Client Update

New Public and Private Efforts to Contain Healthcare Costs: What It Means for the Healthcare Industry

Healthcare costs remain a significant concern to both public and private payors. According to recent government data, in 2016, U.S. healthcare spending increased 4.3 percent to $3.3 trillion ($10,348 per person), including $1.1 trillion on hospital care, $664.9 billion on physician and clinical services, and $328.6 billion on prescription drugs. At both the federal and state levels, government payors and other entities have developed initiatives to contain costs and promote accessibility to reasonably priced healthcare. Private payors are pursuing similar objectives through vertical integration. These developments create strategic opportunities and risks for different healthcare industry subsectors.

People will always need healthcare. As the U.S. population ages, demand for costly healthcare will only increase. Entities that can develop cost-effective strategies for delivering healthcare will prosper in this environment. For providers, that could mean developing new settings where care can be provided that is both accessible and affordable, *e.g.*, a pharmacy clinic instead of an emergency room. It may also mean developing technologies that facilitate the provision of care, such as monitoring devices linked to a cellular telephone that notify both the patient and provider when there is a problem. Pharmaceutical and medtech companies are likely to be successful when they can demonstrate that their product has demonstrably greater clinical efficacy or cost-effectiveness than other products on the market.

INITIATIVES IMPACTING DRUG PRICING

The FDA's Efforts to Promote Generic Competition

Although drug pricing is technically outside of the FDA's statutory mandate, the agency has implemented a number of initiatives that may encourage competition and indirectly reduce drug prices:

First, the FDA is expediting the review of Abbreviated New Drug Applications ("ANDAs") for generic drugs when there are fewer than three drugs in the marketplace. Research has confirmed that when there are three or more versions of the same drug in the marketplace,

prices drop substantially as compared with no generic or even a single generic option. Relatedly, the FDA published a list of off-patent and off-exclusivity drugs that do not have an approved generic and now includes patent submission dates in Orange Book listings. This enables generic companies to determine the earliest date when they may be able to market new generics. Even though this information has always been available to interested stakeholders, FDA is streamlining the presentation of the data in an effort to make it easier for generic companies to determine which drugs should be prioritized.

Second, the FDA is facilitating approval of generic versions of "complex drugs." Complex drugs include drugs that act locally (*e.g.*, an eye drop that acts on the eye's surface) or drugs that require administration through a device such as metered dose inhaler or auto-injector. These drugs possess features that may make it difficult for an ANDA sponsor to satisfy the requirement of establishing therapeutic equivalence to the branded drug. The FDA has developed guidance documents to facilitate development of such complex generic drugs. The FDA has also developed channels for enhanced communication between the FDA and the sponsors of complex generics to allow for more efficient development and regulatory review of such drugs.

Third, The FDA is continuing to target practices of innovator drug manufacturers who attempt to prolong marketing exclusivity beyond the period allowed by law. For example, the FDA is continuing to express concern regarding innovator drug manufacturers who, for a variety of legal reasons, are reluctant to provide a branded drug product to generic companies for bioequivalence and bioavailability studies.

State Proposals to Create Closed Medicaid Drug Formularies

State Medicaid programs are required to cover the cost of all prescription drugs that are part of the federal Medicaid rebate program. Massachusetts and Arizona are seeking permission from the Center for Medicare and Medicaid Services ("CMS") to develop closed formularies that would exclude certain drugs from coverage.

Massachusetts has detailed its approach in a September 2017 submission for a "Section 1115 waiver." Section 1115 waivers are requests from states to be exempted by CMS from specific Medicaid requirements. MassHealth, Massachusetts' Medicaid program, argues that it cannot adequately control prescription drug costs because it is required to cover all drugs in the Medicaid Drug Rebate Program. MassHealth therefore proposes to adopt a "closed formulary." Under this plan, the formulary would include at least one drug in each therapeutic class—but not necessarily more. MassHealth believes that maintaining a closed formulary would allow it to negotiate volume discounts for the drugs it includes on its formulary.

