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The Double-Down: Trump Administration Digs in its Heels

While much attention was being paid to the midterm elections over the last several weeks, the Trump Administration has been busy [doubling-down](#) on various health policy proposals. Many of these policies are either unpopular, legally suspect, or both. In normal times, weaknesses like these might lead an Administration to change course. But these are not normal times. In this edition of *Health Care in Motion*, we examine three developments that may have flown under the radar amid the midterm election hype.

Marketplaces: HHS spoon-feeds states proposals for Section 1332 waivers

We have [previously examined](#) the Trump Administration's new guidance on the rules governing waiver of the Affordable Care Act's requirements under Section 1332 of the Act. This guidance will allow states to more aggressively undermine access to and the quality of ACA Marketplaces as early as 2020. On the heels of its legally suspect October decree, CMS has now released a factsheet on "[waiver concepts](#)" to hurry states along. The factsheet outlines four potential concepts for states to consider, tackling financial assistance program structure and risk-stabilization strategies.

- **Financial Assistance Programs:** Financial Assistance under the ACA refers to the various methods that the federal government uses to use its spending power to defray the cost of health insurance for enrollees in health insurance plans. The new CMS factsheet offers three ideas for states relating to financial assistance programs: (1) adjusted plan options; (2) account-based subsidies; and (3) the establishment of new, state-administered premium assistance programs with altered subsidy design.

Adjusted plan options would permit states to divert ACA subsidies away from Qualified Health Plans and into non-Qualified Health Plans (i.e., plans that do not meet ACA cost and coverage standards). Similarly, under the CMS instruction on "account-based subsidies," states would be able to direct subsidies into a consumer-directed account used to pay insurance premiums or other health care expenses. Ultimately, under the guise of promoting "consumer choice," the account-based subsidies and adjusted plan options concepts facilitate the diversion of ACA subsidies away from Qualified Health Plans and into non-Qualified Health Plans. These concepts could encourage people to buy coverage that is not held to ACA standards and may not meet their needs, thereby threatening the stability of the ACA Marketplaces.

- **Risk Stabilization Strategies:** States have the option to set up reinsurance programs, by which insurers are reimbursed for coverage of certain high cost enrollees. The factsheet highlights the impact of reinsurance programs on market stability, and the range of models employed. Not much that is new or newsworthy here. To date, this is where we have seen the most activity with Section 1332 waivers. [Several states](#) used Section 1332 waiver authority and the *guidance in place prior to October 2018* to implement state-based reinsurance programs.

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It's not surprising that CMS is spoon-feeding states opportunities to take advantage of the revised waiver flexibility given the tight turnaround time for parties interested in rolling out an initiative in 2020. It would further undermine the credibility of the Administration if, after [HHS bypassed important checks on the powers of administrative agencies](#), states did not take advantage of the effort.

Medicaid: Work requirements court decision? What court decision?

We've also written [previously](#) about the successful [challenge](#) in a federal district court to Kentucky's Medicaid waiver that authorized work requirements. Since then, key developments have unfolded in the saga of struggle between the Administration and advocates opposed to work requirements.

Undeterred by legal pressure, on October 31, the Administration approved Wisconsin's waiver request to implement a work requirement, bringing the number of states with approved work requirements to five (Arkansas, Indiana, Kentucky, New Hampshire and Wisconsin). Meanwhile, Arkansas, the only state to have actually initiated implementation, has removed a total of [12,277 individuals](#) from their Medicaid program due to non-compliance with new work requirements. Rollout began in June. A [case](#) similar to the one filed in Kentucky remains pending in Arkansas.

This shocking loss of coverage was so quick and devastating that it prompted a response by members of the Medicaid and CHIP Payment and Access Commission ([MACPAC](#)), a non-partisan legislative branch agency that provides policy and data analysis and makes recommendations to Congress and other federal agencies. MACPAC sent a [letter](#) to the Administration urging them to hold off on any further approvals of work requirements pending more thorough consideration of implications, and suggested that Arkansas should slow down its implementation given the growing coverage losses.

Undeterred by the court decision in [Stewart v. Azar](#) that found work requirements in Kentucky to be inconsistent with the objective of Medicaid, the Administration seems similarly insensitive to MACPAC's plea. The judge in the Kentucky case focused on how the Administration failed to consider the impact of the waiver on coverage for Medicaid beneficiaries. This allowed a path forward for Kentucky: the Administration re-opened Kentucky's waiver application for [public comments](#), of which they received over 11,000 mostly unfavorable responses. On November 20, the Administration formally [re-approved](#) Kentucky's waiver, which is now set to take effect in April 2019. The waiver is nearly identical to the previous version, and the [approval letter](#) does little to assuage the court's concerns about the potential loss of coverage to 95,000 individuals. Instead, the Administration engages in some perfunctory hand-waving, suggesting that this number is both overblown and cannot be *entirely* attributable to the new work requirements.

