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Oncology Transactions and the 340B Drug Pricing Program

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Abstract

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The authors provide a summary of the 340B program and certain business models that allow participating covered entities to expand to new locations.

As health care systems and physician groups assess strategic paths for providing high-quality, cost-effective, and efficient medical oncology services into the future, they are likely to be confronted with numerous options and competing concerns. Availability of the 340B Drug Pricing Program (340B program) can significantly reduce the cost of providing oncology services while enabling enhanced patient access to valuable oncology drugs. In light of a changing regulatory landscape and increased scrutiny of the 340 program, hospitals and other providers would be well advised to fully vet and understand the components of any transaction that would affect enrollment in the 340B program. This article provides an overview of the 340B program and discusses various business and transaction models through which 340B drug pricing may be available.

340B Program

The 340B program is a federal program that requires drug manufacturers to provide significant discounts for the purchase of outpatient drugs by eligible covered entities. Eligibility for the 340B program is limited to specified covered entities that meet certain conditions laid out in the statute, including certain public and nonprofit hospitals that serve a disproportionate percentage of low-income patients, children's hospitals, critical access hospitals, and federally qualified health centers and specialty clinics that receive federal grants to provide care for an underserved medical communities. In 2010, federal health care reform expanded eligibility to include freestanding cancer centers meeting certain conditions; however, to date, only two cancer hospitals (City of Hope, Duarte, CA, and University of Miami, Miami, FL) have enrolled under this category. The federal database of participating covered entities is available online (http://opanet.hrsa.gov/opa/). Physicians and physician groups do not qualify as covered entities eligible to participate in the 340B program.

The program does not require manufacturers to provide discounts on drugs administered in an inpatient setting.

It is fundamental to the 340B program that drugs purchased at the 340B price may only be dispensed or administered to individuals who qualify as patients of the covered entity. To qualify as a patient of a covered entity, an individual must meet the following conditions established by the Health Resources and Services Administration (HRSA), the division of the US Department of Health and Human Services that oversees the 340B program:

- The covered entity must have a relationship with the individual such that it maintains records of the individual's health care
- The individual must receive health care services from a health care professional who is either employed by or provides health care under contractual or other arrangements (eg, referral for consultation) with the covered entity such that responsibility for the care provided remains with the covered entity
- The health care services received must be consistent with the service/range of services for which the grant funding of the covered entity has been provided to the entity; this requirement does not apply to hospitals[1]

The prohibition on diversion of 340B program drugs to individuals who are not patients of a covered entity is intended to ensure that the direct benefit of participation in the 340B program is limited to facilities that qualify as covered entities, to help these federally supported facilities continue to serve low-income and medically underserved populations. In some cases, participating 340B covered entities may desire to expand their defined patient base to make 340B drugs available to patients treated at new locations. There are several business models, such as affiliation arrangements and joint ventures, that, if properly structured, would allow a 340B covered entity hospital to operate a new outpatient clinic in conjunction with nonqualifying entities (including physician groups or noneligible hospitals), while still allowing patients treated at the locations to qualify for 340B drugs.

Business Models for Expanding 340B Access

The 340B program rules allow a covered entity hospital to expand its purchasing and dispensing of 340B drugs to patients treated at new locations, so long as the new locations are an integral part of the hospital, as demonstrated by satisfying the Medicare provider–based rules and being listed as reimbursable cost centers on the Medicare cost reports of the hospitals.[2] In addition, the individuals receiving care at the new locations would need to meet each of the components in the definition of patient, as listed in this article. Parties interested in expanding access to 340B program drugs have several options from which they may choose that meet these standards.

