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Testimony of Henry M. Bartlett

Vice President for Government & Community Relations

Before the New York State Legislature

On the 2021 – 2022

Budget for The Department of Health

February 25, 2021

I want to focus my comments today exclusively on the DOH plan to carve-out the Medicaid Pharmacy Benefit from managed care. This is a profoundly bad idea which will severely damage the healthcare safety-net for the most vulnerable New Yorkers in the midst of a once-in-a-lifetime healthcare crisis. The carve-out will cut off safety-net providers across New York State from the benefits of the Federal 340B program, which is used to fund otherwise uncompensated care and care expansion in impoverished communities.

The impact of the carve-out is very different from provider to provider, but let me explain what the impact will be at Damian Family Care Centers. Damian operates a network of fourteen Federally Qualified Health Centers serving more than twelve thousand patients across the greater New York metro area, extending to the lower Hudson Valley, and to Long Island. Many of our health centers are closely linked to NYS OASAS licensed substance abuse treatment centers, while others serve a broader cross-section of the communities in which they operate. We have a strong focus on providing healthcare to those individuals in treatment for substance use disorder. A majority or our patients are ethnic minorities, approximately half are homeless, most are below the poverty level, and more than half abuse one or more psychoactive drugs.

Currently, Damian uses the drug discounts available to us, and the fiscal benefits of the 340B program, to provide lifesaving medications (and wrap-around services) to all of our patients regardless of ability to pay. If this carve-out goes forward, the hit on our annual budget will be well over one million dollars. This means we will no longer be able to provide free medications to the uninsured and the underinsured. More than a thousand Damian patients will lose access to their HIV medications, medications for substance use disorder, medications for hepatitis C, medications for psychiatric disorders, and medications to treat a variety of other physical and mental health diseases.

For other FQHCs and Ryan White providers the impact will be even more severe and truly existential. Many providers, in our poorest communities, will simply cease to exist.

This is also a social justice issue, because this carve-out clearly exacerbates the healthcare disparities for impoverished communities of color. The State has acknowledged that public health crises such as HIV and COVID-19 disproportionately impact the poor, indigenous populations, and people of color. The State also claims to be working toward equitable distribution of the COVID-19 vaccine. There's a glaring disconnect between these assertions and the stark reality that a 340B carve-out will threaten the survival of the very safety-net providers that have the power to remedy these issues every day. Furthermore, Governor Cuomo himself has made a promise to work with community health providers to end the AIDS epidemic in New York State, and the implementation of this policy would signal that he has broken this promise.

Moreover, the State's plan for a pharmacy carve-out violates the spirit of President Biden's 1/21/21 "Executive Order on Ensuring an Equitable Pandemic Response and Recovery". This executive order points out that poor people and people of color have been disproportionately impacted by COVID, largely because of healthcare inequities. It is clear that cutting financial support to the very health care providers who serve this population flies in the face of the President's order.

All of this is stunningly tone-deaf on the part of DOH. While this would be ill-advised public health policy at any time, it is certainly counter-indicated as we grapple with a global pandemic and the resulting explosion of physical and mental health sequela of that pandemic. Some providers have felt so strongly about this issue and about the unresponsiveness of the State, that they have notified the Governor of an intent to sue, particularly around the issue of the State's 1115 MRT Waiver Extension. A copy of that "intent to sue" letter is attached.

If the negative impact of this carve out is so obvious and so undeniable, why would DOH be moving forward? They say it is necessary in order to save money. This is where the Department of Health has engaged in some fiscal legerdemain, which is at best naive, and at worst disingenuous. While DOH has stated that the carve-out will achieve $87 million in State savings in FY22, it will likely result in an approximately $245 million annual loss to the most vulnerable healthcare providers in the State. FQHCs, alone, stand to lose a collective $100 million per year. A survey of just fifteen FQHCs and Ryan White providers (that provide HIV prevention and care) found they would lose at least $56 million in 340B savings annually. A small subset of hospitals reported that they would lose an additional $87 million in the first year. The Menges Group has also refuted the State's projected savings, calculating that the State will actually lose $154 million in the first year of the carveout and a total of $1.5 billion over five years, largely due to increases in avoidable emergency and inpatient costs.

