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Can Congress Coalesce Around The 21st Century Cures Bill?

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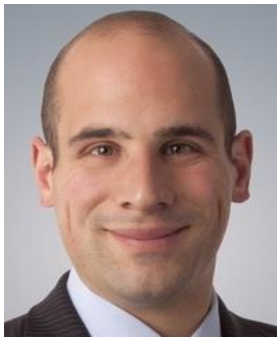

Nick Manetto

Following nearly a year of foundational work that featured scores of hearings and other events throughout the nation that captured the interests of a wide array of stakeholders, the U.S. House Energy and Commerce Committee last week released the much-anticipated first draft of its 21st Century Cures package.

Coming in at nearly 400 pages, the draft bill — a top legislative priority of Committee Chairman Fred Upton, R-Mich., as he completes his term at the helm of the panel — includes more than 100 provisions across five titles and focuses on reforms intended to accelerate the pace of developing medical breakthroughs and delivering them to patients. Many of the provisions are relatively noncontroversial and build upon pre-existing bills or ideas that bubbled up during the past year, though some are more surprising and have drawn flack.

Two days after the discussion draft was released, key counterparts in the U.S. Senate — Health, Education, Labor and Pensions Chairman Lamar Alexander, R-Tenn., and Sen. Richard Burr, R-N.C. — released a lengthy white paper that lays down a marker on their priorities in the space and focuses extensively on regulatory reforms for medical products.

While both of these developments signal forward movement, some concerns are on the horizon, notably the absence of Rep. Diana DeGette, D-Colo., who has been co-leading the 21st Century Cures package with Chairman Upton since last spring, and other caucus members identified with provisions in the discussion draft, as well as some highly critical comments from House Democrats.

Additionally, the Senate paper lacked a Democrat author even though support from Democrats will be necessary to move any package through the upper chamber. Sen. Alexander and top HELP Democrat Sen. Patty Murray, D-Wash., did release a statement on 21st Century Cures on Tuesday. Both focused on the U.S. Food and Drug Administration, but Alexander's emphasis was on modernizing the agency while Murray focused on patient safety.

Overall, the discussion draft was widely lauded by a diverse array of medical innovation stakeholders, including patient advocacy organizations, industry, research proponents and others. The 21st Century Cures initiative has been a rare bipartisan bright spot on Capitol Hill so far, and many leaders in the sector remain hopeful that all of this work will not make it the latest victim of partisan gridlock.

The Two "Rs" of More Cures

In teeing up the 21st Century Cures initiative last spring, Chairman Upton and Rep. DeGette focused on a simple message: It takes too long to deliver therapies and treatments to many patients with significant needs. At a high level, Democrats and Republicans agreed on many underlying points aired during several hearings, roundtables and field events held during the summer and fall.

Many of the proposals put forward by members and stakeholders revolve around two “Rs” — reform and resources.

Reform is needed to address a research and regulatory system that is outdated and does not keep pace with advances in technology, making it more costly and time consuming to develop products and deliver them to patients. Further, resources are needed to upgrade technology, fill hundreds of review positions and revive a once vibrant national research engine that has been short on funds for about a decade.

Multiple lawmakers on both sides agree with these premises, yet Democrats tend to emphasize a need for more resources, particularly to support research at the National Institutes of Health, while Republicans tend to focus more heavily on the need for structural reforms to the regulatory process, particularly operations at the FDA. For the 21st Century Cures initiative to get back on the bipartisan track, any package will likely need to address concerns over both reform and resources.

Tuning Up the NIH

The House discussion draft does contain multiple NIH provisions, including some that would authorize additional funding, with specific amounts still to be determined, for priority research areas such as high-risk, high-reward projects supported by the NIH Common Fund and BRAIN Initiative. It also contains several reforms, including one to require NIH to develop a five-year strategic plan with focus priorities and another that sets renewable terms of four years for directors of the 27 individual NIH institutes and centers.

