

McDermottPlus Check-Up: November 1, 2019

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This Week's Dose: Drug pricing discussions continued in Congress. The full House and the Senate Health, Education, Labor, and Pensions (HELP) Committee advanced health bills.

Congress

House Approved Bills on Drug Pricing Transparency. The Public Disclosure of Drug Discounts Act ([H.R. 2115](#)) and the Payment Commission Data Act of 2019 ([H.R. 1781](#)) unanimously passed the House.

- H.R. 2115 would require the Centers for Medicare and Medicaid Services (CMS) to publish payment information reported by pharmacy benefit managers (PBMs), specifically, information related to generic dispensing rates, drug discounts and rebates, and payments between PBMs, health plans and pharmacies.
- H.R. 1781 would give the Medicare Payment Advisory Commission and the Medicaid and Children's Health Insurance Program Payment and Access Commission access to drug pricing and rebate data to help them better inform Congressional efforts on drug pricing.

Both bills aim to increase transparency in the prescription drug supply chain, representing one small area of bipartisan compromise in the ongoing drug pricing fight in Congress. The bills now await consideration in the Senate where there will likely be an effort to include them in a broader drug pricing package.

Senate Democrats Forced a Vote on Administration's 1332 Waiver Guidance. The Senate resolution, which failed with a vote of 43-52, sought to reverse a [2018 Trump Administration regulation](#) allowing states to waive certain Affordable Care Act insurance requirements by relaxing the guardrails that are statutorily outlined for 1332 waivers. Specifically, the guidance released by the Trump Administration focuses on access to coverage rather than the number of people that actually

purchase insurance. It also focuses on the total aggregate effects of a waiver rather than requiring that the coverage guardrail be met for specific sub-populations. Unlike the Obama policy, the Trump interpretation allows for increased use of association health plans and short-term, limited-duration insurance plans, which many Democrats argue offer insufficient coverage and do not protect people with pre-existing conditions. Though the resolution would not have become law (President Trump said he would veto it if it reached his desk), the vote represents a move by Democrats to continue messaging on pre-existing conditions ahead of the 2020 election, building on their success with this message in 2018. This week, Georgia became the first state to announce a 1332 waiver proposal under the new guidelines (see below). The plan is likely to face lots of vocal criticism from Democrats and patient groups as it moves forward.

Top Republican Walden Announced Retirement. Representative Greg Walden (R-OR), Ranking Member of the Energy and Commerce Committee, will leave office at the end of this Congress. Walden was first elected to the House in 1999 and has been the lead Republican on the Committee since 2017. Walden's announcement comes as a surprise to many given his influential position with two years remaining in his committee leadership term. He is the fourth House Republican committee leader, and seventeenth House Republican, to announce retirement this cycle, increasing Republicans' concerns that Democrats will keep control of the House in 2020.

Administration

New Rules Under Review at Office of Management and Budget.

- Final guidance from the Food and Drug Administration (FDA) is expected to prohibit the sale of all non-tobacco flavored e-cigarettes. The guidance follows a September announcement from the Trump Administration that FDA would be finalizing a policy aimed at reducing e-cigarette use among teens and young adults. The biggest question is whether the new guidance will include mint and menthol in the ban, flavors that are more popular among adults, rather than solely targeting the fruit and candy flavors that appeal to teens. [Draft guidance](#) released by FDA in March did not include mint and menthol, though the Administration has since clarified its desire to ban those flavors as well. Public health and anti-smoking groups have supported a comprehensive flavor ban, though many vaping companies oppose it. Some conservative groups have also suggested that a flavor ban would contradict the Trump Administration's push for deregulation.
- The [21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program](#) final rule would implement certain provisions of the 21st Century Cures Act including conditions and maintenance of certification requirements for health information technology (IT) developers under the ONC Health IT Certification Program, the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The rule also takes steps to advance interoperability, enhance health IT certification, and reduce burden and costs.

Courts

Legal Battle Over Work Requirements Continues. New Hampshire is appealing a lower court ruling that blocked the state from implementing Medicaid work requirements, joining Arkansas and Kentucky with similar cases before the US Court of Appeals for the DC Circuit. A panel of judges heard oral arguments in the Arkansas and Kentucky cases earlier this month, during which they

voiced doubts about the legality of the policy. A ruling in those cases is expected in the next few months. A case concerning work requirements in Indiana is also currently working its way through the lower court. The state announced this week that it would suspend its requirement, set to take effect in January 2020, until the lawsuit concludes. It is possible that the issue could make it to the Supreme Court next year.

States

Nebraska Released Plan for Two-Tiered Version of Medicaid Expansion. The [draft 1115 waiver proposal](#) would add restrictions to the Medicaid expansion that passed by ballot measure in Nebraska in 2018. Specifically, it would divide the new expansion group into a “basic” tier, which would cover medical expenses, behavioral health and prescription drug benefits, and a “prime” tier, which would add vision and dental benefits. To qualify for the prime tier, beneficiaries would have to participate in various wellness activities and, beginning in the waiver’s second year, comply with work requirements. Unlike in other states that have sought to implement work requirements, beneficiaries would not lose eligibility for failure to comply, but would simply not qualify for the prime tier. The proposal faces significant opposition from advocates of Medicaid expansion who argue it does not follow the intent of the Medicaid program, nor comply with the will of the voters who approved the ballot measure for full expansion. The state will accept public comment on the proposal through November 26, 2019 before submitting a final waiver request to CMS.

Georgia Announced Plan to Overhaul Individual Market. Governor Brian Kemp (R) [announced](#) that the state plans to submit a Section 1332 waiver proposal to CMS, making Georgia the first state to take advantage of the 2018 Trump Administration guidance that relaxed 1332 waiver requirements. The plan would allow individuals to receive employer contributions in addition to federal subsidies to purchase insurance, and give the state direct control over distributing the federal funds. It would also create a state reinsurance program and would eventually end Georgia’s participation in the federal exchange, having consumers instead purchase coverage directly from private insurers or third-party brokers. Georgia is expected to release an additional proposal next week that would partially expand Medicaid. The state plans to submit both proposals to CMS before the end of the year.

Quick Hits

- **At House Energy and Commerce Committee [hearing](#) on global drug supply, members agreed that US reliance on China for generic drugs poses a risk to national security.** Read our full summary of the hearing [here](#).
- **Senate Finance Committee [hearing](#) on Medicaid eligibility compliance showed party-line divide.** Read our full summary of the hearing [here](#).
- **HELP Committee [advanced](#) eight public health bills.** Read our full summary of the markup [here](#).
- **CMS issued final rules on the 2020 payment rates for dialysis and home health providers.** Find more information on the [End-Stage Renal Disease Prospective Payment System](#) final rule [here](#) and the [Home Health Prospective Payment System](#) final rule [here](#).

Next Week’s Diagnosis: The House adjourns for a one-week recess, returning November 12 when

Democrats are expected to continue their push to pass the Lower Drug Costs Now Act ([H.R. 3](#)). We expect CMS to release the 2020 Medicare Hospital Outpatient Prospective Payment System and Medicare Physician Fee Schedule final rules any day now.

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