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09.01.2020

Tags: USA, Insurance, AHIP, Association

Matt Eyles, president and CEO of the Association of Healthcare Insurance Providers (AHIP) outlines how the US health insurance landscape has evolved in the last ten years, counters some of the pharmaceutical industry's criticisms of insurance firms, and outlines why greater affordability of healthcare in the US will benefit all stakeholders.

In 2010, the Obama administration passed the Affordable Care Act (ACA). What has its impact been on the US health system at large and the insurance market in particular?

The ACA has had wide-ranging effects on the entire US healthcare system, from health insurance providers to physicians, hospitals, pharmaceutical manufacturers, and a host of other actors. The Act aimed to substantially expand coverage via the Medicaid program and create new exchange markets.

That has not worked out exactly as planned. The original law intended to expand coverage via Medicaid to all US citizens who had an income up to 138 percent of the federal poverty level of around USD 15,000 per annum for an individual. However, when a legal challenge was presented, the Supreme Court eventually ruled that the Medicaid expansion would instead be voluntary for individual states. About 36 states have expanded coverage so far and even the more conservative states are now deciding to do the same.

This has been incredibly important in plugging some of the coverage gaps caused by how Medicaid was formerly structured. Adults had to have an extremely low income of below 100 percent of the federal poverty level. In some states, for example Texas, a person's income had to be less than USD 3,000 per year to access Medicaid – in other words, extremely low.

Medicaid has expanded coverage to more than ten million people and the uninsured rate has dropped from 18 percent to around nine percent. This does however still mean that over 25 million Americans are uninsured today.

Overall, the industry is very different ten years down the line from the passing of the ACA, especially in terms of being much more consumer- and patient-oriented. Previously, insurance was much more of a business-to-business type of operation.

How has the ACA changed the health insurance landscape in the US?

Private health insurance providers are the entity that delivers most of the coverage in these government-sponsored public programs. The vast majority of individuals who have coverage in Medicaid receive that coverage through a private Medicaid-managed care company. Roughly 55 million Americans are enrolled in a Medicaid managed care plan and about 70 million are covered by Medicaid in total. There are around 15 million citizens that are in that government-administered portion of the program.

In terms of Medicare, since the ACA became law, we have seen significant growth in terms of people choosing private plans to get their Medicare benefits, which are called Medicare Advantage plans. There are roughly 60 million Medicare beneficiaries and today, 22-23 million seniors get their coverage through a Medicare Advantage plan. Most of them offer prescription drug coverage along with access to physicians and hospitals etc. The other 40 million individuals are covered by a standalone prescription drug plan in Medicare (also administered by private plans).

Medicare is a public-private partnership. The government tells the health insurance companies the kinds of benefits that they need to offer and sets the rules and regulations; the private companies administer the services.

Our aim is to ensure that all Americans have access to health coverage. Post-ACA, health insurance companies can no longer look at an individual's health status or consider their pre-existing medical conditions before offering comprehensive coverage – it must be on the same terms as that which is offered to everyone else.

Many of AHIP's member companies are scaling up in order to gain efficiency and reduce operational costs. This has led to a wave of industry consolidation. Is this good news for American consumers?

In the long run, yes, it will be a good thing because the incentives will be aligned. When thinking about an individual patient, their physical health needs will not be thought of as separate from their prescription drug needs or their mental health needs. Insurers will be able to look more holistically at the person and understand how they can provide more effective benefits and coverage.

This has also led to greater recognition of addressing the social determinants of health – things like access to transportation, access to nutritious food, and social isolation – and how can we provide additional services. For example, individuals with depression or social isolation often have higher health expenditures because of other conditions that they have. If someone gets out of surgery and does not have access to nutritious food, their recovery might take much longer or they might have to go back into the hospital because they are not healing in an appropriate way.

These larger structures will be able to cover the entire patient journey more completely. Health insurance companies are recognizing that these areas represent good investments as they will lead to healthier populations and lower health expenses overall. A great example is the Medicare Advantage program, where the private plans are able to offer "supplemental benefits" that are not available in the government-run program such as giving someone with asthma an air conditioner to avoid winding up in the emergency room. In August, ride-sharing firm Uber announced that it would be partnering with health insurance plans to provide transportation to physicians' offices and pharmacies for patients.

