POLICY BRIEF

Temple University
Beasley School of Law

Center for
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Law Research

Patient Affordability and Debt Collection Policies at 340B Program Hospitals

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Introduction

While the COVID-19 pandemic has presented historic challenges to the entire health care ecosystem in the United States, affordability of care predates the pandemic and remains a central issue as patients seek to access care among continuing economic uncertainty and structural challenges. The high cost of health care in the United States often leads people to forgo that care and their medicines.[1] With a pandemic that has exacerbated these and other existing health disparities, it is essential to better understand the mechanisms that may support reductions in costs for patients.

Section 340B of the Public Health Service Act establishes a drug pricing program for qualifying hospitals and clinics that requires pharmaceutical manufacturers to give discounts based on a statutorily-set ceiling price on specified outpatient drugs.[2,3] The program was intended to help hospitals access discounted medicines to treat low-income or otherwise underserved communities.[4] Under the 340B program, hospitals may expand their existing services for patients with low income by allowing the hospital to pass along cost savings on pharmaceuticals to patients, among other service expansions.[5] However, there is no specific requirement in the law that savings from the discount program be passed along to patients or insurers.[6]

340B program participation for certain private, non-profit hospitals is partly contingent on those hospitals contracting with state or local governments to provide health care services to people with low income who are not eligible for Medicare or Medicaid. But specific details of those contracts are not reported to the Health Resource and Services Administration (HRSA), and are therefore often unclear or missing, according to a December 2019 report by the US Government Accountability Office (GAO).[7] Further, an October 2021 study suggests that hospitals participating in the 340B drug pricing program have not increased their charity care offerings compared to non-340B hospitals, due in part to a lack of specific incentives to do so.[8] These gaps highlight a need for objective analysis to determine how effectively 340B program savings are benefitting or actually passed onto patients.

Financial assistance policies (FAPs) provide a lens to evaluate patient affordability.[9] FAPs are meant to increase transparency for patients seeking financial assistance, and related debt collection policies are meant to explain protections for patients unable to afford their medical care at hospitals. Based on their non-profit status, 340B hospitals are required under the Affordable Care Act to maintain and publicize written FAPs including records of the actions the hospital may take if a patient is unable to pay for care. The elements in these policies, referred to in Internal Revenue Service (IRS) regulations,[10,11] provide a framework for analysis:

1. Indication of which providers the FAP applies to in relevant hospital facilities
2. Eligibility criteria for financial assistance and whether such assistance includes free or discounted care
3. Method for applying for financial assistance
4. Basis for calculating amounts charged to patients that qualify for financial assistance
5. In the absence of a separate billing and collections policy, the actions that may be taken in the event of patient nonpayment

Each element can impact a patient's experience navigating financial assistance. The specifics of these elements may differ from state to state, as the federal standards, while providing a baseline, are silent on certain finer details (e.g., a lack of mandatory minimum for eligibility criteria). States can, and have in numerous instances, passed laws filling in some of those gaps in the federal regulation, mandating stronger FAP and related debt collection policy requirements than those set at the federal level. For example, New Jersey and Rhode Island mandate that a 100% discount be provided for residents at or below 200% of federal poverty guidelines (FPG).[12,13] And regardless of any existing laws, hospitals may choose to provide more generous charity care than the state-defined minimums.

Researchers at the Center for Public Health Law Research (CPHLR) at Temple University's Beasley School of Law collected FAP and related debt collection policies from a representative sample of 75 340B hospitals. The first 51 hospitals in this sample were the largest 340B hospitals by revenue in the 50 states and the District of Columbia for the 2017-2018 or 2018-2019 fiscal years. The remaining 24 hospitals were the next largest 340B hospitals by revenue in the nation.

