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Via Email: victoria.wachino1@cms.hhs.gov

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Deputy Administrator and Director
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Centers for Medicare & Medicaid Services
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Re: Delaware Medicaid State Plan Amendment & CMS Guidance to States on Implementation of Covered Outpatient Drug Final Regulation Provisions Related to Medicaid Reimbursement of 340B Drugs

Dear Ms. Wachino:

We are writing to request a meeting with you to discuss two issues involving the Medicaid program's treatment of drugs purchased through the 340B federal drug discount program. Our organizations represent thousands of safety-net providers that participate in the 340B program. First, we would like to share our concerns regarding Delaware Medicaid's State Plan Amendment (SPA) that would prohibit 340B providers (aka "covered entities") from using a 340B drug for any Medicaid patient.[1] We urge the Centers for Medicare & Medicaid Services (CMS) to disapprove the SPA because it is contrary to longstanding federal law and congressional intent, and is based on incomplete and inaccurate information.

Second, we would like to discuss CMS's February 11, 2016 letter to State Medicaid Directors regarding, among other issues, implementation of covered outpatient drug final regulation provisions related to Medicaid reimbursement of 340B drugs.[2] We are concerned that some of the language used in the letter to describe payment for 340B drugs is inconsistent with the final regulation. While the preamble to the regulation suggests that CMS is willing to consider 340B

[1] Delaware Department of Health and Social Services, Division of Medicaid and Medial Assistance, State Plan Amendment (SPA) Regarding Reimbursement for Pharmaceuticals (Jan. 19, 2016), http://regulations.delaware.gov/register/february2016/final/19%20DE%20Reg%20748%2002-01-16.pdf. ("Del. SPA").

[2] Centers for Medicare & Medicaid Services (CMS) Letter to State Medicaid Directors about Implementation of Covered Outpatient Drug Final Regulation Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program (Feb. 11, 2016), https://www.medicaid.gov/federal-policy-guidance/downloads/smd16001.pdf. ("CMS Letter").

payment rates proposed by states that are above acquisition cost,[3] the letter states that 340B rates are capped at the 340B ceiling price.[4] To ensure states' implementation of the final regulation is consistent with the rule itself, we ask that CMS issue further guidance clarifying that the agency will consider 340B rates above the 340B ceiling price.

As CMS evaluates our letter, we ask that the agency also carefully consider how its 340B-related policies could inadvertently increase Medicaid drug spending. A recent report found that Medicare Part B pays 340B hospitals less for drugs per beneficiary than non-covered entities.[5] Although the report focused on Medicare spending, there is nothing to suggest that this outcome would be any different for Medicaid programs. This potential impact on spending should certainly be considered and evaluated before prohibiting covered entities from using 340B for Medicaid. While well-intentioned, these policies could be a "penny wise, but pound foolish" proposition.

I. CMS Should Disapprove Delaware Medicaid's SPA

Delaware Medicaid has published a proposed SPA that would prohibit covered entities from giving 340B drugs to patients enrolled in either fee-for-service (FFS) Medicaid or a Medicaid managed care organization (MCO).[6] We ask CMS to disapprove the SPA for several reasons. First, it is predicated upon incomplete and inaccurate information that misrepresents the impact the SPA would have on covered entities. Second, the proposed policy contravenes federal law permitting a covered entity to decide whether to use 340B drugs for Medicaid patients. In addition, requirements like Delaware's SPA would significantly raise drug costs for many 340B hospitals and clinics. We are concerned that, if CMS were to approve the proposed SPA, it would serve as a template for other states, multiplying the harm to covered entities. For these reasons, we ask CMS to disapprove the SPA. If CMS approves the proposed SPA, the agency should require the state to create an exemption process and, at a minimum, to review the policy annually.

