

**COMMENTS OF THE PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA**

**SUBMITTED TO THE HEALTH
RESOURCES AND SERVICES
ADMINISTRATION**

**CONCERNING RIN 0906-AB08,
340B DRUG PRICING PROGRAM
PROPOSED OMNIBUS
GUIDANCE**

OCTOBER 27, 2015

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October 27, 2015

BY EMAIL (340BGuidelines@hrsa.gov)

Captain Krista Pedley
Director, HRSA Office of Pharmacy Affairs
5600 Fishers Lane, Room 8W10
Rockville, Maryland 20857

Re: 340B Drug Pricing Program Proposed Omnibus Guidance; Regulatory Information
Number 0906-AB08

Dear Captain Pedley:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on the proposed 340B program omnibus guidance (the Proposed Guidance) published by the Health Resources and Services Administration (HRSA).¹ PhRMA is a voluntary, non-profit organization representing the nation's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to lead longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested more than \$600 billion in the search for new treatments and cures, including an estimated \$51.2 billion in 2014 alone.

PhRMA supports the 340B program, which was enacted to help make prescription drugs more accessible to uninsured or vulnerable patients, and these comments are intended to help assure the program is both strong and sustainable into the future. Over the years, we have been concerned that the program has grown into something that is no longer centered on strengthening the care provided to needy patients. We would like to be very clear and emphasize that the grantees and true safety net hospitals participating in the 340B program are dedicated to serving these patients, and we value and strongly support their work. Notably, HRSA grantees typically must demonstrate that they serve a specified vulnerable population on an income-based, sliding-fee scale and are required to reinvest any additional resources derived from their grants into services for those populations. Grantees and the true safety net hospitals are a key part of our nation's public health infrastructure and it is crucial that they can continue to use the 340B program to support this important role. These requirements placed on grantees also help assure that the 340B program is used appropriately. In contrast, hospitals face no such requirements. While some hospitals provide a significant amount of charity care and use 340B to strengthen that safety net role, other hospitals provide relatively little charity care.² PhRMA supports reforms instituted by HRSA that advance the goals of preserving the program for grantees and safety net hospitals -- and the patients they serve -- and preventing abuse by parties that simply see the program as another source of revenue. To the extent that statutory changes may be required to reform certain parts of the 340B program in order to achieve these goals, we would support those reforms as well.

¹ 80 Fed. Reg. 52300 (Aug. 28, 2015).

² GAO, "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals." June 2015.

Several factors have led the 340B program to have “expanded beyond its bounds,” as one former Secretary of Health and Human Services noted in 2014.³ One source of this growth is the lack of safeguards necessary to adhere to the statutory framework and to ensure its integrity and sustainability. This has contributed to the lack of focus on directing 340B discounts to the vulnerable and needy patients the program was created to serve. In other cases ill-advised 340B policies and weak oversight have allowed program benefits to be diverted from serving the program’s intended beneficiaries.

At this juncture, it is critically important that HRSA institute major reforms to re-align the 340B program with its authorizing statute and ensure that its benefits flow to underserved patient populations. The Proposed Guidance takes some important steps in that direction. In particular, the Proposed Guidance would add greater clarity to the definition of a covered entity “patient” who may receive a 340B drug, and would therefore reduce opportunities for abuse. PhRMA has several refinements to suggest to the proposed patient definition (which we detail below), but overall we support the approach HRSA has taken as it would reduce the uncertainty about when an individual is properly considered a “patient” of a covered entity and reduce the potential for unintended program growth.

In other important areas, however, we are concerned that the Proposed Guidance would solidify or even exacerbate problems rather than reduce them. To cite some key examples, the Proposed Guidance does not clarify the criteria for private hospitals to participate in the 340B program -- even though the Government Accountability Office (GAO) recommended in 2011 that HRSA clarify the 340B eligibility criteria for private hospitals,⁴ and in the intervening four years the percentage of U.S. hospitals participating in the 340B program (created to help needy and vulnerable patients served by safety net providers) has grown from 33% to 40%,⁵ even as the percentage of Americans without health insurance drops. HRSA’s failure to propose any standards for determining when a private hospital is 340B-eligible based on a contract with a State or local government to provide care for low-income people who are ineligible for Medicare and Medicaid is particularly disappointing, because setting clear standards for a hospital to fit within this eligibility category could benefit low-income, uninsured individuals.

PhRMA was also surprised and dismayed that HRSA made no proposals to curb the sharp and abusive growth in “child sites” of 340B hospitals that are not actually an integral part of the covered entity hospital and thus not legally entitled to participate in the 340B program -- and that increasingly are serving higher-income communities instead of the patient mix that makes their “parent” hospital 340B-eligible.⁶ Hospital acquisitions of formerly independent community physician practices -- which account for many of these new “children” -- are trending

³ President’s fiscal year 2015 health care proposals: hearing before the Committee on Finance, US Senate. April 10, 2014. Statement of Kathleen Sebelius. Kathleen Sebelius, US Secretary of Health and Human Services.

⁴ GAO, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (Sept. 23, 2011) at 23, 32, 34-36.

⁵ GAO, Manufacturer Discounts in the 340B Program Offer Benefits, supra, at 20 (nearly one-third of U.S. hospitals participated in the 340B program at that time); GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 5, 2015) at 1 (currently, approximately 40% of U.S. hospitals participate in the 340B program).

⁶ See e.g., Rena M. Conti and Peter B. Bach, The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities, *Health Affairs*, 33 no. 10 (2014): 1786-1792.

upward,⁷ and Medicare typically pays higher rates for care provided at these acquired practices once they are characterized for billing purposes as hospital outpatient sites.⁸ The availability of deeply discounted 340B pricing allows 340B hospitals to generate higher net revenues than independent physician offices for administering the same medicine.⁹ This opportunity creates financial incentives for 340B hospitals to purchase independent physician practices and bring them under the 340B umbrella, and recent studies suggest that these incentives are in fact driving 340B hospital acquisitions of formerly independent physician practices.¹⁰ This current state of affairs of the 340B program goes beyond legislative intent -- and text. The hospital "child site" is a doctrine developed by HRSA alone, which should not be used to extend 340B eligibility to offsite facilities -- including formerly independent physician practices -- that are distinct from the covered entity hospital and serve distinct patient populations that the 340B program was not created to assist. PhRMA had expected that HRSA would not simply ignore this growing problem. This issue calls for HRSA's prompt and focused attention.

Further, the Proposed Guidance would not establish any limits on contract pharmacy arrangements -- even though the number of contract pharmacies has increased dramatically since 2010, these arrangements (which are not mentioned in the 340B law) have been cited by GAO and the HHS Office of Inspector General (OIG) as increasing diversion and double discounting risks, and a 2014 OIG report suggests that 340B hospitals' contract pharmacies generally do not pass 340B discounts through to low-income, uninsured patients. Often it is not until after the point of sale that an individual who filled a prescription at a contract pharmacy is identified as a covered entity "patient" who was dispensed a "340B drug" -- too late to provide a discount to the patient at the point of sale.

Another serious problem that the Proposed Guidance does nothing to solve is increased violations of the 340B law's ban on duplicate discounts (where a manufacturer sells a drug at a 340B discount and is then billed for a Medicaid rebate on the same unit). Due to a combination of two factors -- HRSA's 2010 policy ending its previous limits on contract pharmacies, and the fact that the Affordable Care Act (ACA) extended Medicaid rebates to Medicaid managed care

⁷ These trends have raised concerns about increased costs to Medicare and the entire health care system. See Baltic, Scott. "Monopolizing Medicine: Why hospital consolidation may increase healthcare costs," Medical Economics. February 2014.

⁸ See IMS Institute for Healthcare Informatics. Innovation in cancer care and implications for health systems. Published May 2014. See also Berkeley Research Group. Impact on Medicare payments of shift in site of care for chemotherapy administration. White paper. Published June 9, 2014.

⁹ According to a 2013 Congressional Budget Office (CBO) report, the average total Medicaid rebate on brand drugs (the "basic rebate" plus the "additional rebate") was about 58% of Average Manufacturer Price (AMP) in 2011. See Options for Reducing the Deficit: 2014 to 2023 at pg. 234 (Nov. 2013). The 340B ceiling price is AMP minus the drug's Medicaid rebate. CBO's estimate of the average Medicaid rebate for a brand drug thus puts the average 340B ceiling price at about 42% of AMP.

¹⁰ New data from Avalere Health finds that 340B hospitals are more likely than other hospitals to purchase independent physician offices that administer medicines. Avalere Health. Hospital acquisitions of physician practices and the 340B program. White paper. Published June 8, 2015. The study authors found that 61 percent of hospitals identified in the study as potentially acquiring physician practices participated in the 340B program compared to a 45 percent 340B participation rate among all hospitals in the dataset. Also, a 2014 *Health Affairs* study concluded that 340B is a "powerful contributor" to driving these hospital acquisitions of physician practices. Bradford Hirsch, Suresh Balu and Kevin Schulman, "The Impact of Specialty Pharmaceuticals As Drivers of Health Care Costs," *Health Affairs*. October 2014 vol. 33 no. 10 1714-1720.

organization (MCO) utilization -- identifying and preventing duplicate discounts have become increasingly difficult over the past five years. But the Proposed Guidance merely advises covered entities to take unspecified steps to prevent duplicate discounts. This failure to embrace any solutions to the growing duplicate discount problem is a major concern. We are especially disappointed because PhRMA prepared a white paper for HRSA in 2014 with a number of thoughtful recommendations to reduce the risk of duplicate discount violations, but none of our recommendations on this issue are even discussed in the Proposed Guidance. To make things worse, HRSA has made several proposals that would increase the complexity of covered entities' carve-in/carve-out policies and thus affirmatively frustrate duplicate discount prevention and increase HRSA's own administrative burdens as it continues to audit and engage in oversight activities.

We urge HRSA to address these critical problem areas, and to build on its clearer "patient" definition, in its final omnibus guidance while also introducing some necessary flexibilities for grantees. We appreciate the challenges HRSA faces in issuing guidance that will help covered entities and manufacturers in complying with the statute, and all the efforts HRSA put into developing the Proposed Guidance. The improved "patient" definition is critical to the integrity of the 340B program and we strongly support HRSA's approach. In addition to the top-priority points just highlighted, we have comments on many issues raised by the Proposed Guidance, and we look forward to further dialogue with HRSA on these issues.

Our key recommendations can be summarized briefly as follows:

Ensuring Clarity in the Final Omnibus Guidance and the Overall Body of 340B Guidance

- To ensure that the final omnibus guidance is comprehensive, consistent, and complete, we recommend that HRSA: (1) state clearly in the final guidance that it supersedes all prior guidance on the topics covered; (2) explicitly incorporate into the final guidance the substance of all prior guidance that HRSA intends to keep applying; (3) clarify the status of 340B prime vendor pronouncements; (4) resolve inconsistencies between some of its statements in the Proposed Guidance itself, and between statements in the Proposed Guidance and other HRSA documents; and (5) list a post-publication date on which the final guidance becomes effective.

Grantee Eligibility

- We request that HRSA provide more detail with respect to certain grantee eligibility issues, and permit sub-recipients of federal grants that meet criteria we specify below to register independently for the 340B program.

Hospital Eligibility

- HRSA should specify that private nonprofit hospitals that are 340B-eligible due to being "formally granted governmental powers" by a state or local government must be granted (1) actual governmental powers (not anything less than "powers," such as authorization to perform activities "on behalf of" a unit of government), (2) that relate directly to the provision of healthcare (not unrelated or loosely-related powers).
- HRSA should specify that for a private nonprofit hospital to be 340B-eligible due to "a contract with a State or local government to provide health care services to low income

individuals [ineligible for Medicare and Medicaid],” (1) the hospital must submit the contract to HRSA, and (2) HRSA must review the contract and confirm that it requires the hospital to provide at least a specified amount of care to low-income people ineligible for Medicare and Medicaid (with the specified minimum threshold selected so as to ensure that a minor contract to care for this population cannot confer 340B eligibility).

- HRSA should list on the 340B covered entity database whether each hospital is 340B-eligible because it is (1) publicly owned or operated; (2) a private nonprofit hospital formally granted governmental powers by a State or local government (in which case the database should also list the power granted to the hospital, the unit of government that granted the power, and the instrument that granted the power and its date); or (3) a private nonprofit hospital with a contract with a State or local government to provide health care services to low-income individuals ineligible for Medicare and Medicaid (in which case the database should also include specified information about the contract that supports 340B eligibility).

The GPO Prohibition

- HRSA should not finalize its proposal permitting an exception to the GPO prohibition if a hospital cannot obtain a drug at the 340B price or at WAC, as the statute makes compliance with the GPO prohibition an unwaivable condition of eligibility for DSH, cancer, and children’s hospitals.

Hospital Child Site Eligibility

- Reforms are needed to reconcile the hospital “child site” concept with statutory eligibility criteria:
 - HRSA should reaffirm that a hospital “child site” must be an “integral part” of the covered entity hospital, but with strengthened standards that improve clarity for stakeholders and assure alignment with the text and purpose of the 340B law. Specifically, HRSA should specify that to be an “integral part” of a covered entity hospital, an outpatient facility must: (1) meet the provider-based standards in 42 C.F.R. § 413.465; (2) be wholly owned by the hospital; and (3) be listed as reimbursable on the hospital’s Medicare cost report and have Medicare outpatient charges.
 - HRSA should further specify that a hospital child site must: (1) provide the full range of outpatient health care services; (2) adhere to the parent hospital’s charity care policy; and (3) adhere to the sliding scale fee schedule (if any) of the parent hospital for providing covered outpatient drugs to low-income patients who lack minimum essential coverage.
 - Finally, HRSA should specify that a hospital child site must serve a similar patient mix as the patient mix that makes the parent hospital 340B-eligible, and should impose a temporary moratorium on enrollment of new child sites for nonprofit private hospitals while it develops and implements appropriate standards to meet this criterion.

The “Covered Outpatient Drug” Definition

- HRSA should abandon its proposal to broaden the definition of “covered outpatient drug.” In particular, HRSA’s Proposed Guidance would narrow the Medicaid rebate statute’s “limiting definition” so that it would only apply to a drug provided as part of specified services listed in

the statute when Medicaid pays for the drug via a bundled payment, and Medicaid actually is the payor in that instance. HRSA should instead return to its longstanding guidance conforming to the Medicaid rebate statute and the 340B law.

Individuals Eligible to Receive 340B Drugs

- PhRMA appreciates HRSA's efforts to spell out the elements of the "patient" definition, which are essential to improving program integrity. We generally support the six criteria HRSA proposes to define a covered entity patient. We also recommend certain refinements to the six criteria, including certain refinements that are needed to ensure that the patient definition does not inadvertently hinder grantees' ability to carry out their mission.
 - PhRMA supports HRSA's proposed criterion that a "patient" must receive a health care service at a registered covered entity site listed on the public 340B database.
 - We support the principle that an individual who receives services from an "affiliated" entity is not a covered entity patient and recommend that HRSA restate its previous guidance clarifying that this principle applies in the ACO context.
 - HRSA should also specify explicitly that a visit by an individual to a contract pharmacy of a covered entity neither establishes nor refreshes a "patient" relationship between an individual and a covered entity.
 - PhRMA supports HRSA's proposed criterion that the individual must receive health care services from a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity (such that the covered entity may bill for the provider's services). To improve clarity, HRSA should specify that the covered entity must be accountable for the care provided by the independent contractor. We also believe it would be appropriate for HRSA to recognize a limited exception to this element for certain entities that have grant-related obligations to provide a medical home model of care or otherwise to coordinate care for certain patient populations.
 - PhRMA supports HRSA's proposed third criterion that an individual must receive a drug that is ordered or prescribed by the covered entity provider as a result of the service described in the second criterion. We also support HRSA's clarification that a patient relationship cannot be established merely by the dispensing or the infusion of a drug.
 - PhRMA agrees that to be a patient, the individual's health care must be consistent with the scope of the Federal grant, project, designation, or contract of the grantee. However, it is important that HRSA apply this same approach to private hospitals that are 340B-eligible by virtue of being formally granted a governmental power or having a contract with a State or local government to care for low-income individuals who are not eligible for Medicare and Medicaid.
 - PhRMA supports the proposed criterion that the individual's drug must be ordered or prescribed pursuant to a health care service classified as outpatient. HRSA should also clarify that for insured patients, the service provided to the individual must be billed and paid for as an outpatient service. HRSA should also specify that this element of the patient definition would preclude filling "discharge prescriptions" with 340B drugs, but should state specifically that "discharge prescriptions" do not include prescriptions filled

by non-hospital (grantee) covered entities that are responsible for managing the care of the individual both before hospital admission and after discharge.

- PhRMA agrees with HRSA that the individual's healthcare records must be accessible to the covered entity and demonstrate that the entity is responsible for care. We recommend specifying that the records of a "patient" must not only be "accessible" to the covered entity, but maintained, owned, controlled, and possessed by the covered entity. In addition, we recommend HRSA specify that the provider/patient relationship must be "ongoing."
- PhRMA agrees with the principle that covered entity employees are not "patients" unless all elements of the patient definition are met.
- We support HRSA's retention of the special patient definition for ADAPs.
- PhRMA supports telemedicine services, and we agree with HRSA that telemedicine services in the 340B context must be provided in compliance with all applicable State and Federal laws and all 340B program requirements. We recommend that HRSA create a carefully-crafted opening for grantees to develop a 340B "patient" relationship via real-time audiovisual encounters if key safeguards (including an initial face-to-face visit) and applicable State and Federal laws are followed.

Drug Inventory/Replenishment Models

- PhRMA agrees with HRSA's statement that covered entities are responsible for requesting 340B pricing at the time of the original purchase; however, the Proposed Guidance apparently would permit transactions to be reclassified as 340B drug purchases after the fact. To resolve this paradox, we recommend that HRSA adopt standards whereby (1) entities and their agents must design systems adequate to identify patients (and non-patients) at the time a drug is dispensed or administered; (2) entities with well-designed real-time patient identification systems may reclassify a drug as a 340B drug within 30 days of the purchase, and with notification to the manufacturer and a clear audit trail (and not otherwise); and (3) manufacturers must always be notified of any improper 340B purchases.

Duplicate Discounts

- PhRMA recommends that all stakeholders -- including HRSA, CMS, State Medicaid agencies, covered entities, and manufacturers -- work together collaboratively to develop solutions to prevent duplicate discounts. Below we list a menu of several recommendations to help achieve this objective:
 - HRSA should require covered entities to identify prescriptions for 340B "patients" when the prescription is written, which would enable both in-house and contract pharmacies to identify a prescription as one filled with 340B drugs at the point of service.
 - HRSA should work with CMS to require that Medicaid MCOs issue pharmacy benefit cards that include an individual's Medicaid managed care status, rather than just listing the BIN/PCN for the MCO sponsor.

- HRSA should work with stakeholders to create a 340B “National Database on States’ Processing Requirements” that would provide information assisting covered entities and contract pharmacies to identify Medicaid MCO enrollees.
- HRSA should not finalize its several proposals to permit covered entities’ carve-in/carve out policies to become more complicated, and instead should require one carve-in/carve out decision across all of a covered entity’s sites and for all Medicaid payors.
- HRSA should require that, when billing Medicaid or other payors, covered entities and their contract pharmacies should use a system like that developed by the National Council for Prescription Drug Programs (NCPDP) -- or revised and refined by NCDPCP -- to identify claims filled with 340B drugs.
- HRSA should work with CMS to create a standardized claims-level reporting format for drug utilization data that accompanies Medicaid rebate invoices submitted to manufacturers, and also standardize the method for identifying and documenting utilization of 340B drugs across Medicaid.
- HRSA should work with CMS to require that all Medicaid utilization data submitted to manufacturers (both FFS and Medicaid MCO) contain the “Pharmacy Identifier” field so that manufacturers can verify that the data has been correctly screened for duplicate discounts, or can communicate with the State about potential errors.
- HRSA should work with CMS to require that the utilization data accompanying Medicaid rebate invoices include additional specified fields that would assist manufacturers in identifying potential duplicate discounts.
- HRSA should work with CMS to require that contract pharmacies report the NPI number of the covered entity (not their own NPI number) when submitting or retroactively identifying a claim for a 340B drug. We also urge HRSA and CMS to develop a mechanism whereby the Exclusion File flags contract pharmacy claims even if the 340B entity itself has developed a method to avoid dispensing 340B drugs to Medicaid FFS and MCO beneficiaries and thus does not submit its NPI number to the Exclusion File.
- 340B entities or contract pharmacies that fail to follow the recommended requirement to adopt a system like the NCPDP 340B identification system should have an affirmative obligation to report to the MCOs that they do not use the required 340B identifier system; MCOs must then be required to exclude all claims from covered entities that do not comply with the 340B identifier system from the utilization data they report to the State.
- HRSA should work with CMS to ensure that Medicaid MCOs review their claims retroactively back to 2010 (when Medicaid MCO utilization first became subject to Medicaid rebates) to make sure they have not previously invoiced State Medicaid programs for 340B drugs, and make corrections as appropriate.
- HRSA should clarify that a manufacturer may dispute instances of duplicate discounts with States via the Medicaid rebate dispute resolution process, but is not required to do so (because covered entities are always ultimately responsible for compliance with the statutory prohibition of duplicate discounts).

Contract Pharmacy Arrangements

- Studies by GAO and the OIG suggest that the use of contract pharmacies presents heightened diversion and double discount risks and (in the hospital context) has resulted in few benefits to patients. Therefore, PhRMA recommends that, at a minimum, HRSA impose reasonable limits on the use of contract pharmacies to balance their heightened compliance risks against any benefit these arrangements are providing to covered entity patients. Specifically:
 - HRSA should limit the number and geographic scope of permissible contract pharmacy arrangements. With certain exceptions, PhRMA recommends that covered entities be permitted to contract with no more than five contract pharmacy locations at any given time, all of which must be located within lower-income census tracts served by the covered entity.
 - Where a covered entity offers a charity care policy or has a sliding fee scale, then its contract pharmacies should be required to follow those policies when dispensing 340B drugs to covered entity patients.
 - HRSA should seek an HHS OIG study and report on covered entity/contract pharmacy arrangements, which should include recommended safeguards to reduce duplicate discounting and diversion within contract pharmacies and reforms to target these arrangements exclusively at improving access to medicines for uninsured or vulnerable patients of covered entities. HRSA should establish a moratorium precluding any covered entity (except those described in 42 U.S.C. § 256b(a)(4)(A)-(K)) from entering into a new or expanded contract pharmacy arrangement until HRSA has evaluated the OIG's report, issued proposed guidance based on OIG's findings and recommendations, and then issued final guidance taking into account public comments.
 - HRSA should require covered entities to conduct annual, independent, on-site audits of their contract pharmacies, and relevant third parties, to identify program violations.
 - HRSA should establish a moratorium barring covered entities (except those described in 42 U.S.C. § 256b(a)(4)(A)-(K)) from registering any mail order contract pharmacies (including pharmacies licensed to dispense specialty drugs) until HRSA has conducted a thorough examination of the risks posed by these arrangements, and set forth clear, auditable, and specific standards to prevent program violations with respect to these arrangements.
 - Both HRSA and manufacturers should be permitted to audit contract pharmacies (and other relevant third parties) directly, to ensure compliance with program requirements.
 - HRSA should establish more stringent requirements regarding covered entities' written agreements with their contract pharmacies, with robust safeguards to ensure that the contract pharmacy adheres to all 340B program requirements, and measures describing specifically how compliance will be achieved. All agreements should be registered with HRSA and made available to HRSA on request.

