NEJM Catalyst

COMMENTARY

The Health Care Utility Model: A Novel Approach to Doing Business

Carter Dredge, MHA, Stefan Scholtes, PhD

DOI: 10.1056/CAT.21.0189

The growth of the Civica Rx health care utility model of addressing shortages of pharmaceutical supplies for hospitals has been gathering momentum since its launch in 2018. The concept is to bypass the major drug makers and to manufacture or subcontract for generic pharmaceuticals that its 1,400-plus member hospitals need. What's unique about the venture is that it is established as a nonstock, nonprofit 501(c)(4) social welfare organization. The money to run the operation comes from the customers (the hospitals) and philanthropic organizations, not banks or investors in need of a healthy return. The aim is to combine the efficiency of a pro-competitive private enterprise with the equitable mission of a pro–social welfare organization. This new organizational construct represents an opportunity that could be adapted and implemented in other areas of the health care landscape.

The promise of innovative disruption in health care is enormous and the ingenuity of health care technology at times seems boundless. And yet, even with all the technological advancements, some of the most crushing health care problems of our society remain: massive inequalities in access to care, widely divergent outcomes, and runaway costs that bankrupt individuals and even countries. Meanwhile, the humans providing this care aren't faring much better. Burnout among clinical workers is at record levels — and that was before the pandemic.[1] It's a quiet indictment of the health care industry that doctors and nurses often find their heroic efforts at odds with misaligned incentives that seem beyond their control.

How can we as a modern society and business community be so capable at solving some health care problems and so inept at solving others? It's an exasperating riddle, and you'd be right if you chose to label it as a *wicked problem*[2,3] like social scientists do. Some stakeholders advocate for more direct private business innovation and competition to be applied, while others argue that

further governmental intervention and regulation is warranted. Both stakeholder groups have compelling data to defend their positions, but there is little willingness to budge on either side. The result is usually a stalemate. This prompts a critical question: Could there be a potential middle-ground solution? One that harnesses the ingenuity and rapid pace of private-sector entrepreneurial innovation and still ensures equitable and affordable pricing and access for everyone? A recent health care venture in the U.S. pharmaceutical industry may have the disruptive potential to do just that.

The Formation of Civica Rx

Unlike many developed countries in the world, it is not common practice in the United States for the government to formally regulate prices for pharmaceutical drugs. Instead, drug prices are set by individual companies. This is generally accepted in the United States, however, there are times when companies take things too far. Such was the case several years ago when Martin Shkreli, a former hedge fund manager who was then the CEO of Turing Pharmaceuticals, increased the price of Daraprim, a drug used to treat patients with toxoplasmosis, by 5,433%.[4] The negative impacts of this price hike were massive — sales of the drug increased to $6.3 million in 2011 from just $667,000 the year before — and patients were literally paying the price through higher costs, lack of access, or alternative treatment that did not include the standard first treatment drug.[5]

Shkreli got his 15 minutes of fame but ended up going to prison for a different reason. Yet he was not the first nor the last pharma executive to boost prices just because the rules failed to protect patients. And while we're unlikely to return to the era of health care pioneers like the trio of scientists who discovered insulin and sold the patent to the University of Toronto for $1 to keep the price affordable for patients,[6] is it possible that there's another way to work for the social good at competitive scale in a free market?

In 2018, a leading group of health systems and philanthropies determined that yes, it is possible, and that time was of the essence. They formed Civica Rx, a new manufacturer of generic pharmaceuticals, with the company being rooted in civic responsibility and stewardship for all citizens. The initial governing members included seven health systems — Catholic Health Initiatives (now CommonSpirit), HCA Healthcare, Intermountain Healthcare, Mayo Clinic, Providence, SSM Health, and Trinity Health — and three philanthropies: Laura and John Arnold Foundation, Peterson Center on Healthcare, and the Gary and Mary West Foundation.

