Howard Brown
Health

March 7, 2022

Administrator, Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

RE: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-P)

Dear Administrator Brooks-LaSure:

On behalf of Howard Brown Health and the more than 40,000 patients that we serve, we write to express our strong support for changes being made to the DIR fees within the proposed rule "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs." Direct and Indirect Remuneration (DIR) fee reform is imperative to save pharmacies from paying retroactive and exorbitant DIR fees to Plan D sponsors (PBMs and Insurers). In the proposed rule, CMS states that pharmacy DIR fees have increased by 107,400% over a 10-year period. This has a drastic impact on pharmacies being able to continue to serve patients and communities. If DIR fees continue to grow at this rate, pharmacies will have to close their doors, which will create serious patient access issues in rural and underserved communities.

We strongly urge CMS to:

1. Finalize the term "negotiated price" to mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug at the point of sale.
2. Require PBMs and insurers to provide claims level details of price concessions to increase price transparency for pharmacies on the total amount being withheld from reimbursement for each prescription.
3. Apply the proposed negotiated price definition across all benefit phases, including the coverage gap.
4. Develop standardized pharmacy measures to regulate the application of price concessions and DIR fees and protect pharmacies from more unfair Part D sponsor contracting practices

4025 N Sheridan Road
Chicago, IL 60613

TELEPHONE 773.388.1600
ADMIN FAX 773.388.1602
MEDICAL FAX 773.388.8936

howardbrown.org

Background Information on CHCs & Pharmacy Services Provided

Howard Brown is the largest LGBTQ+ health center in the Midwest, serving over 40,000 patients across twelve clinic locations in Chicago. It is through our many programs—including primary care, behavioral health, mental health services, HIV/STI prevention, elder services and community outreach initiatives—that Howard Brown fulfills its mission of eliminating health disparities and improving health outcomes experienced by LGBTQ+ individuals and residents of the Chicago area and beyond. As a Federally Qualified Health Center (FQHC), Howard Brown provides comprehensive, high quality and affordable care to all patients, regardless of ability to pay or insurance coverage.

Additionally, Howard Brown truly values the Biden Administration's recognition of the integral role health centers have played in America's COVID-19 pandemic response. Health centers have been on the ground in force for nearly two years, fighting the spread of the virus in hard-to-reach communities, including communities of color and among special populations such as the elderly, homeless, and LGBTQ+ communities. They have tested, vaccinated, diverted non-acute cases from overwhelmed hospitals, and connected affected patients with housing, food, and critical services. With the support of this Administration, health centers across the country have administered over 16 million COVID-19 vaccinations and over 14 million COVID-19 tests. Howard Brown alone has administered over 70,000 vaccine doses and over 64,000 COVID tests in our state.

Providing access to pharmacy services and affordable medications is a key component to health centers' comprehensive care model. The majority of health centers participate in the 340B Drug Discount Pricing Program, enabling them to provide more accessible pharmacy services and affordable medications to their patients. 340B savings allow pharmacists to provide critical services like chronic care management, wellness and prevention services, testing, vaccines, and health and wellness education—but increasing DIR fees threaten to jeopardize our ability to retain 340B savings. Over the last year, when health centers' sole focus should have been on serving and protecting patients, they constantly worried about—and continue to worry about— the viability of the 340B program and the ability to retain critical savings to remain on the front lines. Our pharmacies need a stable business environment that enables them to maximize patient care without operating at a financial loss. Howard Brown has over 177 community pharmacy relationships that expand access to affordable medications for patients all across the greater Chicago area. This is especially important as about 25% of our patients are uninsured and about 50% live below 200% of the federal poverty level. Additionally, about 20% of our patients live with HIV, and wide availability to affordable HIV medication has been a lifesaver for many of our patients.

Recommendation 1: CMS should finalize the term "negotiated price" to mean the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug at the point of sale.

PBMs have abused the "reasonably determined exception" to purposely apply price concessions after the point of sale to increase DIR fees. In the last five years alone, some retail pharmacies went from paying around $9,000 to over a $100,000 in DIR fees. Under the current regulation, Part D sponsors have an incentive to opt for higher negotiated prices at the point of sale, which creates the illusion that pharmacies will receive a higher reimbursement until claw backs occur over six to twelve months later.