The “Must Offer” Requirement

- When the PPA is amended to incorporate the “must offer” language, HRSA should reiterate its previous conclusion that this language incorporates HRSA’s long-standing policy against treating covered entities less favorably than non-340B customers (rather than adopting a new and different “forced sale” requirement that potentially could result in manufacturers being required to disadvantage non-340B customers). We also recommend that HRSA update all of the PPA’s provisions to conform with current law.
- PhRMA disagrees with HRSA’s assertion that by executing a PPA, a manufacturer agrees to subsequent statutory and regulatory changes that are not incorporated into the PPA. We urge HRSA to retract this position, as it is unsupported by the statute or the PPA.

Limited Distribution Networks

- We oppose HRSA’s proposal to require that manufacturers: (1) report information on their limited distribution networks; (2) seek HRSA’s approval before putting a limited distribution arrangement into effect; and (3) agree to have submissions on their limited distribution arrangements published on the HRSA 340B website. HRSA lacks any authority to adopt such requirements, and should not attempt to finalize this proposal.

Procedures for Issuance of Refunds and Credits

- The 340B statute requires HRSA to establish procedures for manufacturers to issue refunds to covered entities in certain circumstances; while the Proposed Guidance proposes a 90-day refund period, it does not actually establish any procedures for making refunds. PhRMA recommends that HRSA engage in an ongoing dialogue with stakeholders to develop the required procedures, and ensure they work as smoothly as possible and avoid undue burdens. With respect to HRSA’s specific refund proposals:
 - PhRMA opposes HRSA’s proposal that manufacturers refund or credit covered entities within 90 days of a “determination” that an overcharge occurred. Because 340B ceiling prices are based on Medicaid rebate metrics that are subject to restatement for 36 months after initially filed, it would be inappropriate for HRSA to require refunds any time before the 36 month restatement window closes and 340B ceiling prices for a given quarter are frozen. Manufacturers also should be permitted a reasonable time to recalculate 340B ceiling prices based on the final restated pricing, calculate entity-specific refund amounts, and then to deliver the refund payments. PhRMA recommends that HRSA allow an additional four quarters (after the 36 month restatement period) for final delivery of refund payments.
 - PhRMA opposes HRSA’s proposal to abrogate manufacturers’ common law right of offset. The 340B law does not preclude offsets or authorize HRSA to do so. In fact, the law makes sub-ceiling prices voluntary, whereas HRSA’s proposal to forbid offsets would effectively make sub-ceiling prices mandatory in cases where the initially-calculated ceiling price turned out to be too low. HRSA must therefore establish a policy recognizing that manufacturers may net overcharges and undercharges associated with ceiling price recalculations.
 - PhRMA urges HRSA not to preclude exceptions for de minimis amounts. Establishing a de minimis standard would reduce transaction costs and administrative burdens for both

manufacturers and covered entities, and it would be consistent with a long-standing line of case law holding that agencies may establish de minimis requirements to statutes they administer unless Congress has clearly precluded such exceptions -- which is not the case here.

Manufacturer Recertification

- PhRMA requests HRSA to provide greater specificity regarding its proposal to create a “manufacturer recertification” process (e.g., what information would be required to “recertify” the manufacturer as a 340B program participant, what type of “supporting documentation” it would need, under what circumstances such documentation would be requested). If HRSA wishes to create a manufacturer recertification process, it should propose specific standards and then publish them for notice and comment.

Rebate Option for AIDS Drug Assistance Programs

- PhRMA supports HRSA’s proposal that ADAPs may receive 340B rebates if they purchase a drug at an amount exceeding the 340B ceiling price or if they pay for the patient’s health insurance premium and pay the cost-sharing on the drug. We understand that this latter proposal would permit 340B rebates as long as the ADAP pays the patient’s share of the premium plus the patient’s cost-sharing.
- PhRMA supports HRSA’s proposal that the amount owed to an ADAP for a covered outpatient drug would be equal to the full Medicaid unit rebate amount.
- PhRMA agrees that no covered entity may obtain 340B pricing (either through a rebate or through a direct purchase) on a drug purchased by another covered entity at or below the 340B ceiling price. We urge HRSA to clarify in its final guidance that non-ADAP covered entities may not bill ADAPs for drugs purchased at the 340B price, and thus trigger a duplicate discount (or take the 340B discount for itself rather than the ADAP).

HHS Audits of Covered Entities

- PhRMA opposes HRSA’s proposal to extend a notice and hearing process to covered entities found in violation of the GPO prohibition, and to permit entities to demonstrate that the violation was an isolated error. HRSA’s proposal is inconsistent with the statute. The 340B law prohibits certain hospitals -- as a condition of eligibility -- from obtaining covered outpatient drugs through a GPO or other group purchasing arrangement. There is no authority for HRSA to waive this eligibility condition.
- PhRMA urges HRSA to provide specific details as to what would constitute a “systematic” duplicate discount or diversion violation that would warrant removing a covered entity from the 340B program; at a minimum, a systematic violation would be one that occurs over and over and over again.

Manufacturer Audits of Covered Entities

- PhRMA agrees with HRSA’s examples of what would provide “reasonable cause” to suspect diversion or duplicate discounts, and we agree that these examples are not exhaustive. We recommend that HRSA’s final guidance on “reasonable cause” remain consistent with the Proposed Guidance.

- We support HRSA's proposal that in an HHS audit of a covered entity, HHS must be provided access to all of the covered entities records pertaining to compliance, including those of any child site or contract pharmacy. HRSA should also emphasize in its final guidance that such records are equally available to manufacturers where pertinent to a manufacturer audit.

HHS Audits of a Manufacturer and its Contractors

- In general, PhRMA agrees with HRSA's proposals regarding HRSA's ability to audit manufacturers, including providing manufacturers a notice and hearing process, and potentially to implement a corrective action plan. HRSA's proposal, however, provides that HHS also could audit relevant records of any of the manufacturer's contractors. This goes beyond HRSA's statutory authority, which extends only to manufacturers and wholesalers (and covered entities),¹¹ and we therefore recommend that HRSA correct this language in its final guidance. HRSA's final guidance also should recognize that its authority to audit wholesalers does not confer any responsibility on manufacturers for ensuring a wholesaler's cooperation with HRSA in any audit.

Covered Entity Audits of Contract Pharmacies

- PhRMA supports HRSA's proposals regarding covered entity audits of contract pharmacies, but given the widespread problems and increased compliance risks associated with contract pharmacies, PhRMA recommends more stringency. We urge HRSA to require that covered entities have annual independent on-site audits conducted of contract pharmacies. Covered entities also should be required to submit the results of these annual audits to HRSA along with a corrective action plan if their audit reports have found 340B program violations.

Public Health Emergencies

- Generally, PhRMA supports HRSA's proposal to provide for "flexibilities" regarding certain aspects of the 340B program in instances where the HHS Secretary has declared a public health emergency, however, we request that HRSA explain (1) how it would decide when a particular public health emergency warranted an exception to 340B requirements; (2) whether it believes it could grant exceptions to statutory requirements; and (3) whether any final guidance would replace the current guidance on public health emergencies that appears on HRSA's website. HRSA also should assure stakeholders that it will exercise these flexibilities very carefully, only when needed, and in a manner consistent with the 340B statute.

¹¹ 42 U.S.C. § 256b(b)(5)(C), (d)(1)(B)(v).

I. ENSURING CLARITY IN THE FINAL OMNIBUS GUIDANCE AND THE OVERALL BODY OF 340B GUIDANCE

HRSA's Proposed Guidance covers a wide range of topics, many of which have been addressed in various documents, including Federal Register notices and policy releases, over the life of the program. PhRMA urges HRSA to state clearly in the final omnibus guidance that it supersedes all prior guidance on the topics covered, and also to ensure that the substance of all prior guidance that HRSA intends to keep applying is explicitly incorporated into the final guidance. As the Office of Management and Budget's Bulletin for Agency Good Guidance Practices emphasized, in developing significant guidance documents "agencies should be diligent to identify for the public whether there is previous guidance on an issue and, if so, to clarify whether that guidance document is repealed by the new significant guidance document completely and, if not, to specify what provisions in the previous guidance document remain in effect."¹² This will be critically important to ensure that stakeholders are not left guessing as to whether certain portions of prior HRSA guidance remain in force, and will make the final guidance an "omnibus" guidance document, as intended.

We also urge HRSA to clarify its views on 340B program issues communicated by the 340B prime vendor. It is unclear to many stakeholders why the 340B prime vendor (currently Apexus) is empowered to communicate HRSA's view on 340B program issues or why FAQs and other statements by the 340B prime vendor should be taken as HRSA interpretations of the 340B law or otherwise given weight on issues concerning 340B program requirements. Formal documented clarification by HRSA (rather than only oral assurances by OPA and Apexus staff) of the status of prime vendor FAQs and other materials would minimize confusion for all stakeholders.

We recommend that in the final guidance HRSA also take the opportunity to resolve and eliminate inconsistencies between some of its statements in the Proposed Guidance itself, and between statements in the Proposed Guidance and other HRSA documents. With respect to resolving inconsistencies within the Proposed Guidance itself, we think that the potential for inconsistencies can be reduced by structuring the final guidance to consolidate the discussion of a particular topic in one place. The Proposed Guidance in several cases contains inconsistent or potentially inconsistent pronouncements on certain topics in the initial preamble-like discussion (Section II, "Summary of the Proposed Guidance") vs. the later Section III, "Proposed Guidance." Bringing all the discussion of a particular issue together in one place may help HRSA to identify and then resolve conflicting or potentially conflicting statements that now appear in the Proposed Guidance, which will improve clarity and readability and reduce uncertainties for stakeholders.

Finally, we recommend that the final guidance list a date after its publication on which it becomes effective (i.e., HRSA will not rely on any new statutory interpretations contained in the guidance until after the listed effective date).

¹² 72 Fed. Reg. 3432, 3436 (Jan. 25, 2007).

II. 340B ELIGIBILITY

A. Grantee Eligibility

HRSA's discussion in the Proposed Guidance of non-hospital (grantee) eligibility states:

An associated site [which is defined as "a health care delivery site which is not located at the same physical address as a non-hospital covered entity, but is part of and delivers outpatient services for the non-hospital covered entity"] which is authorized to provide health care services through the scope of a Federal grant, Federal project, Federal designation or Federal contract of a covered entity as defined in Section 340B(a)(4)(A)-(K) of the PHSA may be eligible to participate in the 340B Program . . . The child site will be listed on the public 340B database, and can purchase and use 340B drugs, if the Departmental division which oversees such grant, project, designation or contract verifies the eligibility.¹³

It is unclear whether an associated site would need to be part of the same corporate entity as the non-hospital covered entity, or whether it could be a separate corporate entity. HRSA should clarify that an associated site must be part of the same corporate entity as the non-hospital covered entity. Permitting an associated site to be part of a separate corporate entity that does not itself qualify to participate in the 340B program would expand the program beyond the intent of the 340B statute.

HRSA also proposes permitting "sub-recipients of federal grants" to register independently for the 340B program if they receive "eligible Federal funds, or in-kind contributions purchased with eligible Federal funds."¹⁴ We are not aware of any statutory provision authorizing an organization to participate in the 340B program by virtue of receiving in-kind contributions purchased with federal funds. We ask that HRSA clarify this point, and also clarify whether this eligibility theory is limited to clinics that treat sexually transmitted diseases or tuberculosis, as a HRSA FAQ suggests.¹⁵ In addition, it is unclear whether the "sub-recipients"

¹³ 80 Fed. Reg. at 52316.

¹⁴ 80 Fed. Reg. at 52301.

¹⁵ An FAQ on HRSA's 340B website provides as follows:

Can the receipt of in-kind contributions through section 317 or 318 of the Public Health Service Act (PHSA) qualify an entity for participation in the 340B Drug pricing Program? What are in-kind contributions for purposes of 340B Program Eligibility?

An entity receiving in-kind contributions through section 317 or 318 may qualify for the 340B Drug Pricing Program provided all the remaining 340B requirements are met. Qualifying in-kind contributions must be paid for by section 317 or 318 grant funds to qualify a site as 340B eligible. In-kind contributions may be in the form of real property, equipment, supplies and other expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.

HRSA discusses are “child sites” of a parent covered entity or different organizations that receive a sub-grant from a grantee covered entity.¹⁶ While we would appreciate more detail regarding this proposal, we support the concept of permitting sub-recipients of federal grants to be eligible non-hospital covered entities listed independently on HRSA’s database and independently responsible for compliance with all program requirements provided that sub-recipients are limited to separately incorporated entities that (i) receive a sub-award of a portion of a grantee’s grant from the grantee; and (ii) would themselves meet the requirements to be a grantee or are Hemophilia Treatment Centers determined to meet the requirements of a sub-recipient grant of the Maternal and Child Health Bureau HRSA Hemophilia grant program.

B. Hospital Eligibility

All 340B hospitals – whether disproportionate share (DSH) hospitals, free-standing cancer hospitals, children’s hospitals, sole community hospitals, rural referral centers, or critical access hospitals – must (among other things) meet specified standards covering the hospital’s relationship with the government: i.e., the hospital either must be publicly owned or operated, or must be a private nonprofit hospital (1) “formally granted governmental powers” by an unit of State or local government, or (2) that has a “contract with a “State or local government to provide health care services to low-income individuals who are [ineligible for Medicare and Medicaid].”¹⁷ The two private hospital categories collectively account for 80% of 340B sales to DSH hospitals (which in turn account for about 81% of all 340B sales to hospitals).¹⁸

With respect to a private nonprofit hospital that is “formally granted governmental powers,” the Proposed Guidance (which is similar to a 2013 policy release)¹⁹ provides that “[e]xamples of governmental powers include, but are not limited to, the power to tax, issue government bonds, and act on behalf of the government.”²⁰ PhRMA appreciates HRSA providing these examples. However, we are concerned by the idea that the power to “act on

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See HRSA website for 340B Drug Pricing Program FAQs under the topic “340B Program Eligibility” available at: <http://www.hrsa.gov/opa/faqs/index.html>. The 317 and 318 references relate to 42 U.S.C. § 256b(A)(4)(K), which lists as 340B-eligible “an entity funded under Public Health Service Act section 318 (relating to the treatment of sexually transmitted diseases) or section 317(j)(2) (relating to treatment of tuberculosis), but only if the entity is certified by the Secretary pursuant to paragraph [256b(a)](7).” HRSA’s 340B website identifies PHS §§ 317 and 318 as 42 U.S.C. §§ 247b as and 247c, respectively; our review of these provisions did not shed any light on why the receipt of in-kind donations financed under these provisions would make an organization 340B-eligible.

¹⁶ HRSA’s proposed, but never finalized, 2007 notice relating to the definition of a “patient” included a brief discussion on “subgrantees and subcontractors,” which seemed to indicate that these subawardees are separate organizations from the covered entity grantee. 72 Fed. Reg. 1543, 1546-47 (Jan. 12, 2007).

¹⁷ 42 U.S.C. § 256b(a)(4)(L)(i), (M) - (O).

¹⁸ Sales data from Apexus Update 2015 – 340B Coalition Winter Meeting; Number of Entities from Avalere Health analysis of the 340B database in March 2015.

¹⁹ “Clarification of Eligibility for Hospitals that are not Publicly Owned or Operated,” Release No. 2013-3 (March 7, 2013).

²⁰ 80 Fed. Reg. at 52301. Guidance also states that “governmental powers” do not include “powers generally granted to private persons or corporations upon meeting of licensure requirements, such as a license to practice medicine or provide health care services commercially.” *Id.* We agree with this statement, except that “governmental powers” should not include “provid[ing] health care” (whether “commercially” or non-commercially) because providing healthcare is an activity or in some circumstances an obligation, but it is not a “power.”

behalf of the government” is a “governmental power,” because this could mean anything. This phrase could introduce ambiguity and invite any private nonprofit hospital seeking to avail itself of 340B discounts to assert that it is carrying out some activity -- providing healthcare, filing reports on communicable disease outbreaks, providing information to the public on community health care resources, etc. -- “on behalf of” a unit of government, and thus has been granted “governmental powers” that make it 340B-eligible. We urge HRSA to distinguish clearly in its final guidance between exercising a bona fide governmental “power” and simply performing an activity. Equally important, HRSA should require that the governmental powers in question must directly relate to the provision of healthcare (as opposed to some type of power unrelated to the provision of healthcare, e.g., the power of eminent domain). This common sense approach would help to ensure that the 340B program does not further expand beyond the limitations envisioned by Congress.

With respect to the second 340B eligibility pathway for private nonprofit hospitals -- having “a contract with a State or local government to provide health care services to low income individuals [ineligible for Medicare and Medicaid]”²¹ -- the Proposed Guidance is substantively the same as HRSA’s current guidance.²² HRSA would require that the hospital and a representative of the governmental unit in question submit a statement that “a contract is currently in place between the private nonprofit hospital and the state or local government to provide health care services to low-income individuals who are not entitled to Medicare or Medicaid.”²³ The contract “should create enforceable expectations for the provision of health care services, including the provision of direct medical care.”²⁴

Notably, HRSA does not propose: (1) that the hospital submit the contract to HRSA; or (2) that the contract require the hospital to provide any particular amount of care to low-income people ineligible for Medicare and Medicaid. A 2011 GAO report identified the lack of these requirements as deficiencies in HRSA’s guidance on private hospital eligibility. GAO stated:

HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals. Therefore, hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended.²⁵

In enacting the 340B law, Congress expressly emphasized that it would not allow participation by a private nonprofit hospital with “a minor contract to provide indigent care which

²¹ 42 U.S.C. § 256b(a)(4)(L)(i).

²² “Clarification of Eligibility for Hospitals that are not Publicly Owned or Operated,” Release No. 2013-3 (March 7, 2013).

²³ 80 Fed. Reg. at 52301.

²⁴ 80 Fed. Reg. at 52301.

²⁵ “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement.” (Sept. 2011) at 23 (emphasis added).

represents an insignificant portion of its operating revenues,” and described the law as reducing drug costs for “specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans.”²⁶ By failing to specify that a minor contract to provide care to low-income uninsured individuals cannot make a private hospital 340B-eligible, HRSA invites abuse, by opening the program to many private hospitals that Congress never intended to become 340B-eligible. This failure to set any minimum threshold for the contractually-required care provided to low-income uninsured individuals likely also accounts for the startling percentage of U.S. hospitals that participate in 340B today. As noted earlier, the GAO reported recently reported that a full 40% of U.S. hospitals now participate in the 340B program; similarly, RAND estimates that 340B hospitals now account for approximately 48% of outpatient hospital visits in the U.S.²⁷

In its final guidance, HRSA should follow GAO’s recommendations and take the opportunity to: (1) require that a hospital seeking 340B eligibility based on a contract with a unit of government to care for low-income individuals ineligible for Medicare and Medicaid submit the contract for HRSA to review (which would enable HRSA to check whether the contract creates “enforceable expectations” for the provision of “direct medical care,” as well as the amount of care required); and (2) provide that a hospital’s contract with a state or local government will only make the hospital 340B-eligible if the contract requires the hospital to provide more than a minor amount of medical care to low-income uninsured patients (as determined by whether the level of care required under the contract meets or exceeds a specified threshold).

HRSA should also list each hospital’s eligibility pathway on the 340B covered entity database. Specifically, HRSA should include in the database whether a hospital is 340B-eligible because it is (1) publicly owned or operated; (2) a private nonprofit hospital formally granted governmental powers by a unit of State or local government (in which case the database should also list the power granted to the hospital, the unit of government that granted the power, and the instrument that granted the power and its date); or (3) a private nonprofit hospital that has a contract with a State or local government to provide health care services to low-income individuals who are ineligible for Medicare and Medicaid (in which case the database should also list the unit of government with which the hospital has contracted, the date of the contract, and a summary of the hospital’s specific contractual obligations to provide healthcare for low-income individuals ineligible for Medicare and Medicaid). To promote transparency in the program, this information then could be made available to stakeholders by incorporating into the HRSA 340B database a hospital sub-category that would identify how each individual hospital is eligible under the program.

To participate in 340B, all hospitals (except critical access hospitals) must meet a statutorily prescribed disproportionate share (DSH) adjustment percentage for the most recent cost reporting period.²⁸ Although PhRMA understands that HRSA may not deviate from the DSH adjustment percentages set forth in the statute, we wanted to take this opportunity to mention the problems associated with using the DSH metric for 340B eligibility purposes. The

²⁶ H.R. Rep. 102-384 (II) (1992), 12 (emphasis added).

²⁷ The RAND Corporation, *The 340B Prescription Drug Discount Program: Origins, Implementation, and Post-Reform Future* at 8 (2014).

²⁸ The minimum percentage is 11.75% for DSH, cancer, and children’s hospitals and 8% for sole community hospitals and rural referral centers.

DSH adjustment percentage has two flaws as a 340B eligibility criterion. First, the DSH adjustment percentage reflects care provided to low-income Medicare and Medicaid patients, but does not account for care provided by a hospital to uninsured or charity care patients who the 340B program is intended to benefit. Second, the DSH metric only reflects inpatient care, while the 340B program is limited to outpatient drugs. As a result, a hospital could potentially provide no charity care – inpatient or outpatient – and satisfy the applicable DSH adjustment percentage requirement.

In 2011, GAO concluded that “current HRSA guidance may allow some entities to be eligible for the program that should not be. Hospitals qualify for the 340B program in part based on their DSH adjustment percentage... [and while] nearly a third of all hospitals in the U.S. are participating in the 340B program, more are currently eligible and not participating, and more may become eligible as Medicaid is expanded through PPACA.”²⁹ Further, GAO noted:

as the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system. As such, it is critically important that HRSA take additional action to ensure that eligibility for the 340B program is appropriately targeted.³⁰

While the distortions in 340B eligibility associated with the DSH adjustment percentage await a legislative solution, they also increase the importance of HRSA using its existing tools to target hospital eligibility appropriately. Therefore, we urge HRSA to establish appropriate criteria in its final guidance for determining whether private hospitals have been “formally granted governmental powers” or have a contract with a state or local government to care for low-income uninsured individuals. Particularly given the large percentage of 340B sales these private hospitals account for, to align the 340B program with its statutory purpose and avoid the unintended consequences GAO warned about, it is essential that HRSA interpret the private hospital eligibility criteria in a reasonable and specific manner.

