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Timely, Substantive Updates on Policy Shifts · Actionable Advocacy to Protect Health Care

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Rx Rollback Part 2 + New Resource on Public Comments

Things are Heating Up

With Washington D.C. barreling toward a [political tempest](#) threatening to engulf the summer, you would be forgiven for assuming that the more routine business of Congress has ground to a halt. But health care policy [waits for no one](#). Policy proposals in the drug pricing reform world continue to march forward slowly, [despite the distractions](#). Our [last dispatch](#) noted that political realities make it likely that any policy reforms in the near future will not be dramatic steps to [burn down the house](#), but rather more incremental reforms able to pass muster under the banner of bipartisanship. The last few weeks have proven this prediction to be largely true, with no blockbuster proposals making headway. Still, with election season fast coming into view, the [heat is on](#) for any hard “wins” in the drug pricing reform push.

Administration Backs Down on Medicare Part D

At the top of the list of recent updates in health care access is a hopeful note for Health Care in Motion readers. As we wrote about [previously](#), the Administration had begun to take steps to remove traditional protections for chronically ill Americans in Medicare Part D, under the stated rationale of cutting the program’s prescription drug spending. Fired up advocates [spoke out](#) against this rule, in particular pushing back on proposals to expand the use of prior authorization and step therapy that could cause delays and expose patients to needless additional [risk](#).

The Administration released its [final rule](#) last week, abandoning the proposal in favor of codifying existing policy guidance for Medicare drug plans. Thus, the status quo remains. This represents a significant win for access to health care, not just because these barriers were defeated, but also because of the Administration’s acknowledgment that advocacy mattered. In the preamble to the [final rule](#), the Centers for Medicare and Medicaid Services responded directly to public comments that highlighted the negative impacts this change would have for people living with chronic health conditions. The agency explained that its decision was motivated by concerns brought up by commenters, stating that it was “persuaded by comments that expressed significant concern for the potential disruption of ongoing therapy of protected class Part D drugs. . .” and thus decided to reconsider and instead codify existing guidance.

A victory of this sort underscores the ongoing need for all of us to engage with the public comment process. We [previously](#) flagged this rule as an opportunity to submit comments and will continue to highlight important comment periods as they open. In the meantime, check out our [resource](#) explaining why public comments matter.

Building on recent real world examples of public comments influencing government rulemaking, our new [CHLPI factsheet](#) helps organizations and individuals mobilize and navigate the public commenting process.

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Final TV Ad Rule

Next up, we bring you news of a different sort. The Administration's baby-steps toward reform recently took the shape of release of a final rule requiring list prices be shown in television advertising for prescription drugs. In a rare move towards greater regulation, the Administration's [final rule](#) requires television ads for prescription drugs covered by Medicare and Medicaid to include the list price (i.e. the wholesale acquisition cost) if it exceeds \$35 for a month's supply. As written, the rule would allow pharmaceutical companies to include additional information as well, such as competitors' prices and information about what patients are most likely to pay via their insurance co-pays and co-insurance.

It remains to be seen if this rule, which could go into effect as soon as July, will light a [fire](#) underneath drug manufacturers. As [stated](#) by the Administration, the purpose of the rule is to encourage manufacturers to lower their prices as well as to enable consumers to make better choices. Alex Azar, Secretary of the Department of Health and Human Services, [echoed](#) this sentiment when he announced: "Patients have a right to know, and if you're ashamed of your drug prices, change your drug prices. It's that simple."

While the rule has garnered positive statements from groups like the [American Medical Association](#) and the [Campaign for Sustainable Rx Pricing](#), the impact of the rule is unclear. Recent [research](#) has suggested that when advertising regulations are permissive to the point of allowing qualifiers like "you may be able to get the drug for as little as \$0," the benefit of disclosing list prices is at best reduced, and at worst eliminated. Disclosure of price in those circumstances is unlikely to steer patients away from more expensive drugs, eliminating the incentive for drug makers to curb price increases. Further, as the Federal Trade Commission [notes](#), transparency in health care markets may not always yield the desired effect, particularly where the information issued is not particularly useful to consumers, but also allows competitors to figure out their rivals' pricing. Disclosure of list prices seems to fit this bill, particularly if coupled with information that it is not the price consumers will pay at the pharmacy counter.

Adding more fuel to the fire of its opponents, the rule is likely to face [challenges](#) on First Amendment grounds, with drug manufacturers arguing that the rule compels speech they would not otherwise convey. We will keep you updated on whether or not this rule flies too [close](#) to the sun.

House Fires Up the Oven, but Senate's on Ice

Lastly, the House has been busy turning up the [temperature](#) on its drug pricing agenda. There have been multiple hearings addressing broad [concerns](#) as well as specific access [issues](#). However, the most significant movement seen recently was last [Thursday](#), when the House passed the "MORE Health Education Act" by a vote of 243-183. The [bill](#), originally a measure to restore education and outreach funding for the Affordable Care Act's [Navigator](#) program that helps individuals sign up for coverage, was amended to add three drug pricing bills that had been [passed](#) out of the Energy and Commerce Committee in April.

The measures included are seemingly "low-hanging fruit" that could have some impact on what people pay for their medications. Generally, they focus on non-controversial efforts to encourage greater competition in drug manufacturing. One provision modeled after the Bringing Low-Cost Options and Competition while Keeping

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Incentives for New Generics (BLOCKING) [Act](#), discourages manipulation of the generic exclusivity period to keep competitors from entering the market. Another provision copied from the Protecting Consumer Access to Generic Drugs [Act](#) would prohibit “[pay-for-delay](#)” agreements where a brand-name drug manufacturer pays a generic manufacturer to keep a generic equivalent off the market. A third provision includes language from the Creating and Restoring Equal Access to Equivalent Samples (CREATES) [Act](#), which facilitates generic manufacturers obtaining brand-name drug samples for testing by penalizing manufacturers that withhold samples from generic rivals.

While this package of bills is the House’s first real attempt to rub sticks together and get a [fire](#) going, the Senate seems content to sit on [ice](#) for now. By combining the bills with the restoration of Navigator funding, House Democrats have drawn [criticism](#) from their Republican colleagues over tying bipartisan legislation to a perceived “bail out” of the Affordable Care Act, making its chances in the Senate remote at best. Senate leaders are [reportedly](#) working on their own package of health bills, including drug pricing reform, but plans to take them up this summer at the earliest.

For now, turning up the thermostat on drug pricing degree by degree seems to be the path forward in the imminent future. We will keep you updated on these and other efforts in Washington to solve our drug pricing woes in future Health Care in Motion dispatches.

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