October 27, 2015

Captain Krista Pedley, Director
Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, MD 20857

Re: Comments on HRSA Notice – 340B Drug Pricing Program Omnibus Guidance (RIN 0906-AB08)

Dear Captain Pedley:

The undersigned associations appreciate the opportunity to comment on the proposed guidance, *340B Drug Pricing Program Omnibus Guidance*. On August 28, 2015, the Health Resources and Services Administration (HRSA) issued proposed guidance on a broad range of 340B program issues. We appreciate HRSA's effort to improve program compliance through new and updated guidelines. However, we are deeply concerned about the substantial negative impact that some of the proposed changes in the guidance would have on safety-net providers and, most importantly, their uninsured, underinsured, and vulnerable patient populations.

Our organizations represent thousands of safety-net providers participating in the 340B program. Accordingly, we are uniquely positioned to present the perspective of 340B covered entities on the guidance. Our comments concern the sections of the guidance related to duplicate discounts and the maintenance of auditable records.[1] As explained more fully below, our comments include the following concerns and requests:

- HRSA's interpretation of the duplicate discount prohibition, which the agency believes applies to 340B drugs given to Medicaid managed care organization (MCO) patients, conflicts with the plain meaning of the 340B statute and would be operationally burdensome for covered entities to meet. We ask HRSA to make clear that the duplicate discount prohibition does not apply to 340B Medicaid MCO drugs and that covered entities have a right to choose whether or not to use 340B drugs for Medicaid MCO patients. We also request that HRSA, instead of creating an exclusion file for Medicaid managed care, encourage states to work with covered entities to identify 340B Medicaid MCO claims.

- While the 340B statute undoubtedly permits HRSA to audit a covered entity and to use the entity's records to making findings and determinations regarding 340B compliance, the agency does not have statutory authority to treat maintenance of auditable records as a standalone eligibility requirement for covered entities. Therefore, the agency cannot remove a covered entity from the 340B program simply for failing to have auditable records. We ask HRSA to clarify that a failure to demonstrate compliance with a certain 340B program requirement (e.g., the duplicate discount prohibition) due to a lack of auditable records is only punishable under statutory provisions relevant to the particular requirement.

[1] Our organizations also individually submitted issues other issues addressed in the proposed guidance.

Part D – Covered Entity Requirements – Duplicate Discounts

We support HRSA's determination that covered entities can make different carve-in and carve-out decisions for Medicaid fee-for-service (FFS) and Medicaid MCO claims, and even make different decisions by MCO. However, we think that covered entities also need flexibility to be able to decide whether to use 340B on a drug-by-drug basis. We also recognize the interest in ensuring that manufacturers do not pay a 340B discount and a Medicaid rebate on the same drug, and we support having all stakeholders involved in ensuring that this is the case. However, the proposed guidance puts the burden of protecting manufacturers solely on covered entities, which is contrary to the plain meaning of both the 340B and the Medicaid rebate statutes and is operationally outside the covered entities' control. Moreover, we are concerned that an exclusion file for MCOs would be too complicated to maintain and may not be effective in helping states ensure that their rebate requests do not include 340B claims.

HRSA should instead promote state programs that have been proven to address the need for 340B Medicaid MCO claim identification. States should develop 340B Medicaid claim identification arrangements that account for differences between covered entities, including different inventory models. Because of these differences, a one-size fits all solution to this issue will not work. At least two states having demonstrated that 340B Medicaid MCO claim identification can be achieved by identifying appropriate claims after they have been processed and submitting that information directly to states. Other states, as well as MCOs, use modifiers, such as the National Council for Prescription Drug Programs' (NCPDP) value "20," to have 340B claims identified at the point of sale (POS). In addition to encouraging such arrangements, HRSA also should prohibit states and MCOs from mandating that covered entities "carve out" (i.e., use non-340B drugs) for Medicaid MCO patients.

We also ask HRSA to withdraw the proposed guidance regarding contract pharmacy Medicaid MCO billing. Not only does the 340B statute not provide HRSA with the authority to provide guidance in that area, but the proposal would improperly grant states and MCOs veto power over the ability of covered entities to access 340B discounts. Given that more and more states are moving their Medicaid populations to managed care, it is critical that the 340B program continue to assist those safety net providers that provide such a significant share of the Medicaid population.

In addition, we suggest improvements to the Medicaid MCO guidance if HRSA moves forward with it, call on HRSA to retain its current requirement for contract pharmacies that dispense 340B drugs to Medicaid FFS patients, ask that the FFS Medicaid Exclusion File (MEF) be made more dynamic and customizable, urge HRSA not to require covered entities that carve in to report to states or MCOs individual instances in which 340B drugs are not used, and request clarification regarding the rules governing contract pharmacies that dispense 340B drugs to Medicaid patients.