As legal advocates, we find this move to be a head-scratcher. The Administration did little to address the core concerns that led a judge to overturn the initial waiver approval despite having ample opportunity to do so. Instead, the Administration largely re-stated the same arguments that failed in court. The Administration was quick to note that Kentucky provides *optional* coverage to the Affordable Care Act's Medicaid Expansion population. Given Governor Bevin's threat of ending this coverage if their waiver proposal fails, the Administration asserts that *this* loss of coverage has to be balanced against the potential loss of coverage to 95,000 as a result of the waiver, a theory the court already rejected. The Kentucky case is still open and the lawyers representing Kentucky Medicaid beneficiaries have indicated that their challenge will be renewed: ["We intend to pursue the next court challenge as vigorously as we have before when we won. We have no reason to believe that the results will be any different this time."](#)

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Medicare: Redefining the protections for ‘protected classes’ of drugs

CMS is also taking concerning steps to remove traditional protections for chronically ill Americans with another [proposed rule](#) focusing on Medicare and prescription drug costs. Of particular note, the rule takes aim at the prescription drug benefit (Part D) “protected classes” policy—the [requirement](#) that Part D plan formularies generally have to include all drugs in six classes/categories: (1) antiretrovirals (used to treat HIV); (2) antidepressants; (3) antipsychotics; (4) anticonvulsants (used to treat epilepsy); (5) immunosuppressants for treatment of transplant rejection; and (6) antineoplastics (used to treat cancer).

The protected classes policy is intended to ensure that beneficiaries have comprehensive, continuous, and timely access to drugs in these protected classes. One stated [rationale](#) is to “mitigate the risks and complications associated with an interruption of therapy” for vulnerable Medicare beneficiaries reliant upon these medications. Consider, for example, the serious [risks](#) associated with disruptions, discontinuations, and delays in access to treatment for HIV, which include resistance to a medication, co-morbidities, and hospitalizations.

In its [comments](#) regarding the proposed rule, CMS notes its concerns that the protected class policy weakens a plan’s position in negotiating drug prices and that the policy “potentially facilitates the overutilization of drugs.” While these are important objectives, efforts to introduce price controls should not target protections that are specifically designed to secure access to life-saving treatments for some of our most vulnerable Medicare beneficiaries.

Of particular concern, the proposed rule that would give health plans greater flexibility to introduce prior authorization (PA) and step therapy (ST) requirements. This is where a person must try a specified medication, typically a generic or lower cost one, and the medication must not be effective for them, before the person is able to “step up” to another, typically more expensive, medication. The table below shows current policy as to how PA and ST requirements are applied to the six protected classes, and what the proposed rule would introduce.

CURRENT POLICY	PROPOSED POLICY
PA or ST requirements cannot be used to steer a beneficiary who is already taking a medication to a “preferred alternative.”	Subject to review and approval by CMS, PA and ST requirements can be implemented to: <ul style="list-style-type: none">promote utilization of preferred formulary alternatives without distinguishing between new starts or existing therapiescollect information (e.g., lab tests) to confirm that use is intended for a protected class indication (facilitating a drug’s exclusion from the formulary for non-protected class indications)ensure clinically appropriate use
PA or ST requirements applied to persons newly starting a protected class drug are not applicable after any first filling of the prescription has been provided.	
CMS’ expectation is that utilization management tools will be used in a way that is consistent with best practice models. PA and ST are not generally applied to antiretrovirals in best practice formulary models.	

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CMS superficially addresses significant concerns about the harmful impacts of utilization management, such as PA and ST, with statements such as “we would not approve onerous prior authorization criteria that are not clinically supported” and assertions that Part D mechanisms already in place will minimize harm to beneficiaries affected by the protected classes policy. The agency does ask for feedback on whether additional safeguards should be introduced to minimize “(1) interruptions in existing therapy...and (2) increases in overall Medicare spending from increased utilization of services secondary to adverse events from interruptions in therapy.” However, as discussed above, the Trump Administration has fallen short in its consideration of and responsiveness to comments on the public record.

Plans would also be permitted to exclude newer formulations of a single-source drug/biological that does not provide a unique route of administration *even when the older version is taken off the market*. This is clearly a strike at “[evergreening](#),” a form of patent maneuvering where drug manufacturers extend a drug’s exclusivity through the release of new formulations. A recent study found that 74% of FDA drug patents awarded between 2005 and 2015 were awarded to existing medications as opposed to new ones. Plans would also be allowed to exclude drugs for which [price increases outpace inflation](#).

Efforts to control drug pricing are critical, but the proposed revisions to the protected classes policy dangerously treat people as leverage in a showdown between health plans and pharmaceutical companies. Medications are not always interchangeable, and treatment decisions should generally be in the hands of patients and their health care providers. Categorical exclusions from formularies leave people without access to the medications they need.

[Comments are due](#) January 25, 2019. This is an important opportunity for advocates to shape and inform sound policy-making on the complex issues of access to treatment and drug pricing. Advocate feedback—whether CMS listens or we make the Agency listen—matters.

While many people’s attentions have been fixed heavily on the midterm elections and their implications for health care going forward, we hope that today’s *Health Care in Motion* can serve as a reminder that the Administration can and will continue to advance its health care agenda regardless of congressional support. In the never-ending flurry that we call a 24-hour news cycle, advocates must keep their eyes open for developments that are unlikely to make the front page.

Remember: Open Enrollment on HealthCare.gov continues until December 15th!

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