April 22, 2021

Via online comment portal at Medicaid.gov

United States Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-25-26
Baltimore, Maryland 21244-1850
Attn: State Demonstrations Group

Re: New York's Proposed Request to Extend Section 1115
Medicaid Redesign Team Waiver (11-W-00114/2)

Dear Sir or Madam:

I write on behalf of 340B Grantees to comment on New York's waiver extension proposal, dated March 4, 2021, with respect to its Section 1115 Medicaid Redesign Team (MRT) Waiver demonstration (the "1115 MRT Waiver").

340B Grantees represents safety-net providers that receive grants from the Health Resources & Services Administration ("HRSA") Health Center Program to provide primary care services in underserved areas. These include Federally Qualified Health Centers ("FQHCs"), Ryan White Clinics, Rural Health Clinics and other community-based healthcare providers.

We object to New York's proposal to amend the 1115 MRT Waiver to move pharmacy coverage from the Medicaid managed care benefits package to a fee-for-service delivery system (the "Pharmacy Carveout"). We oppose the proposal because the diversion of benefits under the 340B drug pricing program (the "340B program") from safety net providers to the State will deprive safety net providers of the use of 340B drug discounts "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services," as Congress intended. We are concerned that the Pharmacy Carveout would degrade the scope and quality of care available to serve medically underserved Medicaid enrollees and to help other low-income New Yorkers obtain essential care and services from 340B grantees.

We discuss specific objections to the proposed Pharmacy Carveout in more detail below.

1. The Proposed Pharmacy Carveout Lacks Legislative Authorization and is Premature

We object to the proposed application on the ground that the New York State Department of Health ("NYS DOH") lacks statutory authorization to implement the proposed Pharmacy Carveout for the next two years. For this reason, without more, CMS should reject the proposal as premature.

In the prior 2020-2021 State fiscal year, the New York State Legislature had authorized the NYS DOH to "exercise its existing administrative authority to remove the pharmacy benefit from [the] managed care benefit package and instead provide the pharmacy benefit under the fee for service program." L. 2020, ch. 56, Part FFF. The legislative authorization was subject to a limitation prohibiting NYS DOH from implementing the transition sooner than April 1, 2021.

Effective April 1, 2021, the New York State Legislature amended the statute to withdraw authorization for NYS DOH to implement the transition for a period of two years. Under the current statute, the NYS DOH "shall not implement the transition of the pharmacy benefit from the managed care benefit package to the fee for service program sooner than April 1, 2023." L. 2021, ch. 57, Part C.

As a result, NYS DOH currently lacks authority to transition the pharmacy benefit from the managed care benefit package to the fee-for-service program until April 1, 2023. Consequently, any determination with respect to the Pharmacy Carveout would be theoretical and wholly premature.

2. The Proposed Pharmacy Carveout Vitiates the Legislative Intent of the 340B Program

We also object because the proposed Pharmacy Carveout conflicts with the legislative intent of Section 340B of the Public Health Service Act by diverting essential benefits from resource-limited organizations serving disadvantaged populations to the State's coffers, contrary to the purpose and intent of the 340B program. This will have a negative impact on the resources and ability of 340B grantees to deliver care and services to the needy populations they serve. It will also jeopardize their patients by depriving them of protections otherwise available under the 340B program.

The 340B program requires manufacturers to provide discounts on covered outpatient drugs to statutorily defined safety-net hospitals and clinics – so-called "covered entities" – as a condition of receiving Medicaid coverage and reimbursement for the manufacturers' drugs.[1] The purpose of the 340B program was "to enable…certain federally-funded clinics to obtain lower prices on the drugs that they provide to their patients" so that covered entities, like 340B grantees, can stretch their scarce resources and thus "reach more patients" and furnish "more comprehensive services." *See* H.R. Rep. 102-384, 102d Cong., Part 2 at 12 (2d Sess. 1992); *see also* Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,493 & 52,493 n.18 (Nov. 13, 2017) (codified at 42 C.F.R. Part 419). The 340B program is a vital and indispensable tool to help offset the costs of uncompensated and under-compensated care.

[1] Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71.

The 340B grantees we represent are on the front lines of providing health care to the historically medically underserved minority populations hit hardest by the COVID-19 pandemic. According to 2019 data from the HRSA, for example, FQHCs in New York served 2,255,154 patients, and a majority of these consisted of minorities: 37.38% Hispanic/Latino, 33.04% Black/African-American, and 7.62% Asian. Nearly one-third – 29.10% – were best serviced in a language other than English. HRSA data for 2019 also reflect that 45.26% of patients had incomes at or below 100% of Federal Poverty Guidelines, 7.40% had incomes between 101 – 150%, 4.08% had incomes between 151-200%, and only 6.23% had incomes higher than 200% of Federal Poverty Guidelines. Of these New York FQHC patients, 52.16% were covered by Medicaid, and 14.85% were uninsured. In 2019, New York's FQHCs had 6,474,154 medical visits, 1,332,174 dental visits, 1,180,424 mental health visits, 169,140 visits for vision services, and 490,651 visits for enabling services. FQHC look-alikes and other 340B grantees serve similar medically underserved populations.

