The 340b Drug Discount Program: Oncology's Optical Illusion

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Figure: "My Wife and My Mother-in-Law" by William E. Hill (1915).
High-quality oncology care can be very expensive, and often entails resource-intensive therapy given over moderate to prolonged periods of time. Patients who either do not have insurance or are underinsured can have difficulty accessing therapy. The 340b program was instituted approximately 2 decades ago with the intent of improving access to prescription drugs for indigent patients. The initial program was never oncology-specific, but in recent years it has become a key source of revenue for many oncology programs.

As the 340b program has expanded, so has its scrutiny. Proponents contend that it provides much-needed funds for institutions that treat patients in financial need; they further contend that these institutions would be unable to continue with this mission in 340b's absence. Critics charge that the program is used to create windfall profits for specific types of oncology entities by allowing the drug discounts to be used for well-insured patients, rather than just for the indigent.

The 340b program is a policy version of the optical illusion by British illustrator William Hill in which the viewer sees either a young woman or an old woman—but not both simultaneously (Figure). The program's advocates and detractors each have radically different views of it, and the middle ground does not seem to exist.

History and Evolution of the 340b Program

The 340b program was established in 1992. Its name refers to the statutory provision included in the Public Health Service Act that allows certain facilities to access discounts on outpatient drugs similar to those offered to state Medicaid agencies.[1] The original purpose of the program was to provide poor patients with enhanced access to prescription drugs.[2]

To be eligible, qualifying institutions and other facilities—also known as “covered entities”—must either receive one of ten types of federal grants or belong to one of six types of hospitals.[2] Examples of covered entities include federally qualified health centers, family planning and sexually transmitted disease clinics, black lung and tuberculosis clinics, comprehensive hemophilia diagnostic treatment centers, and qualifying disproportionate-share hospitals.

Although the qualifications that must be met to become a 340b entity are varied and complex, analysis of the current state of the 340b program can be greatly simplified by recognizing that approximately 70% to 90% of estimated outpatient drug costs under the program come from entities that qualify under the disproportionate-share hospital (DSH) provision.[2] To qualify under this category, a hospital must meet specific disproportionate-share criteria and either be owned or operated by a state or local government or be a private nonprofit hospital with certain arrangements with the state or local government.

340b-eligible hospitals must have a DSH adjustment percentage above a certain threshold, typically either 11.75% or 8%, depending on the type of hospital. The DSH adjustment percentage is based on ratios of inpatient days for Medicare and Medicaid patients. *The DSH metric that hospitals must satisfy to qualify for 340b has no direct relation to care of uninsured, outpatient patients with cancer or other conditions that require specialty drug therapy.* In addition to receiving drug discounts, DSH hospitals receive a specified DSH amount for each Medicare discharge. Previous MedPAC reports have established little relationship between DSH adjustment percentages and the proportion of care costs accounted for by the care of uninsured patients.[2,3] Paradoxically, as more patients move from being uninsured to being covered by Medicaid under the provision of the Affordable Care Act, more hospitals will become eligible to participate in the 340b program, if the threshold does not change.[2]

All patients at a 340b facility, including uninsured and insured patients—and in the latter category, patients insured through Medicare or private insurance—can be treated with drugs purchased at deep discounts under the 340b program. These discounts can be substantial, ranging from 20% to 50%.[4,5] Given the high and escalating cost of oncology drugs, these margins can generate huge profits for qualifying institutions.[6] The definition of who, within an institutional structure, is an eligible patient is vague. Generally, the covered entity must maintain a record of the individual’s care, and the treating healthcare professional must be employed by or under contract with the institution.[2]

340b drug dispensing has broadened through the greater use of contract pharmacy arrangements. In the contract pharmacy model, the 340b entity contracts with an outside pharmacy for drug dispensing. Prior to 2010, a 340b entity could use either an in-house pharmacy model or a single contract pharmacy, but not both. Subregulatory guidance issued in 2010 by the Health Resources and Services Administration (HRSA), an agency within the Department of Health and Human Services, enabled all 340b entities to contract with multiple outside pharmacies independent of whether they had an existing in-

house pharmacy.[1,2] These outside pharmacies are not required to have any specific geographic relationship to the hospital.[7]

When the 340b program was initially created, legislators anticipated that approximately 90 hospitals would qualify under the DSH metrics.[7] In 2005, 591 hospitals participated in the 340b program. By 2011, this number had grown to 1,673, representing almost one-third of all US hospitals.[1] 340b hospitals account for almost half (46%) of outpatient drug spending by all US hospital facilities.[2] Drug purchases under the program are estimated to increase from $6 billion in 2010 to $12 billion by 2016.[2]

As previously stated, drug discounts in the 340b program can range from 20% to 50%. With billions of dollars worth of drugs purchased annually through this program, the profits to eligible hospitals can be extraordinary. Just one oncologist employed by an eligible hospital can create up to $1 million of profit under the program through typical use of chemotherapeutic and supportive care drugs.[5] Larger institutions can derive profits of tens of millions of dollars per year.[6,7] While 340b institutions may use these profits to provide care for the indigent or for other charitable activities, nothing in the 340b program rules mandates how the funds are to be deployed. Once a hospital qualifies for the program, it is left to the discretion of the institution how the profits from the program are to be utilized. Many of the same institutions that derive huge profits from the program have low proportions of truly uninsured patients and low proportional spending on charity care.[6,7]