I. HRSA's Interpretation of the Duplicate Discount Prohibition Conflicts with the Plain Meaning of the 340B Statute and Is Operationally Impossible for Covered Entities to Meet

The guidance states that the 340B statute's duplicate discount prohibition applies to 340B drugs given to Medicaid MCO patients.[2] This interpretation conflicts with the statutory language because (1) drugs covered by MCOs are not subject to the 340B statute's duplicate discount prohibition and (2)

[2] Throughout this section, MCO only refers to Medicaid MCOs.

states, not covered entities, are responsible under federal law for protecting manufacturers from paying both a 340B discount and a Medicaid rebate on 340B drugs billed to Medicaid MCOs.

Since its enactment in 1992, the 340B statute has recognized that drug manufacturers might be subjected to "duplicate discounts" if a state Medicaid agency requested a Medicaid rebate on a drug that was sold to a covered entity at or below the 340B ceiling price.[3] The 340B statute states that a covered entity "shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under [the 340B statute] **if the drug is subject to the payment of a rebate** under [the Medicaid drug rebate statute]."[4] HRSA was directed to create a mechanism to ensure compliance with that requirement, which has taken the form of the MEF maintained by HRSA and accessible through its public website.

From 1990 to 2010, the Medicaid drug rebate statute only allowed state Medicaid agencies to claim a statutory rebate on covered outpatient drugs when the drug was paid for on a fee-for-service (FFS) basis.[5] Drugs that were covered by Medicaid MCOs were not eligible for a rebate. When the Affordable Care Act was enacted in 2010, it amended the Medicaid drug rebate statute to permit states to seek rebates for drugs covered by MCOs.[6]

Congress did not amend the duplicate discount provision in the 340B statute when it made drugs covered by an MCO rebate-eligible, but it did explicitly state in the Medicaid rebate statute that 340B Medicaid MCO drugs are not subject to a Medicaid rebate, providing that "[c]overed outpatient drugs **are not subject to the requirements of this section** [i.e., not subject to a rebate] if such drugs are … (A) dispensed by health maintenance organizations including Medicaid managed care organizations … and (B) subject to discounts under section 340B of the Public Health Service Act."[7] To ensure that states have the data needed to not seek rebates on 340B Medicaid MCO claims, Congress amended statutory contracting rules for MCOs to require MCOs to exclude National Drug Codes (NDCs) for 340B drugs from the reports they provide to states.[8]

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[3] *See* Veterans Health Care Act of 1992, Pub. L. 102-585, § 602, 106 Stat. 4943, 4968-69.

[4] 42 U.S.C. § 256(a)(5)(A) (emphasis added).

[5] *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508, § 4401 104 Stat. 1388, 1388-143 to -159. This is the subject to the mechanism described above, whereby a state may not collect a rebate covered outpatient drugs purchased at the 340B price.

[6] Patient Protection and Affordable Care Act, Pub. L. 111-148, §2501(c), 124 Stat. 119, 308 (2010).

[7] 42 U.S.C. § 1396r-8(j)(1) (emphasis added).

[8] *Id.* § 1396b(m)(2)(A)(xiii). In June 2015, the Centers for Medicare and Medicaid Services (CMS) proposed a regulation to implement this statutory requirement. Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability, 80 Fed. Reg. 31098, 31257 (proposed June 1, 2015) (to be codified at 42 C.F.R pt. 438.3(s)(3)). The proposed regulation would require MCOs to identify 340B claims and exclude those claims from the utilization reports that the MCOs provide to states for purposes of requesting Medicaid rebates from pharmaceutical manufacturers. Comments submitted by several of our organizations called for CMS to provide flexibility by permitting states to establish procedures that do not rely upon utilization data submitted by MCOs. Under this approach, an MCO would not remove 340B claims from the utilization report, and covered entities would instead send information on 340B claims directly to the state or its rebate contractor, not the MCO. A state might decide to take this approach if its MCOs do not possess the technological capability to identify and exclude 340B claims or do not have the necessary relationships with entities to develop successful 340B claim identification mechanisms. As we explain later in these comments, Oregon has already adopted this approach.

