

Look for Drug Pricing, Other Government Changes—But Be Prepared to Wait

MARCH 4, 2021

By Karen Blum

Political divisiveness on Capitol Hill, a focus on impeachment activity and financial relief for the COVID-19 pandemic, as well as delays in confirming President Joe Biden's nominees for cabinet and subcabinet positions, so far have caused a slowdown in the new administration's ability to make sweeping changes affecting health care, a policy expert said during the opening day of Informa's HUB and SPP Model Optimization 2021 virtual event.

As cabinet positions are filled, more aspects of the Biden plan for public health and the health care environment will take clearer shape. Until then, legislative action from Congress is likely to be limited and focused on very particular areas, said James Kim, JD, MPH, the lead partner of the law firm McDermott, Will and Emery, in Washington, D.C.

There are a few issues to watch this year, Kim said. They include:

International Reference Pricing/Most Favored Nation Drugs. Court injunctions put the previous administration's "Most Favored Nation" (MFN) interim final rule aimed at lowering prescription drug prices in limbo, but experts said this probably isn't the last we'll see of international drug reference pricing. The rule, which was set to take effect Jan. 1, proposed to restrict costs for the top 50 physician-administered Medicare Part B drugs—which account for almost 80% of Part B spending—to no more than the lowest price that drug manufacturers receive in other similar countries, as reported in [Specialty Pharmacy Continuum](#).

However, there are indications that the Biden administration is interested in looking to foreign pricing of certain products in the pharmaceutical sector as a way to negotiate lower prices for U.S. beneficiaries, Kim said. But the use of such a pricing model has significant legal and policy considerations, he stressed, and drugs elsewhere are regulated under different environments. Adoption of MFN-like pricing in the United States also may have unintended consequences for the overall global community—something that has to be examined carefully, Kim said.

340B Drug Pricing. Significant debates abound in the legal community regarding 340B drug pricing. One contentious issue is the use of third-party contract pharmacies by institutions that qualify for 340B drug pricing but do not have in-house pharmacies. The use of contract pharmacies can yield significant cost savings for these hospitals, but the practice has drawn the ire of drug manufacturers, many of which have sought to block these arrangements over the past year. The conflict has resulted in an administrative ruling by the U.S. Department of Health and Human Services (HHS) to uphold the rights of contract pharmacies to access 340B prices.

The HHS summarized its ruling in a [Dec. 30, 2020, statement](#): "HHS has become aware of drug manufacturers refusing to provide 340B discounts to covered entities when covered entities order the drugs themselves but then have the drug physically delivered to patients through contract pharmacies." Based on its advisory opinion, "HHS has clarified that drug manufacturers must provide 340B discounts when a contract pharmacy is acting as an agent of a covered entity, providing services on behalf of the covered entity."

“There does need to be a resolution of this issue,” Kim said, because it is now affecting beneficiaries. Xavier Becerra, attorney general of California and one of the lawyers leading the charge against manufacturers’ refusal to allow contract pharmacy access to 340B drugs, is President Biden’s pick to head HHS. If he takes over leadership, there is likely to be a resolution of this issue sooner than later, Kim said. But he stressed that it will require an enormous amount of effort and discussion among providers, distributors and pharmacies.

Medicare Drug Price Negotiation. A big part of President Biden’s plan to control drug prices and access to drugs is to authorize Medicare to negotiate the prices of its reimbursed drugs. The factors that will go into the negotiations are extraordinarily complex, Kim said. “It will not be an easy question to answer, but I think this is a very serious lever on control of drug prices and access that the Biden administration intends to utilize as much as possible.”

Meanwhile, division among political parties “limits the ability for real substantive changes to occur,” Kim said. “I am hopeful over the course of the year that some issues that have bipartisan support, such as drug pricing issues, can have some sort of effective change. The key question is how we are going to come to a single model that all parties can at least agree to disagree on. No one’s going to be happy with the result from all perspectives, but there is common ground to be met on these issues.”

Kim reported no relevant financial disclosures.