The US spends around 18 percent of its GDP on healthcare, compared to an EU average of 9.6 percent. How do you explain this discrepancy and how can US healthcare get more value for its spending?

In a direct comparison, the difference between US and EU healthcare spending might not be as far apart as first appears, given European investments in social aspects of healthcare.

However, the US spends much more on healthcare because prices for pharmaceuticals are much higher here, as are the prices for physician and hospital services.

As a result, we are now looking at novel outcome-based arrangements, especially when the price for very innovative treatments, such as CAR-T therapies, can be in the hundreds of thousands to millions of dollars.

In 2019, several drug companies have testified to the Senate Finance Committee on medicine price hikes. Their narrative has revolved around the discounts they give to health insurance companies and pharmacists, which are then not passed onto consumers. How do you counter this claim?

The pharmaceutical industry actually created prescription drug rebates. They wanted to be able to provide lower price products to hospitals and to health insurance companies but not to provide those same low prices to pharmacies, wholesalers and others. Essentially, pharma companies wanted to really direct the rebates only to entities that were able to ensure that they were getting additional market share.

For a greater share of the market the drug companies were willing to provide a rebate or a discount in order to get preferred placement on a hospital or health insurance plan formulary. They would be willing to give a 20-30 percent rebate for a preferred position and the knowledge that a competitor product would be excluded or in a less advantageous position. In that way they would get higher market share.

There are several legal cases around price discrimination and how manufacturers are able to provide these discounts to certain entities. Over time, as pharmacy benefit managers became much more prevalent and covered many more lives, they realised that they could get lower prices by using other market mechanisms to drive down prices.

When it really started to change was with Medicare Part D, also called the Medicare prescription drug benefit. The pharmacy benefit managers and healthcare insurance providers began to question the fairness of manufacturers increasing prices so rapidly, sometimes two or three times in a single year. They questioned whether such practices should be allowed, considering access and preferred positioning on the drug formularies was being offered.

It is important to remember that drug manufacturers were getting paid 100 percent of the list price, whatever the list price was. Some customers were paying 100 percent of the list price themselves and the manufacturers were getting reimbursed for that full amount. Others were getting very significant price discounts but as they increased the price, some people were paying

it.

That is why we are seeing the growth of rebates that represent a small percentage of the list price to those that represent a higher percentage of the list price. The manufacturers have consistently increased prices, year after year, multiple times a year.

What is the health insurance industry's stance on prescription drug rebates?

Health insurance providers negotiate with drug companies to lower out-of-pocket costs and premiums for millions of patients. But they are not wedded to prescription drugs rebates as long as we can use market-based tools to get to a lower price for patients. Through our board of directors, we stated that if there is an alternative such as manufacturers voluntarily lowering their list prices, we should discuss it.

It is also important to remember that most manufacturers are publicly-traded entities that want to develop new drugs and make a profit for their shareholders. Pharma companies do not compete directly with each other at an enterprise level, they compete at a therapeutic level: Novartis does not compete with Merck in every area of business but might compete in cardiovascular diseases or certain types of oncology.

There is currently not enough competition in the marketplace to drive down costs. Greater transparency in how list prices are set and increased competition are needed to ensure patients have access to the medications they need.

Is there real discussion ongoing between the health insurance providers and pharmaceutical manufacturers?

Yes. Our member companies are committed to ensuring patients have access to the medications they need, and are often engage directly with manufacturers on general contracting, value-based arrangements and other areas, or they use a pharmacy benefit manager to do so on their behalf to lower costs for consumers.

Real-world-evidence (RWE) and data collection tend to be more liberal in the US compared to other jurisdictions. How well-positioned is the healthcare insurance

industry in terms of using this health data?

It is important to recognize that the data collected by health insurance providers is governed by strict privacy standards under the Health Insurance Portability and Accountability Act (HIPAA). Insurance firms can use the data to understand the correlation between certain disease conditions and other business purposes but cannot use it on an individual level to determine a consumer's specific premiums, as is required by the Affordable Care Act.

What is interesting is how data is now being used to understand how one disease connects to another, who may be more likely to develop a particular medical condition, and over what period of time, so that a health insurance provider can develop a program or initiative to actually meet someone's needs before or at an early stage of their medical condition.

For example, it is now possible to identify people who may be pre-diabetic and ensure that they can be worked with to improve their health and wellness so that they do not progress to full-stage diabetes.