HRSA's proposed guidance clearly conflicts with the 340B statute because it states that the statute's duplicate discount prohibition applies to both FFS and MCOs, when it clearly only applies to FFS.[9] When describing contract pharmacies, the proposed guidance cites Section 340B(a)(5)(A)(ii) as authority for creating a mechanism for preventing duplicate discounts on MCO drugs, though that passage is also inapplicable to non-rebatable MCO drugs. The guidance should make clear that the duplicate discount provision in the 340B statute and the current MEF only apply to FFS**.**

The guidance should also make clear that the 340B statute gives covered entities the right to choose whether to use 340B drugs for Medicaid MCO patients, as they have been able to since the beginning of the program.[10] The only restrictions on how those drugs are used are explicit – the covered entity may not resell or otherwise transfer the drug to an individual who is not a patient of the entity, and the covered entity may not bill Medicaid for any drug subject to payment of a rebate to the state.[11] Not only did Congress refrain from placing any other restrictions on covered entities, it implicitly recognized that covered entities have a right to choose whether or not to use 340B drugs for Medicaid MCO patients by declaring such drugs to be non-rebatable, and therefore, not subject to the 340B statute's duplicate discount provision.[12]

HRSA's guidance should prohibit MCOs and states from mandating that covered entities carve out for Medicaid MCO patients, which impinges upon a covered entity's right to choose whether or not to use 340B drugs for Medicaid MCO patients. The agency also should prohibit states from requiring carving out FFS Medicaid patients. Mandatory carve outs force covered entities to pay higher prices for the drugs, especially hospitals that are subject to the GPO prohibition. In addition to harming covered entities, they lead to increased safety-net provider operating costs that can be borne by the taxpayer.

In addition to not being legally obligated on this issue for Medicaid MCO claims, there are significant operational issues that limit covered entities in this area, and that can only be addressed by states and/or MCOs and their pharmacy benefit managers (PBMs). Bank Identification Numbers (BINs) and Processor Control Numbers (PCNs) are used in combination to process electronic pharmacy claims. Some MCOs and PBMs use a single BIN-PCN combination for both their Medicaid and commercial lines of business. As noted by the HHS Office of Inspector General (OIG) in a February 2014 report, this poses a problem for a pharmacy because the pharmacy cannot distinguish between Medicaid and commercial claims.[13] The OIG noted that, for these reasons, it is important that covered entities have a complete list of BIN-PCNs, since there is no reliable way for covered entities to obtain complete information on their own.[14] Only the MCOs can make this change, though state Medicaid agencies could also require it as part of their contracts with MCOs. Covered entities, however, cannot. Therefore, it is operationally unworkable to impose the burden of identifying all Medicaid managed care claims on the backs of covered entities. We recommend that HRSA encourage State Medicaid plans to require MCOs or, if applicable, their PBMs, to have separate BIN-PCN combinations for their Medicaid Plans and to share

[9] Proposed Guidance at 52,308.
[10] 42 U.S.C. § 256b(a)(1).
[11] *Id.* § 256b(a)(5)(A), (B).
[12] *Id.* § 1396r-8(j)(1).
[13] HHS Office of Inspector General, Memorandum Report: Contract Pharmacy Arrangements in the 340B Program 13 (Feb. 4, 2014).
[14] *Id.*

the combinations with covered entities. We note that Minnesota Medicaid has already instituted such a requirement for its MCOs.[15]

Proposed Provision: *Prohibition of Duplicate Discounts*. **Section 340B(a)(5(A)(i) of the PHSA prohibits duplicate discounts whereby a State obtains a rebate on a drug provided to a Medicaid fee-for-service ~~or managed care organization~~ patient when the same drug was discounted under the 340B program. This provision does not apply to drugs provided to a Medicaid managed care organization patient.**

II. HRSA Should Not Create a Medicaid Exclusion File for Managed Care and Should Instead Encourage States to Collaborate with Covered Entities to Identify 340B Medicaid MCO Claims

We appreciate that HRSA is considering the creation of an MCO MEF in order to ensure that covered entities can make different carve-in and carve-out decisions for FFS and MCO. However, after careful consideration, we have concluded that an MCO MEF is unlikely to help states meet their statutory obligation to protect manufacturers from having to pay both a Medicaid rebate and 340B discount on the same drug by excluding 340B claims from their rebate requests. In addition, an MCO MEF would impose a significant and inappropriate burden on covered entities.

Because Congress has already provided that states are responsible under federal law for protecting manufacturers from duplicate discounts on drugs paid for by Medicaid MCOs, we oppose the expansion of the MEF to managed care, as described in the proposed guidance. HRSA has the statutory authority to create a mechanism for the avoidance of FFS Medicaid duplicate discounts, but that authority, like the duplicate discount prohibition itself, is only applicable to drugs that are "subject to the payment of a rebate."[16] Because covered entities have a right to choose whether or not to use 340B drugs for their patients, except when billing FFS Medicaid, HRSA could not compel covered entities to describe their MCO billing requirements and keep those descriptions current. Further, some MCO contracts may prohibit the disclosure of specific terms.