The Menges Group also pointed out a huge error in calculation made by DOH regarding projected savings to New York. This error relates to the premium tax. For-profit health plans pay a premium tax. To achieve actuarially sound rates, the amount of the premium tax must be included in Medicaid plan premiums. Pharmacy is approximately 30% of the premium, so removing it reduces the amount of the tax paid based on that portion of the premium. While DOH accounted for the *savings* related to the state share amount that would no longer have to be paid after carve-out, it did not account for the *loss* of related federal funds, which accrue to the benefit of the General

Fund and which we estimate to total $39 million on a full annual basis for FY22. A $39 million "oops" is memorable, even in the annals of the New York State Budget.

There is another stark number to consider here. That number is $177 million. This is how much New York will send back annually to the Federal Government as a result of the carve-out policy. While safety-net providers are dealing with the multipronged crises of economic collapse, COVID-19, HIV, and the rise in mental health and substance abuse issues, we should be creating policies to keep every healthcare dollar we can find in our state.

Let's turn to the State's plan to compensate providers who will be negatively impacted by the carve-out. The state has proposed a compensation fund of $102 million dollars. This is not nearly enough to offset losses. Let's remember that this fund is only partial compensation, and there is no guarantee (or even a credible promise) to extend it beyond the first year. We are being asked to forego a reliable and ongoing reimbursement system authorized in Federal law, for one which is inadequate, time limited, and fraught with the vicissitudes of the annual budget process. Also, the state seriously undercounted just how many providers would need to share in this limited fund. For example, DOH did not realize that Ryan White providers would be adversely impacted until that fact was pointed out by the advocacy community. This, of course, further dilutes the compensation pool, by dividing it between more providers than DOH had originally intended.

Then there is the issue of just how the State plans to divvy up this limited and utterly inadequate compensation pool. With only about five weeks to go before an April 1st implementation date surely DOH must have a clear and comprehensive plan for how to divide and distribute this pool… and surely that plan must have been communicated to the provider community…right? Wrong on both counts. DOH and the Governor's Office created and handpicked an eighteen member "340B Advisory Council" to provide expert insight and guidance to the state in how to implement the carve out in a way that made the most sense for our patients. After being frustrated by a top-down process, which was not open to meaningful input from the Advisory Council, seven members (39% of the membership) sent an en masse letter of protest to DOH. A copy of that October 1, 2020 letter is attached. Clearly DOH viewed this "Advisory" Council as window-dressing mean to endorse the State's preordained plan. These seven Advisory Council members are to be congratulated for refusing to rubber-stamp a scheme which would damage the health care system for so many New Yorkers. Absent the advice and consent of the largely defunct Advisory Council, DOH has given ***no*** guidance to the provider community about how such a compensation pool would be divided and disbursed. Five weeks from the implementation date, DOH has kept the provider community in the dark about their plan to distribute this woefully inadequate compensation pool.

So, even if the State has not figured out the mechanics on how to compensate providers who lose money after April 1, surely they must have worked out how to administer a carved-out pharmacy benefit for the six million New Yorkers on Medicaid? That, also, seems highly doubtful. Based on reports from the technical workgroup meetings (which the Medicaid managed care plans have been having with DOH) we anticipate a shambolic launch if this goes forward on April 1st.

DOH confidently asserts that the transition will be smooth and seamless for the six million Medicaid recipients. Central to this assertion is the Department's claim that it will be able to

duplicate the prescription and prescriber data that currently allows managed care plans to resolve problems with medications in real time---often with a single phone call. There is ample evidence for skepticism.

Central to being able to administer the pharmacy benefit is real time access to data. When pharmacy is part of the managed care benefit package (as is now the case) plans have the ability to access real time data, allowing care managers to work with plan pharmacy teams to coordinate care. Failure to provide real-time data to health plans will make it challenging for plans to provide information to providers, pharmacies or patients about potential health issues related to their medications and will lead to diminished health outcomes for Medicaid members.

As of April 1, the data for all six million NYS Medicaid recipients will reside with Magellan, the pharmacy benefit manager (PBM) selected by the State. Data on six million beneficiaries will need to be parsed out and sent to the appropriate managed care plan via a daily claims file. With only five weeks until launch date DOH is still in the process of finalizing how the daily claims file will be securely transmitted to plans when the benefit is centralized in this single PBM. At this time, plans have not received any test files and have not been provided a date on when they can expect to receive them. This data transfer is integral to ensuring a seamless transition process for Medicaid enrollees. In a February 9th technical workgroup meeting, all plans reported issues with the layout of the file and the transfer method. The proposed transfer method will be manually intensive for some time which is likely to creates both errors and delays. The State plans to use a drop-off-and-pick-up approach of file transfer via secure site (known as SFTP). This is not a method for automated file distribution and the Rx file testing timeframe is six weeks. This is not a realistic timeframe. Finally, the pace of this project is not giving plans adequate time to perform necessary IT systems tests.