> *"This universally equal and low-cost pricing approach established Civica Rx in a new business genre — that of a health care utility— with the termutility referencing other commonly shared basic services such as water and electricity. The mission of a utility is not to offer a service to individual or segmented groups of customers, but to make an essential service accessible to everyone at the same low cost."*

Since its launch in September 2018, Civica Rx now provides more than 50 generic drugs to more than 50 health systems that, together, comprise approximately 1,400 hospitals that represent more than 30% of all inpatient hospital capacity in the United States. To put this into perspective, that's akin to adding 40 to 50 member hospitals per month, every month, since Civica's inception. Civica Rx also supplies generic medications to the U.S. Department of Veterans Affairs and the U.S. Department of Defense, has supplied millions of medication vials to the U.S. Strategic National Stockpile, and has provided 11 essential medications used to help care for Covid-19 patients. Civica Rx's growth has outpaced even the most aggressive business model forecasts in a complex industry notorious for squeezing out new entrants. A key to this success is its innovative business model.

Four Tenets of the Novel Business Model

The founders of Civica Rx set a very clear mission for the new venture — to make quality generic medicines accessible and affordable to everyone — and agreed on four novel business model tenets that have contributed to its rapid growth:

Nobody would own the company.

The new venture would be set up as a nonstock, nonprofit generic drug manufacturer that would also be classified as a 501(c)(4) social welfare organization. There would be no equity holders, no dividends, and no stock options, and, if the company or its assets were sold, the proceeds would go to charity. The venture would be managed by stewards instead of owners, including multiple philanthropies directly on the board. With no individual or group owning Civica, the growth of the company was entirely non-dilutive with each joining entity always bringing upside value because they brought more scale and never took a cut of the overall enterprise.

Everyone would be charged the same price and there would be no special deals.

Every organization that joined Civica would get the exact same contract terms and prices. This operating model was completely different from the volume discounts used by traditional manufacturers, and this simple contracting approach made joining Civica very straightforward: As more organizations joined Civica, the quantities being ordered would go up and the prices would go down — for everyone equally. This universally equal and low-cost pricing approach established Civica Rx in a new business genre — that of a *health care utility* — with the term *utility* referencing other commonly shared basic services such as water and electricity. The mission of a utility is not to offer a service to individual or segmented groups of customers, but to make an essential service accessible to everyone at the same low cost. In Civica's case, joining organizations never had to second-guess if they were getting a good deal, and the resulting need for an external marketing budget for Civica has been immaterial.

However, getting to this equality-promulgating principle didn't just randomly occur. It required some of the largest health care systems in the United States to voluntarily choose to give up their individual purchasing advantages. These systems traded the short-term tactical for the long-term strategic approach and ultimately embraced a broader societal objective that could not be achieved by a single organization. The pain of the previous market pricing failures with Daraprim and other

essential medications, such as insulin, which has cumulatively increased more than 1,200% in the past several decades,[7] had produced conditions necessary for future collaborative success.

The company decided to go big and go long.

The company decided to start big and to play long; when Civica was launched, it became a national-scale enterprise literally overnight with long-term purchase commitments on multiple drugs from more than 500 hospitals on Day 1.[8] Civica's founders knew the company would need to withstand a future potential predatory pricing backlash from incumbent pharma firms, who could drop their prices to drive out Civica and then raise prices again once Civica was gone. To preemptively address this threat, Civica utilized both scale and longevity of commitment — instituting a specifically designed*take-or-pay* purchasing agreement referred to as a*minimum viable volume* (MVV) contract. The MVV contract was the mechanism by which members would agree, on a drug-by-drug basis, to buy approximately 50% of their expected drug volume from Civica for a minimum of 5 years, while purchasing the balance of needed generic pharmaceuticals from other existing manufacturers.

> *"Civica utilized both scale and longevity of commitment — instituting a specifically designed take-or-pay purchasing agreement referred to as aminimum viable volume (MVV) contract. The MVV contract was the mechanism by which members would agree, on a drug-by-drug basis, to buy approximately 50% of their expected drug volume from Civica for a minimum of 5 years."*

The MVV contract solved two important problems: (1) it provided demand stability for Civica to take on the most critical hospital-based shortage drugs even if competitors sharply reduced their prices; and (2) it provided supply stability for existing generic drug manufacturers with excess capacity to competitively reenter the market. This last point is critical to Civica's success. Here's why: If a company wants to sell a generic drug in the United States, it needs what is called an Abbreviated New Drug Application (ANDA) issued by the U.S. Food and Drug Administration (FDA). It was originally forecasted that Civica would need to develop its own ANDAs, thus potentially requiring several years to produce a single drug. However, with the MVVs in place, Civica soon discovered it was able to secure supply contracts with numerous contract manufacturing organizations (CMOs) that already held many of the needed ANDAs. Prior to Civica's market entry, many of these ANDAs were underutilized or even dormant because the CMOs couldn't break into the market by themselves with enough scale and staying power. (To take on the pharma heavyweights is a daunting challenge.) Over time, in addition to partnering with CMOs, Civica will produce its own ANDAs and is also building a dedicated essential-medications manufacturing facility in Virginia.[9]