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[3] Medicaid Program, Covered Outpatient Drugs Final Rule, 81 Fed. Reg. 5170, 5320 (Feb. 1, 2016). ("Final Rule").
[4] CMS Letter at 3.
[5] Dobson DaVanzo & Associates, Analysis of Separately Billable Part B Drug Use Among 340B DSH Hospitals and Non-340B Providers 14 (Feb. 10, 2016), http://www.340bhealth.org/files/Dobson_DaVanzo_Part_B_Drug_Spending.pdf. "Across all Part B separately billable drugs for all beneficiaries, beneficiaries who received drugs in 340B [disproportionate share] hospitals [(DSH)] had an average drug spending per beneficiary of $112.15 compared to $128.91 for beneficiaries treated in non-340B providers."[5] The difference was even more dramatic for the most expensive drugs. "Among beneficiaries who received at least one of the top 50 drugs provided by 340B DSH hospitals (ranked by total Medicare spending), drug spending per beneficiary was 60 percent lower than spending in non-340B providers ($240.92 versus $556.02)."
[6] Del. SPA.

A. Delaware Medicaid Relied upon Incomplete and Inaccurate Information to Support the SPA

The SPA states that "[p]harmacy providers enrolled with Delaware [Medicaid] have declared that they do not use public health service products" (i.e., 340B drugs) and that the purpose of the proposed carve-out requirement is "to clarify that providers of pharmaceutical services who have access to 340B medications are not dispensing nor administering them to treat Medicaid patients."[7] While the providers that Delaware Medicaid spoke with might have indicated they do not use 340B drugs for Medicaid patients, we have since verified that the state did not speak with all covered entities prior to proposing the SPA. In addition, we have confirmed that some covered entities do use 340B for at least some Medicaid patients. Therefore, the purpose of the SPA is based on incomplete and inaccurate information. Although it is not clear from the notice, the state might have relied upon the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs' (OPA) Medicaid Exclusion File to determine whether covered entities use 340B drugs for Medicaid. However, this would be an inappropriate use of the file, as HRSA has indicated that the file applies to Medicaid FFS drugs only.[8] A state should not rely upon the file to find out whether a provider uses 340B drugs for Medicaid MCO patients because the file was not created to capture or convey that information. Given that the SPA is predicated upon incomplete and inaccurate information, both in terms of current practice and the proposed policy's impact on covered entities, we request that CMS disapprove the SPA.

B. HRSA's Duplicate Discount Mechanism Protects a Covered Entity's Right to Choose Whether or Not to Use 340B Drugs for Medicaid FFS Patients

When creating the 340B program in 1992, Congress directed the Secretary of Health and Human Services (HHS) to develop a mechanism to protect manufacturers from giving both a Medicaid rebate and 340B discount on the same drug, often referred to as a "duplicate discount."[9] At the time, only Medicaid FFS drugs were eligible for rebates from manufacturers. As we explain in more detail in the next section, this congressional mandate still only applies to Medicaid FFS drugs, although the Medicaid rebate program was expanded to include Medicaid MCO drugs in 2010 as part of the Affordable Care Act. Under the duplicate discount mechanism that HRSA created in 1993, a provider can (1) buy its drugs for Medicaid FFS patients outside the 340B program and accept a state Medicaid program's standard reimbursement rate ("carve out") or (2) notify HRSA that it intends to purchase its drugs for Medicaid beneficiaries at 340B prices, so that the state can exclude 340B claims from its Medicaid rebate requests to

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[7] *Id.*
[8] Clarification on Use of the Medicaid Exclusion File 1 (Dec. 12, 2014), http://www.hrsa.gov/opa/programrequirements/policyreleases/clarificationmedicaidexclusion.pdf.
[9] 42 U.S.C. § 256b(a)(5)(a)(ii).