The success of the pharmacy data transfer is dependent on the accuracy and timeliness of enrollment data. While Magellan may be able to create the data file and send it on a daily basis, history suggests that Magellan's base information will be inaccurate. Issues present in the State's disparate enrollment data systems will contaminate the pharmacy data and compromise the accuracy and usability of the file shared with plans. The State's enrollment data systems and files continue to include conflicting and erroneous information about enrollment status and health plan attribution. Attribution to multiple or wrong health plans is common. Reconciliations and recoupments for premium payments sent to wrong plans take years to resolve.

Enrollment discrepancies between various systems, files, and processes will result in prescription data not being shared with the "true" plan the member believes they are enrolled in. As a result, the prescription claims data will not make it into the right health plan in time to provide the "near real time" support DOH is so assuring of. The myriad issues in the State's untimely, inaccurate and conflicting enrollment data and instructions augurs a challenging future within the complex environment of Rx claims data. Disruptions to care and increased costs will occur when these same unresolved problems interfere with access to medicines at the pharmacy counter.

Given all of this, it would be foolhardy to think that the State is ready for a seamless launch in five weeks, or even five months.

Summary:

- The pharmacy carve out will result to severe damage to the safety-net providers, and the patients we serve. Specifically:
    - It will exacerbate the health care disparities for poor people and people of color.
    - It will mean that uninsured and underinsured patients will have to go without life-saving care and medications.
    - It will hamper an already fragile COVID-19 vaccine response among the most vulnerable New Yorkers.
    - It violates the spirit of President Biden's Executive Order.
    - It derails New York's historic effort to end the HIV epidemic
- The projected savings of the carve out are fallacious, overstated, and fraught with error. And they come at the cost of giving back many millions of Federal dollars.
- The State's plan to compensate impacted providers is utterly insufficient in scope, and without any discernable plan to administer it.
- The State's own data sharing and administrate rules to administer the pharmacy benefit for six million Medicaid recipients is a tangled mess, guaranteed to result in an administrative debacle and dangerously poor-quality patient care if the implementation date goes forward on the current deadline.

Conclusion:

- Clearly what is called for here is a pause to work on and resolve each of these critical factors in a thoughtful and deliberate way, without damaging our fragile safety-net in the midst of a pandemic. Assemblyman Gottfried and Senator Rivera are to be complemented for recognizing this and for promoting legislation which would delay implementation for three years in order to resolve each of these critical issues. We in the provider community are committed to being good-faith partners with DOH and the legislature in this process…but first we need to turn from this reckless and disastrous rush to an April 1, 2021 implementation date.

Henry Bartlett
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Damian Family Care Centers, Inc
DamianHealth.org

October 1, 2020

Donna Frescatore
State Medicaid Director, Deputy Commissioner
State of New York, Department of Health
VIA EMAIL

RE: 340(b) Advisory Council

Dear Ms. Frescatore:

We, the undersigned, wish to thank the Office of Health Insurance Programs and the Department of Health for the consideration given to yield a set of recommendations regarding the carve-out of pharmacy benefit from Managed Care including the 340(b) benefit. At this time, those undersigned believe a more productive dialogue can be attained outside of the Council's process as described below.

As part of this year's State Budget, the Governor and the Legislature agreed to language implementing a Medicaid Redesign Team II (MRT II) recommendation that would decimate many safety net providers across New York State. 340B financial resources are used to support clinical and wrap around care to our most vulnerable populations. These provisions would shift the New York Medicaid managed care pharmacy benefit to fee-for-service (FFS) coverage and reimbursement – known as the "carve out" provisions – costing safety net providers millions of dollars in federal assistance at a time when our organizations are facing historic challenges.

As part of that agreement, the Governor's Office and the Department of Health created a *340B Advisory Council* to make real policy recommendations that would help mitigate the impact on the safety net. Upon our naming to this Advisory Council, we were eager to participate in this process and work collaboratively to develop recommendations that could generate savings for the State while allowing 340B covered entities to continue to serve communities throughout the State.