C. The GPO Prohibition

By law, DSH, children’s, and cancer hospitals are ineligible for the 340B program if they obtain “covered outpatient drugs”³¹ through a GPO or other group purchasing arrangement.³² In its Proposed Guidance, HRSA proposes three exceptions to the GPO prohibition:

²⁹ “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement,” supra, at 34.

³⁰ “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement,” supra, at 34.

³¹ PhRMA understands that in some cases there may be confusion as to whether these covered entities may purchase vaccines through a GPO or other group purchasing arrangement. For clarity, PhRMA recommends that HRSA state in its final guidance that the GPO prohibition only relates to purchases of covered outpatient drugs, and does not apply to vaccines as they are excluded from the definition of “covered outpatient drug” under Social Security Act § 1927(k)(2)(B).

³² 42 U.S.C. § 256b(a)(4)(L)(iii).

- An off-site outpatient facility not participating in 340B or listed on the 340B database may purchase covered outpatient drugs through GPOs if it has a separate purchasing account and does not provide drugs purchased through GPOs to the parent hospital or 340B-participating child sites;
- A hospital would not lose 340B eligibility by providing a 340B drug to an “inpatient” whose status is later changed to outpatient by a third party or due to a hospital review; and
- An exception would be allowed “to prevent disruptions in patient care” if the hospital “cannot access a drug at the 340B price or at [WAC],” provided that the hospital documents the facts surrounding the purchase, provides HRSA with the name of the drug, and describes its attempts to purchase the drug at the 340B price and WAC before purchasing through a GPO.³³

PhRMA is puzzled by the third proposed exception. As a practical matter, we do not understand how a drug could be unavailable at both the 340B price and WAC, yet somehow be available for purchase via a GPO. Perhaps, the exception is meant for when a hospital has GPO inventory on hand but no 340B or WAC priced product available for immediate patient use. In any case, we are unaware of any statutory provision that would permit such an exception. Accordingly, we recommend that HRSA not finalize this proposed exception and instead recognize that the statute makes compliance with the GPO prohibition a condition of eligibility for DSH, cancer, and children’s hospitals. HRSA may not extend eligibility to hospitals that are ineligible to participate due to violating an applicable eligibility requirement, and should make this point clear.

The Proposed Guidance also states that a “large number of hospitals use replenishment models to operationalize the 340B Program,” and refers to HRSA’s 2013 guidance on the interaction between replenishment models and the GPO prohibition.³⁴ HRSA states that where a 340B hospital subject to the GPO prohibition uses a replenishment model and orders drugs based on actual prior usage, it may not “tally 340B-ineligible outpatient use for drug orders on a GPO account” (because this amounts to buying covered outpatient drugs via a GPO).³⁵ Under the Proposed Guidance, hospitals must maintain records demonstrating that replenishment models/split billing software are not being used “contrary to statute.”³⁶

As explained further in Section VI.B, a 340B drug should only be dispensed to an individual who is clearly identified – at the point of sale – as a “patient” of the 340B covered entity. We believe that the concepts of “re-characterizing” a drug dispensed to an individual not initially identified as a “patient,” or “banking,”³⁷ are inappropriate and invite diversion. If HRSA

³³ 80 Fed. Reg. at 52305.

³⁴ 80 Fed. Reg. at 52305 (referencing Policy Release No. 2013-1, “Statutory Prohibition on Group Purchasing Organization Participation” (Feb. 2013)).

³⁵ 80 Fed. Reg. at 52305.

³⁶ 80 Fed. Reg. at 52305.

³⁷ 80 Fed. Reg. at 52308.

were to permit re-characterization (which PhRMA opposes) then HRSA should: (1) establish a short and specified timeframe after which no re-characterization could take place; and (2) require that any covered entity wishing to re-characterize must first notify the manufacturer and provide the manufacturer with a fully transparent audit trail demonstrating that any units of drug the entity seeks to re-characterize as 340B drugs were not initially purchased under 340B, did not generate a Medicaid rebate, and were dispensed to a covered entity “patient” in the quarter for which the covered entity is seeking the 340B price.

D. Hospital Child Site Eligibility

1. Proposed Guidance and Background

The 340B law makes certain hospitals eligible for 340B participation. The statute describes these hospitals with great specificity. But the statute never mentions outpatient facilities associated with a 340B hospital. It was HRSA that decided that outpatient facilities of a 340B hospital may participate in 340B, and decided which outpatient facilities may participate. In 1994 guidance (which remains in effect), HRSA reasoned that certain off-site outpatient facilities could properly participate in 340B because

Section 340B(a)(4)(L) describes a subset of “hospitals” as defined in section 1886(d)(1)(B) of the Social Security Act as eligible to participate in the program. Because section 1886 addresses Medicare payment for hospital inpatient services only, the scope of the term “hospital” has been limited to the hospital inpatient services. However, section 340B deals exclusively with outpatient drugs. Although Congress clearly intends this narrow definition be used to identify the Medicare disproportionate share hospitals which are eligible for section 340B drug discounts, we do not believe it is reasonable to use this same definition to limit where the section 340B outpatient drugs can be used. Some disproportionate share hospitals offer outpatient services in off-site or satellite outpatient facilities. Further, the movement of nonprofit hospitals in recent years has been to reorganize and offer a variety of services, other than traditional inpatient hospital services, through separate divisions, lines of business, or entities. Therefore, for purposes of section 340B drug discounts, a further interpretation of “hospital” is needed.³⁸

The 1994 guidance further concluded that an outpatient facility of a 340B hospital may participate in 340B if it is an “integral part” of the hospital (as evidenced by the facility being “a reimbursable facility included on the hospital’s Medicare cost report”).³⁹

Under the Proposed Guidance, an off-site outpatient facility would be eligible to participate in 340B if: (1) the site is listed on a line of the hospital’s Medicare cost report that is

³⁸ 59 Fed. Reg. 47884, 47885 (Sept. 19, 1994) (emphasis added). This guidance only addressed DSH hospitals, because they were the only category of 340B-eligible hospital at that time. Outpatient facilities that are permitted to participate in 340B and registered with HRSA are now called “child sites.”

³⁹ 59 Fed. Reg. at 47886.

reimbursable; and (2) the services provided at the site “have associated outpatient Medicare charges and costs.”⁴⁰ The second requirement apparently means that the child site must provide at least some Medicare-reimbursed outpatient services. For outpatient facilities of children’s hospitals, the Proposed Guidance would require that the registration demonstrate that the site: (1) is an integral part of the hospital; and (2) would be included on a reimbursable line on a Medicare cost report and have reimbursable charges and costs if a cost report were filed.⁴¹

Although HRSA currently uses the “cost report test” as a way to determine whether an outpatient facility is an “integral part” of the 340B hospital, the Proposed Guidance does not mention the underlying integral part standard (except with respect to children’s hospital child sites). We recommend that HRSA provide that an off-site outpatient facility may not participate in 340B (even assuming it passes the cost report test) unless it is an integral part of a 340B hospital. While the cost report test may often be a good indicator that a facility is an integral part of the hospital, this will not always be the case. Moreover, Medicare’s rules on when a facility may be listed as reimbursable on a hospital cost report are not fully transparent.⁴²

Our understanding is that HRSA generally reviews relevant sections of the cost report to see if the outpatient site in question is included as reimbursable, but does so without looking behind the hospital’s decision to treat a facility as reimbursable on the cost report, and thus without applying any substantive standards to this issue, which is problematic. Moreover, even determining whether a particular facility is included as reimbursable on the hospital’s cost report is not always straightforward; for example, HRSA has previously said that it reviews additional documentation (beyond the cost report) “in cases where the name of the clinic is not the same as the [name on the] cost reporting listing”⁴³ -- thus raising questions about the transparency and objectivity of the cost report test, even apart from whether it is grounded in any substantive standards.

It is crucial that HRSA retain the “integral part” test and develop clear standards for its application. The requirements that a facility be listed as reimbursable on the hospital’s cost report and have outpatient services paid by Medicare are necessary but not sufficient conditions for recognizing an outpatient facility as an integral part of a covered entity hospital. Unless a hospital outpatient facility is truly an integral part of the covered entity hospital, there is no statutory basis for treating the facility as 340B-eligible -- or for treating patients of that facility as patients of the covered entity hospital. We discuss the integral part standard and how it should be applied below.

⁴⁰ 80 Fed. Reg. at 52302 (emphasis added).

⁴¹ 80 Fed. Reg. at 52302.

⁴² However, Medicare regulations indicate that an outpatient facility must be provider-based in relation to the main hospital in order to be treated as reimbursable on the hospital’s cost report. This is because (1) costs of servicing “free-standing” facilities must be eliminated from the allowable costs shown in the hospital’s cost report, which “may be done by including the costs of the free-standing entity on the cost report as a non-reimbursable cost center” (42 C.F.R. § 413.24(d)(7)) and (2) a “free standing” facility is one that is “not integrated with any other entity as a main provider, a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity” (the categories covered by the provider-based regulation) (42 C.F.R. § 413.65(a)(2)).

⁴³ October 21, 2011 HRSA letter to Senator Charles Grassley responding to questions about the 340B program.

2. HRSA's "Integral Part" Guidance

HRSA's current guidance, published in a 1994 final notice, set out its policy on when outpatient facilities of a 340B hospital could participate in 340B. In explaining its reasoning, HRSA emphasized that the off-site facility should be well integrated with the hospital:

When a [hospital] attempts to certify multiple components as a single hospital for purposes of Medicare certification, it must follow guidelines developed by HCFA [now CMS]. These guidelines (Provider Certification, State Operation Manual, section 2024) establish tests to determine whether an additional hospital facility, geographically separated but in the same metropolitan area, is a separate facility from or a component of a single hospital. These tests include: (a) all components subject to the control and direction of one common owner (i.e., governing body) which is responsible for the operational decisions of the entire hospital enterprise; (b) one chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of all components; (c) integration of the organized medical staff (e.g., all medical staff members having privileges at all components); and (d) one chief executive officer through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of all components

If the off-site clinic meets these tests, it would be included in the [hospital's] Medicare cost report. This test clearly determines whether a facility is an integral part of a . . . hospital, and is an appropriate standard to determine [340B] eligibility. It incorporates Medicare criteria that are not ambiguous and forms an independent and objective basis on which to determine eligibility.⁴⁴

Based on this reasoning, HRSA adopted the following policy: "The outpatient facility is considered an integral part of the 'hospital' and therefore eligible for section 340B drug discounts if it is a reimbursable facility included on the hospital's Medicare cost report."⁴⁵

3. Medicare's "Provider-Based" Regulation

As noted above, HRSA's 1994 guidance on hospital outpatient facilities referenced guidance from § 2024 of the Centers for Medicare & Medicaid's (CMS') State Operations Manual. As described by HRSA, this manual provision only permitted an outpatient facility to be treated as part of a hospital if certain tests were met regarding integration of the outpatient facility and the hospital.⁴⁶ CMS revised this manual provision at some point after 1994, and it no

⁴⁴ 59 Fed. Reg. at 47885 (emphasis added).

⁴⁵ 59 Fed. Reg. at 47886.

⁴⁶ HRSA described these tests as follows: "(a) all components [of the hospital] subject to the control and direction of one common owner (i.e., governing body) which is responsible for the operational decisions of the entire hospital

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longer lists specific criteria for outpatient facilities to be certified as part of a single hospital, but does provide that “where two or more previously separate hospitals merge, all locations of the surviving hospital must meet the criteria found in [State Operations Manual] § 2004” and “all non-hospital providers . . . that state they are part of a single hospital must meet the criteria for provider-based designation in § 2004 in order to be treated as a single hospital for payment purposes.”⁴⁷ In turn, section 2004 refers to the provider-based rules at 42 C.F.R. § 413.65.⁴⁸ Thus, the State Operations Manual provision HRSA cited in its 1994 guidance now leads to 42 C.F.R. § 413.65, Medicare’s provider-based regulation.

The provider-based regulation, promulgated after HRSA’s 1994 guidance, is designed to determine whether a particular facility is “a subordinate and integrated part of the main provider”⁴⁹ (generally a hospital), and thus may bill Medicare as a part of the hospital.⁵⁰ As CMS has explained, the provider-based regulation “provides a high level of assurance that a facility complying with [the regulation] is, in fact, an integral and subordinate part of [the main provider] and does not accord provider-based status to facilities that . . . have only a nominal relationship with [the main] provider.”⁵¹

The requirements for “provider-based” status generally parallel the types of integration requirements cited in HRSA’s 1994 guidance. While these requirements vary to some extent for different types of facilities (e.g., off-campus facilities must satisfy additional requirements not applicable to facilities on the hospital campus), the provider-based regulation includes requirements on (among other things) common licensure of the hospital and the facility; integration of clinical services performed by the hospital’s and the facility; financial integration of the hospital and facility; common ownership and control of the hospital and facility; common administration and supervision of the hospital and facility; and public awareness that the facility is part of the hospital.⁵² HRSA proposed in 2007 to use the provider-based regulation to decide

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enterprise; (b) one chief medical officer who reports directly to the governing body and who is responsible for all medical staff activities of all components; (c) integration of the organized medical staff (e.g., all medical staff members having privileges at all components); and (d) one chief executive officer through whom all administrative authority flows and who exercises control and surveillance over all administrative activities of all components.” 59 Fed. Reg. at 47885.

⁴⁷ CMS, State Operations Manual § 2024.

⁴⁸ CMS, State Operations Manual § 2004 (emphasis added).

⁴⁹ CMS Program Memorandum A-03-030 (Apr. 18, 2003).

⁵⁰ A “provider-based entity” means “a provider of health care services . . . that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section.” 42 C.F.R. § 413.65(a)(2).

⁵¹ 67 Fed. Reg. 49981, 50088 (Aug. 1, 2002).

⁵² 42 C.F.R. § 413.65(b)(3)(ii). Currently, a hospital is not required to obtain CMS’ approval to treat a particular entity as provider-based, but it may do so at its option by submitting to CMS a form attesting that the facility in question meets the relevant tests for provider-based status. CMS determines whether the facility is provider-based in relation to the hospital after the hospital submits a completed form attesting to the facility’s compliance with the applicable provider-based criteria and (for an off-campus facility) supplies “documentation of the basis for its attestations.”

whether an outpatient facility of a covered entity hospital could participate in 340B, explaining that:

In order for an outpatient facility of a DSH to be eligible for the 340B program, it must be demonstrated that the outpatient facility is an integral part of the DSH. . . . HRSA believes that the requisite integration of facilities necessary to demonstrate that the secondary facility is functioning as part of the DSH under 42 CFR 413.65 is appropriate for facilities eligible under the 340B Program. Compliance with the rule for provider-based facilities would provide clear guidance to DSHs that wish to prescribe 340B drugs to patients at these outpatient facilities and ensure that the individuals are truly patients of the DSH.⁵³

4. Summary of PhRMA Recommendations Regarding “Child Site” Status for Hospital Outpatient Facilities

As discussed earlier, the 340B statute makes certain hospitals 340B-eligible, but does not provide that any of their associated outpatient facilities are 340B-eligible, or even mention 340B hospitals’ outpatient facilities. It was HRSA that decided that certain outpatient facilities of a 340B hospital could share the hospital’s 340B status. Originally, 340B eligibility criteria, was based upon a formula that reflected the activity at the (parent) hospital in terms of the needier patients that the hospital served. Yet, HRSA has failed to set up any guardrails on outpatient expansion. To make HRSA’s outpatient facilities approach defensible, however, any off-site outpatient facility that is treated as a part of the hospital for 340B purposes must be a genuinely well-integrated part of the hospital, which shares the characteristics of the hospital that make it 340B-eligible.

To provide a defensible basis for allowing an off-site hospital facility that is not described in the 340B law to participate in the 340B program, HRSA should establish several criteria. First, HRSA should reaffirm its substantive “integral part” concept, but with strengthened standards that would provide greater clarity for stakeholders and assure alignment with the text and purpose of the 340B law. In its final guidance, HRSA should therefore specify that to be “an integral part” of a covered entity hospital, an outpatient facility must: (1) meet the provider-based standards in 42 C.F.R. § 413.465;⁵⁴ (2) be wholly owned by the hospital; and (3) be listed

⁵³ 72 Fed. Reg. 1543, 1545, (Jan. 12, 2007) (emphasis added).

⁵⁴ HRSA states in the Proposed Guidance that it has previously explored the use of 42 C.F.R. § 413.65, but many hospitals choose not to seek provider-based designation for outpatient facilities “even though these facilities may qualify” and it has had “difficulty in verifying whether outpatient facilities and clinics meet provider-based standards.” 80 Fed. Reg. at 52302. However, if HRSA wants to avoid difficulties in verifying provider-based status, HRSA could require that hospitals get provider-based determinations approved by CMS – which is an option under the provider-based regulation if a hospital wishes to be certain that a particular facility qualifies as provider-based; this would also provide a simple mechanism for testing whether hospital facilities that assertedly qualify as provider-based actually do.

Moreover, HRSA’s reference to past comments on the use of the provider-based regulation likely refers to the March 13, 2007 letter of 340B Health (then called Safety Net Hospitals for Pharmaceutical Access (SNHPA)). This letter brazenly complained that facilities that assertedly “may meet the eight regulatory standards [for provider-based status]” but that CMS does not designate as provider-based facilities include “ambulatory surgical centers, home health agencies, ESRD facilities, and skilled nursing facilities.” SNHPA March 13, 2007 letter to HRSA, “Comment on

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as reimbursable on the hospital's Medicare cost report and have Medicare outpatient charges.⁵⁵ We also recommend a more stringent review of the cost report. Specifically, HRSA should confirm that there are outpatient claims on the report for service dates within the most recent 12 month period. In addition, HRSA should require that the actual name of the child site appears on the cost report listing -- not a different name, or just a bundled dollar figure representing multiple clinics. There should be no "piecing together" of various external documents needed to confirm the identity of the child site.

PhRMA is deeply concerned about the explosive growth in hospital "child sites" generally, and in particular about 340B hospital-acquired physician practices that are treated as 340B-eligible "hospital outpatient departments" following the acquisition. There is no public policy reason or statutory basis for these new children to be partaking of 340B benefits when they are distinct from the safety net "parent" and (consistent with the fact that they are not an integral part of the parent) serve a different demographic than a true safety net facility. This trend is extending the 340B program -- a drug discount program intended for safety net facilities that serve the uninsured and vulnerable --much deeper into our healthcare system than Congress intended and the law permits, while taking the program further and further from its mission.

This problem helps to highlight the importance of HRSA requiring that "child sites" of 340B hospitals must meet the provider-based standards in 42 C.F.R. § 413.65. The provider-based regulation has a special provision with particular relevance to free-standing physician practices that are acquired by a hospital, which provides that: "A facility that is not located on the campus of a hospital and that is used as a site where physician services of the kind ordinarily furnished in physician offices are furnished is presumed as a free-standing facility [i.e., not a provider-based facility], unless CMS determines the facility has provider-based status."⁵⁶ This provision indicates that an acquired physician practice (assuming it is not located on the hospital campus) could not qualify as a provider-based entity unless the hospital went through the attestation process and obtained a CMS determination that the practice qualified as provider-based in relation to the hospital -- which would require that the practice actually be a well-integrated part of the main hospital, as indicated by specific tests set out in the regulation. In light of the growing (and often inappropriate) expansion of the 340B program to these hospital acquired physician practices, it is more important than ever to apply the provider-based rule as a safeguard in this context. PhRMA urges HRSA to do so.

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Proposed Guidelines on 340B Patient Definition (Published in 72 Fed. 1543, 1546 (January 12, 2007))," at 16, 17 (emphasis added). Congress plainly did not make ASCs, home health agencies, ESRD facilities, or nursing facilities eligible to participate in the 340B program. Consequently, it should not be necessary to take any special measures to keep these various facilities out of the program -- they are just not hospitals of any sort, child or otherwise. If requiring that hospital "child sites" have provider-based status helps to keep these facilities out of this program for which they are ineligible, however, then this is more evidence about how critically importance it is for HRSA to institute this reform.

⁵⁵ PhRMA understands that there may be some hospitals that do not serve Medicare patients. We think that it would be appropriate for HRSA not to apply the requirement that there be Medicare outpatient charges in these limited instances.

⁵⁶ 42 C.F.R. § 413.65(b)(4) (emphasis added).

We also recommend that a child site must: (1) provide the full range of outpatient health care services (not just drugs or drug administration services); (2) adhere to the parent hospital's charity care policy; and (3) adhere to the sliding scale fee schedule (if any) of the parent hospital for providing covered outpatient drugs to low-income patients who do not have minimum essential coverage (as defined in section 5000A(f) of the Internal Revenue Code). Further, HRSA should require the 340B hospital to demonstrate, when seeking to register a would-be child site, that the site serves similar patient mix as the parent (*i.e.*, the hospital should demonstrate that the child site serves a patient population with a mix of low-income and uninsured patients similar to that of the parent hospital's outpatient and emergency departments).

To implement this policy, HRSA should develop a methodology, with stakeholder input, to determine whether a hospital outpatient facility has a similar percentage of low-income patients as the parent hospital.⁵⁷ As it will take some time to develop such methodology (in addition to refining any documentation requirements to be applied to the remainder of the child site criteria), it would be appropriate and sensible for HRSA to put a temporary moratorium on enrollment of new child sites for nonprofit private hospitals as it considers this issue. Such a moratorium is critically important because recent research suggests that hospital child sites increasingly are located in areas serving patient populations that are more affluent than the parent hospital's patient population, and that the 340B statute was never intended to assist.⁵⁸ "Compared to 340B DSH hospitals," this study reports, their child sites "served communities with lower poverty rates and higher mean and median income levels than their 340B DSH parents did," thus "suggesting that the expansion among DSH hospitals run counter to the program's original intention."⁵⁹ Given that the 340B law does not even refer to off-site outpatient facilities being 340B-eligible in the first instance, there clearly is no justification for admitting those facilities to the 340B program if they are not even integral parts of 340B hospitals that share the characteristics making the parent 340B-eligible by serving a disproportionate share of the uninsured, or underinsured and indigent patient population.

III. THE "COVERED OUTPATIENT DRUG" DEFINITION

The 340B law applies to "covered outpatient drugs," and defines this term by reference to Social Security Act § 1927(k).⁶⁰ Social Security Act § 1927(k)(3), the limiting definition, excludes from the definition of covered outpatient drugs a drug that is "provided as part of or as incident to and in the same setting as [specified services, including hospital inpatient and outpatient services]" and "for which payment may be made under this title [Social Security Act title XIX, the Medicaid statute] as part of payment for [the specified services] and not as direct

⁵⁷ The DSH metric is not available to evaluate whether an outpatient facility serves a patient mix similar to the parent as it is based solely on inpatient days; therefore HRSA would need to evaluate different candidate measures that could be used to assess whether an outpatient facility serves low-income patients (or perhaps low-income Medicare and Medicaid patients specifically) to the same extent as the covered entity hospital.

