Health Industry Alert

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Cures 2.0, A Deeper Dive on ARPA-H and MCIT as Congress Considers Accelerating Innovation from Bench to Bedside

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Background on Cures 2.0

The COVID-19 pandemic response demonstrated the tremendous impact innovation can have on a global scale. The unprecedented experiences of the past year and a half have spurred renewed interest in accelerating the development of promising drugs and devices so that patients can benefit from medical advances as soon as possible. This is not the first time the Congress has considered how to more quickly and efficiently bring forward promising safe and effective treatments and cures to patients and ensure broader access to these technologies.

On December 13, 2016, President Obama signed the 21stCentury Cures Act into law. The Cures Act (P.L. 114-255) passed Congress with overwhelming bipartisan support and represented the culmination of a dedicated, multi-year bipartisan and bicameral effort to accelerate the development of promising innovations on behalf of patients. This was no small undertaking. The provisions of the Cures Act spanned discovery, development and delivery—in other words it reflected the considerations of what it takes to advance innovations from bench to bedside.

The five-year anniversary of the enactment of the Cures Act is fast approaching, coinciding with preparations by Congress to consider the drug and device user fee reauthorizations, and the buzz is picking up around what policies and reforms a "Cures 2.0" package might include. There is also speculation about whether such a package could pass as a stand-alone effort, as the Cures Act did five years ago, or in pieces considered as part of other legislative vehicles.

On June 22, 2021, Reps. Diana DeGette (D-CO) and Fred Upton (R-MI) unveiled a much-awaited discussion draft of their Cures 2.0 legislation, which seeks to build on the Cures Act. The sponsors have invited feedback from stakeholders on the discussion draft legislation and a request for information through July 16th.

As Congress recognized with passage of the Cures Act, there are many considerations for innovators as they seek to navigate the path from concept to commercialization. There is value in assessing the impact the Cures Act has had on

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accelerating innovations on behalf of patients and asking what more can be done as Congress continues to contemplate how to harness the power of innovation to save and improve lives. It is likely that Congress and the Administration will continue to consider how to answer this question in concepts that span areas related to medical product development and coverage, and provisions included in Cures 2.0 may also offer an early preview of legislative proposals that may be included in the user fee reauthorization legislative package next year. Taking a closer look at the Advanced Research Projects Agency for Health (ARPA-H) concept and Medicare Coverage of Innovative Technologies (MCIT) provisions provides some initial insight into how these two issues may be considered in the coming months.

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Accelerating Innovation in Development: A closer look at the ARPA-H concept

The President's Fiscal Year (FY) 2022 Budget Request proposed creating an ARPA-H, a concept inspired by the Defense Advanced Research Projects Agency (DARPA), with a sizeable investment of $6.5 billion to initially focus on cancer and other conditions such as Alzheimer's disease and diabetes.

The Cures 2.0 discussion draft legislation contains a placeholder for the ARPA-H concept, opting to only include a potential stated mission to fund projects to speed transformational innovation in research and the application and adoption of health breakthroughs. The draft language suggests that such projects could create new capabilities, support high-risk exploration that could establish entirely new paradigms, or overcome market failures, including through financial incentives. In conjunction with the release of the discussion draft, Reps. DeGette and Upton have asked for input on specific questions related to the ARPA-H concept, including fundamental questions such as:

- What aspects of DARPA should be replicated in this concept?
- How ARPA-H should relate to, and coordinate with, other federal health care entities?
- How ARPA-H should work with the private sector?
- What are appropriate funding levels?

It is also noteworthy that the discussion draft does not enumerate specific diseases or conditions, instead asking for input on what areas ARPA-H should focus on as well as avoid.

This would not be the first time that DARPA has served as a model for how to accelerate development of medical products. In December 2006, Congress created the Biomedical Advanced Research and Development Authority (BARDA) within the Department of Health and Human Services (HHS) to accelerate the advanced research and development of medical countermeasures as part of the Pandemic and All-Hazards Preparedness Act (P.L. 109-417). Congress looked to DARPA as a model to inform what tools BARDA needed to help medical countermeasures bridge the "valley of death" in product development as part of our nation's preparedness and response framework.

