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Blueprint for U.S. Rx Price Controls

(Sources: edited excerpts from an article written by Catherine Kelly and published by Scrip)

The Trump Administration's much-anticipated drug pricing plan proposes ideas for finding savings in Medicare Part D [the federal government's pharmaceutical benefit for the elderly] by modifying the protected classes policy. The notion of changing the protected classes is among several policy proposals that had not been previously discussed by the Administration but are included in its "Blueprint to Lower Prices and Reduce Out-of-Pocket Costs."

The 44-page document, which includes more than 50 policy proposals, was released by President Trump and Health and Human Services (HHS) Secretary Alex Azar during an event in the White House Rose Garden on May 11. The breadth and number of polices included surprised many stakeholders and was greeted with concern by biopharma and pharmacy benefit managers.

"Today my administration is launching the most sweeping action in history to lower the price of prescription drugs for the American people," President Trump said. "We will have tougher negotiations, more competition, and much lower prices at the pharmacy." For example, the blueprint suggests, HHS may "support" better drug price negotiation in Medicare by "providing plans full flexibility to manage high cost drugs that do not provide Part D plans with rebates or negotiated fixed prices, including in the protected classes." Currently, 'Part D plans are unable to negotiate lower prices for high-cost drugs without competition,' the document says. "This change could allow Part D plans to use the tools available to private payers outside of the Medicare program to better negotiate for these drugs."

Part D plans are required to cover "all or substantially all" drugs in six protected classes, including antineoplastics, antidepressants, antipsychotics, immunosuppressants, anticonvulsants, and antiretrovirals. The protected classes policy has hampered plans' ability to negotiate price concessions with manufacturers because they are not able to challenge manufacturers with non-coverage - every drug in a class must be on formulary. As a result, pricing for those drugs has not been subjected to the same pressure as non-protected classes. "It will take months for the kind of actions that we need here .... It took decades to erect this very complex, interwoven system," stated HHS Secretary Azar.

The protected classes policy has long been the subject of criticism by insurers. The Centers for Medicare and Medicaid Services (CMS), which is the government entity that administers the Medicare program, attempted to narrow the number of drugs that could benefit from the protected classes policy in a proposed rule released in early 2014. But fierce opposition from biopharma and patient groups led CMS to abandon the effort.

The blueprint also seeks stakeholder feedback on: a) whether manufacturers of protected classes drugs that have increased prices or failed to provide rebates should have their protected status revoked; b) Should manufacturers of drugs who have increased

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In Brief...

- **McKesson Corporation** reported fourth-quarter fiscal 2018 earnings of US$3.49 per share, missing estimates, but improving from the year-ago quarter's figure by 2.3%. Sales of US$51.63 billion, were up 6%. North America pharmaceutical distribution and services revenues came in at US$42.73 billion, up 5.1% from the prior-year quarter and International pharmaceutical distribution and services reported revenues of US$7.28 billion, which increased 18.6% from the year-ago quarter. McKesson also announced its 3 reporting segments moving forward: U.S. Pharmaceutical and Specialty Solutions (which includes the U.S. Pharmaceutical and McKesson Specialty Health businesses); European Pharmaceutical Solutions; and Medical-Surgical Solutions.
- **IFPMA**, representing research-based pharmaceutical companies and associations, launched "50 Years of Global Health Progress". The report traces global health progress over the past 50 years and emphasizes the collaborative role that the research-based biopharmaceutical industry has played with the goal of delivering prevention and treatment as well as strengthen health systems around the world. "Over the past 50 years, we have witnessed a tremendous advancement of healthcare globally. Much of this progress is due to improved access to medical services and to the discovery of life-saving and life-enhancing medicines and vaccines that have extended and improved the quality of life for millions of people," said *Ian Read*, Chairman and CEO of Pfizer and IFPMA President. The launch came at the same time as the *71st World Health*

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Limit Distribution in Specialty Pharmacy

(Source: edited excerpts from an article written by Alex Toman, PharmD and published by Specialty Pharmacy Times)

In many drug product releases, especially in the world of specialty pharmaceuticals, manufacturers will often limit the number of specialty pharmacies that can dispense their medications. Pharmaceutical manufacturers will determine this distribution strategy based on product characteristics, education for the patient, market reach, and administration and dispensing characteristics.

One of the popular phrases in pharmacy and the pharmaceutical industry today is, "the Patient Journey." Everyone involved in the health care of the patient wants to understand how the patient moves through the health care system. The process as well as the patient relationship with stakeholders along this pathway is referred to as the patient journey.

Pharmacy is a very important segment of that patient journey. Pharmacies and manufacturers want to impact the patient journey in the best possible way. By doing so, patients are adherent to medication, more involved with their therapy, and more satisfied with their treatment. In turn manufacturers and pharmacies benefit

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Blueprint (cont.)...

their prices over a particular look-back period or have not provided a discount be allowed to be included in the protected classes; and, c) Should drugs for which a price increase has not been observed over a particular look-back period be treated differently when determining the exceptions criteria for protected class drugs, the document asks.