⁵⁸ Rena M. Conti and Peter B. Bach, The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities, *Health Affairs*, 33 no. 10 (2014): 1786-1792.

⁵⁹ Conti and Bach, The 340B Drug Discount Program; Hospital Generate Profits By Expanding to Reach More Affluent Communities, *supra*, at 1790.

⁶⁰ 42 U.S.C. § 256b(b)(1).

reimbursement for the drug.”⁶¹ In the Proposed Guidance, HRSA repeats its 1994 guidance stating that:

in the settings identified in the limiting definition, “if a covered drug is included in the *per diem* rate (i.e., bundled with other payments in an all-inclusive, a per visit, or an encounter rate), it will not be included in the [340B Program]. However, if a covered drug is billed and paid for instead as a separate line item as an outpatient drug in a cost basis billing system, this drug will be included in the program.”⁶²

This longstanding guidance is consistent with the covered outpatient drug definition in Social Security Act § 1927(k), and thus consistent with the 340B law.⁶³

HRSA’s Proposed Guidance, however, would then broaden what would be considered a “covered outpatient drug” under the 340B program by interpreting the limiting definition in such a way that it would only apply to a drug provided as part of the services listed in the statute when Medicaid pays for the drug via a bundled payment and Medicaid actually is the payor in that instance. Specifically, HRSA states that: “[A] drug provided as part of a hospital outpatient service which is billed to any other third party or directly billed to Medicaid would still qualify as a covered outpatient drug.”⁶⁴ This statement -- which apparently would make any drug a “covered outpatient drug” whenever it is not reimbursed by Medicaid (or when it is reimbursed by Medicaid, but not in one of the specified settings or not in a bundled payment) -- is inconsistent with the language in Social Security Act § 1927(k)(3) referring to a drug provided in specified settings for which payment “may be made under [Medicaid]” as part of a bundled payment.”⁶⁵ Under HRSA’s proposed interpretation, for example, a drug provided to an inpatient who is covered by Medicare would be considered a “covered outpatient drug.” This cannot be reconciled with the covered outpatient drug definition in Social Security Act § 1927(k), which is expressly incorporated by the 340B law.⁶⁶

HRSA must return to the description of “covered outpatient drug” articulated in its 1994 guidance, which conforms to the statute. The statutory definition also avoids unworkable consequences that would flow from the definition in the Proposed Guidance. For example, HRSA’s proposed definition of “covered outpatient drug” could extend the GPO prohibition (providing that, as a condition of 340B eligibility, certain hospitals not obtain “covered outpatient drugs” through a group purchasing arrangement)⁶⁷ to virtually any drug, since the prohibition applies to “covered outpatient drugs” and at the time of purchase any drug could end up being reimbursed by a payor other than Medicaid and could thus be a “covered outpatient drug” under the proposal. In addition, the proposed definition implies that a drug’s status as a “covered

⁶¹ Social Security Act § 1927(k)(3).

⁶² 80 Fed. Reg. at 52306 (quoting 59 Fed. Reg. 25510, 25513 (May 13, 1994)).

⁶³ 42 U.S.C. § 256b(b)(2).

⁶⁴ 80 Fed. Reg. at 52306 (emphasis added).

⁶⁵ Emphasis added.

⁶⁶ 42 U.S.C. § 256b(b)(1).

⁶⁷ 42 U.S.C. § 256b(b)(4)(L)(iii).

outpatient drug” could vary from State to State and unit to unit depending partly on whether -- in any particular case -- the drug was reimbursed by a State Medicaid program via a bundled payment; a drug’s “covered outpatient drug” status could thus vary among and even within States (e.g., a State Medicaid program might have different payment methodologies for the drug in different settings specified in § 1927(k)(3), or a State’s fee-for-service Medicaid program might have a different payment methodology for the drug than one of its Medicaid MCOs).

IV. INDIVIDUALS ELIGIBLE TO RECEIVE 340B DRUGS

A. The Six Proposed Elements of the 340B “Patient” Definition

The 340B law prohibits covered entities from reselling or otherwise transferring drugs purchased under the 340B program to anyone but a “patient” of the covered entity.⁶⁸ Thus, a clear definition of “patient” is critical to the integrity of the 340B program. However, throughout the history of the program, there has been great confusion as to when an individual qualifies as a “patient” of a covered entity; as a result, the GAO stated in 2011 that “HRSA’s current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity” and “[a]s a result of the lack of specificity in the guidance, [HRSA] has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity.”⁶⁹ In addition, the OIG observed in a report focused on contract pharmacy arrangements:

Covered entities . . . reported different methods of identifying 340B-eligible prescriptions, and in some cases their determinations of 340B eligibility differ from one covered entity to another for similar types of prescriptions. This suggests a lack of clarity on how HRSA’s patient definition should be applied in contract pharmacy arrangements. Covered entities appear to have differing interpretations of what HRSA guidance requires . . . there is inconsistency within the 340B Program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible.⁷⁰

The “patient” provisions in the Proposed Guidance, if finalized, would make important strides in clarifying the patient definition and resolving many of the inconsistencies in the way stakeholders have interpreted this key term. We appreciate HRSA’s efforts to spell out the elements of the patient definition, which are essential to improving program integrity. However, we recognize that there may be some instances where the proposed patient definition could unintentionally hinder grantees’ ability to provide services within their scope of grant.⁷¹ In our

⁶⁸ 42 U.S.C. § 256b(a)(5)(B).

⁶⁹ “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement” at 23. GAO-11-836. Sept. 2011.

⁷⁰ OIG, Contract Pharmacy Arrangements in the 340B Program, OIE-05-13-00431 at 16. Feb. 2014.

⁷¹ For example, state Sexually Transmitted Disease (STD) and Tuberculosis (TB) programs provide necessary public health medications purchased under the 340B program to patients who have not received a prescription from a provider associated with the STD/TB program. It is our understanding based on meeting with grantees that when

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comments we tried to identify sections of the guidance that could unintentionally frustrate grantees' ability to carry out their mission effectively, and to craft recommended refinements to avoid these problems. But we recognize that additional flexibility may be necessary, as it has been difficult to identify and evaluate all the consequences -- intended and unintended, for a variety of covered entity types with different missions and ways of operating -- in the 60 day comment period allotted. We urge HRSA to work with all stakeholders through a public and transparent process to ensure the new patient definition adopted in its final guidance is carefully crafted to promote clarity and program integrity, and to avoid unnecessary rigidities that might impede the ability of grantees and safety net hospitals to advance 340B program goals.

HRSA would interpret a "patient" of a covered entity "on a prescription-by-prescription or order-by-order basis," such that six requirements would have to be met for an individual to be a "patient" of a covered entity in the context of a particular prescription or order.⁷² Below we provide our comments on each of the six proposed criteria, in turn, and on HRSA's remarks explaining each criteria.

1. "The individual receives a health care service at a facility or clinic site which is registered for the 340B Program and listed on the public 340B database."⁷³

PhRMA supports this criterion, as it establishes a critical link between the individual receiving the services and the covered entity site. This criterion makes clear that an individual who receives services from a covered entity provider, but not at a site listed on the 340B database for the covered entity, "even as follow-up to care at a registered site,"⁷⁴ would not be considered a patient.

The Proposed Guidance also specifies that an individual receiving care from an organization with an "affiliation arrangement" with a covered entity is not a patient of the covered entity.⁷⁵ This principle is similar to HRSA's 2012 guidance clarifying that just because a person receives care from one organization in an Accountable Care Organization (ACO) that includes a covered entity does not mean that the individual is a patient of the covered entity,⁷⁶ and presumably also would apply in the ACO context. To remove any ambiguity or need to consult earlier guidance on a closely related point, however, we recommend that HRSA restate its previous ACO guidance in the final version of the omnibus guidance.

Finally, we recommend that HRSA specify explicitly that a visit by an individual to a contract pharmacy of a covered entity neither establishes nor refreshes a "patient" relationship between an individual and a covered entity. This is implicit in HRSA's statement that the

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STD/TB programs provide necessary treatment to patients diagnosed by a private provider, the STD/TB programs pay for the entire cost of the medication purchased at the 340B price. HRSA should focus on these groups as two of the types of entities that target the populations the 340B program was intended to serve.

⁷² 80 Fed. Reg. at 52306.

⁷³ 80 Fed. Reg. at 52306.

⁷⁴ 80 Fed. Reg. at 52306.

⁷⁵ 80 Fed. Reg. at 52306.

⁷⁶ 340B Drug Pricing Program Notice Release No. 2012-2 "Clarification of Covered Entity Eligibility Within Accountable Care Organizations." (May 23, 2012.)

individual must receive care at a registered “facility or clinic site” (as well as the principle that merely dispensing a drug does not create a patient” relationship), but to promote clarity HRSA should spell out this point.

2. “The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider.”⁷⁷

PhRMA strongly supports this proposal. It eliminates language in the 1996 patient definition treating a patient of a provider under “contractual or other arrangements” with a covered entity as a patient of the covered entity. This loose “other arrangements” language has been a long-standing concern due to the potential for abuse it creates. For example, HRSA observed in its 2007 proposed patient clarification:

Some [hospitals] have been contracting with health care providers to create a loose affiliation model for outpatient health care services. . . . The individuals enrolled in these programs are treated by health care providers too loosely affiliated with the covered entity for the ongoing responsibility to rest with the covered entity for the patient's health care resulting in the use of . . . 340B drugs. This model improperly seeks to expand the definition of a patient beyond that envisioned by Congress in prohibiting the resale of 340B drugs outside the eligible covered entity limits.⁷⁸

The GAO also reported on HRSA’s concern that the “other arrangements” language in the patient definition was so vague, stating that:

HRSA officials told us that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through “other arrangements,” as long as the responsibility for care provided remains with the entity. However, HRSA does not define “other arrangements,” and officials told us that what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, the agency has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity . . . does not actually have the responsibility for care.⁷⁹

Covered entities are institutions (e.g., hospitals or clinics) that can only provide care and establish “patient” relationships through individual healthcare professionals who act on behalf of the entity. Only a healthcare professional who is either an employee or an independent

⁷⁷ 80 Fed. Reg. at 52306.

⁷⁸ 72 Fed. Reg. at 1546-47 (emphasis added).

⁷⁹ GAO, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvements, supra, at 23.

contractor that works at the covered entity facility and assigns the right to bill and collect payment for his or services to the covered entity can treat a patient on behalf of the covered entity. An employee or independent contractor works under the supervision of the covered entity and the covered entity is responsible for the care provided to the patient -- including the quality of care. To emphasize this point, we recommend that HRSA specify in the final guidance that an independent contractor must be acting on behalf of the covered entity such that the entity would be accountable for the care provided by the independent contractor.

We agree with HRSA that “[s]imply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that privileged provider is a patient of the covered entity for 340B Program purposes,”⁸⁰ and appreciate HRSA’s examples of covered entity-provider relationships that qualify as independent contractor relationships (*i.e.*, faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs).⁸¹ We also recommend that HRSA state explicitly in its final guidance that the first element of the definition always applies (*i.e.*, the covered entity employee or independent contractor must provide the care at a registered covered entity site listed on the public 340B database), because each one of the six elements of the patient definition must be satisfied. Further, we support HRSA’s clarification that a prescription from a provider at a non-covered entity to which a patient is referred by a covered entity is not eligible for a 340B discount.⁸²

PhRMA supports HRSA’s statement that “[p]rescriptions that result from referrals to non-340B providers are not 340B-eligible,” but that “when the patient returns to the covered entity for ongoing medical care, subsequent prescriptions written by the covered entity’s providers may be eligible for 340B discounts.”⁸³ While individuals may receive care from several entities, for an individual to be considered a patient of a covered entity with respect to a particular prescription, a covered entity provider should write the prescription.

However, we also recognize that special circumstances may be presented in a case where an entity is 340B-eligible by virtue of a HRSA grant that requires it to operate a medical home model of care or otherwise to coordinate the care of certain patient populations. In those cases, ensuring that the patients served by the grantee entity are referred to other providers as appropriate and closely coordinating with those providers are central to the grantee entity’s ability to fulfill its grant obligations. Creating a 340B-related financial disincentive for making referrals may be problematic for such entities and could compromise their ability to fulfill their mission to make medical care accessible to their patients as well as requirements of their grants. Consequently, we consider that it would be appropriate for HRSA to recognize a limited exception to the ordinary referral principle for such grantee entities, permitting them to fill prescriptions with 340B drugs that are written by providers to whom the grantee referred its patient for medical services or treatment. In crafting this exception, HRSA should take care to ensure that its standards for such qualifying referrals are clear and auditable and that it does not result in two covered entities claiming 340B discounts on the same prescription.

⁸⁰ 80 Fed. Reg. at 52306.

⁸¹ 80 Fed. Reg. at 52306.

⁸² 80 Fed. Reg. at 52306-52307.

⁸³ 80 Fed. Reg. at 52306-52307.

3. *“An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in (2).”*⁸⁴

PhRMA supports this element of the “patient” definition. Coupled with the overarching “prescription-by-prescription or order-by-order” requirement, this element helps to ensure that the proper nexus exists between the service that was provided to an individual and a drug resulting from the service that generates a 340B discount. PhRMA supports this interpretation, and recommends confirming in the final guidance that a covered entity cannot provide one type of care to a person and dispense or administer a 340B drug to the person for something unrelated (e.g., provide dental services to an individual and dispense an antidepressant). We suggest HRSA specify that the 340B prescription must be directly related either to the individual’s primary diagnosis or a comorbidity of that diagnosis. Such a requirement is reasonable, easily operationalized, and auditable.

The Proposed Guidance also clarifies that a patient relationship cannot be established merely by the dispensing or the infusion of a drug.⁸⁵ This is an important clarification that HRSA should finalize. Because HRSA adds that dispensing or infusion alone “without a covered entity patient-to-provider encounter” does not establish a patient relationship, HRSA also should specify that infusion of drug is not considered a “covered entity patient-to-provider encounter.”

4. *“The individual’s health care is consistent with the scope of the Federal grant, project, designation, or contract.”*⁸⁶

PhRMA supports this element, however, we ask that HRSA provide greater clarity regarding exactly what would constitute health care “consistent with the health care service or range of services designated in the Federal grant, project, designation, or contract.”⁸⁷ HRSA would limit this principle to grantees. HRSA does not propose to apply this approach -- where a “patient” must be an individual who receives services from a covered entity consistent with the reason why the entity is 340B-eligible -- to hospitals. Yet it should. For example, HRSA should specify that where a private nonprofit hospital is 340B-eligible because it has a contract with a state or local government to care for low-income individuals ineligible for Medicare and Medicaid, a “patient” of the hospital must receive services under that contract. Likewise, for a private nonprofit hospital that is 340B-eligible because it has been formally granted governmental powers, a “patient” of the hospital should be an individual who receives healthcare services furnished by the hospital in connection with its governmental powers.

Requiring that a “patient” of a covered entity hospital receive the services for which Congress made the hospital 340B eligible would promote the purposes of the 340B law (which was intended to allow participation by a private nonprofit hospital that contracts to care for “low-income individuals who are not eligible for Medicaid or Medicare,” but not by a private nonprofit hospital with “a minor contract to provide indigent care which represents an insignificant portion of its operating revenues”)⁸⁸ and would make the “patient” definition more symmetrical as

⁸⁴ 80 Fed. Reg. at 52307.

⁸⁵ 80 Fed. Reg. at 52307.

⁸⁶ 80 Fed. Reg. at 52307.

⁸⁷ 80 Fed. Reg. at 52307.

⁸⁸ H.R. Rep. 102-384 (II) (1992), 12.

between grantees and hospitals. HRSA has not even sought to explain why it would apply this principle to grantees but not hospitals, and we see absolutely no rational basis for this disparate treatment of covered entity grantees and hospitals. Accordingly, HRSA should specify in the final guidance that a “patient” of a private hospital that is 340B-eligible by virtue of having a contract with a state or local government to care for low-income individuals ineligible for Medicare and Medicaid must receive care under that contract.

5. “The individual’s drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.”⁸⁹

In the Proposed Guidance, HRSA recognizes that because the 340B law creates an “outpatient” drug discount program, an individual can only be considered a patient of a 340B entity if his or her healthcare is billed as outpatient to the patient’s payor, or (for self-pay patients) classified as outpatient under the covered entity’s “documented auditable policies and procedures.”⁹⁰ PhRMA agrees with HRSA and supports this proposed standard. HRSA should also clarify that for insured patients, the service provided to the individual must be billed and paid for as an outpatient service.

We note that this element of the patient definition would preclude filling “discharge prescriptions” with 340B drugs, and we support that result. HRSA should note this specifically in the final guidance. In addition, HRSA should state specifically in the final guidance that “discharge prescriptions” do not include prescriptions filled by non-hospital (grantee) covered entities that are responsible for managing the care of the individual both before hospital admission and after discharge.

6. “The individual’s patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care.”⁹¹

Under HRSA’s Proposed Guidance, to be considered a patient of a covered entity, an individual must have an “established relationship such that the covered entity maintains auditable health care records” demonstrating that all elements of the “patient” definition are satisfied, including the covered entity’s retention of responsibility for the individual’s healthcare.⁹² The records must show that “all of the [patient] criteria above were met for every prescription or order resulting in a 340B drug being dispensed or accumulated through a replenishment model.”⁹³ PhRMA supports this concept, but believes that further specificity would be useful.

First, we urge HRSA to make clear in the final guidance that the records of a “patient” must not only be “accessible” to the covered entity, but must be maintained, owned, controlled, and possessed by the covered entity. This would mean that the records are either physically stored or immediately accessible.

⁸⁹ 80 Fed. Reg. at 52307.

⁹⁰ 80 Fed. Reg. at 52307.

⁹¹ 80 Fed. Reg. at 52307.

⁹² 80 Fed. Reg. at 52307.

⁹³ 80 Fed. Reg. at 52307.

Second, we recommend HRSA specify that the provider/patient relationship must be “ongoing.” HRSA’s 2007 proposed clarification provided that the covered entity must have “ongoing responsibility” for “the outpatient health care service that results in the use of (or prescription for) 340B drugs,” and that “[t]o demonstrate the necessary retention of ongoing responsibility for the health care it is expected that, at a minimum, the covered entity will provide health care to the individual in the [340B hospital] or the qualified provider-based facility of the [hospital] within 12 months after the time of the referral.”⁹⁴ This 12-month standard is reasonable and appropriate. Thus, we recommend that HRSA specify in its final guidance that the 340B provider/patient relationship may begin with an individual’s first visit to a covered entity (provided all other elements of the patient definition are met), but that this relationship will end if the individual does not visit the covered entity within 12 months following the visit that resulted in the 340B prescription. Therefore, a prescription filled with a 340B drug could not be refilled with a 340B drug 13 months later if the individual has not gone back for a visit to the covered entity in the intervening period.

B. Covered Entity Employees

HRSA’s Proposed Guidance states that covered entity employees are not considered “patients” unless all elements of the patient definition are met.⁹⁵ PhRMA supports this clear principle conforming to the 340B law. We also agree with HRSA that this principle has always been laid out in HRSA’s guidance.

C. AIDS Drug Assistance Programs (ADAPs)

PhRMA agrees with HRSA’s proposal to reaffirm its longstanding position that “an individual enrolled in a Ryan White HIV/AIDS Program AIDS Drug Assistance Program funded by Title XXVI of the PHSA will be considered a patient of the covered entity for purposes of this definition.”⁹⁶

D. Telemedicine

The Proposed Guidance states that “the use of telemedicine involving the issuance of a prescription by a covered entity provider is permitted, as long as the practice is authorized under State or Federal law and the drug purchase otherwise complies with the 340B Program.”⁹⁷ To put this issue in some context, “telemedicine” has many definitions but generally involves “the use of electronic information and communication technologies to provide and support health care when distance separates participants.”⁹⁸ HRSA defines “telehealth” (which is sometimes

⁹⁴ 72 Fed. Reg. at 1543, 1544 (Jan. 12, 2007).

⁹⁵ 80 Fed. Reg. at 52307.

⁹⁶ 80 Fed. Reg. at 52307.

⁹⁷ 80 Fed. Reg. at 52306.

⁹⁸ A Guide to Assessing Telecommunications in Health Care, Institute of Medicine (now named the National Academy of Medicine) Committee on Evaluating Clinical Applications of Health Care, 1996. See also, e.g., Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine, Federation of State Medical Boards (FSMB) (April 2014), adopting the American Medical Association’s definition of “Telemedicine” as “the practice of medicine using electronic communications, information technology or other means between a licensee in one location, and a patient in another location with or without an intervening healthcare provider. Generally, telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation, or fax. It typically involves the application of secure videoconferencing or store and forward technology to provide or support healthcare

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used interchangeably with telemedicine) as “the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health, and health administration.”⁹⁹ As explained recently by the Agency for Healthcare Research and Quality, telehealth “encompasses several technologies that have been applied to a wide range of health conditions, populations, and settings,” which “makes it challenging to quickly and easily monitor the body of evidence as the technology and the evidence base is rapidly expanding.”¹⁰⁰ These technologies include real-time interactive audiovisual technologies, store-and-forward technologies that transmit information not in real time, remote patient monitoring, and mobile health services.

PhRMA supports telemedicine services, as they can play an important role in improving individuals’ access to needed care that otherwise may not be available. Further, in many instances, telemedicine offers the potential to reduce healthcare costs and to reduce individuals’ travel costs and increase their satisfaction with care.

We agree with HRSA that telemedicine services must be provided in compliance with all applicable State and Federal laws and (in the 340B context) all 340B program requirements. However, it is important to be mindful that 340B prescriptions often involve a heightened financial incentive that is not present in other telemedicine encounters, which potentially could encourage the use of telemedicine in circumstances where it does not benefit patient care. For example, recent GAO work suggests that 340B hospitals prescribe many more drugs to Medicare beneficiaries than comparable non-340B hospitals, raising questions about whether financial incentives for 340B prescribing adversely affects patients’ quality of care.¹⁰¹ To reduce the possibility for abuse, HRSA should remind covered entities to pay careful attention both to 340B program requirements and to applicable legal requirements imposed by other Federal laws and by State laws (including Federal and State privacy laws). For example, any prescribing of medications to an individual by a physician located at a distant site (or any dispensing by an out-of-state pharmacy) would implicate State laws, which vary significantly.¹⁰² Should HRSA address telemedicine in its final guidance, safeguards to protect and promote the quality of care also would be important. For example, the American College of Physicians (ACP), in a new position paper with a series of thoughtful recommendations on telemedicine,

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delivery by replicating the interaction of a traditional, encounter in person between a provider and a patient.”
American Medical Association, Council on Ethical and Judicial Affairs, Fundamental Elements of the Patient-Physician Relationship (1990).