One big lingering question is what the final package will do, if anything, to authorize an infusion of new funding for the NIH. For years, agency officials and research stakeholders have lamented the negative impact of flat or reduced budgets after the NIH’s budget was doubled in the late 1990s and early 2000s. They typically cite statistics like declining paylines, grant funding levels and workforce growth.

Chairman Upton and other Republicans have publicly recognized the resource challenges confronting the agency, but the discussion draft did not include a NIH-wide funding proposal. For such a scheme to work, Chairman Upton and others would need to obtain buy-in from congressional appropriators who would most likely be charged with delivering the money through annual spending bills.

Drug Development and FDA Reforms

The draft bill is heavy with FDA reforms. These include provisions that build upon recent efforts to strengthen the influence of patient voices and perspectives on medical product review decisions. Of particular importance to patient stakeholders, particularly those suffering from diseases that lack treatment today, are the patient-focused drug development proposals in the draft bill. These seek to provide greater agency clarity on how it would use tools such as benefit/risk data and guidance documents.

A lack of clarity from the FDA is often cited by industry and patient groups as being an impediment to drug development efforts, and the draft contains several provisions directing the agency to develop these guidance documents in a number of areas.

The bill includes a policy proposal that would develop a pathway and process by which the FDA would review and, ultimately, qualify biomarkers for use in clinical trials. Another concept seeks to promote greater use of centralized or similar types of institutional review boards with the intent being to streamline and shorten the clinical research process.

The discussion draft provisions would provide additional incentives for companies to develop therapies in challenging areas, such as rare diseases and conditions that require lengthy clinical trials. These concepts in particular have drawn the ire of some key Democrats and stakeholders such as the generic pharmaceutical industry, which has long opposed these approaches.

The draft bill also includes a requirement for drug companies to develop and make publicly available their plans for providing access to experimental therapies to patients in need but who are not eligible to participate in clinical trials. Known as expanded access or compassionate use, the issue has been in the news during the past year following some high-profile access battles and a growing state-based push to enact so-called right-to-try laws. These state laws present a potentially more aggressive means of opening access to experimental drugs outside of a clinical trial and doing so much earlier in the development process. At present, five states have enacted right-to-try laws and bills are pending in 22 state legislatures.

Coverage and Access

The draft does contain a number of targeted provisions focused on coverage, though it does not touch the thorny and complex topic of affordable access to high-cost medications, a topic elevated in the national view over the past year by breakthrough, but high-cost, Hepatitis C treatments. Coverage provisions include changes and greater levels of clarity on various coverage processes at the Centers for Medicare and Medicaid Services.

Two of the more sweeping provisions would bring reimbursement parity to certain telehealth services and create care coordination networks to deliver care to children with complex medical conditions.

What to Watch

One key barometer will be the response by Democrats and stakeholders to the white paper from Sens. Burr and Alexander as well as the continued reaction and recommendations to the draft house bill. House passage of the 21st Century Cures package is possible without a single Democrat as long as the Republican caucus stays largely united. But Senate procedures will require at least some level of Democratic support to reach the 60 votes needed to break any filibuster.

Chairman Upton and the Energy and Commerce Committee have stated multiple times that they view the discussion draft as an initial step that will change significantly over the weeks and months ahead. At the same time, they have also laid out an aggressive path that would have the full House of Representatives pass the bill by the Memorial Day holiday, which is less than four months away.

Ultimately, the release of a discussion draft is an early action in the legislative process and much more

remains ahead. Evolving from concepts and themes to specific legislative language often raises questions and criticisms, and plenty of time remains in the Congress to place the 21st Century Cures package on a solid track.

At the same time, a number of factors, including continued fiscal challenges, high levels of partisan rancor and the reality that most attention and energy will shift to the 2016 elections, makes the next few weeks and months a particularly critical window to determine if the 21st Century Cures initiative moves from the idea laboratory into law.

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