Medicare Part D has effectively used negotiating tools since it was launched but its approach needs an update, Azar later told a White House briefing with reporters. “Over 15 years, as so often happens with government programs, it got frozen into place,” he said. “And the private sector kept adapting and learning, especially after the economic crisis in 2007, how to control drug spend even better .... we need now to bring the same tools that arc available to the private sector to those Part D drug plans so they can negotiate even better.”

Azar also highlighted a lack of price negotiation in the Medicare Part B program [the federal government’s medical/doctor benefit for the elderly], which covers drugs administered by a physician. A plan to move at least some Part B drugs to the Part D program to subject them to more pricing pressure was included in the President's 2019 budget proposal. “We've got to figure out ways to move those drugs, especially the high-cost ones, into the private Part D plan negotiations so that we can get a deal and start getting bargains on that for our seniors and for taxpayers,” he said. The blueprint seeks comment on how that might be accomplished.

The Pharmaceutical Research and Manufacturers of America took issue with such policies in a statement on the blueprint. “The proposed changes to Medicare Part D could undermine the existing structure of the program that has successfully held down costs and provided seniors with access to comprehensive drug coverage,” the group said. “We must also avoid changes to Medicare Part B that could raise costs for seniors and limit their access to lifesaving treatments.'"

Azar highlighted several other points in the blueprint during the briefing. Notably, he raised serious questions about how pharmacy benefit managers (PBMs) are compensated and of the rebating system altogether. His comments about rebates echoed those made recently by FDA Commissioner Scott Gottlieb, who question whether the post-transaction price concessions should have a place in drug pricing anymore. “We are calling into question today the entire structure of using rebates as the method of negotiating discounts in the pharmacy channel,” Azar said. “What if instead we said: 'No rebates; flat price; fixed price in the contracts?'" The blueprint seeks comments on that approach. It also invites input on imposing a fiduciary duty on PBMs to act “solely in the interest of the entity for whom they are managing pharmaceutical benefits” without receiving payment or remuneration from manufacturers.

“We have a real issue that we've got to look at, which is the role of compensation for pharmacy benefit managers,” Azar maintained. “They're taking it now from both sides. They're getting compensated by their customers - the insurance companies - but they're also getting compensated by the drug companies they're supposed to be negotiating against.” In a statement on the blueprint, the Pharmaceutical Care Management Association argued that “getting rid of rebates and other price concessions would leave patients and payers, including Medicaid [the federal & state government’s healthcare program for the poor] and Medicare, at the mercy of drug manufacturer pricing strategies ... Simply put, the easiest way to lower costs would be for drug companies to lower prices.”

Another important theme in the blueprint is out-of-pocket costs for patients. One policy proposal that has been strongly supported by pharmceutical manufacturers is a requirement that plans redirect a portion of negotiated rebates to the point-of-sale to offset patient cost sharing. The President's proposed budget includes a plan to implement point-of-sale rebates, the blueprint notes. However, the document does not solicit further comments on how such a program could be designed.

Asked how long it would take to implement the reforms in the blueprint, Azar said many of the proposals could be implemented relatively quickly through administrative action. Others would need legislation, which would be a more drawn out process. Still, “it will take months for the kind of actions that we need here,” he cautioned. “It took decades to erect this very complex, interwoven system. We're talking about entrenched market players, complex financial arrangements that would have to be redesigned. So, I don't want to over-promise that somehow on Monday there's a radical change. But there's a deep commitment” to pursue change.

Limit Distribution (cont.)...

as well.

When deciding to include a pharmacy in a distribution network, a manufacturer will look for factors that positively differentiate the pharmacy, as well as factors that will likely help the target patient population. For example, if a specialty pharmacy specializes in oncology products, that pharmacy may provide better medication adherence tracking, patient follow-up, patient education programs, and financial assistance programs.

By contracting with a pharmacy that can better aid at producing positive outcomes for patients, the patient experiences better health outcomes. In other words, limiting a network to pharmacies that can provide high touch clinical care is preferred, over a larger network with pharmacies that are not as proficient at these services.

It is also important to understand the financial incentives to limited distribution. Adding one specialty pharmacy to a distribution network, can cost a manufacturer US$90,000 or more. Therefore, it can be cost prohibitive for a pharmaceutical company to have a large network of contracted pharmacies.

Additionally, many payers view more than 12 or 13 pharmacies in a network like products available in open distribution. With more contracted pharmacies, payer reimbursement rates tend to go down and patient populations spread out and become diluted.

In a limited distribution model, the pharmaceutical manufacturer is able to control supply and better influence patient services, such as Risk Evaluation and Mitigation Strategies, Safety Monitoring and Medication Adherence.

Although the practice of limited distribution is often debated, it is a practice that is continuing to grow within the industry. Accordingly, it is necessary for many pharmacies to differentiate themselves to earn limited or exclusive distribution contracts.

Accreditations are one step but are now mandatory for most payers. Therefore, pharmacies that can demonstrate expertise patient populations or disease states have an advantage. Showing a manufacturer that the pharmacy can execute medication safety programs or patient care and adherence programs to improve patient outcomes are imperative.

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Limit Distribution (cont.)...