⁹⁹ HRSA Glossary and Acronyms, <http://www.hrsa.gov/ruralhealth/about/telehealth/glossary.html#t>

¹⁰⁰ AHRQ, Evidence-Based Practice Center Technical Brief Protocol, Project Title: Telehealth Evidence Map, www.effectivehealthcare.ahrq.gov (Aug. 11, 2015).

¹⁰¹ GAO, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals (June 5, 2015).

¹⁰² See e.g., American Medical Association, Telemedicine: Is Prescription Writing Allowed? (providing in part that “While the AMA supports the practice [of prescribing using telemedicine], it is essential that a physician-patient relationship exists. The issues that arise are when does that relationship develop, can that relationship be established through remote interaction alone (i.e., in the absence of any physical encounters), and if a relationship exists is it permissible for the physician to issue prescriptions. The second question is where States differ the most”). <http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/telemedicine.page>.

emphasizes that telemedicine has both the promise to improve access to care and potential drawbacks.¹⁰³ The ACP notes, for example, that

[Telemedicine] presents several challenges to maintaining continuity of care and a strong patient-physician relationship. . . . Several variable factors (such as the medical history provided to the consulting physician by the patient, ability of the consulting physician to access the patient's electronic health record, or even technology failure) may increase the likelihood that the [telemedicine] visit may become an orphan event in the medical history, leaving the patient's physician or health care team without knowledge of the visit, prescriptions that may have been written, or recommendations. In addition, not being able to do a physical examination hinders certain therapeutic elements associated with touch or interpersonal communication and raises concerns about the accuracy of diagnoses when the physician cannot touch the patient to, for example, detect tenderness or swollen glands.¹⁰⁴

While telemedicine can “potentially be a beneficial and important part of the future of health care delivery,” ACP concludes, it is “also important . . . to balance the benefits of telemedicine against the risks for patients.”¹⁰⁵ We support this approach of balancing telemedicine benefits against risks. Accordingly, it is important to consider the key benefits of telemedicine. Then HRSA-Administrator Mary Wakefield explained those benefits well at a 2012 Institute of Medicine conference on telemedicine:

Telehealth is a key component in ensuring access to health care services in isolated geographic areas across the United States. More effective deployment of telehealth technologies will enhance our ability to better serve the health care needs of those in rural and frontier parts of the country. However, telehealth is important not just for rural communities, but for the underserved community.¹⁰⁶

As Administrator Wakefield also noted, HRSA's grantees serve the “underserved and vulnerable populations.”¹⁰⁷ Therefore, given both the unanswered questions about telemedicine and the urgency of improving access to care for the underserved and vulnerable, HRSA should focus on creating a carefully-crafted opening for grantees to develop a 340B “potential”

¹⁰³ Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings: An American College of Physicians Position Paper, Ann. Intern Med. doi:10.7326/MIS-0498 (2015).

¹⁰⁴ ACP Position Paper on Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings, supra (footnotes omitted) (emphasis added).

¹⁰⁵ ACP Position Paper on Policy Recommendations to Guide the Use of Telemedicine in Primary Care Settings, supra.

¹⁰⁶ Institute of Medicine (now the National Academy of Medicine), The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary (2012) (emphasis added).

¹⁰⁷ Institute of Medicine, The Role of Telehealth in an Evolving Health Care Environment, supra.

relationship via real-time audiovisual encounters if key safeguards and applicable State and Federal laws were complied with.¹⁰⁸

As part of these safeguards, it would be critical for HRSA to specify that to be considered a “patient” of a covered entity an individual must be seen initially at a registered facility of the covered entity for an in-person visit. This minimum safeguard serves two important purposes. First, it helps to reduce the visits highlighted by ACP of prescribing for an individual without a physical examination, which raises concerns about the accuracy of diagnoses. Second, the face-to-face encounter at the entity’s registered site provides important evidence of a legitimate physician-to-patient relationship. This latter issue is important in light of the heightened financial incentives (as noted above) that exist in the 340B context. Without the assurance that an individual who receives telemedicine services from a 340B grantee has had a face-to-face encounter with a covered entity provider, allowing a telemedicine encounter to generate a 340B prescription could invite abuse and put individuals at risk of receiving sub-standard or unnecessary care. We believe that HRSA should also require that, to renew a patient relationship, a face-to-face visit should occur at least every 12 months.

If HRSA decided to craft criteria in its final guidance whereby grantees could use appropriate telemedicine encounters to develop a 340B “patient” relationship in specified circumstances, HRSA should specify clearly: (1) how “telemedicine” was defined for this purpose;¹⁰⁹ (2) what safeguards (apart from satisfying the usual elements of the “patient” definition, and the requirements for an initial and annual face-to-face visit discussed above) would need to be satisfied to protect the quality of care,¹¹⁰ and what documentation a grantee would be required to maintain in order to show that each one of those safeguards were followed; and (3) what procedures a grantee would need to follow to (a) determine and document the State and Federal laws that applied to the encounter (and any resulting prescription) and the specific requirements of these laws, and (b) document the fact that all applicable requirements had been followed. Without these basic due diligence and documentation practices, it would not be possible to verify whether a particular telemedicine encounter by a grantee could properly be used to develop a 340B “patient” relationship and thus to test for compliance with these aspects of the “patient” definition.

¹⁰⁸ HRSA also should encourage all covered entities to use telemedicine modalities as an important adjunct to the care provided under a physician-patient relationship built on traditional face-to-face visits between the physician and patient. Telemedicine can have a key role in expanding the information that can be analyzed and the interactions that can occur in those relationships, such as enabling remote monitoring of patients with chronic conditions.

¹⁰⁹ We note that at one point the Proposed Guidance states that “the use of telemedicine, telepharmacy, remote, and other health care service arrangements (e.g., medication therapy management) is permitted, as long as the practice is authorized under State or Federal law and otherwise complies with the 340B Program.” 80 Fed. Reg. at 52307 (emphasis added). Certainly many practices are permitted if they comply with all applicable 340B program requirements and State and Federal laws; however, HRSA should make clear in its final guidance that such a broad and vaguely-described group of practices (including “other health care arrangements”) may not be used by any covered entity (including a grantee) for purposes of establishing a 340B “patient” relationship. Otherwise HRSA could negate its efforts to clarify the criteria for 340B “patient” status.

¹¹⁰ For example, The Federation of State Medical Boards’ Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine recommends several safeguards to promote the safety and quality of care in the telemedicine context. PhRMA believes these safeguards are worthy of HRSA’s consideration

V. DRUG INVENTORY/REPLENISHMENT MODELS

Covered entities use replenishment systems to tally the drugs dispensed to various types of patients (such as inpatients, 340B-eligible outpatients, and other outpatients) and then replenish the drugs used for each patient type by reordering from the appropriate account (e.g., GPO, 340B, non-340B outpatient). PhRMA strongly supports HRSA's proposed clarifications that "[t]o avoid a violation of the statutory prohibition on diversion, a covered entity that utilizes a drug replenishment model may only order 340B drugs based on actual prior usage for eligible patients of that covered entity"¹¹¹ and that "[i]f the covered entity improperly accumulates or tallies 340B drug inventory, even if it is prior to placing an order, the covered entity has effectively sold or transferred drugs to a person who is not a patient, in violation of [the diversion prohibition]."¹¹²

HRSA also describes two categories of reclassifications with respect to 340B drug purchases made through replenishment models:

- "[E]rrors in purchasing data" that are identified and corrected within 30 days of the initial purchase; and
- A process sometimes called "banking," in which "covered entities have attempted to retroactively look back over long periods of time at drug purchases not initially identified as 340B eligible," and then "attempt to re-characterize these purchases as 340B eligible," (in which event the entity should "first notify manufacturers and ensure all processes are fully transparent with a clear audit trail").¹¹³

We agree with HRSA that a distinction exists between "banking" and the immediate and regular (30-day) correction of inadvertent purchasing errors. However, both of these practices depart from HRSA's principle that "[c]overed entities are responsible for requesting 340B pricing at the time of the original purchase"¹¹⁴ and (since HRSA apparently would permit both practices), the Proposed Guidance as a whole appears to undercut HRSA's first principle that entities must request 340B pricing at the time of the initial purchase. To give effect to this first principle and set out a clear and internally consistent set of ground rules, we recommend that HRSA adopt the following standards in its final guidance:

- Entities and their agents must design all patient-identification systems so that "patients" (and non-patients) can properly be identified at the time a drug is dispensed or administered (and replenishment activities follow from these real-time correct "patient" identifications);

¹¹¹ 80 Fed. Reg. at 52319.

¹¹² 80 Fed. Reg. at 52308. We also support HRSA's recognition that "[a] similar violation would occur if the recorded number of 340B drugs does not match the actual number of 340B drugs in inventory, if the covered entity maintains a virtual or separate physical inventory." Id.

¹¹³ 80 Fed. Reg. at 52308.

¹¹⁴ 80 Fed. Reg. at 52308.

- Entities with well-designed real-time patient identification systems may reclassify a drug as a “340B drug” (with prior notification to the manufacturer and a clear audit trail) if an error nevertheless occurs and the error is detected and corrected within 30 days of the initial purchase; and
- Errors identified at any time before or after the 30-day period that result in improper 340B purchases must always be notified to the manufacturer and corrected promptly after they are identified.

Finally we support HRSA’s proposed clarification that covered entities should conduct regular reviews of 340B drug inventory to ensure that any inventory discrepancy is accounted for and properly documented to demonstrate that 340B drugs are not diverted.” We also agree that covered entities should follow standard business practices to return unused or expired drugs purchased at the 340B price and appropriately account for waste of such drugs, and that covered entities should maintain policies and procedures, as well as auditable records, regarding 340B drug inventory discrepancies to assist in meeting this standard.

We urge HRSA to incorporate these important program integrity principles as HRSA conducts its audits of covered entities. We are concerned that HRSA’s audit protocol may not be capturing violations of the GPO and/or diversion prohibitions that result from inappropriate replenishment practices. We believe it is imperative from a program integrity perspective for HRSA to ensure that its oversight and audit activities are identifying noncompliant replenishment practices and pursuing appropriate corrective action and enforcement requirements in cases of identified violations.

VI. DUPLICATE DISCOUNTS

A. Background and Current Landscape

The 340B law’s “duplicate discount” ban prohibits covered entities from purchasing a drug that generates a Medicaid rebate claim at a 340B discount.¹¹⁵ This is an absolute prohibition, and the intent of this statutory provision is zero instances of double discounts. Since the inception of the 340B program, identification and prevention of duplicate discounting has been an ongoing challenge for covered entities, CMS, State Medicaid programs, and manufacturers. Although historically only drugs for Medicaid fee-for-service (FFS) beneficiaries triggered Medicaid rebates, the ACA extended the rebate requirement to drugs used by Medicaid MCO enrollees. The inclusion of MCO utilization in State Medicaid rebate invoices, coupled with the proliferation in the use of contract pharmacies, has sharply increased the risk of double discount violations.

Today duplicate discount violations are a widely acknowledged and growing problem. For example, a recent OIG report found evidence that some 340B providers have violated basic requirements designed to prevent contract pharmacy arrangements from generating duplicate discounts.¹¹⁶ Even HRSA’s own audit experience demonstrates extensive evidence of duplicate

¹¹⁵ 42 U.S.C. § 256b(a)(5)(A)(ii).

¹¹⁶ OIG, Contract Pharmacy Arrangements in the 340B Program, February 4, 2014.

discounts -- as of October 2015, in 343 audits (since 2012), 73 have involved duplicate discount findings. PhRMA is an important stakeholder in the 340B program, and has made a number of submissions detailing several thoughtful and substantive recommendations that, if implemented, would reduce the risks of duplicate discounts. Our comment letter to CMS on its 2012 proposed rule for covered outpatient drugs under the Medicaid rebate program included several practical recommendations in this regard. In 2014, PhRMA submitted a white paper to HRSA entitled *Current State of the 340B Duplicate Discount Prohibition and Proposed Solutions for Program Compliance* that provided a comprehensive analysis of the heightened double discount problems that exist today and included several solutions for HRSA's consideration. In June 2015, PhRMA submitted a comment letter to CMS on its Medicaid Managed Care proposed rule, in which we included a robust discussion detailing MCO-related duplicate discount challenges and our proposed solutions.

On the face of HRSA's Proposed Guidance, it appears that PhRMA's recommendations have not been adequately considered. Not only did HRSA fail to respond to or acknowledge our 2014 white paper, but none of its recommendations were even acknowledged in HRSA's Proposed Guidance -- not as proposals for stakeholders to consider, and not even as ideas that HRSA thoughtfully considered, assessed, and rejected as unworkable or flawed in some way. Notably, the Proposed Guidance briefly refers to "certain modifiers and codes which identify individual claims as associated with 340B drugs and therefore not eligible for rebate" (including NCPDP identifiers), but then asserts without any explanation that "[s]uch billing instructions are beyond the scope of the 340B program."¹¹⁷ We disagree. A method to prevent double discounts is squarely within the scope of the 340B program and in fact should be a top HRSA priority. HRSA has an express statutory mandate "to establish a mechanism to ensure that covered entities comply" with the prohibition on duplicate discounting.¹¹⁸ As discussed below, the mechanism that HRSA has established currently is insufficient to satisfy this mandate.

HRSA must not ignore this problem; since the current mechanism does not "ensure" covered entity compliance, HRSA must replace, enhance, or supplement the mechanism to ensure compliance and thus fulfill its statutory mandate. We appreciate HRSA's statement that "[r]isks of duplicate discounts can increase with certain drug purchasing and distribution systems, including covered entity contract pharmacy arrangements," and "therefore, in accordance with the statutory requirement under 340B(a)(5)(B)(ii) to establish a mechanism to prevent duplicate discount violations, HHS will examine these systems and determine if adjustments have to be made to the system to prevent duplicate discounts,"¹¹⁹ We can assure HRSA that adjustments are necessary and overdue.

As noted above, the law requires "the [HHS] Secretary [to] establish a mechanism to ensure that covered entities comply" with the duplicate discount prohibition.¹²⁰ HRSA established the Medicaid Exclusion File as that mechanism. Covered entities may "carve-in" 340B drugs (use 340B drugs for their Medicaid patients) or "carve-out" (buy drugs for their Medicaid patients outside the 340B program). Entities must inform HRSA -- "by providing their Medicaid billing number" -- if they carve-in; this information is then reflected in the Exclusion File

¹¹⁷ 80 Fed. Reg. at 53209.

¹¹⁸ 42 U.S.C. § 256b(a)(5)(A) (emphasis added).

¹¹⁹ 80 Fed. Reg. at 52309 (emphasis added).

¹²⁰ 42 U.S.C. § 256b(a)(5)(A).

that permits “States and manufacturers [to] know that drugs purchased under that billing number are . . . not eligible for a Medicaid rebate.”¹²¹ In a June 2011 report, the OIG found that most States are not using the Exclusion File, but it was not clear whether these States had developed reliable alternative methods of identifying duplicate discounts.¹²² Moreover, as described below, even if a State uses the Exclusion File, it will not prevent duplicate discounts in all instances. Recall that the statutory objective is zero instances of double discounts.

PhRMA was surprised and disturbed by HRSA’s proposal to permit covered entities to make more complicated carve-in/carve-out decisions, especially in light of the ongoing and widespread violations of the duplicate discount prohibition. Specifically, under the Proposed Guidance, HRSA would permit covered entities to make different carve-in/carve-out decisions for FSS Medicaid beneficiaries and MCO beneficiaries, and even MCO-by-MCO.¹²³ HRSA apparently would also permit different elections by parent and child sites.¹²⁴ Further, the Proposed Guidance seeks comments on alternative mechanisms to allow covered entities to “take a more nuanced approach to purchasing,” e.g., only using 340B drugs for Medicaid patients “when appropriate for service delivery.”¹²⁵ Although we do not understand exactly what HRSA means by this, one thing is clear -- now is not an appropriate time to introduce more complicated and “nuanced” aspects to the double discount problem; now is the time to reduce double discount risks instead of increasing them. If HRSA were to finalize these proposals (which we oppose), the challenges that HRSA, covered entities, and State Medicaid programs would face in developing a system that could effectively handle all of the complex variations HRSA is proposing would be substantial and the permitted variations inevitably would reduce the ability to detect and prevent duplicate discounts. HRSA’s proposals would move the system further away from zero tolerance of duplicate discounts, to benign neglect.

In the Proposed Guidance, HRSA also includes a number of broad recommendations, but fails to provide any meaningful detail as to how the recommendations would be operationalized. For example, HRSA “encourages covered entities, States, and Medicaid MCOs [to] work together to establish a process to identify 340B claims” and states that “covered entities should have mechanisms in place to be able to identify MCO patients.”¹²⁶ However, HRSA does not require (or even discuss) any specific mechanisms. HRSA also states that “covered entities and States should continue to work together on various methods to prevent duplicate discounts on Medicaid MCO drugs.”¹²⁷ This is accurate but incomplete. Prevention of duplicate discounts cannot be left solely to covered entities and States, but -- as discussed in our recommendations, below -- will require HRSA itself to cooperate with stakeholders and to enlist the cooperation of multiple parties, including CMS.

¹²¹ HRSA, 340B Release No. 2013-2, “Clarification on Use of the Medicaid Exclusion File.”

¹²² HHS OIG, State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs (June 2011). The report found that 30 States did not use HRSA’s Exclusion File, ten because they believed it to be inaccurate; but neither of the alternative methods used by the 30 States “necessarily ensures accurate identification of 340B claims.”

¹²³ 80 Fed. Reg. at 53209.

¹²⁴ 80 Fed. Reg. at 52309.

¹²⁵ 80 Fed. Reg. at 53209.

¹²⁶ 80 Fed. Reg. at 52309 (emphasis added).

¹²⁷ 80 Fed. Reg. at 52309.

HRSA acknowledges in the Proposed Guidance that “[r]isk of duplicate discounts can increase with certain drug purchasing and distribution systems, including covered entity contract pharmacy arrangements.”¹²⁸ PhRMA applauds HRSA for publicly acknowledging this fact. Having done so, HRSA should not further expand this risk. Also, HRSA states that it will examine its systems to determine “if” adjustments are needed to the system to prevent duplicate discounts¹²⁹ (adjustments certainly will be needed). The Proposed Guidance provides that due to the heightened risks of duplicate discounts, contract pharmacies listed on the 340B database will be presumed not to dispense 340B drugs to Medicaid FFS or MCO patients.¹³⁰ Under the Proposed Guidance, contract pharmacies could not dispense 340B drugs to Medicaid beneficiaries unless HRSA approves an agreement to prevent duplicate discounts between the contract pharmacy, covered entity, and State Medicaid program or MCO, in which event the contract pharmacy would be listed on the 340B database as dispensing 340B drugs to (certain) Medicaid beneficiaries.¹³¹ However, HRSA says nothing about how duplicate discounts could be prevented in the context of a contract pharmacy dispensing 340B drugs to Medicaid beneficiaries, and thus about what specific criteria HRSA would require in order to approve an agreement “to prevent duplicate discounts” in that context. We recommend that HRSA either identify specific standards that would need to be adopted in such agreements -- if genuinely effective standards actually can be identified -- or simply provide that contract pharmacies must not dispense 340B drugs to Medicaid beneficiaries and to achieve this must have an effective, tested method for identifying Medicaid FFS and MCO beneficiaries. In addition, pharmaceutical manufacturers should have access to any such agreement to facilitate the review and dispute process (and potentially avoid costly, burdensome, and time-consuming audits).

B. Key Problems Inhibiting Duplicate Discount Prevention and Detection

As context for our proposed solutions, it is important to have a clear understanding of the most significant challenges in preventing duplicate discounts. Two of the major obstacles that now inhibit the prevention of duplicate discounts relate to contract pharmacies and to Medicaid MCOs. These are independent but intersecting problems, both of which were highlighted by a 2014 OIG report on contract pharmacies.¹³² The OIG’s contract pharmacy report has provided a better understanding of the double discount problem generally and in the contract pharmacy setting specifically.

The OIG’s findings reinforce the concerns that PhRMA has identified in our own analyses of duplicate discount problems. Of 30 covered entities surveyed by OIG, 22 reported that, to prevent double discounts, their contract pharmacies do not dispense 340B drugs to Medicaid beneficiaries -- but two of these 22 entities acknowledged they did not know whether their contract pharmacies dispense 340B drugs to Medicaid MCO beneficiaries,¹³³ and covered entities’ contract administrators reported “difficulties” identifying Medicaid MCO beneficiaries, for two reasons:

¹²⁸ 80 Fed. Reg. at 52309.

¹²⁹ See 80 Fed. Reg. at 52309.

¹³⁰ See 80 Fed. Reg. at 52309.

¹³¹ See 80 Fed. Reg. at 52309.

¹³² HHS OIG, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (Feb. 2014).

¹³³ OIG Contract Pharmacy Report at 12.

- Pharmacies use the Bank Identification Number and Processor Control Number (BIN/PCN) on patients' health cards to identify the payor for a prescription, but BINs/PCNs for Medicaid MCO plans are "not readily available"; and
- Many insurers that operate Medicaid MCO plans and private plans use the same BIN/PCN for both.¹³⁴

Given these difficulties in identifying Medicaid MCO beneficiaries, it is likely that many contract pharmacies -- and in-house covered entity pharmacies as well -- are dispensing 340B drugs to Medicaid MCO beneficiaries without knowing it. Therefore, even contract pharmacies that believe they are not dispensing any 340B drugs to any Medicaid beneficiaries are probably doing so. This is particularly troubling in the contract pharmacy context, because currently claims for 340B drugs that are dispensed by contract pharmacies will not be flagged and excluded from Medicaid rebate invoices via the Medicaid Exclusion File, since contract pharmacies bill for drugs using their own NPI (not the covered entity NPI), and contract pharmacy NPIs are not listed in the Medicaid Exclusion File. As a consequence, 340B drugs that are dispensed to Medicaid beneficiaries by contract pharmacies will be included in Medicaid rebate invoices and generate prohibited double discounts.

Of the 8 covered entities reporting to the OIG that their contract pharmacies do dispense 340B drugs to Medicaid beneficiaries, 6 did not report any method to prevent double discounts¹³⁵ -- even though HRSA's current guidelines expressly require that covered entities "fully meet[] statutory obligations of ensuring against . . . creating a situation that results in a State Medicaid program seeking a rebate on a discounted drug."¹³⁶ Moreover, only 5 of these covered entities notified their State Medicaid program of this practice and none notified HRSA¹³⁷ -- even though HRSA's current guidelines require entities' agreements with contract pharmacies to ensure that "[n]either party will use drugs purchased under 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported . . . HRSA."¹³⁸ Therefore a full 20% (6/30) of the covered entities surveyed by the OIG reported to OIG that they were in violation of basic, very straightforward HRSA requirements designed to reduce duplicate discount risks.