Howard Brown strongly supports CMS interpretation that the statute requires the negotiated price provided to pharmacies at the point of sale to reflect the lowest possible reimbursement that they can receive for a Part D drug. The lowest possible reimbursement should reflect all price concessions defined in the statute, including all forms of discounts, direct or indirect subsidies, fees, or performance-based penalties.

Recommendation 2: CMS should require PBMs and insurers to provide claims level details of price concessions to increase price transparency for pharmacies on the total amount being withheld from reimbursement for each prescription.

When DIR fees are applied after point-of-sale, pharmacies lose control over their own revenues and profitability, creating undue financial risk. Providing the lowest possible reimbursement at the point of sale will enable pharmacies to make informed business decisions based on accurate data and mitigate cash flow problems due to delayed reimbursement. Currently, pharmacies have no ability to verify or challenge DIR fees because they are unable to connect DIR fees to the original prescription claim or properly evaluate "performance metrics" under their contracts. CMS should require PBMs and insurers to provide claims level details of price concessions to increase price transparency for pharmacies on the total amount being withheld from reimbursement for each prescription.

Recommendation 3: CMS should apply the proposed negotiated price definition across all benefit phases, including the coverage gap.

When pharmacy price concessions and other price concessions are not reflected in the negotiated price at the point-of-sale, this increases patient cost-sharing, forcing them to cover a larger share of the actual cost of a drug. Sometimes patients can pay up to an additional $10 to $20 for a prescription, based on the DIR fees applied months after a transaction. CMS should finalize this regulation because it will increase transparency for

patients to ensure they are paying the lowest co-pay, and not incurring additional costs for PBMs to profit from the transaction. This is particularly important as higher copays will push patients into the coverage gap, where they must assume a higher liability for covering medications until they reach a certain spending threshold. Howard Brown encourages CMS to apply the proposed negotiated price definition across all benefit phases, including the coverage gap. This will minimize confusion for patients and provide more consistency and transparency at the point of sale.

Recommendation 4: CMS should develop standardized pharmacy measures to regulate the application of price concessions and DIR fees and protect pharmacies from more unfair Part D sponsor contracting practices.

While CMS is taking steps in the right direction, Howard Brown is concerned that PBMs and insurers will find alternative methods to minimize Part D drug reimbursement outside of DIR fees. It's imperative for CMS to standardize the pharmacy performance measures and require Part D sponsors to disclose in detail each pharmacy performance metric being used. This will create transparency on how pharmacies are evaluated and provide them with the tools to negotiate better contracts with adequate reimbursement arrangements. Over the last year, health centers and other 340B-covered entities have endured discriminatory practices by PBMs and insurers creating inequitable contractual arrangements and drastically reducing pharmacy reimbursement. The 340B program is vital to ensuring that all of our patients have access to the care and services that they need to stay healthy and thrive. We reinvest our 340B program savings to sustain and expand the comprehensive and holistic wrap-around services that our patients depend on, such as:

- The Broadway Youth Center (BYC), which provides medical, behavioral, and social support services for LGBTQ+ youth experiencing homelessness. In FY21, the BYC drop-in services (including STI screening, vaccinations, basic needs like sleep and food, etc.) were used over 7000 times.
- The In Power program, which is the first holistic, LGBTQ+ focused sexual assault response program in the nation, providing comprehensive medical, behavioral, and social services to survivors.
- Robust HIV and PrEP patient navigation, education services, and medication access: contributing to the 80% viral suppression rate among Howard Brown patients living with HIV and the over 6,600 unique patients we were able to connect to PrEP in FY21.
- We were also able to provide substantially subsidized or free dental and behavioral healthcare for over 5000 low-income and uninsured patients.

Unfortunately, discriminatory practices by pharmacy benefit managers (PBMs) jeopardize our ability to sustain these vitally important programs that are funded in whole or in part by the 340B program.

For these reasons, we strongly urge CMS to take our recommended amendments to the DIR fee portion of the rule. We appreciate your consideration of these comments, and look forward to continuing to work with you to expand access to affordable, high-quality care for medically-underserved patients. If you have any questions please contact Tim Wang, Director of Policy and Advocacy, at TimothyW@howardbrown.org.

Sincerely,

David Ernesto Munar, President and CEO
Howard Brown Health