States and covered entities are working together to develop solutions. Some states, such as New York, California, and Massachusetts, have adopted the use of NCPDP value "20" or other modifier codes for covered entities that are able to identify 340B drugs at POS. Alternatives are needed, however, for 340B pharmacies, including contract pharmacies, which cannot identify a 340B drug at the point of sale because they use a virtual 340B inventory, the inventory system most commonly used by contract pharmacies.[17] For such pharmacies, 340B patient eligibility determinations are usually made after a drug is dispensed to a patient. The pharmacies do not know at the POS whether a claim is for a 340B drug. HRSA should encourage MCOs and states to create retrospective 340B claim identification methods to accommodate these pharmacies. Reversal and resubmission of retrospectively identified claims should not be considered an acceptable method because doing so would be administratively and financially burdensome. Reversal and resubmission of each claim would be time consuming and would be a drain on a safety-net provider's already limited and precious financial resources. A 340B provider

[15] Minnesota Health Care Programs Provider Update PRX-14-01 (Mar. 26, 2014), http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_182830.

[16] 42 U.S.C. § 256b(a)(5)(A)(i), (ii).

[17] For a survey conducted by 340B Health in May 2015, 88.43% (84/95) of respondent hospitals said that all their contract pharmacies use a virtual 340B inventory.

would have to devote greater staff time or, in the case of a contract pharmacy arrangement, would likely have to pay the pharmacy more to handle the reversals and resubmissions.

At least two states have already developed solutions that work for pharmacies with a virtual 340B inventory. For example, both Oregon and Hawaii have created systems where the covered entity and the state Medicaid agency communicate directly to identify 340B managed care claims. Oregon Medicaid has instituted a retrospective identification mechanism that permits entities to send directly to the state's rebate contractor a quarterly claims file for 340B Medicaid MCO drugs dispensed by the entities' contract pharmacies.[18] This allows the state to remove those claims from their rebate requests. Hawaii Medicaid directs covered entities that want to carve in Medicaid managed care to notify the state of that decision and then submit a quarterly spreadsheet that identifies all non-340B medications that were dispensed to Medicaid patients and paid by a Hawaii Medicaid MCO in the prior quarter.[19] The state knows from the spreadsheet the claims for which it can request Medicaid rebates and refrains from collecting rebates on any other claims submitted by the covered entity.

The use of modifiers for POS identification and retrospective claim identification methods for covered entities or pharmacies unable to identify 340B drugs at POS offer manufacturers the best protection against having to pay both a 340B discount and a Medicaid rebate on the same drug because they allow the covered entity to accurately identify when a 340B drug is used. Accordingly, HRSA should encourage MCOs and states to adopt arrangements such as these because they protect against MCO duplicate discounts, while not infringing upon a covered entity's right to choose whether or not to use 340B drugs for Medicaid MCO patients.

Proposed Language: **(2) *Medicaid Managed Care*. The covered entity may choose whether to use 340B drugs for its Medicaid Managed Care organization (MCO) patients <u>on a drug-by-dug basi</u>s. ~~The covered entity may make different selections by covered entity site and managed care organization so long as such distinction is made available to HHS. This information may be made available publicly through an Exclusion File or other mechanism. In addition, a covered entity should have mechanisms in place identify Medicaid MCO patients~~.**

III. HRSA Should Withdraw Its Proposed Guidance Regarding Contract Pharmacy MCO Billing and the New Requirement to Establish a Written Agreement for HHS Approval for FFS Contract Pharmacy Billing

HRSA should eliminate any restrictions or presumptions regarding whether and how contract pharmacies can use 340B drugs for Medicaid MCO patients. The proposed guidance states that "when a contract pharmacy is listed on the public 340B database it will be presumed that the contract pharmacy will not dispense 340B drugs to Medicaid FFS or MCO patients."[20] To rebut the presumption, the covered entity must provide HRSA with a "written agreement with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts."[21]

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[18] Policy Notification – Oregon Medicaid 340B Drug Claims File (Feb. 13, 2015), http://www.oregon.gov/oha/healthplan/tools/Policy%20Notification%20-%20Oregon%20Medicaid%20340B%20Drug%20Claim%20File.pdf.

[19] State of Hawaii Department of Human Services, Med-QUEST Division, Health Care Services Branch, Memo No. ACS M13-03 (Mar. 14, 2013), http://www.med-quest.us/PDFs/Provider%20Memos/ACSMEMO2013/ACS%20M13-03.PDF.

