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United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

September 28, 2023

VIA ELECTRONIC TRANSMISSION

Tomislav Mihaljevic, MD
Chief Executive Officer
Cleveland Clinic
9500 Euclid Avenue
Cleveland, OH 44195

Dear Dr. Mihaljevic:

I write regarding your health system's use of funds generated from the 340B Drug Pricing Program (340B Program). In 1992, Congress created the 340B Program to give discounts on prescription drugs to a select group of hospitals and federal grantees, known as "covered entities," that serve a disproportionate share of uninsured and low-income patients.[1] The program, which is administered by the Health Resources and Services Administration (HRSA), is designed to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2]

Drug manufacturers cannot participate in Medicaid unless they agree to sell outpatient medications to 340B Program covered entities at discounted prices, estimated to be between 20 to 50 percent of a drug's list price.[3] These discounted prices, which are often referred to as the 340B price or the 340B "ceiling price," are based on a statutory formula and represent the highest price a manufacturer may charge a covered entity.[4] The 340B Program generates revenue for the covered entity when insurance reimbursements exceed the 340B price.[5] The intent behind the program is

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[1] *340B Drug Pricing Program*, HEALTH RES. & SERVS. ADMIN., https://www.hrsa.gov/opa (last reviewed May 2023).
[2] *Id.*
[3] *See* Karen Mulligan, Ph.D., *The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments*, USC LEONARD D. SCHAEFFER CENTER FOR HEALTH POLICY & ECON. (Oct. 2021), https://healthpolicy.usc.edu/research/the-340b-drug-pricing-program-background-ongoing-challenges-and-recent-developments/.
[4] U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-480, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018), https://www.gao.gov/assets/gao-18-480.pdf.
[5] *See* Mulligan, *supra* note 3.

for covered entities to pass on the revenue generated from the 340B Program to improve health care services for eligible patients.[6]

However, federal law imposes few requirements with respect to how covered entities may spend the revenue they generate from the 340B Program.[7] The 340B Program is regularly reviewed by the Government Accountability Office (GAO) and HHS's Office of Inspector General (OIG), both of which have highlighted issues with the program.[8] GAO has identified the troubling recent pattern of 340B covered entities increasingly serving wealthier communities with higher rates of insurance, which is far afield from the program's intent.[9] Additionally, GAO has found that covered entities often do not share 340B discounts directly with their patients.[10]

According to recent reports, in April 2020, Cleveland Clinic's flagship hospital began participating in the 340B Program as a "rural referral center," even though it is located near central Cleveland.[11] As is the case with Cleveland Clinic, provided that the entity is "[a] private nonprofit hospital under contract with state or local government to provide health care services to low income individuals who are not eligible for Medicare or Medicaid," then it can qualify as a rural referral center under existing federal law.[12] The hospital, which is structured as a nonprofit health system, reported $1.35 billion in net income in 2021.[13] That same year, the hospital generated approximately $136 million in revenue from the 340B Program.[14] However, according to reports, the hospital has not created any new drug discounts for its patients since it began participating in the 340B Program.[15] Moreover, it is not clear how Cleveland Clinic has used the funds it has generated from the 340B Program and whether any portion of those funds has been passed on to patients.

Additionally, the 340B Program can create an incentive for eligible hospitals to purchase independent practices, increasing consolidation in the health care industry.[16] Because hospitals are reimbursed for drugs when they are administered in a hospital-owned facility, hospitals have an incentive to acquire practices with physicians who frequently administer drugs in clinical facilities.[17] According to one study, the 340B Program is "associated with hospital-physician

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[6] *Id.*
[7] *See* Mulligan, *supra* note 3.
[8] *See* GAO-18-480, *supra* note 4; *see also Examining HRSA's Oversight of the 340B Drug Pricing Program, Hearing Before the H. Energy & Com. Comm., Subcomm. on Oversight & Investigations*, 115th Cong. 1 (2017) (Testimony of Erin Bliss, Assistant Inspector General for Evaluation and Inspections, Dep't of Health & Hum. Servs., Off. of Inspector Gen.).
[9] Rena M. Conti & Peter B. Bach, *The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities*, 33 HEALTH AFFAIRS 1786, 1789–90 (Oct. 2014), https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.0540.
[10] GAO-18-480, *supra* note 4.
[11] Anna Wilde Mathews et al., *Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients.*, WALL STREET J. (Dec. 20, 2022), https://www.wsj.com/articles/340b-drug-discounts-hospitals-low-income-federal-program-11671553899.
[12] 42 U.S.C. § 256b(a)(4)(L)(i).
[13] Mathews et al., *supra* note 11.
[14] *Id.*
[15] *Id.*
[16] *See* Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program* 378 N. ENG. J. MED. 539–48 (Feb. 8, 2018).
[17] *Id.*

consolidation in hematology-oncology . . . without clear evidence of expanded care or lower mortality among low-income patients."[18] Relatedly, the 340B Program creates an incentive for a 340B DSH to open an affiliated outpatient clinic, known as a "child site," outside the 340B service area.[19] This arrangement allows the parent 340B DSH to obtain drugs at the discounted 340B price for use at the affiliated clinic. Cleveland Clinic reportedly has opened numerous child sites in areas with higher income levels than its flagship hospital.[20] By structuring the clinics in this manner, Cleveland Clinic is able to purchase drugs for use at these clinics at the discounted 340B price.[21]