manufacturers ("carve in").[10] This choice is consistent with the congressional purpose of the 340B program. The 340B program is intended to help safety-net providers stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.[11] As safety-net providers, our members focus on serving vulnerable patient populations, including uninsured, underinsured, and low-income patients. For example, a June 2015 report found that 340B hospitals' low-income patient loads are nearly twice the size of non-340B hospitals' low-income patient loads.[12] The same report also found that, while 340B hospitals account for only about one third of all disproportionate share hospitals, they provide nearly 60 percent of all uncompensated care.[13] According to the 2014 Family Planning Annual Report, 69% of family planning clinics' patients (2.8 million) had family incomes at or below 100% of the federal poverty level.[14] In addition, 54% of family planning clinics' patients (2.1 million) were uninsured, and 29% (1.2 million) were on public health insurance.[15] While covered entities have called for greater flexibility regarding carving in/out,[16] HRSA's duplicate discount mechanism is nonetheless aligned with the purpose of the 340B program by allowing a covered entity to decide whether carving in or carving out allows the entity to better achieve its safety-net mission.

We recognize that the Delaware SPA, if implemented, would protect manufacturers from duplicate discounts. But it would do so in a manner that conflicts with other parts of the 340B law and, for that reason, is legally unenforceable. As explained above, pursuant to a congressional mandate, the Secretary of HHS developed a mechanism that clearly gives covered entities a choice of buying their Medicaid FFS drugs through the 340B program or not.[17] Because the Delaware SPA would rob covered entities of that choice, it conflicts with not only the Secretary's mechanism, but also the statutory mandate on which the mechanism is based.

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[10] Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 27293 (May 7, 1993). This notice was finalized without change in Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34058 (June 23, 1993).

[11] H.R. Rep. 102-384(II) at 12 (1992); *see also* 42 U.S.C. § 256b (Section 340B of the Public Health Service Act).

[12] Dobson DaVanzo & Associates, Analysis of 340B DSH Hospitals Services Delivered to Vulnerable Patient Populations 16 (June 2, 2015), http://www.340bhealth.org/files/Dobson_DaVanzo_Final_Report.pdf.

[13] *Id.* at 17.

[14] Title X Family Planning Annual Report: 2014 National Summary 21 (Aug. 2015), http://www.hhs.gov/opa/pdfs/title-x-fpar-2014-national.pdf.

[15] *Id.*at 24.

[16] Joint Comments on 340B Drug Pricing Program Omnibus Guidance 2 (Oct. 27, 2015), http://www.340bhealth.org/files/joint_comments_mega_guidance.pdf. In the comments, organizations representing a broad range of covered entities requested "flexibility to be able to decide whether to use 340B on a drug-by-drug basis." HRSA's Medicaid Exclusion File currently only allows a covered entity to make a different carve-in/out decision for each billing number that the entity uses to submit claims for 340B drugs to Medicaid.

[17] 58 Fed. Reg. 27293 (May 7, 1993); 58 Fed. Reg. 34058 (June 23, 1993).

The proposed SPA conflicts with federal law in another way. Under the statute, if the HHS Secretary had not established a mechanism to implement the duplicate discount prohibition within a twelve month period, covered entities would have been required to notify states if they were billing 340B drugs and states would have been required to provide entities with a means for identifying 340B claims and to not submit rebates requests for 340B claims.[18] Congress's decision to include a default mechanism for avoiding duplicate discounts if the Secretary missed the twelve-month deadline is significant. Congress could have structured the default mechanism consistent with the Delaware SPA by prohibiting covered entities from buying Medicaid FFS drugs at 340B discounts. But this is not the solution that Congress adopted. Rather, Congress intended for covered entities to have the option to use 340B drugs for Medicaid FFS patients and for state Medicaid programs to exclude these claims from their rebate requests. The Delaware proposed SPA does the opposite.

It is also possible that implementation of the SPA would leave some covered entities with no choice but to not participate in the 340B program. As we explain in more detail below, carve-out requirements would raise the drug costs for many covered entities. Also, covered entities would incur increased compliance costs to ensure they do not use 340B drugs for Medicaid patients. These costs present barriers to participation in 340B and may prevent some safety-net providers from participating in the program. As such, the Delaware proposed SPA not only violates the 340B statute, it could undermine the very purpose of the law by driving covered entities out of the program.