[20] Proposed Guidance at 52,309.

[21] *Id.*

HRSA would exceed its statutory authority if it implemented the proposal. The 340B statute directs HHS to establish a mechanism to prevent FFS duplicate discounts.[22] The Medicaid rebate statute instructs HHS that states may not collect Medicaid rebates on 340B MCO drugs.[23] Neither statutory provision grants HHS authority to limit covered entities regarding billing and using 340B drugs for Medicaid MCO patients, which they are entitled to purchase pursuant to the 340B statute.[24] Covered entities have a right to choose whether or not to use 340B drugs for Medicaid MCO patients, and the proposal would serve as a substantive restriction on that right. The proposed presumption is actually a substantive rule with serious legal impacts on multiple parties. HRSA should remove it from the final guidance.

The proposed restriction on contract pharmacy billing would also have a devastating impact on some types of covered entities. HRSA originally described the contract pharmacy option as a solution for covered entities, primarily federally qualified health centers and Ryan White clinics that lacked in-house pharmacy services.[25] These same provider types often treat very few patients with commercial insurance. The presumption that contract pharmacies will not use 340B drugs for Medicaid MCO patients would be most difficult for small clinics to rebut, since they would have the least contracting leverage with MCOs. The proposal could virtually eliminate the benefit of the 340B program for such clinics. Since states are responsible under federal law for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on the same drug, HRSA should instead encourage states to work with covered entities to develop arrangements for the identification of 340B Medicaid MCO contract pharmacy claims.

In addition, we oppose the change made in this section regarding the requirements under which a covered entity's contract pharmacy may use 340B drugs for Medicaid FFS claims. The proposed guidance would require a written agreement and preapproval by HRSA, creating a new unnecessary burden and the potential for significant delay in implementing contract pharmacy arrangements that involve Medicaid FFS claims. HRSA has not provided any evidence that its current guidance is inadequate to protect against duplicate discounts. We request that HRSA revise this section of the guidance and continue its current policy.

We also ask the current guidance be changed. Under current guidance, a covered entity cannot have its contract pharmacy dispense 340B drugs to FFS Medicaid patients unless the entity, contract pharmacy, and state Medicaid agency have established an arrangement to prevent duplicate discounts and the arrangement has been reported to HRSA.[26] We recognize that there are special challenges in preventing duplicate discounts on such claims in contract pharmacy arrangements and the need for covered entities, their contract pharmacies, and State Medicaid agencies establish arrangements to prevent duplicate discounts. This requirement has been in place since 2010 and we understand that it has worked for some covered entities. However the requirement does not work if a state is unwilling to work with the covered entity to develop an arrangement. The requirement

[22] *See* 42 U.S.C. § 256b(a)(5)(A)(ii).
[23] 42 U.S.C. § 1396r-8(j)(1).
[24] § 256b(a).
[25] *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996).
[26] Final Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10272, 10278 (Mar. 5, 2010).

effectively gives the state veto power over whether a covered entity can use its contract pharmacies for FFS Medicaid patients. We ask that HRSA make clear that, if a state is unwilling to work with a covered entity to develop an arrangement to identify 340B drugs dispensed by the entity's contract pharmacy, the entity can meet it legal obligation by providing to the state information on which claims billed to the state by the contract pharmacy are 340B.

Proposed Provision: **(c) *Contract Pharmacy*. Unless otherwise noted on the public 340B database, contract pharmacies will not dispense 340B drugs for Medicaid FFS ~~or MCO patients~~. If a covered entity wishes to purchase 340B drugs for its Medicaid FFS ~~or MCO~~ patients and dispense 340B drugs utilizing a contract pharmacy, the covered entity, ~~will provide a written agreement for HHS approval with its contract pharmacy and State Medicaid agency or MCO that describes a system to prevent duplicate discounts.~~ the contract pharmacy, and the State Medicaid agency must have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to HRSA by the covered entity. If a state is unwilling to work with a covered entity to develop an arrangement to identify 340B drugs dispensed by the entity's contract pharmacy, the entity can meet its legal obligation by providing to the state information on which claims billed to the state by the contract pharmacy are 340B.**