Given BARDA's history as a DARPA-inspired model, there is an opportunity to consider what has been learned through BARDA's experiences in advancing innovation since its creation in 2006. There is also an opportunity to consider the lessons learned from the COVID-19 experience as it relates to the challenges and opportunities to advancing groundbreaking innovations, which has applicability beyond medical and public health preparedness and response considerations. As Chair Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) lead the Senate Health, Education, Labor, and Pensions Committee's bipartisan process looking at how to better prepare the nation for future public health emergencies, it is concurrently worth considering how an ARPA-H might be considered in the context of modernizing the development of medical countermeasures to address public health threats.

It will also be worth watching how the House and Senate appropriations processes continue to play out to see whether appropriators provide funding for ARPA-H in a Labor-HHS-Education and Related Agencies Appropriations bill and any further direction in report language, including what areas ARPA-H would prioritize.

It is not surprising that the ARPA-H concept continues to gain traction and bipartisan congressional interest given the support patient-focused initiatives tend to garner; however, the legislative construct is still a work in progress and how those details take shape could have far-reaching implications.

Accelerating Access to Innovation: A closer look at the Medicare Coverage of Innovative Technologies

The Cures 2.0 discussion draft also includes provisions designed to streamline the pathway to nationwide Medicare coverage for innovative technologies and therapies. Notably, the discussion draft would codify and expand the MCIT Rule finalized by the Centers for Medicare and Medicaid Services (CMS) on January 12, 2021. The Biden-Harris administration has twice delayed implementation of the MCIT Rule, citing the need "to ensure that the objections to the rule are adequately considered." As of the date of this alert, the MCIT Rule is set to take effect December 15, 2021.

As with the MCIT pathway, the Cures 2.0 discussion draft would provide for four years of automatic Medicare coverage for designated "breakthrough devices" that receive Food and Drug Administration (FDA) market authorization. However, while the coverage pathway in the discussion draft mirrors the MCIT Rule that CMS finalized in January 2021, some notable differences exist:

- First, the discussion draft would not codify the definition of "reasonable and necessary," a key part of the final rule that is separate from the MCIT pathway, and would apply more broadly to any drug or device being considered for Medicare coverage.
- Second, the discussion draft would require the HHS Secretary to establish a process for more permanent coverage for "breakthrough devices" after the transitional four-year coverage period. Under the MCIT Rule, by contrast, presumptive coverage would end at the expiration of the four-year coverage period. However, manufacturers would remain able to pursue national or local coverage policy through the existing national and local coverage determination process, or default to having Medicare Administrative Contractors adjudicate coverage on a claim-by-claim basis.

- Third, unlike the MCIT Rule, which is silent on coding and payment matters, the Cures 2.0 draft would impose new requirements on CMS for the prompt assignment of billing codes and updates to applicable payment systems to accommodate the new breakthrough device.
- Fourth, under the MCIT Rule, CMS would retain the authority to terminate temporary coverage prior to the expiration of the four-year period, but only when the FDA has taken some adverse action (e.g., issuance of a warning letter or withdrawal of market clearance). Cures 2.0 does not appear to provide CMS with any clear authority to terminate transitional coverage prior to the end of the four-year period.

Both the MCIT Rule and the Cures 2.0 draft recognize that CMS will want a certain threshold of evidence to support a permanent, post-transition period national coverage policy. The Cures 2.0 draft explicitly requires the Secretary, within one year of the beginning of the transitional coverage period, to identify what additional data and evidence it will want to see from the manufacturer for purposes of establishing national coverage policy. Further, it would require the Secretary to develop a proposed permanent coverage policy within two years of the beginning of the transitional coverage period. While the MCIT Rule does not impose any such requirements on the agency, CMS stated that it expects manufacturers to have an incentive to "voluntarily pursue robust evidence development to secure durable coverage after MCIT coverage sunsets." The Rule also encourages manufacturers to engage with CMS after FDA authorization to present a plan for evidence development.

MCIT vs. Cures 2.0 Draft

MCIT Rule	Cures 2.0 Draft
Medicare will nationally cover breakthrough devices are for a period of four years from the date of FDA authorization; coverage could be suspended or terminated when FDA issues a warning letter, safety communication.	Medicare will nationally cover breakthrough devices are for a period of four years from the date the device is assigned a code and the applicable payment system is updated
MCIT coverage could end prior to four years at the discretion of the Secretary subsequent to an FDA medical device safety communication or warning letter. Additionally coverage would end if the FDA removes authorization of a device.	Does not provide for early termination of the transitional coverage period.
Manufacturers must opt into the MCIT pathway, and request a start date for coverage.	Coverage is automatic, beginning on the date of FDA authorization.