Thus, as we have previously advised HRSA, the OIG's findings reinforce PhRMA's concern that HRSA's only current mechanism to prevent duplicate discounts (the Medicaid Exclusion File) is often not preventing duplicate discounts associated with drugs (1) used by Medicaid MCO enrollees; or (2) dispensed by contract pharmacies.

Another breakdown in duplicate discount prevention occurs at the point of sale, because at that point a contract pharmacy typically does not determine whether an individual is a "patient" of a 340B entity with which the pharmacy contracts and thus whether the prescription

¹³⁴ OIG Contract Pharmacy Report at 13.

¹³⁵ OIG Contract Pharmacy Report at 13.

¹³⁶ 75 Fed. Reg. at 10278.

¹³⁷ OIG Contract Pharmacy Report at 13.

¹³⁸ 75 Fed. Reg. at 10278 (emphasis added).

should be classified as a 340B prescription.¹³⁹ In most cases, contract pharmacies retroactively determine whether prescriptions were filled with drugs purchased under the 340B program, and 340B claims therefore are not designated as such by the pharmacy at the time of dispensing. According to 340B Health (formerly the Safety Net Hospitals for Pharmaceutical Access, or SNHPA), the trade association for 340B hospitals, the “overwhelming majority of pharmacies do not know at the time a claim is processed whether or not it relates to a 340B drug.”¹⁴⁰ In-house 340B pharmacies also identify 340B “patients” and prescriptions filled with “340B drugs” retroactively in some cases. This retroactive identification of 340B patients and 340B drugs makes it more difficult to flag 340B drugs as such and therefore drives up the risk of duplicate discount violations. Further, retroactive identification of 340B patients and prescriptions makes it infeasible to pass along discounts to 340B patients at the point of sale.

Another key challenge in identifying and preventing duplicate discounts stems from the fact that the data that manufacturers receive with quarterly State Medicaid rebate invoices do not identify 340B purchasing. The current invoicing for Medicaid rebates – for both FFS and MCO utilization -- provides little or no ability to verify/audit Medicaid rebate claims. Thus, it is difficult for a manufacturer to identify instances of 340B/Medicaid duplicate discounts based solely on the data included on the invoice. Specifically, the Medicaid invoice data typically provide only an aggregated summary of NDC-level utilization for the applicable quarter,¹⁴¹ which means that manufacturers lack claims-level detail (e.g., identification of the provider, date of service, etc.). Moreover, Medicaid rebates may be invoiced on a lagged basis; thus even if a manufacturer were able to identify a specific provider and date of service associated with a rebate claim, the Exclusion File status of the 340B covered entity at the time of the invoice may not be the same as when the manufacturer receives a rebate invoice. Simply put, the data CMS currently requires States to include on Medicaid rebate invoices does not provide the type of claims-level data that manufacturers would need in order to identify duplicate discounting violations.

¹³⁹ See, e.g., Wellpartner Policy Watch, ACA Medicaid Managed Care Rebates and the 340B Exemption available at: <http://www.wellpartner.com/aca-medicare-managed-care-rebates-and-the-340b-exemption/>. (“The in-house method lends itself to real-time 340B claims identification and billing. By contrast, adjudication of 3rd-party claims through community pharmacies does not – in most cases, the pharmacy does not know the 340B status of a prescription or patient at the point of sale and cannot flag such a claim for billing and tracking. 340B identification, purchasing, and replenishment are generally carried out post-adjudication.”)

¹⁴⁰ Safety Net Hospitals for Pharmaceutical Access, Letter to Jason Helgeson, “Concerns Regarding Identification of 340B Medicaid Managed Care Claims,” December 19, 2011 at 2, available at http://www.snhipa.org/files/SNHPA_Letter_and_Testimony_Regarding_NY_340B_Medicaid_Managed_Care_Claims_12-19-2011.pdf.

¹⁴¹ See CMS Medicaid Drug Rebate Program Notice No. 158 (July 13, 2011) at 11. CMS Form R-144, which is the form that States use to provide Medicaid drug utilization data to manufacturers, provides for States to submit data in an aggregated format (as opposed to a claim level format). Further, the form does not currently require that States report to manufacturers – or even collect – the NCPDP 340B identifiers for claims filled by drugs purchased under the 340B program.

C. Recommendations to Prevent Duplicate Discounts

No single stakeholder working in isolation can solve the growing problem of duplicate discounting in the 340B program. It is essential that all stakeholders -- including HRSA, CMS, State Medicaid agencies, covered entities, and manufacturers -- work together collaboratively to develop and implement solutions to prevent duplicate discounts. As noted above, the statutory objective is zero instances of duplicate discounts. Below we provide a menu of several recommendations to help achieve this objective, which we urge HRSA to select from in its final guidance.

- First, HRSA should require covered entities to identify prescriptions for 340B “patients” when the prescription is written (e.g., through a simple notation on the prescription), which would enable both in-house 340B pharmacies and 340B contract pharmacies to identify a prescription as one filled with 340B drugs at the point of service. HRSA itself suggested this approach in its 2010 contract pharmacy guidance.¹⁴² If HRSA instructs 340B entities and their contract pharmacies to use this approach, pharmacies and 340B entities need only use NCPDP’s point-of-sale 340B identifier (which we discuss further below) to identify 340B claims and ensure that State Medicaid programs will exclude them from Medicaid rebate invoices. Importantly, adopting this recommendation also would facilitate passing through all or part of the 340B discount to covered entity patients.
- Second, HRSA should work with CMS to require that Medicaid MCOs issue pharmacy benefit cards that include an individual’s Medicaid managed care status, rather than just listing the BIN/PCN for the MCO sponsor. This will help contract pharmacies to identify these individuals as Medicaid beneficiaries and thus flag the prescriptions dispensed to them as being ineligible for 340B drugs. It also will assist 340B providers that carve out Medicaid beneficiaries to identify these individuals as Medicaid beneficiaries (and thus to carve them out accordingly).
- Third, HRSA should work with other stakeholders to create a 340B “National Database on States’ Processing Requirements” that would provide information assisting covered entities and contract pharmacies to identify Medicaid MCO enrollees. Although several data points could be listed in such a database, they should include the BINs/PCNs for Medicaid MCOs or their PBMs. This information would help (but not be sufficient by itself) to identify Medicaid MCO enrollees as such, so that a 340B contract pharmacy (or an in-house pharmacy of an entity that carves out Medicaid beneficiaries) could avoid filling claims associated with these plans with 340B drugs.
- Fourth, HRSA should not finalize its several proposals to permit covered entities’ carve-in/carve out policies to become more complicated, and instead should require one carve-in/carve out decision across all of a covered entity’s sites and for all Medicaid payors. As discussed above, we do not believe the Medicaid Exclusion File could work effectively if

¹⁴² 75 Fed. Reg. 10272, 12079 (March 5, 2010). The “suggested contract provisions” for entities to consider including in contract pharmacy agreements provide: The pharmacy will dispense covered drugs only in the following circumstances: (a) upon presentation of a prescription bearing the covered entity’s name, the eligible patient’s name, a designation that the patient is an eligible patient of the covered entity and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone . . . by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient. Id.

HRSA were to permit the type of multi-faceted carve-in/carve out policies described in the Proposed Guidance. This is not the time to introduce new complexities into the prevention of double discounts.

- Fifth, HRSA should require that, when billing Medicaid or other payors, covered entities and their contract pharmacies should use a system like that developed by the National Council for Prescription Drug Programs (NCPDP) -- or revised and refined by NCDCP -- to identify claims filled with 340B drugs. Under this system, pharmacies place the value of "20" in the Submission Clarification Code field when a prescription is identified at the point of sale as being filled with 340B drugs.¹⁴³ For physician-administered drugs billed by a clinic, the "UD modifier" should be required on claims to identify those that involve drugs purchased under 340B.
- Sixth, HRSA should work with CMS to create a standardized claim-level reporting format for drug utilization data that accompanies Medicaid rebate invoices submitted to manufacturers, and also standardize the method for identifying and documenting utilization of 340B drugs across Medicaid, *i.e.*, uniform reporting elements and formats and uniform rules for identifying 340B drugs should apply across MCOs and FFS Medicaid, and across all States. Without such standardization at the claim-level, States may continue to develop individualized homegrown reporting systems that make auditing 340B status determinations practically impossible. A comprehensive and uniform rebate invoice, along with the underlying claims-level detail, is also essential, as it would help both States and manufacturers to identify 340B drug utilization and to reduce the resources needed to validate and pay rebate claims. Requiring consistency in reporting across Medicaid will also benefit 340B entities by streamlining the way 340B claims are identified and reported. Among other things, CMS should require the comprehensive use of the NCPDP 340B identification systems for claims for 340B drugs (and use of the "UD modifier" on claims for physician-administered 340B drugs), as well as require the use of HRSA's Exclusion file to identify claims that involve 340B drugs. To promote efficiency and to enable these mechanisms to function effectively, they must be used across the board, *i.e.*, CMS must require State Medicaid programs to flow down these requirements to pharmacies, other providers that serve Medicaid beneficiaries, and Medicaid MCOs (which the State must require also to flow down to pharmacies and providers serving their beneficiaries).
- Seventh, HRSA should work with CMS to require that all Medicaid utilization data that States submit to manufacturers (both FFS and Medicaid MCOs) contain the "Pharmacy Identifier" field so that manufacturers can verify that the data has been correctly screened for duplicate discounts, or to communicate with the State to determine whether the utilization data includes drugs dispensed by a 340B pharmacy. The data also must include the NCPDP 340B identification data element.
- Eighth, HRSA should work with CMS to require that the utilization data accompanying the Medicaid rebate invoices submitted include (in addition to the data elements noted above and those that CMS proposed to require on rebate invoices in its 2012 proposed rule

¹⁴³ NCPDP also has a mechanism to inform payors when a determination is made retroactively that a claim previously billed and paid involved 340B drugs. For more information on NCPDP's 340B identification systems, see NCPDP's 340B Information Exchange Reference Guide, version 1.01 (July 2011) § § 4.1-4.3.

regarding covered outpatient drugs)¹⁴⁴ the following: (1) Date of Service; (2) Service Provider Identifier Qualifier; (3) Service Provider Identifier; (4) Prescription/Service Reference Number; (5) Product/Service Identifier; (6) Quantity Dispensed; (7) Days Supply; (8) Fill Number; and (9) NPI number.¹⁴⁵

- Since States would only be able to meet these reporting obligations by requiring that pharmacies or other providers that dispense or administer drugs to Medicaid FFS or MCO beneficiaries include all these same data elements on their claims to the State or the Medicaid MCO, CMS should require States to flow down to Medicaid MCOs and pharmacies (or other providers that bill Medicaid for drugs) all of the same reporting requirements that should be applied to the State. CMS also should explicitly require States and MCOs to adopt reporting requirements to identify 340B drugs purchased by a provider such as a clinic, to preclude duplicate discounts on such drugs; the mechanism to do this in the clinic setting is to identify 340B drugs using a UD modifier.
- Ninth, with respect to the NPI number included on State invoices to manufacturers, it is critical that HRSA work with CMS to require that contract pharmacies report the NPI number of the covered entity – and not their own NPI number – when submitting or retroactively identifying a claim for a 340B drug. Because contract pharmacy NPIs currently are not listed in the Exclusion File, and contract pharmacies currently bill 340B drugs under their own NPIs, a claim filled by a contract pharmacy would not have the 340B entity's NPI and the Exclusion File would therefore not enable Medicaid to exclude 340B claims from Medicaid rebate invoices even if the covered entity's NPI were listed in the Exclusion File. Consequently, a claim for a 340B drug dispensed by a contract pharmacy could not be flagged and excluded from rebate invoices based on information in the Exclusion File. In addition, we urge HRSA and CMS to work together to develop a mechanism whereby the Exclusion File flags contract pharmacy claims even if the 340B entity itself has developed a method to avoid dispensing 340B drugs to Medicaid beneficiaries – including MCO beneficiaries – and thus does not submit its NPI number to the Exclusion File.
- Tenth, 340B entities or contract pharmacies that fail to follow the recommended requirement to adopt the NCPDP 340B identification system should have an affirmative obligation to report to the MCOs that they do not use the required 340B identifier system. To avoid duplicate discounts, MCOs must then be required to exclude all claims from covered entities that do not comply with the 340B identifier system from the utilization data they report to the State.

¹⁴⁴ CMS proposed that States must report the following data on FFS utilization, and on MCO utilization for MCOs providing drug benefits, to manufacturers and CMS:

Within 60 days of the end of each quarter, the State must bill participating drug manufacturers an invoice which includes, at a minimum, all of the following data: (1) The State code; (2) National Drug Code; (3) Period covered; (4) Product FDA list name; (5) Unit rebate amount; (6) Units reimbursed (7) Rebate amount claimed; (8) Number of prescriptions; (9) Medicaid amount reimbursed; (10) Non-Medicaid amount reimbursed; and (11) Total amount reimbursed. [77 Fed. Reg. 5318, 5366 (proposed 42 C.F.R. § 447.511(a), (c)) (Feb. 2, 2012).]

¹⁴⁵ With the exception of the NPI element, this information is provided to manufacturers under the Medicare Part D Coverage Gap Discount Program Agreement to help manufacturers verify claims.

- Finally, and importantly, given the heightened risk of duplicate discount violations in the MCO/contract pharmacy context -- as recognized by OIG in its 2014 contract pharmacy report¹⁴⁶ and also by HRSA itself in the Proposed Guidance¹⁴⁷ -- HRSA should work with CMS to ensure that Medicaid MCOs review their claims retroactively back to 2010 (when Medicaid MCO utilization became subject to Medicaid rebates pursuant to the ACA) to make sure they have not previously invoiced State Medicaid programs for drugs subjects to 340B discounts. If any such invoicing has occurred, the MCO must be required to correct the utilization data as promptly as possible. To ensure that a correct review of past claims can be conducted, Medicaid MCOs also should be required to flow down this retrospective review obligation to their network pharmacies. CMS also should expressly require that any corrections of past claims discovered by the MCOs be forwarded to the State, which must then submit revised utilization data to manufacturers.

PhRMA would welcome the opportunity to meet with HRSA (or to meet with HRSA and CMS) to discuss any of these recommendations if that would be helpful.

D. Repayment

HRSA states in the Proposed Guidance that covered entities found in violation of the duplicate discount prohibition “may be required to repay manufacturers if duplicate discounts have occurred”¹⁴⁸ As a threshold matter, covered entities are always responsible for violations of the statutory prohibition on duplicate discounts.¹⁴⁹ That said, manufacturers should be permitted to exercise one of two options to recoup monies attributed to duplicate discounts. Currently, manufacturers either recover the monies from the covered entities themselves, e.g., via a check or a credit and rebill, in which case a Medicaid rebate is appropriate. Alternatively, manufacturers use the dispute resolution process to resolve the issue with the State Medicaid agency, in which case (assuming the drug was identified as a 340B drug in the Medicaid dispute resolution process) a Medicaid rebate would not be due. PhRMA urges HRSA to clarify in its final guidance that although a manufacturer may choose to resolve instances of duplicate discounts with individual States via the dispute resolution process, this is not the required mechanism -- the statute makes clear that covered entities are always ultimately responsible for compliance with the statutory prohibition of duplicate discounts.¹⁵⁰

¹⁴⁶ HHS OIG, Contract Pharmacy Arrangements in the 340B Program, OEI-05-13-00431 (Feb. 2014).

¹⁴⁷ 80 Fed. Reg. at 52309.

¹⁴⁸ 80 Fed. Reg. at 52309. (emphasis added.)

¹⁴⁹ 42 U.S.C. § 256b(a)(5)(A).

¹⁵⁰ 42 U.S.C. § 256b(a)(5)(A) states “A covered entity shall not request payment under title XIX of the Social Security Act [42 U.S.C. § 1396 *et seq.*] for medical assistance described in section 1905(a)(12) of such Act [42 U.S.C. § 1396dd(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 U.S.C. § 1396r-8].

VII. CONTRACT PHARMACY ARRANGEMENTS

In the Proposed Guidance, HRSA acknowledges that contract pharmacies increase duplicate discount risks.¹⁵¹ The GAO and the HHS OIG have both reported that contract pharmacies increase diversion risks as well.¹⁵² But the Proposed Guidance would continue HRSA's current policy of allowing any covered entity to have an indefinite number of contract pharmacies, rather than proposing any limitations on covered entities' use of contract pharmacies. In addition, HRSA proposes that, "[i]f permitted under applicable State and local law, a covered entity may contract with one or more pharmacies on behalf of its child sites, or a child site may contract directly with a pharmacy." HRSA also suggests that covered entities may contract with one contract pharmacy site or with a "pharmacy corporation to include multiple pharmacy locations."¹⁵³ Particularly in light of the heightened risks associated with the use of contract pharmacies (as described below), we urge HRSA to demonstrate its commitment to preventing diversion and duplicate discounts and to abandon these proposals. Instead HRSA must take steps to rein in the use of contract pharmacies and reduce the compliance risks they pose.¹⁵⁴

By way of background, HRSA published guidelines in 1996 creating the theory that covered entities could use contract pharmacies.¹⁵⁵ Accordingly, HRSA has complete discretion to limit or eliminate the use of contract pharmacies by covered entities. The 1996 Guidelines permitted a covered entity with no in-house pharmacy to contract with one outside pharmacy to receive 340B drugs and then dispense those drugs to patients of the covered entity. Thus, these guidelines were confined to circumstances where the covered entity may have been unable to participate in the 340B program except through a contract pharmacy.

HRSA lifted these restraints in 2010, when it issued new guidelines that "replace[d] all previous 340B Program guidance documents addressing non-network contract pharmacy services".¹⁵⁶ The 2010 Guidelines eliminated all restrictions on the types of covered entities that could use contract pharmacies and on the number of contract pharmacies a covered entity could use, providing that, "[i]n addition to contracting with a single pharmacy for each clinical site, covered entities may pursue more complex arrangements that include multiple pharmacies."¹⁵⁷

In the preamble to the 2010 Guidelines, HRSA dismissed stakeholder concerns that a limited number of "demonstration projects," where eleven covered entities used contract

¹⁵¹ 80 Fed. Reg. at 52309.

¹⁵² GAO, Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement, at 28; OIG, Contract Pharmacy Arrangements in the 340B Program, at 1-2.

¹⁵³ Notably, HRSA does not discuss how these various contract pharmacy arrangements must be listed in the 340B database.

¹⁵⁴ As a threshold matter, we note that the 340B law does not authorize HRSA to permit the use of contract pharmacies. We do not address this issue further in this comment letter, as we believe that today all concerned can at least agree that the evidence on risks vs. benefits of contract pharmacies calls for limits on their use.

¹⁵⁵ 61 Fed. Reg. 43549 (Aug. 23, 1996).

¹⁵⁶ 75 Fed. Reg. at 10277.

¹⁵⁷ 75 Fed. Reg. at 10277-10278.

pharmacies as test cases, did not provide HRSA with sufficient evidence to justify a dramatic expansion of contract pharmacy arrangements.¹⁵⁸ HRSA similarly rejected calls for enhanced penalties and consequences in connection with diversion or duplicate discounting, stating that “there are appropriate safeguards in place, based on the parameters of the program.”¹⁵⁹

The 2010 Guidelines made clear that HRSA was allowing multiple contract pharmacies at that time because (1) HRSA believed it had fully assessed the risk of diversion and double discounting and found them negligible; and (2) the potential benefits to patients appeared significant. Thus, HRSA explained that “[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities,” plus “the [Alternative Methods Demonstration Project] provides concrete examples of the ability of covered entities to utilize multiple contract pharmacies without sacrificing program integrity.”¹⁶⁰ HRSA concluded that: “Upon review of the evidence and current circumstances, HRSA does not find sufficient basis to continue limiting contract pharmacies to a single site.”¹⁶¹ But the premises on which HRSA based its 2010 Guidelines have proved incorrect, and HRSA’s current policy has sacrificed program integrity.

In 2014, the HHS OIG issued a troubling report suggesting that HRSA’s lack of safeguards around the use of contract pharmacies has compromised program integrity with few benefits to patients – at least not from hospital covered entities’ contract pharmacies. HRSA’s failure to require that covered entities pass along any savings to 340B patients means that the grantees have largely passed through 340B savings to uninsured low-income patients and the hospitals largely have not. Specifically, the OIG’s study, which included 15 DSH hospitals and 15 FQHCs, found a startling disparity: of the 15 DSH hospitals in the study, approximately 47% (seven hospitals) did not pass along discounts to uninsured patients in any of their contract pharmacy arrangements;¹⁶² whereas only 7% of the sampled grantees (one grantee) did not pass along discounts to uninsured patients in any of its contract pharmacy arrangements.¹⁶³

In addition, the OIG report identified serious compliance violations and found that, “contract pharmacy arrangements create complications in preventing diversion.”¹⁶⁴ Covered entities’ contract administrators, which may decide which prescriptions dispensed by a contract pharmacy are 340B-eligible, “use different methods to identify 340B-eligible prescriptions,” which leads to “differing determinations of 340B eligibility across covered entities.” For example, some administrators classify as 340B-eligible all prescriptions written by physicians that split their time between a covered entity and a non-covered entity, while others treat none of these prescriptions as 340B eligible and still others make case-by-case decisions.¹⁶⁵

¹⁵⁸ 75 Fed. Reg. at 10273.

¹⁵⁹ 75 Fed. Reg. at 10274.

¹⁶⁰ 75 Fed. Reg. 10272, 10273 (March 5, 2010) (emphasis added).

¹⁶¹ 75 Fed. Reg. at 10273 (emphasis added).

¹⁶² Id.

¹⁶³ These percentages are not precise because for four of the covered entities in the sample, it was unclear whether contract pharmacies offered the discounted 340B price to uninsured patients. See id. at 14.

¹⁶⁴ HHS OIG, Contract Pharmacy Arrangements in the 340B Program, supra at 1.

¹⁶⁵ OIG Contract Pharmacy Report at 9.

The OIG also found that “contract pharmacy arrangements create complications in preventing duplicate discounts.” Six of eight contract pharmacies that dispensed 340B drugs to Medicaid beneficiaries told OIG they lacked even “a method to avoid duplicate discounts,” some covered entities disclosed that they did not even know whether their contract pharmacies dispense 340B drugs to Medicaid beneficiaries, and others admitted “difficulties” identifying Medicaid MCO beneficiaries.