IV. If HRSA Moves Forward with Guidance on MCO Billing, We Suggest Improvements to the Proposed Guidance

If HRSA moves forward with guidance on covered entities' use of 340B drugs for Medicaid MCO patients, HRSA should consider improvements to the proposed guidance. Any MEF or similar mechanism used to provide information on covered entity MCO elections should be capable of accommodating drug-by-drug decisions in addition to state-by-state, site-by-site, and MCO-by-MCO decisions. Such a mechanism could include the use of a static file supplemented by claims identification arrangements like the use of NCPDP value "20" for covered entities that can identify 340B claims at POS and the Oregon and Hawaii models described above for pharmacies with a virtual 340B inventory. The MEF elections could be reserved for situations in which the covered entity wishes to make an all-or-nothing election. HRSA should also adopt the guidelines to ensure that state or MCO action does not frustrate the purpose of the 340B program by depriving the covered entities of the ability to use 340B savings from Medicaid MCO drugs to reach more patients and provide more services. In these guidelines, we recommend that HRSA (1) prohibit MCOs and states from requiring covered entities to not use 340B drugs for Medicaid MCO patients, (2) encourage MCOs and states to develop both POS and retrospective 340B claim identification methods, (3) discourage MCOs and states from using HRSA's MEF to identify 340B Medicaid MCO claims, and (4) encourage states to require MCO to have separate BIN-PCN combinations for their Medicaid Plans and to share the combinations with covered entities.

If HRSA moves forward with creating a mechanism to prevent MCO duplicate discounts in the contract pharmacy setting, it should revise its proposal that the parties submit a written agreement between the covered entity, contract pharmacy, and MCO or state for approval prior to billing MCOs. This requirement is overly burdensome. HRSA has not provided any justification for altering the current process applicable to FFS Medicaid, in which the covered entity submits notice to HRSA that an arrangement exists avoid duplicate discounts is in place. As the Oregon model described above proves, an agreement with individual MCOs is not needed to implement an adequate mechanism. Arrangements to prevent duplicate discounts can be made directly between the covered entity and state.

V. HRSA Should Make the MEF More Dynamic and Customizable

The proposed guidance primarily restates existing HRSA guidance as it relates to FFS duplicate discounts. We would like to suggest the following improvements to the MEF and the existing FFS duplicate discount prevention tools.

We propose that HRSA replace the MEF with a web-based tool. The tool should allow for more detailed carve-in/out elections than what is permitted using the current MEF, including state-by-state elections using the National Provider Identifier (NPI). For the current MEF, HRSA directs covered entities to submit to the agency any billing numbers that they use to bill 340B drugs to FFS Medicaid. A covered entity that uses its NPI as its billing number for multiple state Medicaid programs could not carve in some states, but carve out others, because the NPI is not state-specific and the MEF does not allow a covered entity to identify for which states it is using its NPI to bill 340B drugs. The tool should also permit covered entities to provide an exception list containing 11-digit NDCs representing those that the covered entity will carve in if it generally carves out, or will carve out if it generally carves in. As an alternative to listing NDCs in the tool, HRSA could allow covered entities and state Medicaid programs to develop arrangements like the Oregon and Hawaii models described above for FFS.

The tool also should allow covered entities to make changes to its MEF elections at any time, and not just on a quarterly basis. Changes to practices (or billing numbers) rarely align with the beginning of a calendar quarter, and changes submitted within weeks of the beginning of a new quarter are often not included in the next quarter's file. The lag time is preventable.

VI. HRSA Should Not Require Covered Entities to Report Individual Transaction Exceptions to the 340B Drug Carve-In Election

HRSA should rescind any guidance requiring a covered entity that has indicated it will carve in to notify states or MCOs regarding individual instances in which 340B drugs are not used. Manufacturers are not at risk of providing a duplicate discount when a non-340B drug is given to a Medicaid patient. Any expectation that covered entities must notify Medicaid payers whenever a 340B drug could not be used (or 340B drugs could not be obtained to replenish the drug that was used) is unduly burdensome and beyond the statutory requirement that is focused on protecting manufacturers. It also is unclear how a covered entity could comply with such a requirement in some instances. A state or MCO may be unwilling to work with a covered entity to develop a notification mechanism. In such situations, there would be no clearly compliant way for the covered entity to notify the state or MCO. In addition, the state or MCO may not even want or do anything with the information, in which case, the covered entity would be attempting to comply with a meaningless requirement. At a minimum, HRSA should establish a materiality threshold before a covered entity would be required to make an exception report.