Direct Ownership and Operation

The most straightforward method for extending the benefit of the 340B program to a new location is for a 340B hospital to establish or purchase an outpatient clinic that it operates as an outpatient department of the hospital and to directly employ the oncologists and/or staff based at the site. To meet this requirement, the outpatient clinic must have the following characteristics:

- The clinic must be located within 35 miles of the main hospital campus (certain exceptions apply if the hospital has more than an

11.75% disproportionate share adjustment and is either a public or private hospital under contract with a state or local governmental entity to ensure access in a well-defined service area to Medicare or Medicaid patients)[3]

- The clinic must be operated under the same license as the covered entity, unless otherwise required by applicable state law
- Clinical services must be fully integrated between the covered entity and the clinic, as evidenced by, among other things, the hospital maintaining the same monitoring and oversight over the clinic as it does for any other provider department, with reporting lines between the medical director and the hospital chief medical official or his/her equivalent having the same frequency, intensity, and level of accountability as exist in other hospital departments; in addition, medical staff committees or other professional committees at the hospital must be responsible for medical activities at the clinic, including quality assurance, utilization review, and coordination and integration of services
- The clinic medical records must be integrated with those of the hospital
- Financial operations must also be fully integrated, as evidenced by shared income and expenses, although the hospital may maintain an appropriate cost center for the provider-based facility
- The clinic must hold itself out to the public as part of the 340B hospital[4]

Additional requirements apply if the clinic is not located on the main campus of the hospital (generally, more than 250 yards distant from the main buildings). In particular, specified administrative functions, including billing, records, human resources functions, and purchasing, must be operated under the same contract as the hospital or under the management of the hospital.[5] In addition, the hospital would need to satisfy applicable licensure and accreditation requirements for the proposed addition of facilities and personnel.

From a hospital perspective, this business model offers distinct legal and business advantages and may be preferable to some of the contractual relationships described in this article. However, physician sellers may perceive disadvantages to being employed, including giving up autonomy and control over their former practices.

Hospital/Physician Group Affiliations

Alternatively, a 340B hospital and a medical oncology practice can enter into an affiliation that would allow the practice to retain greater autonomy, while still allowing patients treated by practice physicians to receive 340B drugs purchased by the hospital. Because physicians and physician groups do not qualify as covered entities for purposes of the 340B program, the locations at which they practice would need to satisfy applicable requirements for outpatient departments integrated with the 340B hospital, subject to the Medicare provider–based rules described here. Accordingly, as discussed, the facilities, personnel, and equipment needed to deliver services at the sites would be brought under the name, license, ownership, and financial and administrative control of the hospital.[5] The medical oncology practice would remain a separate legal entity under the control of its physician shareholders and would contract with the 340B hospital to provide clinical and/or management services at the outpatient sites. It would not be eligible to purchase or dispense 340B drugs. Rather, the purchasing and dispensing of 340B drugs would be performed by the 340B hospital.

Oncology professional services agreements: a model for hospital affiliation that preserves private p [J Oncol Pract. 2012]

Under this business model, the parties typically enter into a purchase transaction, under which the 340B hospital acquires the practice assets of the oncology group and assumes direct leasehold responsibility for its practice sites. After the acquisition, the hospital engages the group to effectively run the outpatient oncology department of the hospital. By remaining independent, the physician group would retain autonomy but also potentially reduce administrative overhead. Generally, some or all of the services performed at the site would be eligible for billing under the hospital license and at hospital outpatient rates. The oncology group in turn would be paid on an aggregate work relative value unit basis, with possible additional fair-market fees for administrative, management, and/or medical director fees.[6] All of these fees should be set at an established fair-market rate, determined by independent health care appraisers, for regulatory compliance purposes.

It is important to note that the clinic would not qualify as provider based, or be eligible for 340B drug pricing, if all of the patient care services of the clinic were furnished under arrangements with the oncology group. If achieving provider-based status and extending 340B pricing to patients are the goals of the parties, the hospital would be well advised to provide or arrange from third parties for the provision of certain integral components to the transaction—for example, a direct lease of the space and/or employment of certain individuals who provide patient care services (eg, nurses) at the clinic.

In addition, if the 340B hospital and the medical oncology practice enter into a management arrangement covering a clinic that is not on the main campus of the hospital, the provider-based regulations require the hospital to directly employ clinical staff based at the facility, with the exception of the physicians, nurse practitioners, and physician assistants.[7]

Hospital/Hospital Affiliations

A hospital eligible for the 340B program may also affiliate with a noneligible hospital to establish an oncology clinic that qualifies for 340B program discounts. As with the other business models discussed in this article, to access the 340B program, the clinic would need to satisfy Medicare provider–based requirements and applicable licensure and accreditation standards applicable to the 340B hospital. Two possible affiliation models present themselves. The hospitals may chose to form a new entity that is a joint venture to own and operate the clinic. Alternatively, the 340B hospital could retain ownership and control over the clinic and lease space and/or staff from the noneligible hospital.