Until recently, there has been extremely little oversight of the 340b program. Prior to 2011, the program had never been audited, and only two covered entities had ever been dismissed from the program due to program violations.[1] HRSA is responsible for program oversight. A Government Accountability Office (GAO) report was issued in 2011.[1] Twenty-nine covered entities were selected as a “judgmental sample,” but only five of these entities were general acute-care hospitals qualifying under the DSH provision. As previously mentioned, DSH hospitals comprise at least 70% to 90% of spending under the 340b program. Prior to the GAO report, oversight consisted mainly of self-policing by program participants. This inherently flawed arrangement is made even more difficult by the fact that HRSA did not provide clear guidance on key program requirements. Self-policing is extremely difficult when even the participants are not sure what the rules are. Since the GAO report, HRSA has published additional notices designed to improve the oversight process, but it remains unclear whether HRSA has sufficient resources to accomplish its goals effectively.[2] HRSA recently required all hospitals to recertify for the program.[5]

340b's Effects on Others

The 340b program has grown to represent a substantial proportion of overall oncology drug spending. The hospital outpatient department proportion of Medicare fee-for-service chemotherapy drug payments has increased from 26% in 2005 to 37% in 2011.[8]

There are no regulatory restrictions on the initial price of oncology drugs coming to market. Initial pricing is at the discretion of the manufacturer and can reflect an effort to recoup the substantial investment made in research and development. Manufacturers are acutely aware of existing downstream rebates and discounts available to their purchasers, and of the anticipated future growth in the number of entities eligible for these discounts. It would be implausible to think that the deep 20% to 50% drug discounts under the 340b program are not increasing the initial price of oncology therapeutics today.[4,7] This is not a small problem. Of the 23 new drugs approved by the US Food and Drug Administration in 2012, 11 were oncology drugs.

Additionally, the 340b program creates a substantial discrepancy between the economic viability of eligible hospitals and that of other entities, including private oncology offices, which are reimbursed by Medicare at average sales price (ASP) + 6%—and currently closer to ASP + 4% under the sequester cuts. If one type of care delivery system is financed more advantageously than another, it is predictable that the universe of oncology care will migrate towards the advantaged system. Additionally, the enormous profits derived from the 340b program create a large appetite among hospitals for the acquisition of private oncology clinics.

Unfortunately, this migration from private practice to 340b institutions will cost both payers and patients more. For Medicare patients, oncology care in the hospital outpatient department costs 14% more than care delivered in a physician office.[9] Patient out-of-pocket expenses are also higher in the former setting.[9] For privately insured patients, hospital outpatient departments are 24% more costly than a physician office.[10]

Conclusions

The historical rationale for the 340b program is a good one: indigent patients do need reliable access to prescription drugs, and entities meeting this need should be supported. However, the evolution of the 340b program has strayed widely from its original intent. Currently, eligible hospitals are capable of deriving huge profits from the program without any statutory requirement that these profits be used to benefit those in need. Furthermore, DSH hospitals that qualify for the program do so through archaic metrics of inpatient Medicare and Medicaid patient care, metrics that have little or no relation to outpatient care of uninsured patients. Previous oversight of the program has been lax. All these dynamics are likely increasing drug costs for those not able to participate in the program and driving patient care to higher-cost settings.

While the 340b program should not be eliminated, it is ripe for reform. Allowing the drug discounts to be applied only to the indigent would seem sensible. Alternatively, building patient support programs around the patients themselves, rather than around institutions to which the patient may or may not have access, would ensure that more patients in need are supported.

DISCLOSURES

Dr. Eagle serves on the Select Large Practice Advisory Panel of the International Oncology Network. Dr. Vacirca and Ms. Buell have no significant financial interest or other relationship with the manufacturers of any products or providers of any service mentioned in this article.

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As a patient, I knew nothing about the 340b program. And there is a great deal about the circumstances of this program described in the article that I don't entirely understand. But Dr. Eagle's conclusion pulled it all together for me. I have just one question: what can we do, to implement the program changes Dr. Eagle suggests? Patient mobilization comes to mind - to my mind, because with a stage 4 diagnosis I have enough insecurity to deal with. If I had to wonder if my oncologist's choice of drugs would be available to me if the cancer comes back, is NOT an option I'm willing to leave to chance.

- **reply**

Elaine @ Fri, 2013-11-22 12:40

This analysis, though couched in academic garb, is highly misleading. It parrots the talking points written by Big Pharma against the 340B program and should be treated as suspect.

- **reply**

Randy @ Fri, 2013-11-22 16:01

Suspect, but maybe not wrong? Most government programs seem hobbled by their own weight. If this is a program that can and ought to be improved, improvement should at least be considered.

- **reply**

Elaine @ Fri, 2013-11-22 16:52

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