MassHealth also requests permission to review—and potentially exclude—drugs that have been approved by the FDA under its accelerated approval program. The FDA's accelerated approval

program applies to drugs that are intended to treat serious conditions for which there are no available treatments. The FDA can approve qualified drugs on the basis of surrogate endpoints, which are clinical markers that predict clinical benefit (*e.g.*, tumor shrinkage) rather than the ultimate clinical benefit itself (prolonged life expectancy). Despite the FDA's thorough review and approval, MassHealth separately wants to review those drugs that receive accelerated approval through a partnership with the University of Massachusetts Medical School. If MassHealth concludes that these drugs do not provide sufficient clinical benefit, it requests the authority to exclude them from the formulary (despite FDA review and approval).

Arizona recently informed CMS that it would also like to adopt a closed formulary. Under Arizona's plan, there would generally be at least two drugs per drug category. Arizona requests the ability to exclude drugs for which there is insufficient data regarding cost-effectiveness and costly drugs for which there is a therapeutically equivalent drug in the formulary that is available at a lower cost. Arizona has not yet submitted a formal waiver request to CMS.

California Drug Pricing Statutes

On October 9, 2017, California Governor Jerry Brown signed two bills that are designed to address drug pricing issues. Senate Bill 17 requires a prescription drug manufacturer to notify the California government and private payors in the state 60 days before it issues a price increase that would raise the drug's wholesale acquisition cost by more than 16 percent over two years. The notification must include (among other things), a list of factors that led to an increase in the price of the drug and a description of any changes or improvements of the drug that necessitate a price increase.

While this legislation does not formally restrict drug price increases, it will make it more challenging for drug manufacturers to increase prices by an amount that triggers the disclosure threshold. Once a disclosure is required, payors would have two months to respond to the price increases. Pharmaceutical Research and Manufacturers of America ("PhRMA") recently filed a lawsuit challenging this statute. PhRMA claims that it is unconstitutional because it impermissibly seeks to regulate pharmaceutical manufacturers nationwide and interferes with their First Amendment right to free speech.

Assembly Bill 265 prohibits innovator drug companies from offering any type of rebate that reduces out-of-pocket costs for drugs for which there is a cheaper generic available that is therapeutically equivalent to the branded drug. Proponents of this bill argue that it will help reduce drug costs because it will make it more difficult for innovator companies to promote their products when lower cost generics are available.

INSURER M&A TO GAIN GREATER CONTROL OVER HEALTHCARE COSTS

Two recently announced mergers—if completed—would combine health insurance, healthcare providers, and pharmacy benefit managers ("PBMs") into a single entity.

On December 3, CVS, which operates almost 10,000 pharmacies nationwide, announced that it was purchasing Aetna, a health insurer. Three days later, UnitedHealth Group, an insurer, announced that it was purchasing DaVita's physician group. DaVita operates 280 clinics offering primary and specialist care, 35 urgent care centers, and six outpatient surgery centers. If completed, these transactions should allow the merged entities to control healthcare costs in several ways.

CVS/Aetna would integrate an insurer, a PBM, and pharmacies. This merged entity would have greater leverage to negotiate with drug companies and presumably limit drug prices. This is particularly significant because some have theorized that stand-alone PBMs have incentives to increase drug profits. Aetna would not be the first insurer to have an in-house PBM. UnitedHealth already has its own PBM: OptumRx.

These mergers would result in insurers being directly linked to healthcare providers. Aetna would become connected to CVS's "Minute Clinics," which provide basic healthcare services at CVS pharmacies and other retail locations. CVS already operates more than 1,000 of these clinics and plans to both open new clinics and expand the services provided in clinics already in operation. UnitedHealth will similarly become linked to DaVita's physician practices.

Aetna/CVS and UnitedHealthcare hope that connecting insurers and providers within the same organization will help control medical costs. Many assume that people who forego regular visits to primary care providers ultimately drive up healthcare costs. That could happen because people neglect basic preventative measures like flu shots or do not manage conditions like diabetes or heart disease before they require costly hospitalizations. Additionally, people may make unnecessary—and costly—visits to the hospital emergency room because a primary care provider is not available during nonworking hours. These insurers apparently hope that they can control healthcare costs by encouraging insurers to receive low-cost primary care on a regular basis. For CVS/Aetna, Minute Clinics are an ideal venue to provide such care because people regularly frequent pharmacies. It remains to be seen whether these insurer/provider relationships will actually lower medical costs.