The Medicare provider–based requirements provide that a 340B hospital may partially own a facility through a joint venture that is a separate legal entity and include that facility in its Medicare cost report, so long as the clinic is located on the main campus of the 340B hospital (and not that of its partner hospital) and also meets the requirements applicable to all provider-based facilities.[8]

If the clinic is not located on the main campus of the 340B hospital, the hospitals may contractually affiliate. For example, the 340B hospital may lease a site and/or staff from the noneligible hospital to create an outpatient department of the 340B hospital. Assuming that the provider-based billing requirements are satisfied, the 340B hospital may then include that clinic in its Medicare cost report, such that 340B drug pricing becomes available.

In both of these models, the noneligible hospital would not be entitled to purchase or dispense 340B drugs. Furthermore, the 340B hospital would

only be able to dispense 340B drugs to individuals who qualified as patients of the 340B hospital, which, if appropriately structured, would include patients of the outpatient clinic location that is the subject of the joint venture/affiliation.

Important Considerations and Future Trends

There are several potential pitfalls and considerations of which hospitals and physician groups should be aware when evaluating a proposed transaction involving 340B program drugs. First, the emphasis by HRSA on the Medicare provider–based rules for hospital covered entities has led to significant delays before new hospital locations can access 340B program pricing. HRSA currently takes the position that an outpatient facility is not part of a 340B hospital until after the hospital has included the facility in a filed Medicare cost report, which typically does not occur until 5 months after the close of the fiscal year of the hospital. Off-site hospital facilities must be registered with HRSA to be considered part of the 340B hospital. In addition, HRSA has imposed new deadlines for the registration process, which now must occur during the first 15 days of a fiscal quarter after the filing by the hospital of the cost report covering the new clinic.[9] Registration would be effective at the start of the following quarter. If not properly timed, these requirements can delay access to 340B program pricing for more than 1 year after the creation or acquisition of a new outpatient oncology clinic.

Second, the 340B program has recently come under increased scrutiny from drug manufacturers and HRSA. During 2012, HRSA began conducting both random and targeted audits of 340B hospitals to determine their compliance with program rules, including the prohibition on diversion of 340B drugs to nonpatients. In addition, federal health care reform increased the sanction authority of HRSA over program violations and directed HRSA to develop an annual process whereby covered entities certify their 340B compliance. As a result, covered entities are under greater scrutiny than ever to ensure that drugs purchased at 340B discounts are not diverted to individuals who do not qualify as patients of the covered entity.

Third, the 340B program has also attracted the attention of numerous parties, including the Governmental Accountability Office (GAO) and members of Congress, and changes to the program could be forthcoming. In 2011, the GAO reviewed the administration of the 340B program and concluded that oversight by HRSA of the 340B program was inadequate. Specifically, the GAO recommended that HRSA issue a "new, more specific definition of a 340B patient," which would replace the definition currently in use. This request has been echoed by members of Congress as well. If HRSA revises its definition of patient (or if Congress enacts a statutory definition), participating covered entities will need to come into compliance with the new rules.

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The author(s) indicated no potential conflicts of interest.

Author Contributions

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Conception and design: All authors

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Final approval of manuscript: All authors

References

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1. 61 Federal Register 55156 (October 24, 1996)

2. 59 Federal Register 47884 (September 19, 1994)

3. 42 C.F.R. § 413.65(e)(3)

4. 42 C.F.R. § 413.65(d)

5. 42 C.F.R. § 413.65 (e)(2)

6. Blau ML. Oncology professional services agreements: A model for hospital affiliation that preserves private practice. J Oncol Pract. 2012;8:74–78. [PMC free article] [PubMed]

7. 42 C.F.R. § 413.65(h)

8. 42 C.F.R. § 413.65(f)

9. 77 Federal Register 43342 (July 24, 2012)