

THE 340B PROGRAM, CONTRACT PHARMACIES AND HOSPITALS: AN EXAMINATION OF THE FIRST 25 YEARS OF THEIR INCREASINGLY COMPLEX RELATIONSHIP

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Introduction

- **The Federal 340B Drug Pricing Program**
 - provides discounted drug prices to hospitals and other health care organizations that serve low-income patients
 - purpose of the 340B program has been to use its savings incentives to help safety net providers increase their amount of patient services
 - individuals with low income and/or uninsured were the main targeted patients
 - offers discounts to hospitals for the purchase of outpatient drugs regardless of the patient's' ability to pay



Introduction

- **The Federal 340B Drug Pricing Program**

- between 2010 and 2015, the 340B program more than doubled in size, and between 2013 and 2015 alone it expanded by 66%
- The program is forecasted to exceed \$23 billion in total sales by 2021, with growth largely driven by expanded utilization at existing 340B-covered entities through contract pharmacy programs and from practice acquisitions, physician practice affiliations, and patient referrals



340B Audit Compliance

- Since 2012, HRSA has conducted audits of covered entities to assess whether they complied with statutory prohibitions against diversion and duplicate discounts
- The latest audit results have revealed noncompliance rates that exceeded 69% and have reflected challenges in covered entities' ability to comply with statutory requirements and HRSA's administration of the 340B program

340B and Providers: Hospitals

- The 340B program has increased profits for hospitals through contract pharmacies because they have still received the same reimbursement but acquired drugs at a lower rate
- Although drugs dispensed to hospital inpatients are supposed to be ineligible for purchase through the 340B program, the tracking mechanism regarding how and for how much these drugs were purchased, and to whom and at what price they were dispensed, is simply inadequate

340B and Providers: Hospitals

- Because 340B prescriptions purchased from contract pharmacies cannot be identified at the time of payment, third-party payers are forced to reimburse 340B and non-340B outpatient prescriptions at the same rate
- Therefore, a 340B entity can “arbitrage” the system by buying drugs at the 340B rate and charging for these same drugs at the non-340B rate

340B and Hospitals

- Medicare and commercial payers can't identify the extent of the "excess", because providers are not required to report the payer for 340B prescriptions
 - Duke University Hospital profited \$282 million in 5 years through outpatient departments and other affiliated clinics from their participation in 340B
 - Duke University Hospital's reply: "It is very difficult ... to accurately calculate gross or net revenues from outpatient pharmaceuticals due to many factors, including the complicated reimbursement models for pharmaceuticals"
 - In any event, only 5% of the patients treated at Duke University Hospital were uninsured, so the other 95% had some sort of insurance coverage; i.e., Medicare, Medicaid, or private insurance



340B and Providers: Practitioners

- **Because physicians in private practice are ineligible to purchase drugs for their private patients through the 340B program, they have found it increasingly difficult to compete with hospital-based oncology practices, and consequently many are selling their practices to hospitals which do to participate in the 340B Program**
- **More than 1,200 independent oncology clinics have either closed or been acquired by hospitals in the last decade**

340B and Providers: Practitioners

- a single practicing oncologist whose practice was acquired by a 340B hospital could gain an additional \$1 million profit by purchasing oncology drugs at a discount through the hospital's participation in a 340B program
- the acquisition of oncology practices by hospitals participating in the 340B Program has accelerated
 - in 2012 and 2013, 75% of community oncology practices were purchased by hospitals with 340B programs
 - the rate of closing of community oncology practices having increased 87% per month

340B and Hospital Accountability

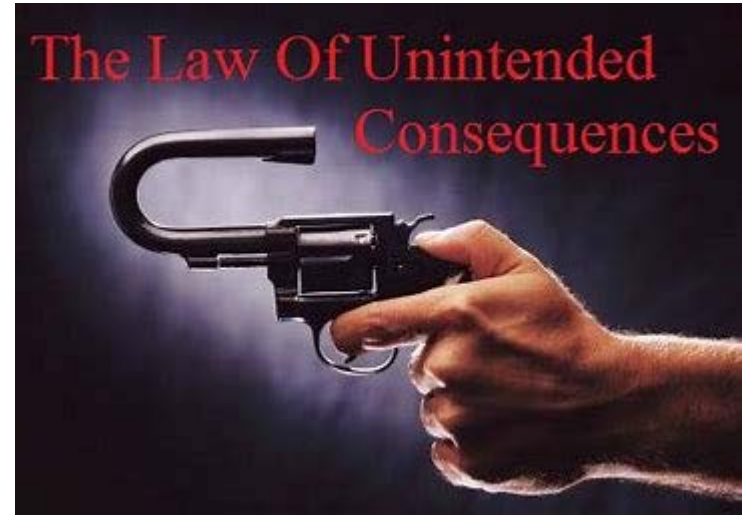
- There is no requirement that hospitals spend any savings from the 340B program directly on patients, let alone on low-income patients, or that hospitals report to anyone, public or private, how the savings are spent
- Desai and McWilliams (2018) found “no evidence of hospitals using the surplus monetary resources generated from administering discounted drugs to invest in safety-net providers, provide more inpatient care to low-income patients, or enhance care for low-income groups in ways that would reduce mortality.”

Recent Developments

- In May, the Trump administration asked 340B stakeholders to weigh in on measures that have been floated in Congress, including a "patient definition" that would specify who qualifies for the drug discount, and moving 340B regulatory authority to HHS

CONCLUSIONS

- The federal 340B Drug Pricing Program has continued to grow since being signed into law
- Although it was originally designed to serve the needs of low-income Americans, it appears to have morphed into a mechanism for healthcare providers to enrich their bottom lines regardless of the income level of the population they serve
- More comprehensive data obtained using a better cost accounting system for providers and analysis by impartial parties will be necessary if the situation is to be resolved



The law of unintended consequences holds that almost all human actions have at least one unintended consequence. Unintended consequences are a common phenomenon, due to the complexity of the world and human over-confidence.