By asking CMS to approve the SPA, Delaware is seeking to implement a state law that conflicts with the federal duplicate discount mechanism and congressional intent. The U.S. Supreme Court recognizes that, pursuant to the Supremacy Clause of the Constitution,[19] any state law that conflicts with a federal law is without effect.[20] Such an impermissible conflict exists when "compliance with both federal and state regulations is a physical impossibility or where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[21] The Medicaid statute creates a federal-state partnership and anticipates a balance between federal and state objectives. The 340B statute, on the other hand, provides qualified safety-net providers the opportunity to take advantage of reduced prices. In this case, Delaware's carve-out requirement undermines federal law and congressional intent by making it impossible for Delaware safety-net providers to exercise their federally protected carve-in option. The state has impermissibly removed the carve-in choice.

CMS should note that it is not unusual for a covered entity to change its carve-in/out status. For example, a provider may carve out when it begins participating in the 340B program but may

[18] 42 U.S.C. § 1396r-8(a)(5)(C).
[19] U.S. CONST. art. VI, cl. 2.
[20] Altria Group, Inc. v. Good, 555 U.S. 70 (2008).
[21] Edgar v. MITE Corp. 457 U.S. 624, 631 (1982) (internal quotations and citations omitted).

later decide that it is more beneficial to carve in. Under Delaware's SPA, that covered entity would be unable to change its carve-in/out status. Therefore, the rule could negatively affect even those Delaware providers that currently carve out.

Federal preemption of Delaware's proposed SPA is supported by standard principles of statutory construction. According to the Supreme Court, "'[a] statute should be construed so that effect is given to all its provisions so that no part will be inoperative or superfluous, void or insignificant.'"[22] Even if Delaware is correct that *one* interpretation of the 340B duplicate discount prohibition allows a state to decide whether covered entities should carve-out all Medicaid claims from the 340B program, the effect of the state's interpretation would render "inoperative" another part of the 340B law, namely, the statutorily mandated mechanism developed by the Secretary that gives covered entities the right to access 340B discounts for outpatient drugs covered by the Medicaid program. The 340B statute must be read so as to render both provisions effective. Delaware's SPA does not meet this fundamental test of statutory construction.

We would like to be clear that we believe the states are free to go above and beyond the federal law, but they cannot create or enforce requirements that conflict with it. For example, some states require covered entities to submit modifiers when billing claims involving 340B drugs. The states use these modifiers to further identify claims that must be excluded for their rebate requests. Such a requirement does not disturb the federal rule. Delaware's requirement, however, directly conflicts with the federal law because it serves to regulate the actions of a favored class of safety-net providers specifically identified by Congress and forecloses a federally authorized method by which those 340B covered entities may bill state Medicaid programs.

C. Federal Law Also Protects a Covered Entity's Right to Choose Whether or Not to Use 340B Drugs for Medicaid MCO Patients

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 FFS basis.[23] 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.[24]

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[22] Corley v. U.S., 556 U.S. 303, 314 (2009) (citing Hibbs v. Winn, 542 U.S. 88, 101 (2004) (citations omitted)).
[23] *See* Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508, § 4401 104 Stat. 1388, 1388-143 to -159. This is subject to the mechanism described above, whereby a state may not collect a rebate covered outpatient drugs purchased at the 340B price.
[24] Patient Protection and Affordable Care Act, Pub. L. 111-148, §2501(c), 124 Stat. 119, 308 (2010).

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 drug rebate statute that 340B Medicaid MCO drugs are not subject to a Medicaid rebate. The duplicate discount prohibition 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]."[25] Instead of applying the duplicate discount prohibition to 340B Medicaid MCO drugs, Congress chose to make such drugs non-rebatable, 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."[26] By declaring MCO drugs to be non-rebatable when covered entities seek 340B discounts, Congress recognized that covered entities have a right to choose whether or not to use 340B drugs for Medicaid MCO patients, as they have been able to since the beginning of the 340B program. Therefore, Delaware's proposed SPA is also contrary to federal law and congressional intent because it infringes upon this right by removing the option to carve in 340B drugs for Medicaid MCO patients.