Does not address coding or payment.	Requires prompt assignment of codes and updates to applicable payment systems.
No requirement for CMS to adopt a permanent coverage policy after the four-year period; manufacturers may pursue such a coverage policy through the normal process.	Requires the Secretary to establish a process for permanent coverage for breakthrough devices after the four-year transition period.
Limited (by statute) to breakthrough devices falling within an existing Medicare benefit category.	Allows for transitional Medicare coverage for certain breakthrough devices that do not fit within a Medicare benefit category.
Codifies the “reasonable and necessary” standard, and indicates that CMS will consider whether the item or service is covered by a majority of commercial insurers.	Does not codify the reasonable and necessary standard, or address how commercial coverage should factor into Medicare coverage decisions.

The Cures 2.0 draft also authorizes a Government Accountability Office (GAO) study on recommendations to enhance Medicare coverage and reimbursement for innovative health technologies that increase access to health care, improve health care quality, decrease Medicare expenditures, or otherwise improve the Medicare program or health care for beneficiaries. Under the draft, HHS would be required to issue a report to Congress on the viability of establishing alternative coverage pathways for innovative technologies. The Cures 2.0 draft does not define “innovative health technologies.” These reports could inform future congressional action to establish new Medicare coverage and reimbursement pathways for innovative health technologies.

It remains to be seen if the Biden-Harris administration will revisit any other aspects of the MCIT regulation beyond delaying the effective date. In a May 18, 2021, notice delaying the effective date of the rule, CMS offered several clues as to possible next steps. For instance, some commenters expressed concerns about providing coverage without evidence of value or efficacy in the Medicare population, and cautioned that “reliance on breakthrough designation ceded decision-making authority on what is reasonable and necessary for Medicare patients to an FDA decision very early in the product lifecycle.” In its response to the evidentiary concerns, CMS appeared to agree with these commenters. CMS stated:

Regarding commenters’ concerns about automatic coverage without evidentiary support, we share commenters’ concerns that guaranteeing coverage for all breakthrough devices receiving market-authorization for any Medicare patient with possibly minimal or no evidence on the Medicare population and no requirement to develop evidence on the Medicare population could be problematic in ensuring these devices are demonstrating value and do not have additional risks for Medicare beneficiaries. For example, a breakthrough device may only be beneficial in a subset

of the Medicare population or when used only by specialized clinicians to ensure benefit.

Without additional clinical evidence on the device's clinical utility for the Medicare population, it is challenging to determine appropriate coverage of these newly market-authorized devices.

Relatedly, CMS seems to be second-guessing its decision to limit its authority to end MCIT coverage during the transitional coverage period. Under the MCIT Rule, CMS would only terminate coverage upon the FDA issuing a "communication, warning letter, or remove[ing] the device from the market." This would be the case even if CMS were to identify increased risk to Medicare beneficiaries: "if a CMS contractor...identifies a pattern or trend of significant patient harm or death related to an MCIT device, there is no procedure to quickly remove coverage for the device until and unless the FDA acts."[1]

While it remains unclear whether CMS will move forward with the MCIT Rule, CMS responses to comments suggest that the agency is taking commenters concerns seriously, and may consider modifications in the name of patient safety:

...the immediacy of coverage must be balanced with ensuring the Medicare program is covering appropriate devices for the Medicare population...We will further consider public comments seeking modifications to MCIT that might allow for expedited coverage while seeking to ensure devices are safe for Medicare patients even when those breakthrough devices do not have an evidence base that is generalizable to Medicare beneficiaries.

Finally, it is important to note that both the MCIT Rule and the Cures 2.0 discussion draft focus on Medicare coverage, and securing Medicare coverage does not guarantee any particular level of reimbursement. Providing for coverage of innovative technologies is necessary to foster innovation and ensure patient access, but it is not sufficient. The policies discussed above do not address the need for coverage to be matched with a viable reimbursement model.

Conclusion

While CMS continues to grapple with the details of MCIT, momentum will continue to build around Cures 2.0. The provisions in the Cures 2.0 draft make clear that coverage of innovative medical products continues to be an area of bipartisan congressional interest.

The path to realizing the full potential of medical innovations for patients is intertwined with development and coverage considerations that are set against the backdrop of an evolving legislative and regulatory landscape. As the latest policy developments underscore, there continues to be bipartisan congressional interest in advancing innovation for patients; however, the ideas for how best to achieve this important policy goal, as always, remains a work in progress.

[1] 86 Fed Reg. at 26,852.

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