CHAPTER 12

340B Implementation and Operations Considerations for Free-standing Cancer Centers

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Free-standing cancer centers (FSCCs) were recently made potentially 340B eligible entities. The majority of the statutes, rules, and guidance related to the FSCC's participation in the 340B program are identical to the provisions of disproportionate share hospitals (DSHs). The orphan drug exclusion, which excludes drugs with an orphan indication from the definition of a covered outpatient drug for free-standing cancer centers, is the notable exception and drives numerous strategic and operational decisions related to participation in the 340B program.

FREE-STANDING CANCER CENTERS DEFINED

FSCCs, as defined by Section 1886(d)(1)(B)(v) of the Social Security Act, are independent non-profit entities distinct from other organizations, such as universities and medical centers, with which they may maintain affiliation agreements.[1,2] In 2010, with the passage of the Patient Protection and Affordable Care Act (ACA), institutions eligible to participate in the 340B program as covered entities was broadened to include free-standing cancer hospitals, critical access hospitals, sole community hospitals, rural referral centers, and pediatric hospitals.[3] Unlike the facilities identified as covered entities in the original 1992 legislation, the majority of the newly added covered entities, including FSCCs, are subject to additional statutory requirements as defined in the Health Care and Education Reconciliation Act (HCERA)—the most significant of which is the orphan drug exclusion.[4] The complex legal and regulatory history of the orphan drug exclusion is covered elsewhere in the book (see Chapters 3 and 11). The focus of this chapter will be the practical, operational implications of implementing and managing a 340B program that confront a FSCC considering 340B program entry.

KEY POINT

A FSCC is an independent, non-profit entity that treats patients with cancer. FSCCs were made eligible to participate in the 340B program with the passage of the Patient Protection and Affordable Care Act.

UNIQUE CONSIDERATIONS FOR FSCCs

The Orphan Drug Exclusion

Congress passed and signed the Orphan Drug Act into law in 1983 with the stated purpose of incentivizing the development of drugs to treat rare diseases and conditions for which adequate treatments have not been developed.[5] With the passage of the ACA and the HCERA, FSCCs became eligible to participate as covered entities in the 340B program with the added restriction that orphan drugs are not considered covered outpatient drugs. Following passage of the ACA, the Health Resources and Services Administration (HRSA) engaged in rulemaking and the development of interpretive guidance that was intended to direct covered entities, manufacturers, and others in complying with the orphan drug exclusion. Ultimately, the regulations and guidance promulgated by HRSA were invalidated through legal action[6]; therefore, the original broad exclusion of orphan drugs as covered outpatient drugs stands with limited guidance and support provided to the FSCCs from HRSA.

The first of several layers of complexity associated with the orphan drug exclusion is the fact that a drug may carry FDA approval for multiple indications, some of which may be orphan indications and some of which may not. Because of the broad exclusion of any drug with any orphan indication from the definition of a covered outpatient drug, manufacturers of numerous drugs may not offer FSCCs the opportunity to make a purchase at a statutorily-calculated 340B price. For example, because midazolam carries an orphan indication for the treatment of status epilepticus, the manufacturer that holds the orphan designation is not required to offer a FSCC the discounted 340B price for that drug even when it is utilized for a non-orphan indication. The financial impact of this exclusion can be significant.

KEY POINT

Drugs with an orphan indication, as defined by the Orphan Drug Act, are not considered covered outpatient drugs for FSCCs.

Group Purchasing Organization Prohibition

The prohibition on group purchasing organization (GPO) participation applies to covered entities that are registered as DSHs, pediatric hospitals, and FSCCs.[7] 42 U.S.C. Section 256b(a)(4)(L)(iii) states that the covered entity may not "obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." The provisions of the orphan drug exclusion notwithstanding, a *covered outpatient drug* is defined in Section 1927(k) of the Social Security Act to include "prescription medications, over-the-counter medications that are ordered on as a prescription, biological products that are dispensed pursuant to a prescription (excluding vaccines), and FDA-approved insulin."[8] Because orphan drugs do not meet the definition of a covered outpatient drug, the GPO prohibition does not apply to drugs with an orphan indication for FSCCs. Therefore, FSCCs may purchase drugs with an orphan indication via traditional GPO arrangements and may also have the opportunity to engage in special purchasing agreements to access sub-wholesale acquisition cost (WAC) pricing for drugs with an orphan designation.

Specialty Pharmacy Considerations

Since the early 2000s, significant growth has occurred in the development and marketing of oral anti-cancer agents.[9,10] As of May 2018, at least 70 oral medications currently on the market are indicated for the treatment of malignancies with 25% of new oncologic agents in the development