While we understand the agreement called for recommendations by October 1, we believe the process is in need of further deliberations and a more concerted effort to explore alternative solutions to achieve savings without severely disrupting safety net providers' ability to render quality and appropriate care. As it stands today, the majority of this Advisory Council simply cannot support a recommendation on how to mitigate the harm caused by this policy decision. Although we are cognizant of the serious budget deficit the State is facing, we believe that the "carve out" of the drug benefit, as it applies to the 340B program, adopted in the SFY21 budget is not a plausible solution to this budget crisis. This language will harm the very people who need us the most.

The 340B program is enabled by federal laws enacted by Congress in 1992 in the *Bipartisan Veterans' Healthcare Act* to "stretch scarce federal resources as far as possible" without putting any additional burden on taxpayers. It allows safety net providers – such as hospitals, FQHCs, and Ryan White Clinics – to pay a discounted price to pharmaceutical manufacturers while using the savings for essential services for underserved populations. The resulting savings are critical to pay for wrap around services to patients – such as outreach, housing, retention in care, counseling, and food pantries that ensure adherence to care in critical instances like Substance Use Disorders or HIV/AIDS viral suppression. In fact, the 340B covered entities throughout the State can largely be credited for New York's nation leading viral suppression rates.

We had hoped this process would allow an opportunity to undo some of that harm and come to an agreement that protects our most vulnerable population and ensures responsible spending on life-saving prescription medications. Instead, the process was overly narrow and offered little opportunity for impacted organizations to provide alternative policy options for consideration. Ultimately, we were asked to simply approve and advance a plan that would cause severe harm to the very organizations we lead and the patients

we serve. While a short term financial infusion was offered to mitigate the negative impact, such relief would be inadequate to provide a long term solution.

In addition, we have deep concerns about the State's savings methodology. While the rationale for this policy speaks to deeper discounts through greater bargaining power, in fact, only a fraction of the projected rebate savings (1%) comes from additional supplemental discounts from drug manufacturers. The reality is that the projected rebate savings are nearly entirely drawn from the Covered Entities' 340B drug manufacturers' discounts. Further, the State did not account for any of the cost impacts of withdrawing such substantial funds from the safety net system.

At the same time, the carve-out policy will send $177 million back to the federal government. While safety net providers are dealing with the dueling crises of economic collapse and COVID-19, we should be creating policies to keep every healthcare dollar we can find in this State, helping New Yorkers.

We understand there is a fiscal crisis, but this new policy will increase racial disparities in healthcare, drive Medicaid recipients to more expensive, taxpayer-funded care and lead to significantly worse outcomes for our most vulnerable populations. With the many difficult choices, trying to balance the budget on the most vulnerable New Yorkers is ill advised meriting a reversal of the carve-out policy.

We believe that there are means to achieve savings in the management of the drug benefit without the disruption of the340B program. We urge the Governor and the Department of Health work with stakeholders that provides a comprehensive solution that does not require carving out the 340(b) pharmacy benefit We would welcome an opportunity to participate in a more productive process focused on demonstrating how the State can achieve savings without hurting safety net providers over the long term.

Thank you.

Sincerely,

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Chief Pharmacy Officer
UR Strong Memorial Hospital

Larry McReynolds
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February 4, 2021

By Email

The Honorable Andrew M. Cuomo
Governor of New York State
NYS State Capitol Building
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Email: Beth.Garvey@exec.ny.gov

Re: Section 1115 MRT Waiver Extension with Pharmacy Carve-Out

Dear Governor Cuomo:

This firm has been retained by the End AIDS NY Community Coalition, including member organizations and the people they serve (the "Coalition"), to challenge your Administration's misguided decision, through the New York State Department of Health ("DOH"), to seek a three-year extension of the existing Section 1115 Medicaid Redesign Team ("MRT") waiver demonstration ("1115 MRT Waiver Extension") from the Centers for Medicare and Medicaid Services ("CMS"), which is set to expire March 31, 2021, while at the same time seeking to reverse a crucial component of the existing waiver—the longstanding carve-in of pharmacy benefits into managed care.