HRSA itself is (and has been) well aware of the rampant violations in the 340B program involving contract pharmacies. In November 2013 HRSA published on its website a chart of audit results that showed that when HRSA audited a covered entity and uncovered diversion, duplicate discounting, or both, about half of the time the diversion or duplicate discounting involved drugs dispensed at contract pharmacies.¹⁶⁶ Merely skimming the audit results displayed on HRSA’s website confirms that these violations continue to exist. Of the 103 audit results listed for FY2015, approximately one third include violations involving contract pharmacies.¹⁶⁷

In addition to the compliance risks stemming from HRSA’s 2010 Guidelines, the evidence suggests that few of the patient benefits HRSA expects from this policy have materialized. As discussed in Section VI.B, typically a contract pharmacy does not determine whether an individual is a “patient” of a 340B entity with which the pharmacy contracts and thus whether the prescription should be classified as a 340B prescription until sometime after the prescription has been filled. This suggests that the covered entity may not be “assum[ing] responsibility for establishing [the 340B drug’s] price” as the 2010 Guidelines require.¹⁶⁸ Presumably, HRSA believed it was “essential” that the covered entity assume responsibility for the price so that savings could be passed along to its patients. This concept is implicit in HRSA’s preamble discussion of drug pricing approaches in its 1996 Guidelines. Specifically, HRSA noted that:

some [covered entities] may pass all or a significant part of the discount to their patients, others may set the price slightly higher than the actual acquisition cost . . . using the savings to reach more eligible patients and provide more comprehensive services . . . A modest section 340B price markup, with savings realized from the discounts used by covered entities only for purposes of the federal program . . . does not appear to be inconsistent with the drug pricing program.”¹⁶⁹

As noted above, however, benefits to patients from the use of contract pharmacies are by no means assured. The OIG’s contract pharmacy report found that 60% of the 30 covered entities OIG sampled reported that they passed through 340B discounts to uninsured patients in at least one contract pharmacy arrangement, but 27% of the covered entities (eight entities)

¹⁶⁶ HRSA, Program Audit Results Chart (Nov. 4, 2013), available at <http://www.hrsa.gov/opa/programintegrity/auditresults/auditreportcurrent.pdf>.

¹⁶⁷ HRSA FY2015 audit results, available at <http://www.hrsa.gov/opa/programintegrity/auditresults/fy15auditresults.html>

¹⁶⁸ See 75 Fed. Reg. at 10277.

¹⁶⁹ 61 Fed. Reg. at 43551.

charged uninsured patients the full non-340B price in all of their contract pharmacy arrangements, and for another 13% it was unclear whether 340B discounts were passed through to uninsured patients.¹⁷⁰ Moreover, seven of the eight entities that did not pass along discounts to uninsured patients in any of their contract pharmacy arrangements were DSH hospitals¹⁷¹ -- and while OIG's sample included 15 DSH hospitals and 15 FQHCs, DSH hospitals actually account for roughly 81% of 340B purchases,¹⁷² suggesting that the largest volume of 340B users are generally not using their contract pharmacies to pass through discounts to uninsured patients.

The OIG reported that "[a]ll but one administrator reported being able to allow covered entities to offer the discounted 340B price to uninsured patients at contract pharmacies," but "some covered entities choose not to do so."¹⁷³ While recognizing that "[n]either the 340B statute nor current HRSA guidance address [whether covered entities must pass discounts through to patients]," the OIG emphasized that "if covered entities do not [pass through], uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies."¹⁷⁴

Benefitting patients was the whole rationale for contract pharmacies. HRSA adopted its current policy allowing an unlimited number of contract pharmacies because the previous policy "restrict[ed] the flexibility of covered entities in meeting the needs of their patients," responding to comments that "some patients currently face transportation barriers . . . obstacles that limit their ability to fill prescriptions [at the covered entity]" and "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements."¹⁷⁵ But patients receive no benefit from going to a pharmacy they could have gone to anyway, without the contract pharmacy arrangement, and paying the same full price they could have paid without the contract pharmacy arrangement.

As HRSA's current policy on contract pharmacies is premised on the theory that the use of contract pharmacies presents low risk and improves patient access -- and this premise has proven wrong -- PhRMA recommends that, at a minimum, HRSA impose reasonable limits on the use of contract pharmacies to balance their heightened compliance risks against any benefit these arrangements are providing to covered entity patients. Below we set forth our recommendations.¹⁷⁶

- First, HRSA should limit the number and geographic scope of permissible contract pharmacy arrangements. Today, there are covered entities with over 100 contract

¹⁷⁰ OIG Report at 13-14.

¹⁷¹ OIG Contract Pharmacy Report at 14.

¹⁷² Sales data from Apexus Update 2015 -- 340B Coalition Winter Meeting; Number of Entities from Avalere Health analysis of the 340B database in March 2015.

¹⁷³ OIG Contract Pharmacy Report at 14.

¹⁷⁴ OIG Contract Pharmacy Report at 14.

¹⁷⁵ 75 Fed. Reg. at 10273.

¹⁷⁶ Many of HRSA's proposals for contract pharmacy arrangements are couched as "expectations" in the Proposed Guidance. PhRMA recommends couching these proposals more strongly to convey the urgency of these reforms more accurately given the widespread compliance violations that currently exist in the program.

pharmacy arrangements, some of which are more than 50 miles away and can include large mail order pharmacies. The need for such contract pharmacy networks is difficult to reconcile with the notion that covered entities must serve individuals who legitimately qualify as patients of the covered entity; further, the research suggests that in many cases contract pharmacies are located in higher income communities.¹⁷⁷ PhRMA recommends that covered entities be permitted to contract with no more than five contract pharmacy locations at any given time, all of which must be located within lower-income census tracts (as determined by HRSA using American Community Survey data) served by the covered entity. We believe certain exceptions would be appropriate, as follows:

- Covered entities described in 42 U.S.C. § 256b(a)(4) (A)-(K).¹⁷⁸
- Rural hospitals (specifically, hospitals eligible to participate in the 340B program under 42 U.S.C. § 256b(a)(4)(N) or (O)).
- Circumstances where a covered entity files a publicly available exception request with HRSA, seeking authorization to establish a particular contract pharmacy arrangement in a higher-income census tract and explaining why in that particular case such a contract pharmacy would best meet the needs of low-income patients of the covered entity, and HRSA grants the request to establish one of the five contract pharmacies in the census tract requested. HRSA's decisions on such requests also should be publicly available.
- Second, where a covered entity offers a charity care policy or has an obligation to have a sliding fee scale (e.g., under a grant that makes the entity 340B-eligible), then its contract pharmacies should be required to offer patient access at the point of sale to the entity's prescription drug charity care benefit and its sliding fee scale. In addition, covered entities should have in place, at each contract pharmacy, a mechanism for documenting the income and insurance status of each covered entity patient who fills a prescription at the contract pharmacy and the amount each patient pays to receive 340B drugs at the contract pharmacy.
- Third, we encourage HRSA to seek an HHS OIG study and report on covered entity/contract pharmacy arrangements, which should address the methods and amounts of remuneration exchanged between covered entities and contract pharmacies, the extent to which contract pharmacies are used by hospitals and grantees, compliance concerns associated with covered entities contracting with mail order pharmacies, and the extent to which contract pharmacies improve access to medicines by covered entity patients. The report should include recommendations that address safeguards to reduce duplicate discounting and diversion within contract pharmacies and reforms to target these arrangements exclusively at improving access to medicines for uninsured or vulnerable patients of covered entities. HRSA should also encourage ongoing OIG monitoring of these issues, ideally in annual OIG reports.

¹⁷⁷ See, e.g., Berkeley Research Group Contract Pharmacy Mapping Analysis, http://www.thinkbrg.com/media/publication/459_Vandervelde_ContractPharmacyMappingAnalysis.pdf

¹⁷⁸ These are grantee covered entities that traditionally have operated under requirements that have followed the original intent of the 340B program, including using contract pharmacy services to increase access for vulnerable populations.

- Fourth, HRSA should establish a moratorium precluding any covered entity (except those described in 42 U.S.C. § 256b(a)(4)(A)-(K)) from entering into a new or expanded contract pharmacy arrangement at least until HRSA has evaluated the OIG's initial report on contract pharmacies (described above), issued proposed guidance based on OIG's findings and recommendations, and then issued final guidance taking into account public comments.
- Fifth, HRSA should require covered entities to conduct annual, independent, on-site audits of their contract pharmacies (which should be required to maintain separate inventories of 340B drugs) to identify program violations. To be effective, these audits should also extend to any third party with which the covered entity contracts for services related to the 340B program. We appreciate HRSA's renewed emphasis on its "expectation" for annual independent audits of contract pharmacies,¹⁷⁹ but we believe the annual independent audit must be (1) on-site; and (2) mandatory. HRSA already established an expectation for annual independent audits of contract pharmacies in 2010, yet the OIG's 2014 contract pharmacy report found that few entities (only 7 out of the 30 in the study) retained independent auditors for their contract pharmacy arrangements.¹⁸⁰ Even more concerning, the OIG found that four of the covered entities neither monitor their contract pharmacies nor retain independent auditors.¹⁸¹
- Sixth, HRSA should establish a moratorium barring covered entities from registering any type of mail order contract pharmacies, including pharmacies licensed to dispense specialty drugs, in the 340B program unless and until HRSA has: (1) conducted a thorough examination of the risks posed by these arrangements, either on its own, or in collaboration with an independent government agency, such as the OIG or GAO; and (2) set forth clear, auditable, and specific standards for the prevention of program violations with respect to these arrangements, including a requirement that covered entities attest that the use of mail order pharmacies is the only available mechanism to secure prescription drug access for their patients, and that the covered entity has implemented controls to prevent program violations. In addition, HRSA should establish a policy specifying that the use of mail order pharmacies in the 340B program should be limited to serve the needs of the covered entities' patients who would otherwise lack access to prescription drugs (e.g., home-bound patients, patients in rural areas). However, PhRMA recommends HRSA to exempt any grantee from the moratorium, so long as the grantee is providing 340B drugs within the scope of its grant.
- Seventh, both HRSA and manufacturers should be permitted to audit contract pharmacies (and other third parties that provide 340B-related services for covered entities) directly, to ensure compliance with program requirements. Adequate recordkeeping requirements also should be in place to ensure that these audits can be accomplished. We agree with HRSA's proposal for a 5-year record retention requirement.
- Eighth, covered entities should be required to have a written agreement with each contracted entity, including with each location of a pharmacy contracted to dispense 340B drugs to patients of the covered entity, which should include robust representations and

¹⁷⁹ 80 Fed. Reg. at 52311.

¹⁸⁰ OIG Contract Pharmacy Report at 15.

¹⁸¹ Id.

warranties to ensure that the contracted entity will adhere to all 340B program requirements. Measures describing specifically how compliance will be achieved should be clearly set forth in the agreement. Covered entities should maintain, and ensure that each contract pharmacy maintains, auditable records that pertain to the compliance of the covered entity and the contracted entity. Further, all agreements should be registered with HRSA and made available to HRSA upon request.

VIII. MANUFACTURER RESPONSIBILITIES

A. The “Must Offer” Requirement

The ACA amended the 340B statute to provide that “each [PPA] . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.”¹⁸² HRSA has not yet amended the PPA to include this “must offer” requirement, but has just taken steps to start this process. The Proposed Guidance states that “[u]nder the PPA, a manufacturer must offer all covered outpatient drugs . . . to covered entities participating in the 340B Program at no more than the statutory 340B ceiling price,” and that by executing the PPA “a manufacturer agrees to all 340B Program statutory requirements, including statutory and regulatory changes that occur after execution of the PPA.”¹⁸³

PhRMA disagrees with HRSA’s assertion that by executing a PPA, a manufacturer agrees to subsequent statutory and regulatory changes that are not incorporated into the PPA. HRSA points to no authority for this assertion; there is nothing in the 340B statute that supports this position, and nothing in the PPA that supports this position (unlike the Medicaid Drug Rebate Agreement, which explicitly requires manufacturers to comply with certain subsequent changes in the Medicaid rebate statute and implementing regulations).¹⁸⁴

Aside from the issue of when the “must offer” provision takes effect, its proper interpretation warrants some discussion. As noted above, it provides that the PPA shall require manufacturers to “offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.”¹⁸⁵ HRSA has previously interpreted this language as reflecting HRSA’s traditional “non-discrimination” policy. We agree that the must offer provision codifies HRSA’s long-standing non-discrimination policy (rather than adopting a new and different “forced sale” requirement that potentially could result in manufacturers being required to disadvantage non-340B customers). HRSA’s non-discrimination policy is expressed in its May 2012 guidance in the context of alternate allocation procedures for drugs in shortage. In that guidance, HRSA required that manufacturers implementing allocation procedures “must demonstrate that 340B

¹⁸² 42 U.S.C. § 256b(a)(1).

¹⁸³ 80 Fed. Reg. at 52311(emphasis added).

¹⁸⁴ Specifically, the Medicaid Drug Rebate Agreement requires manufacturers “[t]o comply with the conditions of 42 U.S.C. section 1396s changes thereto, and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.” Rebate Agreement Between the Secretary of Health and Human Services and Manufacturer, Enclosure A § II(c) (emphasis added).

¹⁸⁵ 42 U.S.C. § 256b(a)(1).

providers are treated the same as non-340B providers,”¹⁸⁶ and pointed to its 1994 guidelines providing that:

manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective [and] . . . must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program.¹⁸⁷

HRSA explained in the 2012 guidance on allocation programs that “[t]his policy is consistent with section 340B(a)(1) of the Public Health Service Act which requires manufacturers to ‘offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at an price.’”

We recommend that HRSA amend the PPA to add the must offer language, and also reiterate its conclusion that the must offer language incorporates HRSA’s long-standing policy against treating covered entities less favorably than non-340B customers. HRSA could re-emphasize that conclusion at the time it amended the PPA to include the must offer language, or beforehand; certainly the final omnibus guidance would present a good opportunity to address that point. This interpretation would allow continuation of HRSA’s sensible approach of permitting manufacturers to limit purchases by 340B and non-340B purchasers alike in certain situations in a nondiscriminatory manner.

When HRSA amends the PPA to activate the “must offer” provision, PhRMA also recommends that HRSA do a full update of the PPA to conform with current law.¹⁸⁸ The PPA includes a number of outdated definitions.¹⁸⁹ Keeping the PPA up to date will serve the important purpose of ensuring that manufacturers know all of their rights and obligations under the 340B program, and can find them all catalogued in an up-to-date source; and will prevent the PPA from becoming a stagnant and (worse) affirmatively unhelpful document that could cause confusion.

B. Limited Distribution Networks

Under the Proposed Guidance, HRSA would expand its current guidance on allocation programs for drugs in short supply to require written notification from manufacturers concerning limited distribution arrangements, stating that this proposal is “pursuant to” the must-offer requirement.¹⁹⁰ HRSA recognizes that:

[c]ertain covered outpatient drugs may be required to be dispensed by specialty pharmacies (e.g., drugs approved with a [REMS]...). As a result, certain manufacturers may use a

¹⁸⁶ “Clarification of Non-Discrimination Policy,” Release No. 2011-1.1 (May 23, 2012).

¹⁸⁷ 59 Fed. Reg. 25110 (May 13, 1994) (emphasis added).

¹⁸⁸ HRSA’s current efforts do not appear to provide for a full update of the PPA.

¹⁸⁹ These include, for example, the PPA’s definitions of Average Manufacturer Price and Wholesaler.

¹⁹⁰ 80 Fed. Reg. at 52312.

restricted network of certified specialty pharmacies, which do not fall under the terms of a contract pharmacy agreement or wholesaler contract for the distribution of drugs to a covered entity.¹⁹¹

Manufacturers “may develop a limited distribution plan” in such cases, but “the plan will be reviewed by HHS to ensure that the manufacturer is treating 340B covered entities the same as all non-340B providers.”¹⁹² HRSA would request five specified categories of information concerning the limited distribution plan, including “[a]n explanation of the product’s limited supply or special distribution requirements and the rationale for restricted distribution among all purchasers” and “an assurance that manufacturers will impose these restrictions equally on both 340B covered entities and non-340B purchasers.”¹⁹³ If HRSA has “concerns,” it would “work with the manufacturer to incorporate mutually agreed upon revisions to the plan prior to posting the plan on the 340B Web site.”¹⁹⁴

As a threshold matter, HRSA lacks any authority under the 340B law to require manufacturers to report information on their limited distribution networks; to require that manufacturers seek HRSA’s approval before putting a limited distribution arrangement into effect; or to require manufacturers to agree to have submissions on their limited distribution arrangements published on the HRSA 340B website. These types of far-reaching powers could create great disruption in the drug distribution system (especially as HRSA lacks the resources and workforce that would be needed to review and clear limited distribution plans promptly), and nothing in the 340B statute suggests that Congress authorized HRSA to set up a prior review process that could delay distribution of drugs to patients, or to publish sensitive and potentially proprietary information on its Web site. Accordingly, HRSA should not finalize this proposal.

We note also that HRSA has not proposed any definitions, and it has used different terminology describing the arrangements that would be covered by this proposal in different parts of the Proposed Guidance. Thus, if HRSA were to finalize this proposal as it stands, exactly what types of arrangements it would apply to is unclear.

As a substantive matter, PhRMA believes that manufacturers may limit distribution of covered outpatient drugs through a subset of distributors, so long as this limited distribution model is applied in the same manner to 340B and non-340B purchasers, and it offers all covered entities at least one avenue to purchase at 340B prices.¹⁹⁵ HRSA should take the opportunity to specify this clearly in the final guidance.

C. Procedures for Issuance of Refunds and Credits

The 340B statute (as amended by the ACA) requires HRSA to establish “procedures for manufacturers to issue refunds to covered entities, in the event there is an overcharge by the manufacturers,” both in “routine instances of retroactive adjustments in relevant pricing data”

¹⁹¹ 80 Fed. Reg. at 52312.

¹⁹² 80 Fed. Reg. at 52312.

¹⁹³ 80 Fed. Reg. at 52312.

¹⁹⁴ 80 Fed. Reg. at 52312.

¹⁹⁵ A pharmacy (including a specialty pharmacy or radiopharmacy) is not a “distributor.”

and in exceptional circumstances (e.g., erroneous or intentional overcharges).¹⁹⁶ HRSA proposes that “the manufacturer must refund or credit that [overcharged] covered entity an amount equal to the price difference between the sale price and the correct 340B price for that drug, multiplied by the units purchased” and do so within 90 days of “the determination by the manufacturer or HHS that an overcharge occurred.”¹⁹⁷ HRSA would not permit exceptions for de minimis amounts and would not permit offsets. A covered entity that fails to cash a manufacturer’s check for an undisputed repayment amount within 90 days would waive its right to repayment. Manufacturers would submit to HRSA “price recalculation information, an explanation of why the overcharge occurred, how the refund will be calculated, and to whom refunds or credits will be issued.”¹⁹⁸

As a threshold matter, while HRSA’s Proposed Guidance purports to “establish[] clarity around the procedures for issuing refunds and credits in the event that there is an overcharge,”¹⁹⁹ HRSA has yet to establish any procedures at all. As noted above, the 340B statute explicitly requires HRSA to establish procedures for manufacturers to issue refunds to covered entities.²⁰⁰ HRSA’s proposal that manufacturers should issue refunds within 90 days does not fulfill HRSA’s mandate to establish procedures. Rather, HRSA itself must develop procedures that are designed to work as smoothly as possible and to anticipate and avoid unintended negative consequences that could be disruptive to the program and to manufacturers’ operations. PhRMA urges HRSA to consider the administrative burdens and operational difficulties that manufacturers and 340B covered entities could face in connection with the refund procedures, and to develop the procedures based on an ongoing dialogue with stakeholders that will be essential to minimizing the costs and burdens that ultimately result from the refund system.²⁰¹ Concurrently, HRSA should establish refund reconciliation and documentation standards to ensure the accuracy, transparency and auditability for confirming initial covered entity ceiling price purchases, as well as verification of associated subsequent manufacturer ceiling price adjustment refund amounts. To that end, we encourage HRSA to engage groups with expertise in remittance advice processing and documentation to assist in developing these detailed standards.

We appreciate that in this Proposed Guidance HRSA has started a discussion of refund related issues and procedures. We have comments on several of the specifics HRSA proposes.

First, HRSA’s proposal that manufacturers refund or credit covered entities within 90 days of the determination that an overcharge occurred is both unrealistic and unclear. HRSA does not explain what constitutes a “determination” that an overcharge has occurred. As recognized in the statutory language, manufacturers make “routine pricing restatements.” These restatements occur frequently, as certain rebate or other discount data may be known

¹⁹⁶ 42 U.S.C. § 256b(d)(1)(B)(ii).

¹⁹⁷ 80 Fed. Reg. at 52312.

¹⁹⁸ 80 Fed. Reg. at 52312.

¹⁹⁹ 80 Fed. Reg. at 52312.

²⁰⁰ 42 U.S.C. § 256b(d)(1)(B)(ii).

²⁰¹ As discussed below, an exception for de minimis amounts would go a long way to reduce these administrative burdens and operational difficulties.

only on a lagged basis. This is particularly common in the Best Price context. Manufacturers may not know the actual net price realized by a customer within 30 days after the end of the calendar quarter -- or in fact within a lengthy period, under some contracts -- and so manufacturers must adjust the Best Price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer. To capture these adjustments, manufacturers may restate the Best Price and AMP for a particular period for 36 months after the initial price reporting.²⁰²

Because CMS permits recalculations in Medicaid rebate metrics for 36 months after the initial price reporting, the 340B ceiling prices derived from those metrics could also change during the 36-month restatement window. Consequently, it would be inappropriate for HRSA to mandate manufacturer ceiling price adjustment refunds any time before the 36 month restatement window closes and 340B ceiling prices for a given quarter are frozen. In addition, manufacturers should be permitted a reasonable time to recalculate 340B ceiling prices based on the final restated pricing, and then to process the refund payments. It would be administratively burdensome (and perhaps infeasible) for manufacturers to recalculate 340B ceiling prices for all of their products, determine which 340B covered entities were entitled to a refund and in what amounts, and then deliver any refunds due, within a 90-day timeframe. PhRMA recommends that HRSA allow an additional four quarters (after the 36 month restatement period) for final delivery of refund payments to 340B covered entities.

Second, PhRMA opposes HRSA's proposal to preclude offsets. HRSA states that "[a] manufacturer may only calculate the refund by NDC, and would not be allowed to calculate refunds in any other manner, including . . . netting purchases."²⁰³ No explanation is given for this proposal not to allow offsets and it has no support in the 340B law or elsewhere.

Manufacturer restatements in AMP or Best Price may result in increases or decreases to 340B ceiling prices. Unless retroactive increases and decreases in ceiling prices are treated symmetrically, manufacturers could effectively be required to give 340B covered entities prices below the correct ceiling price in many cases, as they would charge an initial ceiling price that turned out to be too low and then would be unable to recoup their undercharge by offsetting overcharges to the same covered entity. For several reasons, this is not a reasonable reading of the 340B law. HRSA would be compelling manufacturers to provide sub-ceiling prices on some 340B drugs, even though the law expressly provides that sub-ceiling prices are voluntary.²⁰⁴

In addition, common law principles of "offset" or "setoff" give manufacturers a right of offset in circumstances such as these. Yet HRSA would take those rights away, with no authorization for doing so in the 340B law. The 340B law simply refers to manufacturers making "refunds" when there are "overcharges" -- there is no suggestion that "refunds" are to be calculated without taking into account amounts due to the manufacturer, or that the determination of whether an "overcharge" has occurred is to be made without account for amounts due to the manufacturer. As the Supreme Court has explained, "The right of setoff (also called "offset") allows entities that owe each other money to apply their mutual debts

²⁰² 42 C.F.R. § 447.510(b),(d)(3).