VII. Clarification Is Needed Regarding Conflicting Guidance for Contract Pharmacy

The section of the proposed guidance that addresses duplicate discounts prohibits a covered entity from using its contract pharmacy to dispense 340B drugs to Medicaid FFS or MCO patients, unless the entity has a written agreement with the contract pharmacy and state Medicaid agency or MCO describing a system to prevent duplicate discounts and the agreement has been approved by HRSA. This provision conflicts with the section of the guidance that addresses contract pharmacies. That section prohibits a contract pharmacy from dispensing 340B drugs to Medicaid patients, unless the covered entity has systems in place with the pharmacy and state Medicaid agency to prevent duplicate discounts

and has submitted information about the arrangement to HRSA.[27] The two policies are inconsistent because the first mandates a written agreement approved by HRSA, while the other merely requires an arrangement and notification to HRSA. We remind HRSA that, for the reasons explained above, we oppose agency-approved written agreements for contract pharmacies that dispense 340B drugs to Medicaid MCO patients, but support continuing to require covered entities to notify the agency of arrangements for contract pharmacies that dispense 340B drugs to Medicaid FFS patients. However, regardless of our concerns, HRSA should clarify in its finalized guidance which rules govern contract pharmacies that dispense 340B drugs to Medicaid patients.

Part E- Maintenance of Auditable Records

HRSA's proposed omnibus guidance and the preamble to it would specify that, with regard to maintaining auditable records:

- Covered entities and their child sites and contract pharmacies would have to retain records for a period of not less than five (5) years;
- HRSA would distinguish between systemic violations of the record auditability requirement and isolated instances where records cannot be audited; the former would be sanctioned by exclusion from the program while the latter would simply lead to an adverse finding that another program requirement (e.g., ineligible patients and diversion) has been violated; and
- Covered entities that have been terminated from 340B program due to a systematic violation of unauditable records requirements would be permitted to re-enroll in the program during the regular registration period after they have demonstrated to HRSA that they have the ability to comply with all program requirements, including the auditable records provision.

I. We Support HRSA's Proposed 5-Year Record Retention Period

We agree that there should be a well-defined records retention period, and it believes that the proposed five (5) year period strikes an appropriate balance between agency auditing needs and administrative burdens and expense for covered entities. Because affected parties will tend to adopt any minimum period for their policies (i.e., the mandated floor becomes the operative ceiling), we recommend that the records retention period simply be fixed at five years – a hard and non-subjective limit. We believe that the records retention period for manufacturers should also be five years, as proposed by HRSA. We also ask that HRSA enforce the five-year record retention requirement on a prospective basis. Since no such requirement currently exists, not all covered entities necessarily maintain records for five years for 340B program compliance purposes.

[27] This proposed guidance is similar to HRSA's 2010 contract pharmacy guidances, which prohibits a covered entity from having its contract pharmacy dispense 340B drugs to FFS Medicaid patients unless the entity, contract pharmacy, and state Medicaid agency have established an arrangement to prevent duplicate discounts and the arrangement has been reported to HRSA. Final Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10272, 10278 (Mar. 5, 2010).

II. HRSA Should Not Treat Maintenance of Auditable Records as a Standalone Eligibility Requirement

The 340B statute clearly allows HRSA to audit covered entities for compliance with program requirements.[28] Pursuant to that authority, HRSA can use a covered entity's records to make findings and determinations regarding the entity's 340B compliance. For example, HRSA could find and determine that a covered entity committed diversion and must repay manufacturers based on documents provided by the entity and reviewed by HRSA during an audit. In addition, if a covered entity were unable to provide to HRSA records to demonstrate compliance with a certain program requirement, such as the diversion prohibition, the agency could conclude that the entity violated that requirement based on the absence of records to support proper use of 340B for that claim. However, HRSA does not have statutory authority to treat the maintenance of auditable records as a standalone eligibility requirement for covered entities.

The 340B statute states that [a] covered entity shall permit the Secretary … to audit … the records of the entity that directly pertain to the entity's compliance with [program] requirements."[29] Clearly, a covered entity would violate the provision if it did not allow HRSA to audit its records for 340B compliance. However, the provision does not support HRSA's proposal that a covered entity's lack of auditable records by itself should disqualify an entity from 340B participation. We ask HRSA to clarify that a finding of non-compliance with a certain 340B program requirement due to a lack of auditable records is punishable under statutory provisions relevant to noncompliance with the particular requirement at issue.

III. Systemic Violations Versus Isolated Violations

If HRSA were to treat maintenance of auditable of records as an eligibility requirement, we would support HRSA's proposed distinction between systemic auditable record violations (which would lead to program exclusion) and individual violations (which would result in adverse findings as to the particular program requirement for which the unauditable records pertain). Program exclusions for individual, rare, or non-pervasive instances of unauditable records would needlessly punish patients who are the ultimate beneficiaries of the 340B program. Such cases can be effectively policed through other, less draconian sanctions that are available to HRSA.

