part of a group contract such as emergency department coverage)?
   h. List of contract pharmacies utilized and current contracts?

Duplicate Discounts

1. **Has the entity informed OPA immediately of any changes to the OPA website/Medicaid exclusion file?**

2. **Do the entity's Medicaid billing practices align with its information listed on the OPA website/Medicaid Exclusion File? Is this periodically reviewed for accuracy?**

3. **Has the entity reviewed its state-specific Medicaid program requirements to ensure compliance?**

4. **Is the entity aware of current initiatives at the state level regarding whether covered entities can retain their 340B savings or whether they must bill at acquisition cost?**

Covered Entity Eligibility

1. **Has the entity's data on the OPA database been reviewed to ensure it is complete, accurate, and correct?**
2. **Does the entity only use 340B drugs in outpatient clinics that are registered on the OPA database (or within the four walls of the parent) and reimbursable on the most recently filed cost report?**

Patient Eligibility (Diversion)

1. **Does the entity have a relationship with the patient and maintain records of the patient's healthcare? Does the relationship extend beyond the prescribing of 340B drugs?**
2. **Does the entity maintain an eligible prescriber listing? Is this listing routinely compared against a listing of professionals with contractual or other arrangements with the entity?**
3. **Are auditable records maintained to ensure the patient is an outpatient at time of the prescription?**

Contract Pharmacy Arrangements

1. **At a minimum, do all contract pharmacy arrangements include the following elements:**

a. Written agreement between the entity and the contract pharmacy?
b. List of all contract pharmacy locations?
c. Use of "ship to, bill to" arrangements?
d. Controls for preventing duplicate discounts and diversion (*i.e.*, tracking systems)?
e. Exclusion of Medicaid beneficiaries unless a separate arrangement has been entered into with the state Medicaid agency?
f. Documentation and audit requirements to demonstrate compliance?

2. **Has the entity obtained sufficient information from the contract pharmacy provider to ensure compliance with applicable 340B requirements?**
3. **Are controls in place to ensure the contract pharmacy verifies patient and prescriber for eligibility?**
4. **Have any independent audits of the contract pharmacy arrangements been performed as recommended by HRSA?**

340B Program Intent and Community Benefit

1. **Does the entity have a communication strategy regarding how it uses the savings from the 340B program to benefit low-income and uninsured patients?**
2. **Has the entity assessed its charity care policies in relation to its use of 340B savings?**

Procurement and Inventory

1. **Does the inventory system prohibit the entity from obtaining covered outpatient drugs from a group purchasing organization (GPO)— *i.e.*, disproportionate share hospitals, children's hospitals, free-standing cancer clinics?**
2. **Does the entity maintain records of 340B-related transactions for a period of time (per written policies) in a readily retrievable and auditable format?**
3. **For physical inventories, are all 340B drugs separated from non-340B drugs (*i.e.*, GPO)?**
4. **Does the entity have controls established to ensure orphan drugs are not purchased under the 340B program?**
5. **If the entity uses a split-billing software for mixed-use areas, are procedures clearly written and processes outlined (flowchart) to address the following elements:**

a. Process used for determining inpatient vs. outpatient status?
b. Basis for replenishment orders?
c. Tracking of 340B, inpatient and non-340B drugs (*i.e.*, GPO)?
d. Accurate data capture (*i.e.*, time stamps, EMR split-billing system interfaces, patient eligibility)?

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