After a tumultuous few years of healthcare policymaking, the recent election brought a big victory for Obamacare. It's now all systems go for the law, with sweeping change for the American healthcare system and tens of millions more insured. Expect this status quo to be anything but boring. **Matthew Arnold** reports

FOR

It's survived a tortuous yearlong journey through Washington's legislative sausage mill, a nationwide storm of colorful protests, "Death Panels," a high-wire Supreme Court case and a close presidential election. Whatever uncertainty still attended the Patient Protection and Affordable Care Act (ACA) before Fox News called Ohio for the president on the night of November 6, it's over. As House Majority Leader John Boehner conceded, "Obamacare is the law of the land."

Which is not to say that it's settled, of course. Much of the law, or those parts concerning coverage of most currently-uninsured Americans, anyway, takes effect in 2014 and must now be implemented over the coming year. Many of the details of how the law will operate have yet to be spelled out, or worked out through trial and error, and bits and pieces will be re-legislated as the healthcare industry lobbies go to work on it.

But ACA implementation isn't the most immediate cause for anxiety among healthcare policy types. That honor goes to the "sequester," a high-stakes game of budgetary chicken set to play out over the next month or so. Last year's standoff between the White House and Congressional Republicans over the "debt ceiling" was resolved, in classic Washington fashion, by kicking the can down the road a bit, but with a twist—if the two sides couldn't agree on painful cost savings by January 2, a legislative "trigger" would be tripped prompting brutally deep cuts (of $1.2 trillion over nine years) to defense and

social spending. Medicare is largely exempt from the cuts—limited to 2% of its budget—and Medicaid and CHIP are off-limits. FDA, however, would face deep cuts—projected at $318 million—that would slow approvals and rules-making, according to the Office of Management and Budget, and effectively freeze PDUFA.

"Sequestration would be a complete disaster for all involved," says Peter Pitts, former FDA associate commissioner. "The FDA simply doesn't have any slack in its budget and would not have the bodies to do things on time. This is not the status quo but a significant step backwards."

NIH would lose $2.5 billion and the CDC $490 million, according to White House estimates. That's if Congress and the President, by virtue of inaction, pull the trigger—a scenario that could push the country back into recession, and which many Washingtonians think is exceedingly unlikely. The President said in the second debate in October that the sequester "will not happen." However, going by the past couple years'-worth of gridlock, we wouldn't be too sure of that, and the two sides have mere weeks to come to a consensus.

And then there's Obamacare, where, with deadlines fast approaching, states that have taken a wait-and-see approach to the uncertainty around the law must now make some big decisions in a hurry. For starters, there's the ACA's Medicaid expansion, which accounts for fully half of the projected rise in the number of insured people under the law (or 16 of 31 million projected to gain coverage by 2016). The Supreme Court ruled that the federal government can't make it mandatory, and seven Southern governors, including those of Texas, Florida and South Carolina, have said they won't opt in, fearing that federal subsidies for the expansion, though generous at first, will decline over time, leaving the states to pay more to cover more of their poor. At press time, with the opt-in deadline nearly upon us, more than two dozen other states have not said whether or not they will participate. However, with the election over, so is much of the political incentive to block it, and hospitals, a powerful lobby in many states that would stand to gain greatly from Medicaid expansion, are pushing hard for it.

Similarly, many states have hemmed and hawed over whether or not to set up their own health insurance exchanges. Eleven have said they won't, and another 20 are, at this writing, wavering.

On the whole, Obamacare looks to be a pretty good deal for pharmas, particularly if those big Medicaid expansion holdouts in Dixie fall in line. More patients with health insurance means more patients on medicines, and even if much of that will be generics, prescription drug companies stand to gain back in higher sales volumes more than what they've given away in discounts to government programs as part of the legislation.

That's not to say that the industry likes everything about the law. The Independent Payment Advisory Board (IPAB) is a particular sore point, stoking fears that European-style price controls could take root here. Nobody's sure exactly how this broadly-drawn entity will operate, but the 15-member board—for which members must be nominated by the President, in consultation with both parties' Congressional leaders, and approved by the Senate—will have the power to impose spending cuts on Medicare when the program's spending outpaces projected growth and when Congress fails to pass cuts to offset those increases. Initial cuts will fall on doctors and pharmas, with hospitals and hospices coming in for cuts later on. Critics fear it will evolve into a federal formulary-setting body like the UK's NICE, restricting access to drugs deemed more costly than they're worth (Sarah Palin called it "Death Panel-like").

"IPAB is a black box," says J. D. Kleinke, a fellow at the conservative think tank American Enterprise Institute. "It could be completely benign, but it could put in place some draconian payment recommendations and barricade people's access to rescue care, to heroic care, to end-stage care, to a lot of the big, expensive therapies that don't add great longevity to people's lives or that are highly controversial."