Current Policy Landscape

Using policy surveillance, CPHLR researchers identified FAPs, valid through October 1, 2021, in 74 of the 75 sample hospitals (no FAP was located for University of Mississippi Medical Center). Sixty-four hospitals either included debt collection actions in the FAP, or this information was contained in a separate debt collection policy. Several policy features explored in this dataset are examined below, including but not limited to: (1) publicity around FAPs, (2) income levels required for financial assistance eligibility, (3) logistics to access financial assistance, (4) limits on hospital debt collection actions, and (5) discussion of pharmaceutical assistance in FAPs. The full data are published on LawAtlas.org.

Six hospitals did not specify how FAPs were publicized to patients. There was also wide variation in methods specified for publicizing FAPs.

While many hospitals have a sliding scale fee schedule to determine cost sharing on health services provided to lower income patients, many hospitals also offer free care, also known as charity care, at no expense to the patient. However, eligibility for this charity care varied widely: For seven hospitals, charity care was limited to at or below 100% of FPG. These policies apply to medical services received by eligible patients and may not include cost sharing associated with prescription medicines. On the other end of the spectrum, two hospitals' charity care policies set the eligibility threshold for free care above 500% FPG. This variability in eligibility for charity care may lead to disparities in patient cost burden based on their income.

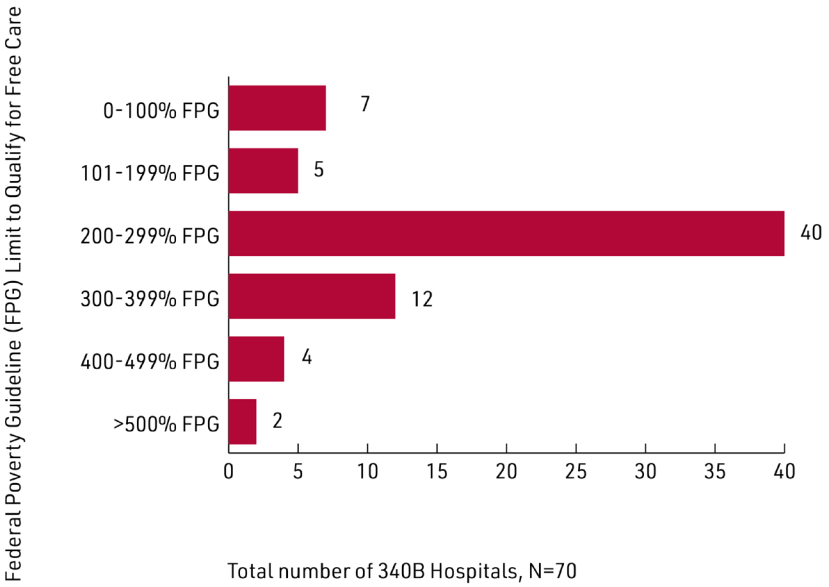

Figure 1. In the CPHLR sample of 75 hospitals, more than half had a Federal Poverty Guidelines (FPG) limit below 300% for free care. Four hospitals did not indicate their FPG limit for free care, and one hospital lacked an FAP.

The logistics around access to financial assistance varies widely: 37 hospitals required an asset test (may include documentation of savings and other property beyond income) as part of the application process while the remaining 37 hospitals did not require an asset test in their FAP. Thirty-five hospitals detailed their appeals process in the FAP, while 39 hospitals did not. Where appeals processes are not clearly stated or absent, patients may have more difficulty navigating a denial of financial assistance, potentially preventing access to assistance which could lead to debt collection actions. While eight hospitals indicated financial assistance for three months upon hospital approval for patient assistance, 23 hospitals provided assistance for 12 months. Variation in length of approved financial assistance suggests potential logistical burdens for patients needing to reapply for assistance more often at some hospitals than others.

Six hospitals specifically prohibited the use of extraordinary collections actions (ECAs).[14] These are specific actions a hospital may take to collect payment when a patient does not meet payment obligations. These actions may include selling of debt; adverse information reporting to credit agencies; deferring, denying, or otherwise requiring payment before rendering of medically necessary care; or legal actions like liens, foreclosure, or civil actions. The IRS provides certain protections to FAP-eligible patients from being subject to ECAs, like requiring hospitals to take reasonable efforts to determine a patient's eligibility for financial assistance.[11] Thirty-nine hospitals did not specify any limitations on ECAs. Forty-five hospitals required specific notice (i.e., official communication from the hospital to the patient) before commencing a debt collection action, while 19 did not. At the 19 hospitals that did not indicate notice in their FAPs, patients may not receive notice of a pending debt collection action.