The U.S. Senate Health, Education, Labor, and Pensions Committee has jurisdiction over the 340B Program, as well as matters related to public health. Therefore, it is my responsibility to conduct oversight over the 340B Program and ensure that it is functioning as Congress intended. Accordingly, we ask that you please respond to the following questions, on a question-by-question basis, no later than **October 12, 2023**. We request that all documents be unredacted, produced in electronic form, and Bates stamped. Unless otherwise stated, the below questions seek information or documentation from September 2018 to the date of this letter.

1. Does Cleveland Clinic pass on all savings generated from the 340B Program to patients at its flagship hospital (the "Hospital") in the form of savings on health care expenses? If not, why not? Please explain in detail.

2. Please provide a complete accounting of the funds Cleveland Clinic generated from the 340B Program from the Hospital. This information should be provided in Excel format. In addition, please include the following information:

    a. The total dollar amount generated from the 340B Program categorized by:

        i. Site of service.

        ii. Therapeutic class of drugs.

        iii. HCPC or CPT code (as applicable).

        iv. Name and address of dispensing pharmacy. If the dispensing pharmacy was an onsite pharmacy, please note whether the pharmacy is wholly or partially owned by Cleveland Clinic.

    b. The specific dollar amount directly passed on to patients at the Hospital excluding offsite outpatient facilities registered as child sites, each year, categorized as:

        i. Direct-to-patient savings, as defined as a discount on the total medical billings that patients would have otherwise have been billed. Total medical billings

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[18] *Id.*
[19] Conti & Bach, *supra* note 9.
[20] Mathews et al., *supra* note 11.
[21] Conti & Bach, *supra* note 9.

should already include applicable federal programs, charity care, discounts, and adjustments from private and public health insurance programs.

ii. Direct-to-patient savings on medical billings other than prescription medications, as defined as a discount on the total medical billings that patients otherwise would have been billed. Total medical billings should already include applicable federal programs, charity care, discounts, and adjustments from private and public health insurance programs.

iii. Indirect patient savings. Please provide significant justification as to the form of the indirect patient savings, and how the patient was able to benefit from these savings.

c. The specific dollar amount spent on capital improvement, executive compensation, or other expenditures associated with:

i. The Hospital, excluding offsite outpatient facilities. Please explain in detail how those funds were spent.

ii. Offsite outpatient facilities registered as a child site of the Hospital, including primary care centers, community health centers, imaging centers, specialty care centers, and any other facilities. Please explain in detail how those funds were spent.

iii. Offsite outpatient facilities, medical centers, and other facilities offering health or medical services in the Cleveland area as part of the Cleveland Clinic system. Please explain in detail how those funds were spent.

3. Please provide copies of all documentation governing the relationship between the Hospital and its offsite outpatient facilities registered as child sites, including how 340B revenue is generated and distributed throughout the Cleveland Clinic system.

4. Please explain in detail how Cleveland Clinic spends the revenue it generates from the 340B Program. In addition, please provide the following:

a. Copies of all internal guidance documents and other policies and procedures explaining how Cleveland Clinic spends 340B revenue. To the extent Cleveland Clinic has any unwritten relevant policies or procedures, please explain them in detail.

b. A list of all Cleveland Clinic officials who have authority over how the health system spends the revenue it generates from the 340B Program.

c. All records, including written and electronic communications, involving Cleveland Clinic's senior leadership related to the expenditure of revenue generated from the 340B Program.

5. Please provide all written and electronic communications in which Cleveland Clinic communicated with its provider staff in regard to the 340B Program. These communications should include all instances in which Cleveland Clinic communicated (whether directly or indirectly) about provider incentives as it related to the 340B Program.

6. Please explain in detail Cleveland Clinic's decision to apply to qualify as a rural referral center. In addition, please provide the following:

   a. The specific date when Cleveland Clinic made the decision to apply.

   b. A list of all Cleveland Clinic employees involved in the decision to apply.

   c. All records, including written and electronic communications, in which Cleveland Clinic employees communicated about the decision to apply and the benefits of qualifying as a rural referral center.

Thank you for your prompt attention to this matter.

Bill Cassidy, M.D.

Bill Cassidy, M.D.
Ranking Member
Senate Committee on Health,
Education, Labor and Pensions