Applying to extend the existing waiver for three years—thus allowing the State to maintain the status quo while taking the time to methodically evaluate the impacts of the COVID-19 pandemic on all aspects of the MRT II redesign project with robust input from all stakeholders—is understandable.[1] However, the rushed decision to move the pharmacy benefit from managed care to fee-for-service (the "Pharmacy Carve-Out"), which will eliminate the

[1] As explained in the draft DOH 1115 Waiver Extension request, "Although the State began planning for a larger renewal effort for the MRT waiver, these efforts has been *significantly impacted* by the COVID-19 pandemic and associated federally declared public health emergency ("COVID-19"). It is essential for the stability of the State's Medicaid program that the current MRT waiver be extended without delay to give the State and its stakeholders time to consider the long-term impacts of the pandemic on its health care delivery system and identify redesign efforts that will best position the State to respond effectively to both COVID-19 and future public health emergencies." That same care and caution should be applied to the hurried decision to simultaneously seek approval for a Pharmacy Carve-Out.

savings realized by covered safety net entities under the Federal Drug Discount Program ("340B"), is not. This change would result in profound negative consequences for medically underserved low-income New Yorkers that rely on the critical care and services provided through the utilization of 340B savings by Coalition members.

For the reasons explained in submissions to the DOH by Coalition members (see attached letters), the Pharmacy Carve-Out and consequent elimination of 340B savings is an ill-considered policy choice that will ultimately cost the State money and degrade the scope and quality of care for low-income New Yorkers, including people with disabilities. While that should be reason enough to change course before it is too late, there is another reason that you should consider carefully before forging ahead: the proposed Pharmacy Carve-Out and consequent elimination of 340B savings violates federal law. First, the Pharmacy Carve-Out violates the 340B statute because it eviscerates the critical benefits for small and resource-limited organizations serving disadvantaged populations that the statute provides for. Second, the rushed process of seeking the extension and Pharmacy Carve-Out has violated the Medicaid Act and its implementing regulations in multiple respects that threaten the viability of the extension itself. Third, the Pharmacy Carve-Out will have an adverse discriminatory effect on persons with disabilities in violation of the Title II of the Americans with Disabilities Act ("ADA") and Section 504 of the Rehabilitation Act of 1973 ("Rehab Act").

Should you persist and begin to implement the Pharmacy Carve-Out with its consequent elimination of 340B savings and/or submit the 1115 Waiver Extension Request to CMS with the Pharmacy Carve-Out proposal, we intend to commence a legal action and seek an immediate injunction to protect Coalition members and the vulnerable people they serve, especially those with disabilities, which will include, without limitation, an order directing you to withdraw the State's 1115 Waiver Extension Request and/or declaring any such extension null and void should it be granted.

1. Impact of the Pharmacy Carve-Out

The pharmacy carve-in and 340B savings that the State now seeks to eliminate, allows Federally Qualified Health Centers (FQHCs), like Coalition member Housing Works, and other covered safety net health care providers, to access pharmaceutical drugs at reduced costs that enable them to utilize those cost savings for initiatives that greatly expand access to care and the scope and quality of health services provided.

For example, Housing Works provides care to more than 8,000 New Yorkers per year and operates four FQHCs located in medically underserved New York City communities, which provide an integrated model of care that seeks to improve the emotional and physical health of the most vulnerable and underserved New Yorkers—those facing the challenges of homelessness, mental health issues, substance use disorders, and incarceration. Like the other 70-plus FQHCs throughout the State with over 800 locations, those centers are a critical component of the health delivery system, providing high-quality, patient centered, community-based primary care to anyone who needs care, regardless of their ability to pay, as well as behavioral health services, dental care and substance use services delivered in a culturally and linguistically appropriate setting.

Another Coalition member, Evergreen Health, fosters healthy communities by providing medical, supportive and behavioral services to individuals and families in Western New York – especially those who are living with chronic illness or who are underserved by the healthcare system. Evergreen currently serves over 14,000 patients per year. Recently designated as an FQHC Look-Alike with three service delivery sites in medically underserved communities in Erie County, Evergreen is actively working to engage in care the more than 160,000 low income people in Evergreen's service area alone who are not being served by existing health centers. This priority population experiences numerous unmet health care needs and health disparities across all points in the lifecycle. As an FQHC Look-Alike, Evergreen accepts all patients regardless of their ability to pay, and addresses barriers to care through a fully integrated model of care, which is designed to treat the whole patient to improve health outcomes.