By simultaneously going large scale *and* long term, Civica aggregated enough demand and supply to produce more than 40 million vials across 50-plus essential medicines that were used to treat nearly 16 million patients at an aggregate price point that was roughly 30% lower than pre-Civica price levels over about 2.5 years. In addition, much of this was achieved while managing through a

global pandemic that led to significant product mix changes: demand plunged for drugs used for elective surgeries that were halted and skyrocketed for drugs for patients on ventilators, spiking as high as 400% over standard levels at their peak, according to internal Civica Rx operations data.

Overall, the Civica model appeared to be both agile and dependable across millions of patients even while being pandemic-tested with massive demand fluctuations. One key to this success was the decision at the company's founding to maintain 3 to 6 months of inventory for each of its products to provide a safety stock if needed. This was feasible due to the long-term MVV contracts and desirable based on the customer-centric mentality where access to essential medications was just as important as cost. So, while still young in its organizational development, the crucible of Covid-19 has provided valuable insights into the robustness of the health care utility model to handle both scale and stress and still achieve the dual objective of better access and lower drug prices. Civica performed as intended — as an access-maximizer versus profit-maximizer.

The purchasers of the products would become the funders of the company.

Instead of raising funds from venture capitalists or banks, Civica raised financing directly from committed Civica institutional customers and philanthropies. This essential customer-financing element eliminated the incentive to push for higher prices and reoriented the sales strategy from "what is the highest cost that the market will bear" to "what is the lowest sustainable cost that we can deliver to the market." Civica's primary focus was on hospital-based drugs that were facing shortages, such as antibiotics, and it raised $100 million in membership donations and low-interest, long-term debt directly from hospitals and philanthropies. In short, it procured money from hospitals to produce drugs for hospitals. This funding strategy eliminates the need to balance competing interests of the business's customers and its financiers.

Additionally, not long after Civica's hospital-based model was showing promise, another Civica entity was formed in partnership with the Blue Cross Blue Shield (BCBS) Association and multiple independent BCBS companies in January of 2020.[10] The entity, recently named CivicaScript,[11,12] focuses on producing generic retail and outpatient drugs. Due to some tax intricacies, CivicaScript was formed as a public-benefit limited liability corporation (LLC) coupled with important health care utility model adjustments. Some of the most notable adjustments include (1) members having no rights to distributions, (2) contractually agreeing to pass on the drug cost savings directly to members, and (3) having aggregated results on the savings generated to be published annually.

As illustrated above, financing was *not* raised from hospitals to launch CivicaScript. This would have violated the customer-financing principle because the vast majority of retail medicines in the United States are purchased outside of hospitals in retail settings. Instead, funds were raised from insurance companies who were the relevant customers that paid for the majority of the costs of the retail drugs. In like fashion to Civica, CivicaScript has grown rapidly; its partners already represent close to 100 million lives and the entity is just getting started. In summary, CivicaScript raised money from retail drug purchasers (i.e., insurance companies) to produce retail drugs. Keeping the customers and the funders the same group is a hallmark of the health care utility model. If money had been raised from hospitals to produce retail drugs, or vice versa, then there would have been

a need for a direct return expectation on the funds themselves rather than from the resulting costs savings from future member purchases.

> *"By simultaneously going large scale and long term, Civica aggregated enough demand and supply to produce more than 40 million vials across 50-plus essential medicines that were used to treat nearly 16 million patients at an aggregate price point that was roughly 30% lower than pre-Civica price levels over about 2.5 years."*

Looking at the Four Tenets Collectively: It's About Structure, not Technology

The model, while novel, is highly replicable. It wasn't about a new technology or a new biological discovery, it was about a new way of working together. When referencing disruptive innovation, we often refer to the new technologies themselves: personal computers versus mainframes, video streaming versus physical movie rentals, etc. However, in the case of Civica, it is the company's structure and business model that enables the disruption, not a new technology. The structure itself is the disruptive innovation. This insight has systemic implications for future applications, which we will now discuss.