New York depends on FQHCs, FQHC look-alikes and other 340B grantees to deliver primary care services to beneficiaries under the New York Medicaid program. Currently, 340B grantees use savings under the 340B program to expand access to care and to enhance services. For some 340B grantees, federal section 330 grants from HRSA do not cover the cost of providing services to uninsured patients, and these 340B grantees use 340B savings to help bridge the gaps. This will no longer be possible if the FQHCs cannot participate in and benefit from the 340B program. The result will be increased disparities in a healthcare system long been riddled with inequality.

If 340B grantees lose the benefit of 340B savings, they will need to implement changes such as curtailing their hours of operation; reducing staffing; discontinuing mental health and substance abuse services; closing unprofitable departments; discontinuing enabling services, such as transportation, translation, referral and outreach, case management, health education, enrollment assistance, food pantry, and walk-in clinics; discontinuing services to at-risk populations, such as the homeless, migrant farmworkers, and vulnerable populations in low access areas; discontinuing coverage for significant portions of lab costs and subsidization of prescription drugs for sliding-fee patients; and potentially shutting their doors. To avert these adverse effects, we urge CMS to reject the proposed modification of the waiver.

3. The Proposed Pharmacy Carveout Would Violate 42 U.S.C. § 1396a(bb) by Failing to Ensure Reimbursement of FQHCs at 100% of their Cost for Pharmacy Services

The Pharmacy Carveout is also legally defective because New York's proposal fails to set out a reimbursement methodology that will guarantee FQHC reimbursement at 100% of their actual costs as federal law requires.

Among the mandatory benefits a state must include in its State Medicaid Plan is a provision for payment for FQHC services, as defined in 42 U.S.C. § 1396(*l*)(2), and any other ambulatory services offered by an FQHC and which are otherwise included in the State Medicaid plan. 42 U.S.C. § 1396d(a)(2)(C). Under Section 1396a(bb) of the Act, if an FQHC provides State plan services, the state must reimburse the FQHC "in an amount (calculated on a per visit basis) that is equal to 100 percent of the average of the costs of the center or clinic of furnishing such services . . . ." 42 U.S.C. § 1396a(bb)(2). The congressional purpose in enacting this "100 percent" reimbursement requirement was "to ensure that health centers receiving funds under § 330 of the Public Health Services Act would

not have to divert Public Health Services Act funds to cover the cost of serving Medicaid patients." *Three Lower Counties Community Health Svcs, Inc. v. Maryland,* 498 F.3d 294, 297 (4th Cir. 2007); *see Community Health Care Ass'n of New York v. Shah,* 770 F.3d 129 (2d Cir. 2014). It reflects the recognition that "FQHCs occupy a unique place in the health services ecology." *Id.* at 157.

We are concerned that the proposed Pharmacy Carveout fails to ensure 100% reimbursement for the cost of the services FQHCs provide. The Pharmacy Carveout would move reimbursement from the existing managed care coverage, based on a negotiated reimbursement rate and subject to supplemental payments, into a fee-for-service delivery system.

The current State plan's description of the FQHC pharmacy fee-for-service reimbursement methodology does not include any basis to conclude that the alternative payment model for pharmacy services, either initially or on an ongoing basis, will result in payment that is not less than the FQHC would be entitled to under the PPS methodology. Instead, it appears to treat those services as a non-FQHC service. By shifting reimbursement for FQHC pharmacy services from a negotiated managed care rate to a yet-to-be developed – or even considered – fee-for-service reimbursement methodology, New York is exposing the providers of most primary care services to Medicaid beneficiaries to undue risk.

In its proposal, New York recognizes – implicitly if not explicitly – that the Pharmacy Carveout will have a negative financial impact on safety-net providers. In recognition of the negative impact, the New York proposal includes a one-time allocation of $102 million to support 340B grantees that benefit from savings under the 340B program. This proposed supplemental fund falls far short of addressing the negative impact. On its face, the $102 million allocation is woefully inadequate to make up for the loss of 340B funds, even in Year 1. Moreover, there is no methodology to allocate this sum among 340B grantees and others that will lose access to 340B savings. Further, with funding subject to the annual state budget process, there can be no assurance of ongoing provider compensation to address lost 340B savings in subsequent years.