We recognize that states need to be able to protect manufacturers from paying both a 340B discount and a Medicaid rebate on an MCO claim. The SPA would achieve this end, however, at the expense of violating a covered entity's statutory right to buy covered outpatient drugs, including MCO drugs, through the 340B program. Again, standard principles of statutory construction must be observed. The U.S. Supreme Court has clearly stated that "where two statutes are 'capable of co-existence, . . . [and] absent a clearly expressed congressional intention to the contrary, . . . each [must be regarded] as effective.'"[27] For Delaware to interpret the Medicaid rebate provisions as allowing it to require all covered entities in the state to carve-out all Medicaid MCO drugs, would render the 340B discount law ineffective. The only interpretation that would give effect to both the Medicaid rebate and 340B discount provisions would be to allow covered entities the choice of whether to carve in or carve out. This choice would maintain covered entities' access to 340B drug discounts while ensuring that MCO drugs are not subject to both a 340B discount and Medicaid rebate.

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[25] 42 U.S.C. § 256b(a)(5)(A) (emphasis added).
[26] *Id*. at § 1396r-8(j)(1) (emphasis added).
[27] Ruckelhaus v. Monsanto Co., 467 U.S. 986, 1018, 104 S. Ct. 2862, 2881 (1984) (quoting Regional Rail Reorganization Act Cases, 419, U.S. 102, 133-34, 95 S. Ct. 335, 353 (1974)). J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124, 143, 122 S. Ct. 593, 605 (2001).

D. Carve-out Requirements Raise the Drug Costs of Safety-Net Providers

Forced carve-out requirements would raise the drug costs of many covered entities. For example, three family planning clinics in Delaware currently purchase long-acting reversible contraceptives (LARCs), such as the intrauterine device, and the contraceptive implant and shot, at 340B prices. While LARCs generally are more expensive forms of contraception, they are considered the most effective, offering contraceptive protection for longer periods of time. The affected family planning providers in the state have estimated that costs for these products will increase by over $210,000 annually for Medicaid patients if the SPA is approved by CMS. In response, these providers will either have to absorb these additional costs, cutting into already scarce resources to serve the uninsured and under-insured, or else no longer offer these products on-site and instead script them out to a commercial pharmacy, resulting in both the disruption of the patient's care and timely access to these products and increased costs for both the patient and state.

In addition, carve-out requirements would create a substantial and permanent added cost for 340B hospitals compared to non-340B hospitals. The increased cost would harm Medicaid patients by hindering the ability of 340B hospitals to serve these patients and posing such a barrier that some hospitals may choose to forego participation in the 340B program. CMS should not permit states to enact requirements that are completely contrary to the purpose of the 340B program.

Some categories of hospitals that participate in the 340B program, including disproportionate share, freestanding children's, and freestanding cancer hospitals, cannot purchase any covered outpatient drugs through a group purchasing organization (GPO) or any other group purchasing arrangement. [28] This rule applies even if a hospital carves out and uses non-340B drugs for Medicaid patients. To be compliant with the GPO exclusion, the hospital must purchase drugs for Medicaid patients at non-340B, non-GPO prices (e.g., wholesale acquisition cost (WAC)), which can be significantly higher than GPO prices.[29] Carve-out requirements inevitably raise the drug costs of these 340B hospitals and are inconsistent with the design of the 340B program.