Of specific note, only 13 hospitals provided details for pharmaceutical assistance in their FAPs. This is partially explained by lack of a statutory mandate for inclusion of information related to pharmaceutical assistance in these policies. Of those hospitals that did provide specific detail, there was broad variation in what was described: Four specifically reference helping patients utilize manufacturer-provided copay assistance programs pay for their medicines; five hospitals detailed their own pharmaceutical assistance programs; and just one hospital specifically referenced 340B in detailing their own pharmaceutical assistance program. Most hospitals in this sample did not clearly indicate pharmaceutical assistance available to patients in their FAPs or how patients may receive discounts on needed medicines.

Evidence

Existing evidence from GAO and other research point to gaps in accountability regarding how 340B drug savings benefit low-income patients.[7,8] Desai and McWilliams suggest that health insurance coverage expansions may have more efficient direct benefit to low-income patients than enrollment in the 340B program.[8]

Research from the National Consumer Law Center (NCLC) has highlighted the limitation of federal requirements for FAPs and related debt collection policies and the actions that states have taken to strengthen protections for low-income patients.[12] The pertinent gaps, reflected in CPHLR research, include no federal minimum standards for eligibility criteria for financial assistance. This lack of standards results in broad variation in hospitals' approaches to eligibility and potential disparities in how patients can access hospital financial assistance across the nation.

With more than 2,500 340B hospitals nationwide, CPHLR's research has identified, collected, and analyzed a representative sample of the highest revenue generating hospitals to provide insight into hospital provision of financial assistance in absence of other legally mandated transparency measures.[9] This analysis indicates many hospitals receiving discounted medicines under the 340B program may not offer low-income patients financial assistance to access medicines and may use extraordinary collection actions, including but not limited to, liens, foreclosures, and civil actions when patients fail to pay bills.

Policy Recommendations

Overall, significant gaps and variability exist in hospitals' FAPs and related debt collection policies. There is a clear opportunity for hospitals to review and update their policies, especially those concerning 340B hospitals' financial assistance for pharmaceutical products. Considering the lack of statutory mandate to

include such information, it could benefit patients and address perceptions of lacking transparency if this information were to be clearly communicated.

NCLC offers a variety of state level recommendations specific to improving FAPs and debt collection policies. Those recommendations include, but are not limited to, clearly stating minimum eligibility criteria for free and discounted care, methods for applying for financial assistance, and providing a billing and collections policy that includes actions that a hospital may take if a patient is unable to pay for care.[12]

Research Agenda

Further evaluation using the CPHLR data could examine how hospitals benefiting from the 340B drug discount program address payment for care delivered to low-income and other patients eligible for financial assistance related to their care. Specifically, this dataset can help identify logistical challenges to financial assistance that patients may be facing, including but not limited to income limits, eligibility criteria, asset tests, duration of financial assistance, and details of appealing denials. This dataset can also help identify variations in debt collection policies among hospitals that may be detrimental to patients. The potential exists to track a broader set of hospital policies beyond this initial sample of FAPs and debt collection policies using policy surveillance over time to determine if substantive changes in these policies may impact patient access to care.

Further comparative research between 340B and non-340B hospital FAPs could help identify variations in charity care or other financial assistance offerings between these hospital types.

Conclusions

Systematically examining financial assistance policies and debt collection policies at 340B hospitals can highlight barriers to patients accessing care that may be addressed at the state and federal levels depending on the type of reform. The broad range of FAP policies in place at 340B hospitals suggests limitations in how the 340B program savings are used to help patients, specifically regarding affordability of medicines for low-income populations.

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