In the same vein, we applaud HRSA's willingness, during the audit appeals process, to accept and review additional records submissions that challenge adverse findings on auditability. Circumstances such as tight schedule deadlines, miscommunications or misunderstandings, or the absence of key personnel often make it difficult for covered entities to provide auditors with all requested records before the audit or while they are on-site. HRSA's administrative flexibility in this respect has been encouraging. Although it does not need to be part of the guidance, HRSA should consider modifying its audit procedures to: (1) furnish a preliminary notification to covered entities after the audit but before any report when it appears that there may be auditability problems; and (2) establish a reasonable deadline after completion of the on-site audit and after such notification for covered entities to supply additional documentation to the auditors. In most cases, this might negate the need for covered entities to do so during the appeals process and will save both HRSA and covered entities time and resources.

[28] 42 U.S.C. § 256b(a)(5)(C).
[29] *Id.*

IV. Re-Enrollment After Program Exclusion For Lack Of Auditable Records

HRSA proposes to permit a covered entity that has been removed from the program for systematic failure to maintain auditable records to re-enroll in the 340B program during the registration cycle immediately after it demonstrates to HRSA's satisfaction that it can comply with all program requirements, including the obligation to keep auditable records. We would support this proposal if HRSA were to treat maintenance of auditable of records as an eligibility requirement.

We believe that it is important not to create a re-enrollment process that is either unduly burdensome or that goes beyond the statutory requirements for program participation. Equally important, HRSA is correct that there should not be any mandatory minimum period for exclusion in these cases. Aside from the lack of statutory authority for this type of sanction, any such violations are not criminal in nature and do not warrant exclusion for a stated period of time regardless of facts and circumstances, including the covered entity's willingness and ability to meet program requirements going forward. In that regard, these types of violations are unlike those which lead to mandatory Medicare or Medicaid program exclusions for specified periods of time. The five-year exclusion penalty of the Medicare and Medicaid programs applies only in connection with a conviction for criminal activity or repeated exclusion offenses. Further, mandatory minimum exclusion periods would be unduly harsh and would hurt the patients who benefit from a covered entity's program participation.

HRSA's enrollment and re-enrollment procedures under current policy and the proposed guidance are and would be sufficiently stringent to provide both reasonable assurances of program compliance and adequate review of a covered entity's capacity to meet program standards.

V. Clarification Of Purpose Of Auditable Records

In the preamble and the proposed guidance, HRSA has alluded to the fact that the auditable records requirement is rooted in the statute and that it pertains to determining compliance with 340B program standards. The proposed guidance contains no definition of "auditable records," and we believe this omission is entirely sensible. No definition is likely to enumerate all of the types or varieties of documents generated and maintained to meet these standards or to anticipate the evolving technology that is employed to assure such compliance. At the same time, we suggest that HRSA emphasize in the final guidance that the purpose of the auditable records requirement is to ensure that a covered entity has records sufficient to enable the agency to assess a covered entity's compliance with 340B program requirements.

Conclusion

We thank HRSA for the opportunity to comment on the proposed guidance. If you have any questions or would like to discuss any of our concerns or requests, please feel free to reach out to any of the attached contacts.

Sincerely,

340B Health
Children's Hospital Association
Hemophilia Alliance

National Alliance of State and Territorial AIDS Directors
National Association of Community Health Centers
National Family Planning and Reproductive Health Association
National Health Care for the Homeless Council
Planned Parenthood Federation of America
Ryan White Clinics for 340B Access

Organizational Contacts

Murray C. Penner
Executive Director
National Alliance of State and Territorial AIDS Directors (NASTAD)
(202) 434.8099; mpenner@nastad.org

Maureen Testoni
Senior Vice President & General Counsel
340B Health
202-552-5851; maureen.testoni@340bhealth.org

Amy Yenyo
Senior Policy Counsel
Planned Parenthood Federation of America
202-973-4870; amy.yenyo@ppfa.org

Mindy McGrath
Policy Director
National Family Planning & Reproductive Health Association
202-286-6877; rsummers@nfprha.org

Jim Kaufman
Vice President of Public Policy
Children's Hospital Association
202-753-5392; liz.parry@childrenshospitals.org

Colleen P. Meiman
Director of Regulatory Affairs
National Association of Community Health Centers
202-296-0158; cmeiman@nachc.org

Joe Pugliese
President
The Hemophilia Alliance
215-439-7173; joe@hemoalliance.org

John N. Lozier, MSSW
Executive Director
National Health Care for the Homeless Council
615-226-2292 ext 224; jlozier@nhchc.org

Dr. Howell Strauss
President
Ryan White Clinics for 340B Access
610-583-1177; howellstrauss@aidscaregroup.org