All hospitals, except critical access hospitals, must provide a significant share of inpatient services to the Medicaid population to qualify for the 340B program and to maintain their eligibility.[30] Because 340B eligibility is directly tied to hospital's share of Medicaid patients, it is

[28] 42 U.S.C. § 256b(a)(4)(L)(iii).
[29] 340B Health has been informed by industry stakeholders that, based on an analysis of pricing data available as of March 17, 2016, WAC pricing is on average 33% higher than GPO pricing for generic drugs and 22% higher for brand drugs.
[30] Acute care, children's, and cancer hospitals must have a DSH adjustment percentage of greater than 11.75% to qualify for the 340B program. 42 U.S.C. § 256b(a)(4)(L)(ii). Rural referral centers and sole community hospitals must have a DSH adjustment percentage of 8% or more. 42 U.S.C. § 256(b)(a)(4)(O). A hospital's DSH adjustment

clear the program is intended to help hospitals treat that population. Recent research shows that the 340B program effectively targets those hospitals that serve a high number of Medicaid patients, as Congress intended. As mentioned above, a June 2015 report found that 340B hospitals' low-income patient loads, which include Medicaid beneficiaries, are nearly twice the size of non-340B hospitals' low-income patient loads.[31] In addition, a February 2015 report found "340B DSH hospitals were more than twice as likely to treat dual eligible beneficiaries as non-340B providers."[32] Leaving some hospitals with no choice but to pay high prices for their Medicaid drugs would contradict the program's goal of enabling safety-net providers to better serve Medicaid patients. If hospitals were forced to carve out, the financial challenges facing these providers could be exacerbated as states move to AAC-based reimbursement for 340B Medicaid FFS retail drugs to comply with the covered outpatient drug final regulation. If a state were to establish payment rates for non-340B drugs based on surveys of pharmacies' non-340B actual acquisition costs, the rates would likely understate 340B hospitals' costs because the survey probably would include providers that are permitted to purchase drugs through group purchasing arrangements.

E. CMS Should Encourage States and MCOs Not to Use Lower Reimbursement Rates for 340B Medicaid MCO Drugs

While our concerns above focus on the Delaware SPA, we also are concerned about states requiring Medicaid MCOs or MCOs deciding on their own to lower reimbursement for 340B drugs. Like a carve-out requirement, a reimbursement rate for 340B drugs that is lower than a Medicaid MCO's standard rate is contrary to congressional intent and the purpose of the 340B program. As explained above, when Congress expanded the Medicaid rebate program to include MCO drugs, Congress left undisturbed a covered entity's right to choose whether to use 340B drugs for Medicaid MCO patients. In doing so, Congress clearly intended that covered entities continue to benefit from using 340B drugs for Medicaid MCO patients, as they have since the inception of the 340B program. Without that benefit, a covered entity's ability to reach more eligible patients and provide more comprehensive services is hindered.[33] As such, a Medicaid MCO's use of a low reimbursement rate for 340B drugs would contravene congressional intent and frustrate the purpose of the 340B program. Accordingly, we ask CMS to encourage states and MCOs not to use lower reimbursement rates for Medicaid MCO drugs.

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percentage is based in large part on its Medicaid patient volume. 42 U.S.C. § 1395ww(d)(5)(F)(v)-(viii). Generally speaking, the higher a hospital's Medicaid patient volume, the greater its DSH adjustment percentage will be.

[31] Dobson DaVanzo & Associates, Analysis of 340B DSH Hospitals Services Delivered to Vulnerable Patient Populations 16 (June 2, 2015), http://www.340bhealth.org/files/Dobson_DaVanzo_Final_Report.pdf.

[32] Dobson DaVanzo & Associates, Analysis of Separately Billable Part B Drug Use Among 340B DSH Hospitals and Non-340B Providers 11 (Feb. 10, 2016), http://www.340bhealth.org/files/Dobson_DaVanzo_Part_B_Drug_Spending.pdf

[33] H.R. Rep. 102-384(II) at 12 (1992); *see also* 42 U.S.C. § 256b (Section 340B of the Public Health Service Act).

