

CAPITOL STREET

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Healthcare In a Government Shutdown

FDA, FTC/DOJ, SEC, NIH, CMS

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With a potential government shutdown looming (Oct 1 or in December), we wanted to point out what happens at each major agency as it pertains to new medicine or device FDA approvals, FTC reviews, IPO evaluation, Medicare (CMS) payments to hospitals, providers and plans and Medicaid (CMS) redeterminations. See below for the rundown.

»» Key Points

House Republicans are currently still at odds over McCarthy's funding proposal that includes a 30-day continuing resolution setting the current government spending level at \$1.471 T/year, a border security provision, formation of a commission on national debt, and limiting FY 2024 spending to \$1.526 T/year for the various must-pass appropriations bills. This agreement falls \$64 B short from the agreement in the debt ceiling deal and is unlikely to gather bipartisan or bicameral support.

The Senate has also yet to pass appropriations bills with hurdles of its own, and wants to include Ukraine relief, which irks House conservatives. Earlier this summer, the Senate Appropriations Committee [passed](#) all 12 spending bills for fiscal 2024 to be reported to the floor on a bipartisan basis. However, GOP concerns of bundling appropriations together have placed a hold on voting for a "minibus" of appropriations including (1) military construction and the departments of Veterans Affairs (VA), (2) Agriculture, (3) Transportation and Housing and Urban Development (HUD).

Republicans are being portrayed as dysfunctional and are likely to be blamed in the event of a shutdown. We predict a shutdown, if it happens, would likely last a week, two at the most, as members realize their paychecks are impacted as the stock market tumbles. We note that during the last shutdown (2018), President Trump held out 5 weeks and received no concessions.

State of Play: Senate Leader Schumer and Minority Leader Mitch McConnell will likely send the House a bipartisan CR. It will probably include billions of dollars in Ukraine aid as well as disaster relief funding and provisions that conservatives dislike.

Then, Leader McCarthy will have to decide on putting it on the floor for passage with Democratic votes. Or the House could amend it and send it back to the Senate.

FDA: Product review will continue depending on carryover funds in each user fee account. As a reminder, FDA relies on 2 sources of funding: (1) annual funding from Congress, and (2) user fees paid by the industry for the review of certain FDA regulated products (including drugs, generics, biosimilars, and medical devices). During a shutdown, the FDA is expected to continue using the user fees it has already collected to support product review activities. Application reviews are expected to continue during a short shutdown, but a longer shutdown will mean a suspension of FDA activities as funds dry up, including the issuance of guidance. Regardless of funding, the FDA is expected to continue funding staff for critical public health functions including addressing drug shortages and conducting emergency inspections.

NIH: Scientific research would be disrupted as agencies like the National Institutes of Health, the National Science Foundation and the National Oceanographic and Atmospheric Administration would furlough most of their workers.

FTC/DOJ: Premerger notification filings will continue to be accepted and reviewed by the FTC and DOJ. According to the FTC's 2023 [Operations Plan](#), the FTC and DOJ have coordinated on how they will handle mergers or acquisitions in light of a shutdown. They will continue to 1) accept premerger notification filings under HSR, 2) review premerger filings and conduct investigations, 3) litigate cases that challenge mergers or acquisitions, and 4) investigate and challenge anticompetitive practices that do not involve M&As. The FTC's Premerger Notification Office will be open to accept and process new filings, but it will not respond to questions or requests for information from outside parties. Non-merger investigations will be suspended during a shutdown. 50% of the 416 authorized FTE within the Bureau of Competition are excepted personnel in light of a shutdown.

SEC: IPO review will be halted. During a government shutdown, the SEC will have limited operations and limited staff. According to its 2023 [Operations Plan](#), the SEC will not review or approve registration statements, including initial public offerings, if a shutdown occurs.

CMS: There would be no lapse in Medicare or Medicaid funding (hospitals, physicians, health plans) since both are categorized as mandatory spending, but Medicaid redeterminations will slow. While HHS expects to furlough about 40% of its workforce if the government shuts down, staff that work on Medicare and Medicaid will be retained. A shutdown could slow down states' unwinding and eligibility redetermination process as CMS is working with states to provide technical assistance. Since that aid is not considered mandatory spend, that will be affected by a shutdown. Medicare sign ups could also be affected by a shutdown but given that we expect the shutdown to last for likely a week, two at most, this is unlikely to have a large negative affect on signups.

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