Thanks to 340B drug discount savings, safety net programs like Housing Works and Evergreen Health can fill service gaps and thus address the varied and evolving needs of low-income persons, including a significant number of New Yorkers with disabilities. Indeed, the COVID-19 vaccination program, currently underway, is benefitting from 340B drug discount savings; many health centers and clinics use 340B savings to support unfunded costs such as conducting vaccine related outreach and patient education; providing vaccinations to their own staff and partner organizations; and hopefully vaccinating community members who are especially vulnerable to COVID-19.

If the Pharmacy Carve-Out becomes a reality, Coalition members and others like them, will be forced to cut-back and in some cases shutter many of the programs and services that rely exclusively on 340B savings. This will in turn, have adverse and even deadly consequences for tens of thousands of vulnerable New Yorkers, exacerbating already stark health inequities.

2. The Pharmacy Carve-Out Violates the 340B Statute

Congress established the 340B program by adding Section 340B to the Public Health Service Act, codified at 42 U.S.C. § 256b. Health care providers that participate in the 340B program serve as the nation's healthcare "safety net," providing health care to the neediest individuals, regardless of ability to pay. The 340B statute limits participation in the program to certain defined health care providers, referred to as "covered entities," 42 U.S.C. § 256b(a)(4), which include health care providers, like Coalition members, that are relatively small, and receive federal assistance to serve disadvantaged, vulnerable populations with limited resources. *See, id.* (defining covered entities); *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011).

Congress intended the 340B program to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992). By spending less on medications, covered entities can devote more of their precious resources to patient care. The program is a vital and indispensable tool to help offset the costs of uncompensated or under-

compensated care. Without the 340B program savings, covered entities, like Coalition members, will be forced to restrict access to services or even cease operations.

The 340B statute provides covered entities the right to purchase and dispense drugs at 340B discount prices. The 340B statute directs that federal contracts with manufacturers "shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). If the State implements the Pharmacy Carve-Out it is seeking as part of its 1115 Waiver Extension request, it will violate the 340B Statute.

3. The Tardy Submission of a Section 1115 Waiver Extension with 340B Carve-Out Violates the Medicaid Act

As CMS itself emphasizes, a "core objective of the Medicaid program is to serve the health and wellness needs of our nation's vulnerable and low-income individuals and families. Traditional Medicaid approaches to serving this diverse and medically complex population have not always been effective at eliminating barriers to access and quality services, and often lack adequate focus on long-term health and independence. Section 1115 demonstration projects present an opportunity for states to institute reforms that go beyond just routine medical care, and focus on evidence-based interventions that drive better health outcomes and quality of life improvements." *See* CMS explanation of Section 1115 Waiver Demonstrations (available at: https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations/index.html).

Beyond the devastating impact that the Pharmacy Carve-Out will have on Coalition members and the people they serve, the proposed Section 1115 Waiver request is untimely under the Medicaid Act and regulations which expressly mandate an extensive process and submission of extension requests a minimum of six months before expiration. The timing of this process, as mandated by the law and regulations, is no doubt meant to prevent ill-considered actions—such as the Pharmacy Carve-Out and its consequent elimination of 340B savings—by requiring a timeline that allows for substantially more input from stakeholders; that allows state governments the time needed to avoid rushed and poor decision-making; and that allows CMS a minimum of six months to process and meaningfully evaluate all aspects of the extension request, including public comment and input that even now is not completed.

Federal Regulations provide that a "request to extend an existing demonstration under sections 1115(a), (e), and (f) of the Act will be considered only if it is submitted at least 12 months prior to the expiration date of the demonstration when requesting an extension under section 1115(e) of the Act or 6 months prior to the expiration date of the demonstration when requesting an extension under section 1115(a) or (f) of the Act." 42 C.F.R. § 431.412(c). The State's current plan to submit its extension request along with the Pharmacy Carve-Out thus flatly violates this mandate. And, while the State's failure to comply with this requirement is manifest, it is no mere technicality.