Thus, the $102 million allocation does not adequately address the loss or guarantee FQHC reimbursement for their actual cost of providing these services as required by federal law. For these reasons as well, we urge CMS to reject the proposed change.

4. The Proposed Pharmacy Carveout Conflicts with the Structure and Intent of Federal Law

The Pharmacy Carveout also conflicts with the structure and intent of the Medicaid Drug Rebate Program ("MDRP"). The conflict provides an additional reason to scrutinize and to reject the proposed application.

Congress established the MDRP in 1990, as part of the Omnibus Budget Reconciliation Act,[2] to help offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. Codified under section 1927 of the Social Security Act, the MDRP requires manufacturers to provide

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2 *Id.*, codified at 42 U.S.C. § 1396r-8.

rebates to state Medicaid agencies on covered outpatient drugs as a condition to Medicaid coverage and reimbursement of the manufacturer's drugs.[3]

In addition to requiring manufacturer drug rebates, the MDRP advances important patient protection policies in three areas. First, it requires states to establish drug utilization programs "to assure prescriptions (i) are appropriate, (ii) are medically necessary and (iii) are not likely to result in adverse medical results."[4] This includes limits on state formularies to allow for coverage for a broader range of drugs[5] and the requirement that state prior authorization procedures meet standards to ensure they do not undermine patient care.[6] Second, the MDRP supports pharmacies by requiring state reimbursement to meet specified standards, including limits on payment reductions;[7] by encouraging and providing funding for electronic claims processing;[8] and by requiring state programs to educate pharmacists to identify inappropriate utilization or medically unnecessary care and to share information.[9] Third, the MDRP enhances drug transparency by requiring manufacturers to report certain information to the Secretary, including a drug's average manufacturer price, best price, average sales price and nominal price,[10] and by authorizing the Secretary to survey[11] and to enforce[12] the reporting requirements.

When Congress first enacted the MDRP, the rebate requirement applied only to drugs that were subject to Medicaid fee-for-service reimbursement.[13] Two years later, Congress created the 340B program, which requires manufacturers to extend discounts on all covered outpatient drugs that covered entities purchase, including Medicaid fee-for-service drugs. The statute also includes a mechanism to protect manufacturers from –"duplicate discounts" (that is, providing a Medicaid rebate and 340B discount on the same drug).[14]

Subsequently, in 2010, as part of the Affordable Care Act (the "ACA"), Congress enacted the Drug Rebate Equalization ("DRE") Act,[15] which expanded the MDRP to include Medicaid drugs covered and reimbursed by Medicaid managed care organizations.[16] The purposes of the expansion were: (i) to

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3 Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143.

4 42 U.S.C. § 1396r-8(g)(1)(A). Among other things, drug utilization programs must require: patient counseling, the education of practitioners on common drug therapy plans, and the establishment of drug utilization boards.

5 *Id.* § 1396r-8(d)(5).

6 *Id.*

7 *Id.* § 1396r-8(e).

8 *Id.* § 1396r-8(h).

9 *Id.* § 1396r-8(g)(1)(A).

10 *Id.* § 1396r-8(b)(3)(A).

11 *Id.* § 1396r-8(b)(3)(B).

12 *Id.* § 1396r-8(b)(3)(C).

13 *Id.*

14 42 U.S.C. § 256b(a)(5)(A).

15 Drug Rebate Equalization, S. 547, 111th Congress § 2 (2009).

16 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2501, 124 Stat. 119, 306-08 (2010), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1206, 124 Stat. 1029, 1056-57. The MDRP statute uses terms such as "health plan." "health maintenance organization," "HMO", or "organized health care settings" to refer to the managed care organization sector of a state's Medicaid program.

increase the rebates that states could collect from manufacturers, thereby generating revenue to help fund the ACA's expansion of healthcare coverage; and (ii) to deter states from carving the pharmacy benefit out of their Medicaid managed care programs as a strategy to collect rebates on drugs that, due to the MDRP's limitation to fee-for-service drugs, were not subject to rebates. Congress intended that, by extending rebates to managed care, states would abandon the use of the carveout strategy. The concern was that such a strategy would result in continuity of care problems and prevent Medicaid managed care organizations from implementing medication therapy management and disease management programs that are vital to effective pharmaceutical care, especially for patients with chronic conditions taking multiple medications.