In Europe, value-based arrangements are with the government. However, in the US these arrangements are with the health insurance companies. How do these arrangements differ, given that governments want to pay the least amount possible?

Health insurance companies also want to make sure that the consumer gets the best health outcome at the lowest possible cost. The question is how that can be done through novel contracting relationships and paying for what works and what does not.

One of the challenges is labelling. Once a pharma company has gone through the clinical trial process and obtained FDA approval, there may be differences in how the product performs in the real worlds versus the highly controlled clinical trial environment.

For example, people may have different health conditions in the real world and there may be different attitudes to compliance and adherence to treatment regimens. There are all sorts of different elements that can impact a drug performance, and that is why it makes it a little more complicated to enter into some of these value-based arrangements.

One year out from the next presidential elections, what are some of the hot topics around healthcare in the US?

Affordability is driving much of the debate. How much the US spends on healthcare and how much individuals need to pay out of their own pocket are primarily driving the discussion. We would like to see everyone in the US get coverage that includes protections against pre-existing conditions, but we know we have a way yet to go.

Because of how healthcare is financed here, many people get coverage through their employer. Almost all large companies and many smaller businesses provide coverage, but many of these smaller businesses tend to struggle because of underlying cost of health care.

We urgently need to find ways to lower overall costs as well as the price tag of prescription drugs which comprise between 20 and 25 percent of healthcare spending in the US; a percentage that has been growing over time.

A recent article in the American Academy of *Neurology* featured interviews with former pharma pricing executives on how they set prices. Essentially, they revealed that the biggest factor in determining a new drug price was the price of a previously introduced drug in the same therapeutic area. For no obvious reason, this was the benchmark they used and then added additional margin on top of that. It had nothing to do with pharmacy benefit managers, rebates or health insurance providers and had everything to do with the highest price the market can bear.

When I started in pharma, most products cost about as much as a cup of Starbucks coffee – two or three dollars – per day. Some were much more expensive of course, but over time, we have seen this pricing practice over and over again.

Oncology is a great example of that. In the US, the average and median prices for oncology drugs are in excess of USD 15,000 per month. Many products provide great therapeutic value, but there seems to be no limit on the drug prices set by manufacturers and each new therapy is almost always priced higher than the last one approved.

The research strategies of the industry have changed dramatically over time from looking at broad patient populations to very narrow therapeutic areas with small patient populations. Drugs then become very expensive but we need to have a debate about where that ends.

In some ways, the industry has tried to take credit for every direct and indirect medical cost offset when they are the ones setting the price. They are claiming that money will be saved in the long run because money is not being spent on other things like extended care, hospitalization etc., so they have priced that into the product. There is no other sector or part of the healthcare system, including medical devices, that uses this practice.

Pharmaceutical companies often paint the insurance industry in a negative light – how would you respond?

The problem starts with the list price of the drug, which is set solely by the pharmaceutical company. Health insurance providers work hard to get the best outcome at the lowest possible cost for their population – whether they are serving an employer market, an individual market or a Medicare market. However, as costs continue to escalate, either through prescription drug prices or hospital prices, the insurance product becomes increasingly unaffordable,. That is why our incentives are so strong to lower prices. Neither employers, consumers nor patients want continuous price increases. It's also important to remember that health insurance providers must operate under government margin control regulations through minimum medical loss ratio rules and rate review and approval. Drug makers have no analogous standards.

Market dynamics do work, but there is certainly room for improvement and ways in which we can make insurance and pharma markets work better here in the US through the promotion of choice and competition. We want to see more competition in the pharmaceutical industry and promote biosimilars, getting lower-priced products to market more quickly. We support having better open access to information about pharmaceutical prices, how they are set, and if and when they are going to increase, moving to pay-for-value. Those are the major areas we are focused on in terms of pharma coverage and pricing-related issues.

Not only European Big Pharma, but also mid-cap firms are increasingly establishing a stronger presence in the US market. From an insurance perspective, what advice would you give them?

It is important to engage with health insurance companies early and provide transparent information on their therapeutic areas and what they believe their value is, based on data. It is not always easy and there are some areas where manufacturers need to be careful about how they talk about products pre-approval in the US. Nonetheless, this kind of information exchange is generally welcomed in order to understand what is in a company's therapeutic pipeline. Insurers want to know about what products are going to hit the market, how much they are going to cost and what value they are going to provide.

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