Manufacturers do not automatically include the big specialty pharmacy players for their distribution networks. Smaller pharmacies that can demonstrate this expertise are also able to earn those coveted contracts. For example, by providing excellent services to patients who take an open distribution drug, can demonstrate the pharmacies ability to take on a limited distribution medication.

The limited distribution model does limit some specialty pharmacies and typically cuts out retail pharmacies as well. However, remember that it is the duty of a pharmacist to provide clinical care to patients in practice settings where pharmacists are more accessible and arguably more influential than other health care providers.

Therefore, the author concludes, the patient is better served by a pharmacy that can deliver specialized patient care, with pharmacists who are familiar with their unique disease states.

Shipping Logistics Firm Completes Successful Blockchain Pilot

(Source: Blockchain News)

Freight forwarder Marine Transport International (MTI) has completed a successful blockchain pilot program to automate and digitize the entire supply chain process on a decentralized distributed ledger.

MTI has announced details of a blockchain pilot wherein multiple parties – the supplier, shipper, load point, customs and terminal authorities, were able to access real-time data over an interoperable blockchain. The results of the successful pilot were verified by computer scientists at the University of Copenhagen in Denmark and maritime technology leads at Blockchain Labs for Open Collaboration (BLOC).

"All parties involved in the supply chain benefit from automated data flows as the [blockchain] system allows complete interoperability of data sources, even including legacy systems" read an excerpt from a press release, hinting at the possibility of a straightforward implementation of the technology with existing infrastructure at shipping ports.

The CEO of Martine Transport International, added: "The blockchain has proven to be an excellent way of connecting the different parties involved in any supply chain environment due to the transparency and security-by-design of the technology." With the promise of increased security and efficiency, MTI envisions blockchain technology to revolutionize "any type of supply chain business, be it marine-, air-, or land-based" with cost savings "as high as 90%" when compared to traditional, paper-intensive, manual, error-ridden processes.

Globally, some of the world's largest shipping giants and trading ports have already begun investing in blockchain technology. Singaporean shipping giant PIL, one of Asia's largest shipowners and the Port Authority of Singapore (PSA), among the world's largest port operator partnered technology provider IBM in working on proof-of-concept blockchain solutions for the global supply chain as well as linking trade finance solutions with the supply chain business over a blockchain.

In a similar project, the government of Dubai partnered with IBM to execute an initial pilot that saw fruits exported from India to Dubai by sea. A participating bank issued a letter of credit for the transaction wherein the fruits were turned into pulp in Dubai before their export to Spain.

In Brief (cont.)...

Assembly in Geneva, Switzerland.

- U.S. drug wholesaler **Morris & Dickson** was given a reprieve and can temporarily resume selling controlled substances. Earlier this month, the company was ordered to cease sales of controlled substances, as ordered by the **U.S. Drug Enforcement Agency.** *Paul Dickson*, President of Morris & Dickson, gave seven hours of testimony about the threatened future of his family-owned business and the patients it serves. U.S. District court judge *Elizabeth Foote* ruled that the company could resume operations for now.
- **McKesson High Volume Solutions** (HVS) has entered into an agreement with Ohio-based retail drug store chain, **Discount Drug Mart Inc.**, to provide a dispensing automation platform for Discount Drug Mart's central fill pharmacy in Avon Lake, Ohio. Discount Drug Mart will also have access to McKesson's substantial resources through its relationship with HVS. Other benefits of the **McKesson HVS** system include the ability to ensure patient medication safety through robotic counting and packaging, and the opportunity to redirect pharmacy resources to clinical programs that enhance patient care.
- Patient support services company, **Lash Group** (owned by **AmerisourceBergen Corporation**) has launched its newest electronic benefits verification solution. This Smart-powered technology, designed to fit within existing workflows, is an artificial intelligence-powered system aimed at reducing time-to-therapy and improve care delivery through collection of healthcare coverage and payer-related data, then processes the data through machine learning and artificial intelligence to evaluate each incoming benefit.
- The **China Drug Administration** (CDA) released a draft guideline for the implementation of rules on pharmaceutical data exclusivity for public comment. The guideline expands the scope of data protection to include innovative therapeutic biologics, orphan drugs pediatric drugs and drug products that have had success in first generics. The data exclusivity period is up to six years for innovative drugs discovered in China and up to twelve years for innovative therapeutic biologics.
- German wholesaler and distributor **Phoenix Group** purchased Romanian drug distribution company **Farmexim** and the **Help Net** pharmaceutical retail network from Romanian investor Ovidiu Buluc. Farmexim employs approximately 800 people, while Help Net includes approximately 220 pharmacies and employs 1600. Phoenix currently operates in 26 European markets with over 34,000 employees.
- Brazilian wholesaler **Profarma** announced first quarter results for 2018, with adjusted sales for its pharmaceutical distribution unit up 4.7% year over year, and an increase of 6.5% year-over-year for its specialty business. Its retail business enjoyed a 15% rise in average sales per store compared to the prior year.

(Sources: BusinessWire, Company Press Releases, Drug Store News, Lexology, Romania Insider, Lexology, and The Ledger)