F. If CMS Approves the SPA, the Agency Should Require the State to Establish an Exemption Process and, at a Minimum, to Review the Policy Annually

If CMS permits Delaware to mandate covered entities carve out as a general rule, the agency should require the state to develop an exemption process to comply with the federal rules discussed above. The exemption process should include a grandfathering in of any covered entities that currently use 340B drugs for Medicaid patients. In its comments on the SPA, the Biotechnology Industry Organization (BIO), which represents the very pharmaceutical manufacturers that the duplicate discount prohibition and mechanism are intended to protect, expressed support for an exemption process.[34] CMS also should require Delaware to review the policy and exemption process at least annually to ensure they continue to comply with federal rules and do not pose an undue burden on any covered entity seeking to carve in, and to share the results of the review with the public.

II. CMS Should Issue Guidance Clarifying that the Agency Will Consider 340B Ingredient Reimbursement Rates Above the 340B Ceiling Price

On February 1, 2016, CMS published the covered outpatient drug final regulation.[35] On February 11, 2016, CMS sent a letter to State Medicaid Directors regarding implementation of the regulation, including the rule's 340B provisions related to reimbursement of retail 340B drugs given to Medicaid FFS patients.[36] While the regulation requires that 340B payment rates be based on AAC,[37] both the rule and letter make clear that states do not have to pay for each 340B drug at its true AAC (or invoice).[38] In the letter, CMS provided examples of how states could establish their 340B rates, including through state surveys, published pricing data, and 340B ceiling prices.[39] The preamble to the final rule suggests that CMS is willing to consider 340B rates that are above acquisition cost.[40] CMS noted that, when setting rates for a 340B drug's ingredient cost, states can consider the costs 340B entities incur associated with purchasing 340B drugs.[41] Such language suggests, for example, that states could consider the costs incurred by hospitals subject to the GPO exclusion that must initially purchase any new National Drug Code at a high non-340B, non-GPO price (e.g., WAC) or the costs of inventory

[34] *Id.* BIO said the following in its comments: "[W]e are concerned that requiring all covered entities to uniformly carve out (i.e., use non-340B products for Medicaid patients) could impose an undue administrative burden on some of the most vulnerable safety-net providers in the state. Accordingly, we urge the Division to consider creating an exceptions process for covered entities to elect to carve-in, provided that protections are in place to prevent duplicate discounts."
[35] Final Rule at 5170.
[36] CMS Letter.
[37] Final Rule at 5356.
[38] Final Rule at 5319; CMS Letter at 3.
[39] CMS Letter at 3.
[40] *See* Final Rule at 5320.
[41] Final Rule at 5320.

management systems that covered entities use to ensure they purchase 340B drugs for eligible patients only. CMS's letter, however, states that, "[f]or drugs purchased through the 340B program, reimbursement should not exceed the 340B ceiling price."[42] This language suggests states cannot consider the associated costs that 340B entities incur when purchasing drugs. This inconsistency between the letter and final regulation could deter states from setting 340B rates that reflect consideration of the unique costs covered entities incur.

Limiting reimbursement for 340B drugs to the federal ceiling price would also discriminate against covered entities, as non-covered entities are not subject to a similar requirement. The final rule provides states with flexibility when developing an AAC-based reimbursement rate for non-340B drugs. For example, states can rely on a national survey of acquisition costs reported by independent and commercial pharmacies, conduct their own state survey, or rely on benchmarks such as average manufacturer price or WAC.[43] Reimbursement for non-340B drugs is not capped at a particular price.

Lastly, we note that the proposed rule did not include a policy capping 340B reimbursement at the ceiling price. Therefore, stakeholders have not been provided with adequate notice or an opportunity to comment on such a policy. To ensure states' implementation of the final regulation is congruent with the rule itself, we ask that CMS issue further guidance clarifying that the agency is open to considering 340B ingredient rates above the 340B ceiling price.

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We appreciate CMS's consideration of our input and look forward to discussing these issues during our meeting.

Sincerely,

National Association of Community Health Centers
The Hemophilia Alliance
Planned Parenthood Federation of America
National Family Planning and Reproductive Health Association
National Rural Health Association
National Health Care for the Homeless Council
Ryan White Clinics for 340B Access
340B Health

[42] CMS Letter at 3.
[43] Final Rule at 5176, 5338.

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