Hospital Cost Containment Efforts

Hospitals are pursuing a variety of different strategies to control costs:

- Hospitals are using horizontal and vertical integration to create larger organizations, with both more beds and affiliated providers. Hospitals hope that increased scale will give them greater bargaining power vis-à-vis payors and suppliers.
- Hospitals have recognized that treatment in acute care facilities in many cases is neither cost-effective nor in the patient's interest. Hospitals are therefore developing in-house or acquiring entities that provide non-acute care, including urgent care centers and physician provider groups.

Hospitals are using data analytics to determine how care can be delivered in a more cost-effective manner, such as standardizing procedures to reflect best practices and developing policies that reduce the risk of infection and medical errors.

HEALTHCARE INDUSTRY IMPACT

Innovator Drug Companies

The initiatives described above could have either positive or negative effects for innovator drug companies depending on how they are situated. Innovators may suffer significant harm if Massachusetts' Section 1115 waiver is granted and other states develop similar programs. MassHealth's application makes clear that its objective is to avoid paying for as many high-cost medications as possible. It wants to go so far as to exclude drugs approved under the FDA's accelerated approval program even though such drugs by definition treat severe conditions for which there is no other approved drug on the market. If Massachusetts and other states adopt narrow formularies, the sales of many high-cost drugs could drop significantly.

Although CMS has not yet taken a position on Massachusetts's Section 1115 waiver request, the likelihood of it being implemented does not appear to be high. The Trump administration has generally been supportive of the pharmaceutical industry, which strongly opposes Massachusetts' application. CMS is also unlikely to favor Massachusetts' attempt to second-guess the FDA's accelerated approval program. Even if the application were approved, it might be struck down in court. PhRMA has publicly stated that the application is unlawful because the Medicaid Drug Rebate program is not subject to Section 1115 waivers and, with limited exceptions, requires coverage for all qualifying drugs.

The focus on drug pricing may create strategic opportunities for some branded manufacturers. In an era in which payors—both public and private—are looking for proof that drugs are cost effective, innovators that can assemble data proving that their drugs are more cost-effective than competitor drugs or nondrug treatments will have a significant competitive advantage. Innovators will similarly benefit if they can establish that their drug provides a meaningful clinical benefit over drugs currently on the market (whether in improved efficacy or reduced side effects).

Generic Manufacturers

The FDA's initiatives are aimed at encouraging generic competition. That should be beneficial for the generic industry as a whole. Some generic manufacturers may nevertheless suffer if they are currently able to charge high prices for certain drugs due to the absence of competitors on the market and the FDA's initiatives result in the FDA approving additional ANDAs for those drugs. Such ANDA approvals could result in significant reductions in the price of generic drugs that previously had little or no competition.

Health Insurers

In the 1990s, some health insurers sought to control healthcare costs by establishing closed-panel health maintenance organizations ("HMOs"), in which insurers employed or contracted with healthcare providers and generally required insureds to be treated by those providers. Those HMOs strongly incentivized healthcare providers to control costs—but those cost containment efforts proved to be highly unpopular. The recent CVS/Aetna and UnitedHealth/DaVita mergers show that health insurers see strategic benefits to inching back to where they were in the 1990s. While not adopting the old closed panel model, insurers are increasingly merging with providers once again and this trend is likely to continue in the future. Insurers are most likely to be successful if they can develop integrated organizations in which they can analyze data enterprise-wide and can control costs by identifying factors such as who should be receiving preventative care now to avoid costly conditions down the road and which medical procedures or prescription drugs are the most (or least) likely to produce cost-effective results. Although they are not saying so publicly, insurers may believe that in the future, they can also control healthcare costs by reducing reimbursement rates for providers within the same corporate organization.

Hospitals

Hospitals face a challenging environment because public and private payors are working to reduce patient treatment in acute care hospitals and to control the cost of such care when it is provided. That environment, however, creates opportunities for innovative hospital organizations that can both optimize the efficacy and quality of care provided in a hospital setting and offer care in non-acute settings as well. Smaller hospitals, however, that stick to a traditional model of providing acute care are likely to face difficulties surviving and may face pressure to sell themselves to larger hospital systems.

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