²⁰³ 80 Fed. Reg. at 52312.

²⁰⁴ 42 U.S.C. § 265b(a)(10).

against each other, thereby avoiding “the absurdity of making A pay B when B owes A.”²⁰⁵ This absurdity is exactly what HRSA proposes to require here: HRSA would be asserting the authority to force manufacturers to pay out money to covered entities that actually owe the manufacturer money, ignoring debts they were owed by the covered entity. As commentators have emphasized, “It is generally well recognized that the use of setoff promotes efficiency, simplicity and fairness in everyday business transactions. The right of setoff is an equitable remedy that has historically been respected by the laws of every state.”²⁰⁶ This is an important right that has cannot be arbitrarily abrogated with no hint in the 340B law that it was intended to authorized such a result.

Finally, we note that offsets are customary business practice -- as well as a routine part of the Medicaid rebate program, from which 340B ceiling prices are derived -- and HRSA has always emphasized that 340B entities should not be “single[d] out for restrictive guidelines” but are subject to “customary business practices.”²⁰⁷

In short, HRSA must establish a policy recognizing that manufacturers may net overcharges and undercharges associated with ceiling price recalculations. Such a policy would be consistent with the 340B law; consistent with the Medicaid rebate restatement process; and consistent with manufacturers’ common law rights.

Third, PhRMA urges HRSA not to preclude exceptions for de minimis amounts. Establishing a de minimis standard would reduce transaction costs and administrative burdens for both manufacturers and covered entities, and it would be consistent with a long-standing line of case law holding that agencies may establish de minimis requirements to statutes they administer unless Congress has clearly precluded such exceptions²⁰⁸ -- which is not the case here. As the Court of Appeals for the D.C. Circuit has explained:

Categorical exemptions may . . . be permissible “as an exercise of agency power, inherent in most statutory schemes, to overlook circumstances that in context may fairly be considered de minimis” . . . The ability to create a de minimis exemption “is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design.”

....

As long as the Congress has not been “extraordinarily rigid” in drafting the statute . . . “there is likely a basis for an implication of

²⁰⁵ Citizens Bank of Maryland v. David Strumpf, 116 U.S. 286, 289 (1995), citing Studley v. Boylston Nat. Bank, 229 U.S. 523, 528, 33 S.Ct. 806, 808, 57 L.Ed. 1313 (1913).

²⁰⁶ A Creditor’s Right to Setoff: When Does a Creditor Impermissibly Improve Its Position: Ben Caughey, 29-JAN Am. Bankr.Inst.J.32 (Dec/Jan 2011).

²⁰⁷ 59 Fed. Reg. at 25110, 25114.

²⁰⁸ As explained by commentators: “Unless Congress has clearly said otherwise, agencies will be permitted to make de minimis exceptions to statutory requirements by exempting small risks from regulatory controls . . . Unless Congress has clearly said otherwise, agencies will be permitted to decline to regulate past the point where regulation would be economically or technologically feasible.” A new Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis, R.W. Hahn and C.R. Sunstein, 50 U. Penn. L Rev. 1489, 1510 (May 2002).

de minimis authority to provide [an]” exemption when the burdens of regulation yield a gain of trivial or no value.”

[Environmental Defense Fund v. EPA] 82 F.3d 451, 466 (D.C. Cir. 1996), quoting Alabama Power Co. v. Castle, 636 F.2d 323, 360 (D.C. Cir. 1979). Unless it has been “extraordinarily rigid” in expressing itself to the contrary, that is, the Congress is always presumed to intend that “pointless expenditures of effort” be avoided.²⁰⁹

Likewise, a de minimis exception to the 340B refund provisions also would be consistent with a number of precedents where de minimis thresholds have been used in analogous circumstances. For example, in the Medicaid rebate context, CMS permits States not to invoice a manufacturer for Medicaid rebates for a quarter, if that quarter’s rebates do not exceed a de minimis amount -- \$50 per labeler code.²¹⁰ CMS has noted in this context that States should “consider the cost-effectiveness of pursuing invoice collection.”²¹¹ CMS has exercised its authority to create this de minimis principle even though the Medicaid rebate statute does not speak explicitly of not billing for small amounts that may not be cost-effective to collect.

We think it would be reasonable to establish a de minimis amount and then provide that the manufacturer would still have to make a refund below the de minimis threshold if a covered entity expressly requested such a refund – in effect, making the de minimis exception a presumption that a covered entity could overcome if a very small refund warranted the effort of requesting it. But it would not be reasonable to prohibit any use of a de minimis threshold, as HRSA now proposes.²¹²

Finally, the Proposed Guidance states that manufacturers would submit to HRSA the “ceiling price recalculation information [and] an explanation of why the overcharge occurred.”²¹³ In most instances an “overcharge” would only have occurred because manufacturers have to sell to covered entities at the ceiling price in effect for that quarter, as calculated based on Medicaid rebate metrics from two quarters earlier²¹⁴ -- this is the only way to calculate the 340B ceiling price at the time of sale -- but if the ceiling price for a quarter is later recalculated based on restated data from two quarters earlier, then it will differ (and will be lower in some cases). In other words, most “overcharges” will stem from what the 340B law calls “routine instances of

²⁰⁹ Ass’n of Administrative Law Judges v. FLRA, 397 F.3d 957 (D.C. Cir. 2005)

²¹⁰ CMS, Medicaid Drug Data Guide for Labelers, § 7.1.

²¹¹ CMS, Medicaid Drug Rebate Dispute Resolution Program (for States), § II.2, available at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/bestpracst.pdf>.

²¹² PhRMA also would be amenable to adopting a de minimis exception for those instances in which a covered entity notifies a manufacturer of a refund due the manufacturer.

²¹³ 80 Fed. Reg. at 52321.

²¹⁴ The 340B ceiling price equals the AMP minus the Medicaid Unit Rebate Amount (URA), calculated based on the AMP and Best Price values initially filed with CMS. Those values would reflect sales from two quarters earlier because they would be the most recent values available at the time that a 340B ceiling price for a quarter needs to be set. After the AMP and URA for a quarter are initially filed and used to set the 340B ceiling price, they may later be restated with CMS.

retroactive adjustments to relevant pricing data,” in which event this may be the only explanation needed of an “overcharge.”

D. Manufacturer Recertification

HRSA proposes to create a manufacturer recertification process under which HRSA would “list manufacturers as participating in the 340B program” if they annually update their 340B database information.²¹⁵ Manufacturers also “should provide [HRSA] with any changes to 340B database information as changes occur” and HRSA could request supporting documentation.²¹⁶ According to the Proposed Guidance, “[t]his process is designed to prevent pricing violations and improve the accuracy of the public 340B database.”²¹⁷

PhRMA requests HRSA to provide greater specificity regarding its proposals. Specifically, HRSA does not explain what information would be required to “recertify” the manufacturer as a 340B program participant, what type of “supporting documentation” it would need, and under what circumstances such documentation would be requested. Further, there are no timelines proposed as to when manufacturers would be required to update their 340B database information, or how long HRSA would take to confirm that the manufacturer has successfully “recertified.” HRSA also should specify applicable timelines associated with any submission or review of supporting documentation. Finally, since we do not know what information will be required for purposes of the recertification, we do not understand how the process will prevent pricing violations (and HRSA does not provide an explanation). We recommend that HRSA propose the specific requirements, including timelines, that manufacturers would be required to meet, and then publish these standards for notice and comment.

IX. REBATE OPTION FOR AIDS DRUG ASSISTANCE PROGRAMS

HRSA proposes that ADAPs choosing to use the rebate option (either solely or as part of the “hybrid” option) would be eligible for 340B pricing if the ADAP makes a “qualified payment” of covered outpatient drugs. A payment would be considered a qualified payment if the ADAP: (1) purchases drugs at a price above the 340B ceiling price; or (2) purchases the patient’s health insurance (by paying the premium), and pays the cost-sharing on that drug.²¹⁸ This proposal is based on two conclusions HRSA reached: (1) “that the use of ADAP funds to make a qualified payment . . . constitutes a purchase [for 340B program purposes]”; and (2) “that the payment by the ADAP of a copayment, coinsurance, or deductible, in the absence of also paying for the health insurance premium, is too attenuated within the context of the 340B Program to constitute a ‘purchase.’”²¹⁹ We understand that under scenario two this proposal would permit 340B rebates as long as the ADAP pays the patient’s share of the premium plus

²¹⁵ 80 Fed. Reg. at 52312.

²¹⁶ 80 Fed. Reg. at 52312.

²¹⁷ 80 Fed. Reg. at 52313.

²¹⁸ 80 Fed. Reg. at 52313.

²¹⁹ 80 Fed. Reg. at 52313.

the patient's cost-sharing. PhRMA supports this proposal. We urge HRSA to implement this policy in a way that avoids any disruption to patient care.²²⁰

Under the Proposed Guidance, the rebate owed to the ADAP for a drug would equal the Medicaid unit rebate amount (URA), regardless of the amount expended by the ADAP to pay the patients' health insurance premium and cost-sharing.²²¹ HRSA stated that it "considered a percentage rebate whereby an ADAP would be entitled to a percentage of the rebate on a dispensed drug contingent on the percentage of the total cost of the drug borne by the ADAP" but decided this approach would be unworkable.²²² PhRMA appreciates that HRSA considered this alternative approach that arguably would result in a more equitable result for manufacturers. However, PhRMA understands that such an approach would add complexity to an already complex program, and thus we support HRSA's proposal that the amount owed to an ADAP for a covered outpatient drug would be equal to the full Medicaid URA.²²³

Finally, the Proposed Guidance cautions that "no covered entity may obtain 340B pricing (either through a rebate or through a direct purchase) on a drug purchased by another covered entity at or below the 340B ceiling price."²²⁴ However, HRSA does not identify any particular mechanism that ADAPs should use to prevent this. PhRMA supports this general principle, and urges HRSA to clarify in its final guidance that this issue concerns 340B duplicate discounts (as opposed to Medicaid/340B duplicate discounts). We also urge HRSA to specify the mechanism for preventing these "double 340B" discounts and, in particular, to provide that non-ADAP covered entities may not use 340B drugs in instances where an ADAP is the payer. In other words, non-ADAP covered entities may not bill ADAPs for drugs purchased at the 340B price, and thus trigger a duplicate discount (or take the 340B discount for itself rather than the ADAP).

²²⁰ HRSA may want to work with Congress to confirm and further solidify this approach.

²²¹ 80 Fed. Reg. at 52314.

²²² 80 Fed. Reg. at 52314.

²²³ HRSA also proposes that ADAPs would be "expected" to submit claims-level data to a manufacturer to receive a rebate. 80 Fed. Reg. at 52313. PhRMA supports HRSA's proposal for ADAPs to submit claims-level data. We urge HRSA to work with stakeholders to determine the right data points necessary for manufacturers to process claims appropriately and ensure that no double discounting occurs, and that would not be unnecessarily burdensome to ADAPs. We also ask HRSA to make submission of claims-level data accompanying the ADAP's invoice to the manufacturer a requirement, rather than an expectation. HRSA should establish a workable policy within a timeframe that is reasonable to ensure that ADAPs are able to implement the proper reporting mechanisms to meet HRSA's requirements.

²²⁴ 80 Fed. Reg. at 52313-52314.

X. PROGRAM INTEGRITY AUDIT PROVISIONS

A. HHS Audits of Covered Entities

The Proposed Guidance includes a number of audit-related proposals,²²⁵ including a proposal for a “notice and hearing process” to allow covered entities to challenge adverse audit findings and/or other instances of noncompliance.²²⁶ Under this process, HHS would notify a covered entity of a proposed adverse finding, and the entity would have 30 days to respond. If a final determination of noncompliance were made, the covered entity could be removed from the 340B program, or could be permitted to remain in the program if it submitted and complied with a corrective action plan. Entities found in violation of the 340B statute must repay affected manufacturers for 340B purchases “made after the date the entity first violated the statutory requirement” (this statement necessarily must refer to eligibility-related violations).²²⁷

Under the Proposed Guidance, HRSA would extend the notice and hearing process to “covered entities found in violation of the GPO prohibition,” and would permit entities to demonstrate that “the GPO violation was an isolated error as opposed to a systematic violation.”²²⁸ HRSA proposes that “[i]f the covered entity were to demonstrate the GPO violation was an isolated incident and the covered entity is currently in compliance, the covered entity will be permitted to remain in the 340B Program upon submission of a corrective action plan.” HRSA’s proposal is inconsistent with the statute. As HRSA knows, the 340B law prohibits -- as a condition of eligibility -- disproportionate share hospitals, children’s hospitals, and free-standing cancer hospitals from “obtain[ing] covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.”²²⁹ When such a hospital is in violation of the GPO prohibition, it is not a “covered entity” under the 340B program, and HRSA does not have the discretion to permit “non-systematic” non-compliance with the statute. Simply put, a hospital is either eligible or ineligible for the 340B program. Corrective action plan or not, HRSA may not expand the 340B program to hospitals that do not meet statutory eligibility criteria.²³⁰ PhRMA urges HRSA to abandon this impermissible approach in its final guidance.

With respect to violations of the duplicate discount or diversion prohibitions, PhRMA urges HRSA to provide specific details as to what would constitute a “systematic” violation that would warrant removing the covered entity from the 340B program. Because statutory monetary penalties for covered entities are minimal, removal from the 340B program is the only meaningful deterrent for covered entity compliance. Thus, it is important that covered entities have notice as to what behavior will result in removal from the program. PhRMA recommends, at a minimum, that a systematic violation would be one that occurs over and over and over again.

²²⁵ In the Proposed Guidance, HRSA proposes a five year record retention standard for both covered entities and manufacturers. PhRMA believes this time period is appropriate, and supports this proposal.

²²⁶ 80 Fed. Reg. at 52314.

²²⁷ 80 Fed. Reg. at 52315.

²²⁸ 80 Fed. Reg. at 52305.

²²⁹ 42 U.S.C. § 256b(a)(4)(L)(iii), (M).

²³⁰ Our comments are not limited to ineligibility solely related to the GPO prohibition, but apply for all instances of ineligibility according to the terms of the statute, e.g., loss of grant funding, failure to maintain auditable records, etc.

B. Manufacturer Audits of Covered Entities

Consistent with existing guidance, HRSA states that to audit a covered entity a manufacturer must establish “reasonable cause.”²³¹ To satisfy reasonable cause, a manufacturer would have to “document[] to HHS’s satisfaction that a reasonable person could conclude, based on reliable evidence, that a covered entity, its child sites, or contract pharmacies may have violated either [the duplicate discount or diversion prohibition].”²³² HRSA provides a few examples of what could constitute reasonable cause, as follows:

- significant changes in quantities of specific drugs ordered by a covered entity without adequate explanation by the covered entity;
- significant deviations from national averages of inpatient or outpatient use of certain drugs without adequate explanation by the covered entity; and
- evidence of duplicate discounts provided by manufacturers or State Medicaid agencies.²³³

In addition, “a covered entity’s refusal to respond to manufacturer questions related to 340B drug diversion and duplicate discounts may also be construed as reasonable cause.”²³⁴ PhRMA supports HRSA’s proposal, and agrees that these examples would constitute reasonable cause for a manufacturer to audit a covered entity. PhRMA also agrees that the list of examples is not exhaustive. We recommend that HRSA’s final guidance on “reasonable cause” remain consistent with the Proposed Guidance.

Under the statute, a covered entity must permit the Secretary and the manufacturer to audit “the records of the entity that directly pertain to the entity’s compliance” with the statutory prohibition against duplicate discounts and diversion. In HRSA’s discussion in the Proposed Guidance of HHS audits of covered entities, HRSA explains that “HHS must be provided access to all records pertaining to compliance, including those of any child site or pharmacy which is under contract with the covered entity.” PhRMA agrees that all such records -- including those of child sites and contract pharmacies -- are relevant to determining a covered entity’s compliance with the prohibition on duplicate discounts and diversion. HRSA does not explicitly state that such records must be provided pursuant to manufacturer audits, however. PhRMA urges HRSA to clarify in its final guidance that such records are equally pertinent in the context of manufacturer audits and thus manufacturers also should be provided records of child sites and contract pharmacies, as applicable.

Finally, HRSA’s current audit guidelines contemplate circumstances in which multiple manufacturers may have the same concern about a particular covered entity’s practices. According to the current guidance:

²³¹ 80 Fed. Reg. at 52315.

²³² 80 Fed. Reg. at 52315.

²³³ 80 Fed. Reg. at 52315.

²³⁴ 80 Fed. Reg. at 52315.

Consistent with Government auditing standards, the organization performing the audit shall coordinate with other auditors, when appropriate, to avoid duplicating work already completed or that may be planned. Only one audit of a covered entity will be permitted at any one time. When specific allegations involving the drugs of more than one manufacturer have been made concerning an entity's compliance with [duplicate discount and diversion prohibitions], the Department will determine whether an audit should be performed by the (1) Government or (2) the manufacturer.²³⁵

PhRMA recognizes that HRSA has limited resources and that it may take time for HRSA to take on the audit itself in such circumstances. Therefore, HRSA should provide that in cases where multiple manufacturers with overlapping concerns wish to have an audit conducted, the manufacturers may coordinate on audits of the same covered entity so that an audit may promptly proceed and the covered entity will not be overwhelmed by multiple back-to-back audits.

C. HHS Audits of a Manufacturer and its Contractors

The Proposed Guidance provides for HHS audits of "a manufacturer or wholesaler that manufacturers, processes, or distributes covered outpatient drugs in the 340B Program."²³⁶ HRSA also proposes a notice and hearing process, and the potential for a manufacturer to implement a corrective action plan. In general, PhRMA would support HRSA's proposal regarding manufacturer audits; however, we have two comments regarding HRSA's specific proposal. First, we note that the 340B statute specifically permits HRSA to audit "manufacturers and wholesalers" to ensure program integrity.²³⁷ HRSA's proposal provides that HHS would audit "all relevant records retained by the manufacturer or any of its contractors (such as wholesalers) . . ." This goes beyond HRSA's statutory authority, which extends only to manufacturers and wholesalers (and covered entities). We recommend that HRSA correct this language in its final guidance to be consistent with the statute. Second, HRSA's statutory authority to audit wholesalers does not confer any responsibility on manufacturers for ensuring a wholesaler's cooperation with HRSA in any audit. HRSA should recognize this point in its final guidance.

D. Covered Entity Audits of Contract Pharmacies

In the Proposed Guidance, HRSA refers to its 2010 contract pharmacy guidance²³⁸ that recommended that covered entities conduct annual audits of contract pharmacies. The Proposed Guidance "further clarifies the expectations of this recommendation."²³⁹ Given the widespread problems and increased compliance risks associated with contract pharmacies (as described in Section VII), PhRMA recommends that HRSA require (as opposed to simply

²³⁵ 61 Fed. Reg. 65406 at 65409 (Dec. 12, 1996).

²³⁶ 80 Fed. Reg. at 52315.

²³⁷ 42 U.S.C. §§ 256b(d)(1)(B)(v).

²³⁸ 75 Fed. Reg. at 10272 (March 5, 2010).

²³⁹ 80 Fed. Reg. at 52311.

recommend) that covered entities have annual independent on-site audits conducted of contract pharmacies. This requirement also should extend to any third party administrators or other vendors providing 340B-related services for a covered entity. These audits should be performed by an independent third party, and should follow Government Accepted Auditing Standards.²⁴⁰ Covered entities also should be required to submit the results of these annual audit reports to HRSA within 30 days of completion. In addition, covered entities should submit a corrective action plan to HRSA at that same time if their audit reports have found 340B program violations.

XI. MISCELLANEOUS

A. Public Health Emergencies

PhRMA noticed that HRSA's Proposed Guidance provides for "flexibilities" regarding certain aspects of the 340B program in instances where the HHS Secretary has declared a public health emergency.²⁴¹ Specifically, HRSA states that "unique circumstances . . . arise during a public health emergency declared by the Secretary" and proposes to allow "certain flexibilities for demonstrating that an individual is a patient of a covered entity in these situations (e.g., limited medical documentation or a site not listed in the 340B database)."²⁴² In the contract pharmacy context, HRSA proposes to make special provision for public health emergencies by permitting covered entities to request additional contract pharmacy locations under a public health emergency.²⁴³ Also, HRSA envisions mid-quarter covered entity additions or deletions in a public health emergency situation.²⁴⁴

The Proposed Guidance provides little information about how HRSA would decide when a particular public health emergency warranted an exception to 340B requirements and precisely what exceptions were needed, nor does it explain whether it believes it can grant exceptions to statutory requirements (e.g., the diversion ban). HRSA also does not reference its current guidance published on its website, "340B Flexibilities During Disasters,"²⁴⁵ or explain whether it intends the Proposed Guidance (once finalized) to replace its current website guidance. The guidance on the HRSA website appears to limit 340B "flexibilities" to 340B providers "participating in disaster relief efforts."

²⁴⁰ We think this requirement is important, as the covered entity itself may not have the same incentive to detect violations that an independent auditor would have.

²⁴¹ These emergency declarations are made under 42 U.S.C. § 247d (which is scheduled to terminate on September 30, 2018, and permits public health emergency determinations where a disease or disorder presents a public health emergency or a public health emergency (including infectious disease outbreaks or bioterrorist attacks) "otherwise exists)." Public health emergencies terminate after 90 days unless the Secretary declares before then that the emergency no longer exists, or renews the emergency determination.

²⁴² 80 Fed. Reg. at 52307-52308.

²⁴³ 80 Fed. Reg. at 52310-52311.

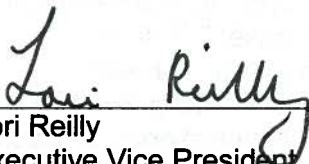
²⁴⁴ 80 Fed. Reg. at 53112, 52318.

²⁴⁵ The guidance on 340B Flexibilities During Disasters is available at: <http://www.hrsa.gov/opa/emergencies.html>.

PhRMA urges HRSA to clarify these points in its final guidance. In general, PhRMA understands and supports the notion that certain emergencies may necessitate certain “flexibilities.” That said, it is important that HRSA exercise these flexibilities very carefully and only when needed. In addition, the exercise of any flexibilities should not depart from statutory requirements or other standards that are central to the integrity of the 340B program.

We hope our comments are useful to HRSA, and we would be happy to discuss these issues with you if you have any questions or need clarification. PhRMA greatly appreciates HRSA's consideration of our concerns and we stand ready to assist with any of the issues raised in our letter. Please contact Sylvia Yu at 202-835-3496 (syu@phrma.org) or Karyn Schwartz at 202-835-3491 (kschwartz@phrma.org) with any questions.

Sincerely,



Lori Reilly
Executive Vice President
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