Broader Application of the Civica Business Model: The "Third Option"

Civica Rx possesses the efficiency and nimbleness of a pro-competitive private enterprise, focusing on continuous improvements and innovation to compete in the open marketplace for customers and resources. In addition, it embraces the equitable mission of a pro–social welfare organization, where the dollars earned are the dollars used by and through the members to serve all people — especially the poor and the vulnerable. Taken together, this new model represents a *third option* by satisfying the demands of both equity and efficiency.

Can the Civica model be expanded beyond a new generic pharmaceuticals business and serve as a template for a *third option* that can be deployed on other problems in health care that public and private companies have failed to solve? In particular, can this model help make affordable health care accessible to more people? Details matter here, because the Civica model is not a panacea. It is important to understand what type of problems it can solve and in what environment it can flourish.

Types of Problems to Be Solved

Identifying the right types of problems that this new structural third option should be used to solve is extremely important. Health care utility models are designed to address market competition failures, particularly those with either (1) high barriers to entry and market concentration that result in excessive margins, significant inefficiencies, or rent-seeking; or (2) non-aggregated/dispersed markets that have historically not been able to adequately organize at scale. Health care utilities can be injected into such markets as internal competition boosters that will spur business model innovation in the market as a whole. From the market perspective, the ultimate success of a health

care utility is not measured in its market share, but in its ability to level the competitive playing field in its market through bringing down prices of goods and services that cost more than they should or in increasing access to a needed product whose supply is artificially constrained.

> *A Civica-type structural and financial model is not a competitor for venture capital and private equity, but rather a complement to these models, leaving the most aggressive forms of highly uncertain innovation to the purely private or governmental sectors, and instead taking a lead in bringing greater efficiencies to well-known and mature products or services, particularly if these are trapped in inefficient private or public delivery models."*

Civica operates in its market as a structural, not a technological, innovator. Its core operational processes are well established and its products have existed for decades. This limited the up-front risk of the founding organizations. In fact, the critical risk for the Civica funders was not driven by technological or demand uncertainty, but it was the classic risk of collaboration: Will all participating organizations play ball and give up short-term individual advantages (their own scale economies) in the interest of the longer-term larger advantages from cooperation? Or will some seek opportunities to free-ride and exploit the good will of others? Civica's structure addresses this collaboration risk head-on through its transparent pricing, long-term contracts, and alignment of the interests of customers and funders, and the collaboration is supported through multiple membership committees that address ongoing operational and drug-selection matters.

While Civica has performed very well in the generic drug market, a Civica-like structure might not be ideal for innovations such as novel drug development, with its high up-front costs and high technological and market uncertainty. Such cutting-edge innovation is better suited for a financial structure that provides a large risk premium for those taking on the disproportionate up-front risks. A Civica-type structural and financial model is not a competitor for venture capital and private equity, but rather a complement to these models, leaving the most aggressive forms of highly uncertain innovation to the purely private or governmental sectors, and instead taking a lead in bringing greater efficiencies to well-known and mature products or services, particularly if these are trapped in inefficient private or public delivery models.

The Civica health care utility model helps harmonize the tension between the focus on profit-maximization and social impact, while still enabling the entrepreneurial employee culture that is the hallmark of private enterprise. It is a modern innovation that harks back to health care's roots as a mission of mercy. And the speed at which Civica has not only grown, but has begun to incrementally influence the pharmaceutical industry demonstrates a potential that even its founders could not have predicted.

Challenges certainly remain. While Civica has reduced the misalignment between individual and organizational incentives, it has not eliminated them. Yes, it is true that no one owns the business

and it can't be sold for private gain, and the vast majority of realized benefits will transfer directly to its members. However, what these members choose to do with the savings is extremely important. In the case of Civica, these members are hospitals, not patients. This is a potential Achilles' heel of the model if it is not proactively managed. Civica's mission is "to make quality generic medicines accessible and affordable to everyone." If the value it generates is extracted by hospitals and their owners, without reaching or benefiting the patient, it will have failed. Civica and CivicaScript are addressing this directly with reporting and other commitments to ensure adherence with the mission.