The legislation contains language specifically prohibiting the board from rationing care or limiting benefits, but opponents fear an end run around those restrictions. Republicans are fiercely opposed, and enough Democrats agree to make repeal a real possibility, say some

PHOTO: © FLICKR. THE WHITE HOUSE'S PHOTOSTREAM. UNITED STATES GOVERNMENT WORK

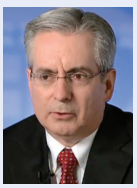
PAY IT WARD

FDA, HHS leadership looks stable

Expect stability at HHS and the FDA, says the Coalition for Healthcare Communication's John Kamp. Kathleen Sebelius at HHS and Peggy Hamburg at FDA are expected to stay most of 2013 at least. Rachel (Behrman) Sherman, who supervises OPDP, will likely stay put. In the Senate, Commerce Committee chair Jay Rockefeller (D-WV) will still push for online privacy legislation, while reelected Sens. McCaskill (D-MO) and Gillibrand (D-NY) often see the industry's side of things.
Some highlights:

STICKING AROUND

Janet Woodcock, director, FDA Center for Drug Evaluation and Research (CDER)



John Jenkins, director, CDER Office of New Drugs

SHIFTING STAFF

Jeanne Ireland, FDA's former top legislative official; now senior advisor, FDA commissioner's office

David Dorsey, former FDA acting associate commissioner; now policy and intelligence chief, Janssen R&D

SIX MORE YEARS

Sen. Jay Rockefeller (D-WV) Commerce Committee chair and online data privacy hawk

Sen. Kirsten Gillibrand (D-NY) Newly reelected and receptive to New York's advertising and pharma industries

Congress-watchers. The board is scheduled to issue its first report in January 2014, so nominations should be forthcoming soon.

Then there's PCORI, the other acronym that pharmas fret over. The Patient-Centered Outcomes Research Institute is the ACA's comparative-effectiveness research arm. As with IPAB, PCORI's charter prohibits it from using "dollars per quality-adjusted life years" as a metric, and early indications are that it will operate at a much more macro level. But the question remains: Will we measure clinical effectiveness or cost-effectiveness? And how will CMS reset the perverse incentives that reward quantity—of diagnostic tests and procedures and products—over quality? NICE offers one model, in which government says, "Prescribe this, not this." Another might be a risk-sharing scheme (aka "Expanded Access"), in which pharmas and federal programs establish a measure of success for a therapy and companies reimburse the government when their products fail to meet that standard.

"The good news is that every time you put in place a board that wants to mobilize evidence about drugs, you almost always find that they do work and that they're underutilized," says Kleinke. "This is one of the paradoxes of managed care."

There's parts of the law that the White House wouldn't mind relitigating, too—biologics exclusivity, for example, which the Administration dearly wanted limited to seven years, but had to settle for 12 after getting rolled by the biopharma lobby. Or the Medicare Part D prescription drug benefit non-interference clause. Vice President Joe Biden, in his debate with Rep. Paul Ryan, suggested he wouldn't mind another bite at the provision, which explicitly prohibits the government from butting into negotiations between companies and private plans that administer the benefit.

"If they allow Medicare to bargain for the cost of drugs like Medicaid can, that would save $156 billion right off the bat," said Biden, whose party's left flank has tried and failed repeatedly to dislodge the clause. With both of these items, given solid Republican control of the House, it seems unlikely that they might succeed now, but with the fiscal reckoning fast approaching, everything is on the table.

Pharmas are still waiting with bated breath to see what the particulars of the Physician Payment Sunshine Act sections of the ACA will look like. CMS blew past its initial October 2011 deadline to issue guidelines on data collection, having bigger fish to fry.

CMS then pushed back the start date for mandatory data collection to January 2013. A final rule is expected by the end of the year, but nothing says CMS couldn't hit snooze again.

"There's so many things that CMS has to deal with," says Kavita Patel, MD, who heads the Brookings Institute's Engelberg Center for Healthcare Reform and previously served in the Obama Administration. "That's not one of their front-burner issues."

The big question on the Sunshine provisions is preemption—will the ACA trump state laws, and if so, will it favor the more lax or the more draconian among them? Also, will the law require health insurers (including government) to report payments to physicians for things like academic detailing and switching patients to generics?

Beyond the ACA and the "fiscal cliff," keep an eye on Congressional efforts to curb the use of data collected online for marketing purposes. Senate Commerce Committee chairman Jay Rockefeller (D-WV) has been an avid proponent of explicit limits and opt-out rules, and his "Do Not Track" bill would restrict digital data collection—meaning, for example, that drug marketers might no longer be able to target online advertising for, say, an asthma treatment to people who frequent sites for asthma sufferers.

"You can bet that if we get down to segregating out types of data, health data will be on top of the list," says John Kamp, executive director of the Coalition for Healthcare Communication.

On the regulatory front, Obama's win means greater stability in the leadership of HHS and FDA (see sidebar), which probably means more refinement of the rules around marketing, as well as a continued opening of the drug- approvals window. Pharmas should see sales volumes pick up as the insurance provisions of the ACA take effect, though they'll have to cope with tighter restrictions, tougher formularies and larger co-pays.

"Add that all up and you get lower prices and much higher volume," says AEI's Kleinke.

"The essence of Obamacare is that we're repatriating people who have no coverage, who live under the shadow of chronic disease, who get hopelessly sick and end up in the ER. They're being brought into the system and given access to primary care. They're going to get diagnosed and prescribed and they're going to start taking meds. That's the good news for the drug industry." ■