Initially, covered entities opposed the DRE Act due to a concern it would undermine their use of the 340B program for Medicaid managed care patients. To address the concern, Congress enacted section 1927(j)(1), which exempted from the MDRP outpatient drugs dispensed by a Medicaid managed care organizations and subject to 340B discounts. Under the exemption, covered entities could continue to buy their Medicaid managed care drugs through the 340B program without worrying about losing access to the benefits of the 340B program. The exemption essentially limited the expansion of the MDRP to the non-340B Medicaid managed care market, leaving the 340B managed care drug market untouched by passage of the DRE Act. The section 1927(j)(1) exemption also protects manufacturers from duplicate discounts by relieving them from the rebate requirement if the drugs are both dispensed by a Medicaid managed care organization and subject to 340B discounts.

A consequence of the section 1927(j)(1) exemption is to exclude the exempted outpatient drugs subject to 340B discounts from the important safeguards – patient protection, pharmacy support, and drug transparency – of the MDRP. To address this adverse effect, CMS promulgated a regulation at 42 C.F.R. § 438.3(s) to require state contracts with managed care organizations to meet the standards of section 1927 when covering outpatient drugs as if the standards applied directly to the managed care organization.[17] In this way, the regulation extends the protections of section 1927 to drugs that are dispensed under the Medicaid managed care pharmacy benefit and subject to 340B discounts.[18]

If New York carves the pharmacy benefit out of Medicaid managed care, the section 1927(j)(1) exemption would continue to apply to drugs that managed care organizations dispense and which are subject to 340B discounts. Nevertheless, the regulation at 42 C.F.R. § 438.3(s) would not apply to these drugs, because the effect of the Pharmacy Carveout would be to remove the pharmacy benefit from the managed care contracts. As a result, the MDRP patient protection policies – patient protection, pharmacy support, and drug transparency – would not apply either through managed care organizations or through the state.

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17 The 2016 Managed Care Rule states that the "managed care standards are based primarily on section 1903(m)(2)(A)(xiii)," the section of the Medicaid statute that governs payments to states. CMS also relied on its authority under section 1902(a)(4) to address all those requirements outside the scope of section 1903(m)(2)(A)(xiii). 81 Fed. Reg. at 27,542.

18 Reinforcing the point, CMS stated in the preamble to the 2016 managed care rule that "when a state is contracting with managed care plans to provide covered outpatient drug coverage, the state must ensure that the standards of coverage imposed by section 1927 of the Act are met when states enroll their beneficiaries into managed care plans." *Id.* at 27,552.

The proposed Pharmacy Carveout thus would conflict, in three ways, with the purpose and function of federal law. First, it would undermine the managed care organization's ability to maintain a comprehensive care and disease management program that includes prescription drugs.[19] Second, it would defeat the purpose of the 340B program – to allow covered entities to stretch their scarce resources so that they may "reach more patients" and furnish "more comprehensive services"[20] – by redirecting the 340B savings to the state, rather than the covered entity. And third, it would lead to the anomalous result that, the protections under the MDRP – patient protection, pharmacy support, and enhanced drug transparency – would not apply to the carved-out drugs due to the operation of the (j)(1) exemption and the inapplicability of the regulation at 42 C.F.R. § 438.3(s).

The Pharmacy Carveout thus would stand as an obstacle to the accomplishment of the full purposes and objectives of both the MDRP and the 340B program, in conflict with the purpose and intent of federal law.

5. The Public Comment Process was Defective

Further, the public comment process preceding New York's waiver application was flawed, because NYS DOH did not comply fully with the demonstration waiver statute and regulations. The demonstration waiver statute, at 42 U.S.C. § 1315, requires a process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input. New York's process did not meet these requirements.

On December 16, 2020, the NYS DOH announced its intention to seek the 1115 Waiver Extension with a Pharmacy Carveout amendment and commenced an abbreviated process for public hearing and comment.[21] Written comments were due no later than January 15, 2021 followed by public hearings on January 21 and. 27, 2021. As NYS DOH noted in its application (at page 35), over 98% of the comments it received during the public comment period related to the Pharmacy Carveout, and "the majority of [them] expressed concern regarding the potential for a negative impact on safety-net providers such as [FQHCs], Ryan White [clinics] and Disproportionate Share Hospitals ("DSH") to use savings from the 340B program to fund gaps in services or care." Notwithstanding this vigorous opposition, on March 4, 2021, NYS DOH submitted its 1115 Waiver Extension application to CMS. The submitted application was materially unchanged from the original December 16, 2020 draft.[22]

In January 2021, in the midst of the public comment period, Centene Corporation announced its plan to acquire Magellan Health, Inc. ("Magellan"). Magellan is the current contracted vendor for the New York State Medicaid program. Notably, under the proposed Pharmacy Carveout, New York

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19 155 Cong. Rec. S2911-01, S2912 (Mar. 9, 2009).