The Federal Regulations establish a timeline and a process that allows time for CMS to meaningfully evaluate any request for an extension, including when an extension request

includes a substantial amendment or modification to the existing demonstration, such as the Pharmacy Carve-Out, whether CMS should "treat the application as an application for a new demonstration." 42 C.F.R. § 431.412(c)(1). When a legally compliant application is submitted, CMS has at least six months to engage the applicant concerning all aspects of the application set forth in 42 C.F.R. § 431.412(c)(2)(i)-(vii), including the materials the State must provide detailing the results of the mandatory public notice and comment requirements. Specifically, the State must submit "a report of the issues raised by the public during the comment period and how the State considered the comments when developing the demonstration extension application." 42 C.F.R. § 431.412(c)(2)(vii). That process is not yet complete. The 1115 Waiver is due to expire on March 31, 2021. The State does not contemplate submitting its "completed" application until March 5, 2021, just 26 days before expiration. Under the circumstances, it is difficult to conclude that the public process mandated by the regulations has been anything more than a sham. CMS will have less than a month to determine whether the demonstration extension application should be treated as a new demonstration, and irrespective of that decision, whether the application should be rejected for multiple reasons, including the State's failure to comply with federal law as detailed in this letter.

4. The Pharmacy Carve-Out will violate the ADA and Rehab Act

Title II of the ADA provides that "no qualified individual with a disability shall, by reason of such disability, be excluded from participation in or be denied the benefits of the services, programs, or activities of a public entity, or be subjected to discrimination by any such entity." 42 U.S.C. §12132; *see also id.* § 12131(1) (defining "public entity" to include state governments). The ADA prohibits state governments from taking actions "that have the effect of . . .discrimination on the basis of disability." 28 C.F.R. §§ 35.130(b)(3)(i), (ii) (1999). The Rehab Act contains the same protections and prohibitions to "any program or activity receiving Federal financial assistance." 29 U.S.C. § 794(a).

The 340B program is utilized by countless organizations that provide critical care and services to persons with disabilities. *See* 340B Is Serving the Underserved (available at: https://340binformed.org/2019/04/340b-is-serving-the-underserved/). The overwhelming majority of persons served by Coalition members are qualified persons with disabilities entitled to protection from unlawful discriminatory effects of state government policies. *See Henrietta D. v. Bloomberg*, 331 F.3d 261 (2d Cir. 2003) (people with HIV are protected by the ADA). Accordingly, here, the negative impacts on the 340B program of the Pharmacy Carve-Out will be suffered disproportionately by people with disabilities. The Pharmacy Carve-Out and its consequent elimination of 340B savings will unquestionably result in a substantial reduction in, or elimination of, critical services and programs for people with disabilities. In many instances, those reductions and eliminations will in turn result in denying people with disabilities meaningful access to medical care. These adverse discriminatory effects violate the ADA and the Rehab Act. If we are forced to commence a lawsuit and seek relief, a court will have to weigh those irremediable health consequences against the dubious claim of cost savings that the State has thus far used to attempt to justify the Pharmacy Carve-Out. The claim of modest cost saving does not withstand even minimal scrutiny, but even if it did, it cannot legally justify

stripping so many marginalized persons of critically needed services designed to address and ameliorate the very disabilities that qualify them for protection under the ADA and Rehab Act.

* * *

Your administration will be forced to abandon this effort by a court if you do not abandon it of your own volition. We urge you to withdraw the Pharmacy Carve-Out and use the three-year waiver extension to carefully and methodically evaluate whether Pharmacy Carve-Out is a good policy choice in conjunction with all other aspects of MRT II and with the benefit of meaningful stakeholder input and cooperation.

Should CMS decide to grant the State's waiver extension application as currently planned, the Coalition, its members and the people they serve reserve the right to commence an action against the Secretary of Health and Human Services seeking an order vacating and nullifying the extension in its entirety due to, among other things, the legal violations outlined in this letter.

Notwithstanding all of the above, the Coalition is always prepared to meet and discuss alternatives to the Pharmacy Carve-Out that will preserve the safety net rather than shred it, but time is running short.

Please note we expressly reserve all rights and remedies concerning the matters raised in this letter. Please also note that you are officially on notice of our intent to sue. You should preserve any and all documents, including texts, phone records, emails, computer searches, and/or any other communication concerning the decision to seek a carve-out of the pharmacy benefit from managed care. Sanctions for any alteration, loss, spoliation, or destruction of any of these documents, whether in electronic, digital, or hard copy form, will be pursued to the full extent allowed by law. Thank you for your attention to this matter.

Very truly yours,

Matthew D. Brinckerhoff

Encls.

c. -Howard Zucker M.D. (by email)
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