EDITORIAL

Budgeting in the time of COVID-19

Projecting future drug expenses is never an easy task. This year, Tichy et al[1] provide key projections that will be needed now more than ever. This year health systems will not only face unprecedented financial challenges due to the coronavirus disease 2019 (COVID-19) pandemic; they may also be facing operational challenges. The section of the ASHP Foundation's 2020 *Pharmacy Forecast* report regarding "black swans" (rare events with serious consequences, as popularized by Taleb[2]) noted that few health-system pharmacy departments had a strategic planning process in place to successfully deal with such an event.[3] Meeting the patient surge and drug shortage challenges posed by the COVID-19 pandemic in addition to planning for costly new pharmaceuticals will test even the most robust organizations.

Many health systems are reopening for elective surgeries and procedures even while COVID-19 infections are not decreasing. This seemingly contradictory action is necessary not only to prevent patient harm from delayed care but also to mitigate the financial stress of lost revenue. Health systems' spending to prepare for a pandemic while facing significant lost revenue from cancelled procedures is resulting in pay cuts, furloughs, and layoffs. As pharmacy departments prepare annual budgets, the usual pressure to maintain the status quo or to decrease costs will be even greater this year.

Despite actions to increase visits and resume elective surgeries, health systems may face additional challenges. Patients are more likely to postpone elective surgeries and procedures due to financial concerns, particularly in the face of income loss. Anticipated increased patient volumes resulting from elective procedures and visits may also not materialize as workers lose health insurance and access to care. An estimated 7.3 million US workers (plus several million family members) will lose their employer-based health insurance coverage (this estimate was based on data compiled through the end of March 2020).[4] Further, patients may simply choose to avoid accessing care out of fear of potential infection while social distancing measures remain in place.

In the current climate, attention to high-cost medications will be more essential than ever. Pharmacists are the most effective resource we have for ensuring appropriate and low-cost medication use. Pharmacy departments facing layoffs must prioritize maintaining these activities in addition to ensuring patient safety with decreased staffing levels. One area of focus identified by Tichy et al[1] is monitoring of older generic and previously unapproved drugs. The Food and Drug Administration's (FDA's) Unapproved Drugs Initiative has a noble cause: ensuring that all medications available for use are FDA approved as safe and effective. However, this initiative has had the unintended consequence of increasing both prices and shortages of these products.[5] This year, some of the largest increases noted were for fluphenazine (98.7%), indocyanine green (41.1%), and vasopressin (34.1%), all of which have been in short supply. Utilizing alternatives when appropriate and changing workflows to decrease waste are 2 strategies for maintaining patient access to these formerly low-cost medications.

Price erosion has impacted many biosimilars (ie, those with sufficient competition). Indeed, biosimilars should be a source of opportunity for health systems to decrease medication costs. Unfortunately, due to a lack of interchangeability, patent litigation, and "pay-for-delay" deals that stave off generic competition, many competitor agents are not marketed, keeping innovator product prices high. There is no better example than with adalimumab, the top drug by expenditures at $22.1 billion. Five biosimilars for adalimumab are FDA approved, with the first approval occurring in 2016, yet a marketed product is not expected until 2023. Even though anticompetitive behavior has been recognized by FDA and the Federal Trade Commission, few actions have been taken to allow health systems and patients to benefit from lower costs.[6]

Continued advocacy is needed for public policy changes to improve the current drug pricing landscape. For example, patent law changes are required to prevent companies from "evergreening," or making small changes to a product that offer minimal benefit for patients. This change would not only improve the overall time to generic competition but could also improve biosimilar competition. Last, changes in the way new therapies are priced are needed. New therapies approved on the basis of surrogate markers or with unclear clinical benefit lend themselves particularly well to value-based contracting. A recent analysis shows that the cost of therapy has no association with clinical benefit.[7] During this uncertain time, pharmacists should continue to demonstrate their value as part of the care team and to the entire health system despite potential staffing constraints due to workforce reductions. In particular, pharmacists should ensure patients receive the most appropriate and low-cost medications.

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Erin R. Fox, PharmD
Drug Information Service
University of Utah Health
Salt Lake City, UT
erin.fox@hsc.utah.edu

Disclosures: Dr. Fox is an unpaid volunteer member of the advisory board for Civica Rx. The University of Utah Drug Information Service (UUDIS) has a contract to provide Vizient (a group purchasing organization) with drug shortage information. The total value of the contract represents less than 5% of the total budget for UUDIS. Dr. Fox is also a member of the AJHP *Editorial Advisory Board. She has declared no potential conflicts of interest.*

DOI 10.1093/ajhp/zxaa185