Looking Ahead

The rise of Civica Rx as a health care utility is promising. It shows what scalable mission-oriented innovation could look like. In the right hands, in the appropriate setting, the Civica model is worth replicating and customizing for other health care sectors. Yes, it takes commitment and scale from large organizations to get some of these ventures off the ground. But given the potential to create more efficient and more equitable health care solutions for patients — and not just for patients in the health care utilities themselves, but for those in the broader industries due to positive externalities — it will be more than worth it.

Carter Dredge, MHA
Lead Futurist, SSM Health, Saint Louis, Missouri, USA

Stefan Scholtes, PhD
Dennis Gillings Professor of Health Management and Director of the Centre for Health Leadership & Enterprise, Judge Business School, Cambridge University, United Kingdom

Disclosures: Carter Dredge serves on the Board of Civica Rx and receives no financial compensation for doing so. Stefan Scholtes has nothing to disclose.

References

1. Kane L. Medscape National Physician Burnout & Suicide Report 2020: The Generational Divide. January 15, 2020. Medscape. Accessed June 6, 2021. https://www.medscape.com/slideshow/2020-lifestyle-burnout-6012460.

2. Rittel HWJ, Webber MM. Dilemmas in a general theory of planning. Policy Sci. 1973;4(6):155-69

3. Camillus JC. Strategy as a Wicked Problem. Harvard Business Review. May 2008. https://hbr.org/2008/05/strategy-as-a-wicked-problem.

4. Alpern JD, Song J, Stauffer WM. Essential medicines in the United States—why access is diminishing. N Engl J Med. 2016;374(6):1904-7

5. Pollack A. Big Price Increase for Tuberculosis Drug Is Rescinded. New York Times. The New York Times Company. September 20, 2015. Accessed June 6, 2021. https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?searchResultPosition=1.

6. Belluz J. The Absurdly High Cost of Insulin, Explained: Why Americans Ration a Drug Discovered in the 1920s. Vox. Updated November 7, 2019. Accessed June 6, 2021. https://www.vox.com/2019/4/3/18293950/why-is-insulin-so-expensive.

7. Roberts DK. The deadly costs of insulin. Amer J Manage Care. June 10, 2019. Accessed June 14, 2021. https://www.ajmc.com/view/the-deadly-costs-of-insulin.

8. Johnson CY. Hospitals Are Fed Up with Drug Companies, So They're Starting Their Own. Washington Post. September 6, 2018. Accessed June 6, 2021. https://www.washingtonpost.com/national/health-science/hospitals-are-fed-up-with-drug-companies-so-theyre-starting-their-own/2018/09/05/61c27ec4-b111-11e8-9a6a-565d92a3585d_story.html.

9. Griset R. $125M Pharma Manufacturing Plant Coming to Petersburg. Virginia Business. January 21, 2021. Accessed June 15, 2021. https://www.virginiabusiness.com/article/125m-pharmaceutical-manufacturing-plant-coming-to-petersburg/.

10. Morse S. Blue Cross Blue Shield Organizations and Civica Rx Partner on Lower Cost Generic Drugs. Healthcare Finance. HIMSS Media. January 23, 2020. Accessed June 15, 2021. https://www.healthcarefinancenews.com/news/blue-cross-blue-shield-organizations-and-civica-rx-partner-lower-cost-generic-drugs.

11. Pifer R. Anthem Joins Insurer-Backed Generics Effort CivicaScript. Healthcare Dive. Industry Dive. June 16, 2021. Accessed June 16, 2021. https://www.healthcaredive.com/news/anthem-joins-insurer-backed-generics-effort-civicascript/601891/.

12. Business Wire. CivicaScript, the Newly Named Civica Initiative to Serve Patients in Retail Markets, Announces a New Health Plan Partner, a New President, and a New Drug Manufacturing Partner. Berkshire Hathaway. June 16, 2021. Accessed June 16, 2021. https://www.businesswire.com/news/home/20210616005264/en/CivicaScript-the-Newly-Named-Civica-Initiative-to-Serve-Patients-in-Retail-Markets-Announces-a-New-Health-Plan-Partner-a-New-President-and-a-New-Drug-Manufacturing-Partner.