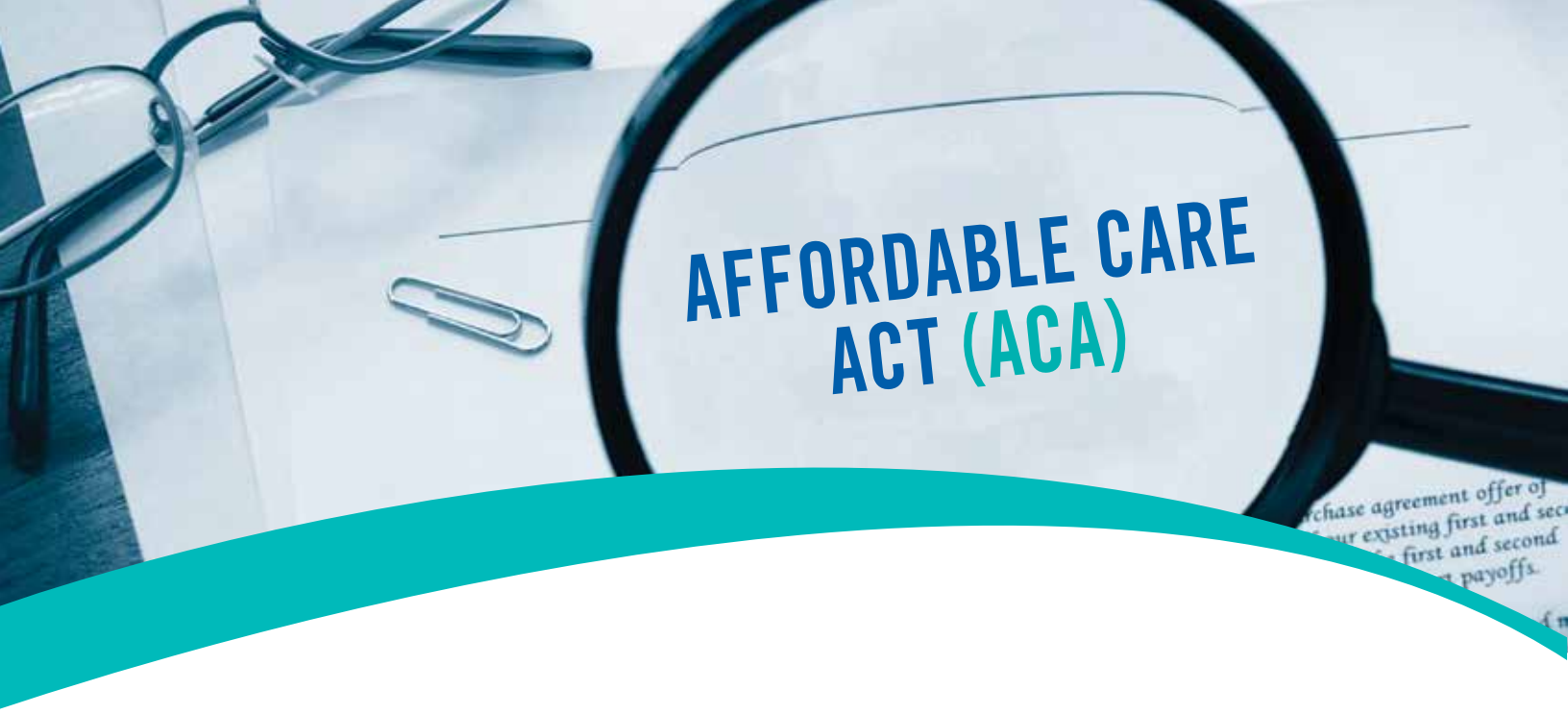


# Patient Access within a Changing Landscape

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Access to plasma protein therapies for patients in the U.S. has been relatively certain and predictable throughout the past decade. Efforts by PPTA, member companies, and stakeholders have resulted in continued reimbursement by both federal and state governments for a wide range of economic situations and private insurers have also provided coverage. The life-saving nature and non-interchangeability of these biologic products has set them apart from many of the more controversial drug therapies that have raised concerns within the health care system, often because of triple digit price increases.

However, the environment that we find ourselves in now is different and challenging. The U.S. is passing from a two-term administration that embraced federal government entitlement to provide health care to as many patients as possible to a yet-to-be-defined market-driven system. Leaders in Congress and the White House have promised to abandon the Affordable Care Act (ACA) and replace it with their own plan, but cannot agree on what that plan should contain. Most Americans like some of the ACA, such as prohibiting exclusion because of pre-existing conditions, extending coverage to children until age 26 on their parent's plans, and eliminating lifetime caps on costs.

However, the exchanges brought costs individuals could not afford, such as the rising deductibles costs and huge monthly premium increases. Very few who bought health care insurance through the state exchanges understood that there could be no caps or protections against rising costs, although they were mandated by law to purchase it.

The largest health care providers, like United Healthcare and Aetna, ended participation in the ACA due to unsustainable losses. This often left patients with no choice in the exchanges or no bargaining power along with forced changes in doctors and hospitals. Access to therapy then became a challenge. Changes in government programs also added to the uncertainty. Recently proposed rules in Medicare—which intended to cut payments for drugs, penalize physicians that prescribe biologics, and restrict access to just a few products—were scrapped soon after the November election when it could not be approved before the new administration takes office.

State Medicaid programs will change under the Trump Administration, but just how they will change is the question. The ACA created a new eligibility group of adults without dependents. More than 14.6 million Americans were able to enroll in Medicaid as members of this "New Adults Group" when 31 states and the District of Columbia expanded Medicaid eligibility. If the ACA is repealed, will they lose their coverage? Will the Republican governors who supported expansion in their states, including Vice-President Mike Pence, allow these individuals to lose their Medicaid eligibility?

Indiana's Medicaid expansion program could serve as an example of changes to come to the entire program. Seema Verma was vital in creating the program and she has been nominated by President Trump to lead the Centers for Medicare and Medicaid Services. The Indiana plan requires the enrollees in Indiana's Medicaid expansion program to pay premiums and co-pays for services. She has set up the program to make it more like commercial insurance.

One commercial insurance strategy that should be watched for is a restricted formulary. A restricted formulary provides insurance beneficiaries with access to only a few therapies in a therapeutic class. Currently this is not allowed in Medicaid and as a result plasma protein deficient individuals have access to all plasma protein therapies in Medicaid. This is because of a federal rule that allows patients access to all pharmaceuticals if the manufacturers pay a federal rebate. This access could change if the Trump administration seeks to repeal this provision of federal law and attempts to negotiate lower pharmacy costs through a restricted formulary where Medicaid recipients have access to only one or two therapies in a therapeutic class. In fact, the federal government could do this for all their health benefit programs including Medicare, Medicaid, and the Children's Health Insurance Program. An administration that promises to provide better health care at less cost through a competitive market system will be a challenge. The health care system in the U.S. has experienced a slowing of growth since a 2002 high of more than eight percent to a more moderate five percent per annum rate in 2015. But even then almost 10 percent of Americans reported that they delayed or did not get care because of cost and this is in a system where over 94 percent of patients are covered by some form of health care insurance or government subsidy.

For a majority of patients, access continues to be tied to the availability of reimbursement, whether through employer sponsored plans, Medicare, or Medicaid. The possibility that the new Congress and Administration will scrap the entire exchange-based system in favor of market driven approaches like health savings accounts, accountable care organizations, and even state block grants can only add to interruptions in access. Vigilance in pursuing reimbursement policies that provide access for patients through chosen providers will require a constant effort with decision-makers during these uncertain times. •


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