20 H.R. Rep. 102-384, 102d Cong., pt.2, at 12 (2d Sess. 1992).

21 The application is available at https://www.health.ny.gov/health_care/medicaid/redesign/mrt2/ext_request/docs/2020-12-14_draft_extension_app.pdf.

22 NYS DOH also convened a 340B Advisory Board but gave it no opportunity to discuss alternatives to the Pharmacy Carveout. Rather than make "nonbinding recommendations," as NYS DOH had requested, members of the 340B Advisory Board publicly refused to offer any recommendations. NYS DOH's determination to move forward, despite the lack of recommendations, reflects the absence of meaningful consideration of stakeholder input.

anticipates a 650% increase in annual paid claims and prior authorizations. Although the application does not disclose the identity of the third-party contractor for this greatly expanded fee-for-service pharmacy program, it would appear likely that the current contractor, Magellan, would continue in its current role and be the beneficiary of the change. Additionally, Centene operates, through subsidiaries, managed care plans and pharmacies that participate in Medicaid. These relationships create potential conflicts of interest with managed care plans and pharmacies that participate in the New York State Medicaid program.

In California, Magellan also is the contracted vendor for the Medi-Cal program. The California Department of Public Health, upon learning about the Centene/Magellan merger, delayed the implementation of its transition of the pharmacy benefit from managed care to fee-for-service due to the need to review "new conflict avoidance protocols" from Magellan. More specifically, California required "additional time for exploration of acceptable conflict avoidance protocols to ensure that there will be acceptable firewalls between the corporate entities to protect the pharmacy claims data of all Medi-Cal beneficiaries, and to protect other proprietary information."[23]

In New York, the proposed acquisition by Centene of Magellan is a material event that the NYS DOH should have disclosed as part of the notice-and-comment process. NYS DOH knew or had reason to know of the Centene/Magellan acquisition, and Magellan's role in the pharmacy transition, but it failed to amend its public notice to disclose the proposed transaction as part of the public comment process. This failure to provide full and fair disclosure of material facts deprived the public of a meaningful opportunity to consider and provide input on the implications of the 1115 Waiver Extension.

These deficiencies, together with the rushed, perfunctory public comment schedule, make it likely that interested stakeholders are neither aware of, nor able to communicate to CMS, the scope and nature of the negative impact of the proposed changes on their ability to provide Medicaid-covered services to their patients.

We urge CMS to return the application to New York to correct the flawed process by providing additional information about Magellan's role in the administrative process, its relationship with Centene, and the development of acceptable conflict avoidance processes to protect pharmacy claims data relating to Medicaid beneficiaries and other proprietary information.

6. The Proposed Pharmacy Carveout Fails to Meet the Requirements of Section 1115 of the Social Security Act

Finally, to warrant CMS approval, New York's request must both promote the objectives of the Medicaid Act, 42 U.S.C. § 1315(a), and be approved only "to the extent and for the period" necessary to carry out the experiment, *id.*, § 1315(a)(1). We are concerned that the proposed Pharmacy Carveout is inconsistent with the objectives of the Medicaid Act and exceeds the scope of what is necessary to carry out New York's project.

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[23] California Department of Health Care Services, "Medi-Cal Rx Delayed Beyond Go-Live of April 1, 2021" (Feb. 17, 2021) (https://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_30429_28.aspx).

The purpose of Medicaid is to enable states to furnish medical assistance to individuals whose income is too low to meet the costs of necessary medical care. The Pharmacy Carveout, as currently envisioned, will not promote but instead will obstruct the realization of this objective. It is unlikely that Congress would have established the right of critical safety net providers to purchase drugs at a discounted rate under the 340B program had it intended to permit states to divert the discount to themselves to benefit purposes separate and apart from those specific to the 340B program.

The adverse consequences will be predictable and significant. They will include: a reduction in access to primary care and enabling services for poor and minority communities; a significant deepening of the financial crisis that 340B grantees and their patients are experiencing due to the ongoing COVID crisis; a reduction in coordination and oversight of pharmacy usage and patient compliance; collateral impact on higher-cost treatment sites such as hospitals, long-term care facilities and specialty care facilities; diminished health outcomes; a reduction in Medicaid's ability to deliver integrated care; and, eventually, a recognition that the anticipated savings associated with moving the pharmacy benefit out of managed care were not achieved.

For all of these reasons, we respectfully urge CMS to reject the proposed amendment to New York's 1115 MRT Waiver to carve the pharmacy benefit out of Medicaid managed care. We appreciate your consideration of these comments.

Respectfully submitted,

340B GRANTEES

By: 

Mark J. Malahosky