



***PG Bulletin***

*February 12, 2019*

## **Government Shutdown – Does It Affect My Research Grant or Contract? It May**

John J. Bartrum and David LesStrang (Squire Patton Boggs, Washington DC)

A lapse in federal funding, or government shutdown, occurs when the Congress and President fail to agree to a new appropriations bill for one or more of the federal government agencies. The most recent partial government shutdown ending in January 2019 affected about 25% of government agencies (in dollar terms). The Department of Homeland Security and the Food and Drug Administration (FDA) were among those agencies whose ability to spend new funds were impacted by the government shutdown. The remaining agencies already funded through enacted appropriations with funds available through the end of September 2019 included agencies like the Department of Defense and National Institutes of Health (NIH).

This article provides insight on the potential impact of a government shutdown for those contractors or grantees who might be affected by a funding lapse, such as academic medical centers (AMCs) or clinical researchers. Like most government rules, those related to a shutdown have room for interpretation. The bottom line: if you have a federal contract or grant, advance communication with the agency is the best preventative medicine. It is always prudent to ask the agency at the onset of the contract or grant work, and to validate just prior to the likelihood of a funding lapse, about how such an event may affect the specific contract or grant.

### **The Shutdown Impact at NIH vs. FDA**

On December 22, 2018, what is now the longest partial government shutdown of 35 days, began for approximately 25% of the U.S. federal government. President Donald Trump signed a short-term spending bill into law on Friday January 25, 2019 to end it with a three-week agreement to reopen the closed parts of the federal government through February 15, 2019.

More importantly, how did the shutdown impact AMCs and researchers who were seeking funding or had funding from the NIH or FDA?

For the NIH, the short and positive answer: the NIH was not impacted directly by this shutdown. It had already received its full year fiscal year 2019 funding. The NIH was able to proceed without impact on functions within the NIH to review and move forward with grant applications. Certainly, where the NIH was required to coordinate and work with other agencies shuttered by the partial government shutdown, there was an impact.

For the FDA, it was not short or positive, as the recent shutdown directly affected the FDA. The ability of the FDA to work with researchers and AMCs was impacted as it was restricted by what work the FDA could perform. The FDA website noted the following:

During the lapse period, the agency will be continuing vital activities, to the extent permitted by the law, that are critical to ensuring public health and safety in the United States. The mission critical, public health activities that will continue include, among other things: maintaining core functions to handle and respond to emergencies – such as monitoring for and quickly responding to outbreaks related to foodborne illness and the flu, supporting high-risk food and medical product recalls when products endanger consumers and patients, pursuing civil investigations when we believe public health is imminently at risk and pursuing criminal investigations, screening the food and medical products that are imported to the U.S. to protect consumers and patients from harmful products, and addressing other critical public health issues that involve imminent threats to the safety of human life. Mission critical surveillance for significant safety concerns with medical devices and other medical products will also continue.

In addition, the FDA will continue to support activities funded by carryover user fee balances, which allows us to continue to bring new therapeutic options to the patients that need them. However, during the lapse period, the FDA will not have legal authority to accept user fees assessed for FY 2019 until an FY 2019 appropriation or Continuing Resolution for the FDA is enacted. This will mean that the FDA will not be able to accept any regulatory submissions for FY 2019 that require a fee payment and that are submitted during the lapse period.<sup>1</sup>

### **Why the Difference When They Are Both Part of the Department of Health and Human Services (HHS)?**

The NIH is primarily funded from the annual Labor-HHS-Education (Labor-HHS) appropriations act with funding that can be spent by the NIH during the current fiscal year. The federal government's fiscal year runs from October 1 to September 30 of any given year. The fiscal year 2019 NIH funding was provided on September 28, 2018 when the President signed the consolidated appropriations act for Labor-HHS and Defense into law.<sup>2</sup> The legislation provided the NIH with \$39.1 billion, a \$2 billion increase over fiscal year 2018.<sup>3</sup>

The Appropriations Subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (Ag) had not enacted its fiscal year 2019 appropriation for the FDA prior to the shutdown. The FDA receives funds primarily from two sources. First, the FDA receives an annual discretionary amount of money from the U.S. Treasury that the Agriculture Appropriations Subcommittees provides through the appropriation bill; these funds are similar to funds the NIH receives. Secondly, the appropriations bill also provides for the amount FDA is allowed to collect and spend from user fees or fees paid by organizations that use specific FDA services.

The FDA user fees are linked to specific activities conducted by the FDA such as work related to medical devices, animal drugs, animal generic drugs, and tobacco products, to list a few. User fees provide agencies with flexibility since funds collected and not spent in the year collected can generally be used in a subsequent year.

### **How Does an Agency Decide What Will Operate During a Shutdown or Lapse of Funding?<sup>4</sup>**

The Office of Management and Budget (OMB) in the Executive Office of the President provides guidance to federal agencies on what actions can be maintained during a lapse of funding (commonly referred to as a shutdown) through OMB Circular A-11, Section 124.<sup>5</sup> It requires agencies to keep these plans up to date, which OMB reviews at least every two years.

In general, the Anti-deficiency Act prohibits agencies from spending money in advance of a Congressional appropriation or that exceeds an enacted appropriation.<sup>6</sup> The Department of Justice (DOJ) has identified exceptions based on express statutory authority, emergency circumstances, or the President's constitutional authority. The continuation of regular government functions outside of these exceptions are not allowed.

Examples of these exceptions:

- **Statutory Authority:**
  - The Civil War-era Feed and Forage Act (41 U.S.C. § 6301) provides authority to the Defense Department to contract for necessary clothing, subsistence, forage, fuel, quarters, transportation, or medical and hospital supplies in advance of appropriations.
  - 25 U.S.C. § 99 authorizes the Bureau of Indian Affairs to contract for goods and supplies; and
  - 41 U.S.C. § 6302 authorizes the Army to contract for fuel.
- **Emergency Circumstances** constitute a high bar as the suspension of government functions must imminently threaten the safety of human life or the protection of property. The DOJ has noted the emergency exception exists if both of these two tests apply:
  - A reasonable and articulable connection between the obligation and the safety of life or the protection of property, and
  - Some reasonable likelihood that either the safety of life or the protection of property would be compromised in some significant degree by failure to carry out the function in question --and that the threat to life or property can be reasonably said to be near at hand and demanding of immediate response.
- **President's Constitutional Authority** such as Commander-in-Chief or conducting foreign relations.

Of course, rules are not always black and white. The DOJ has further identified a limited number of activities “necessarily implied” from the authorized continuation of other activities that may continue in order to implement: (1) an orderly shutdown, (2) one of the excepted items, or (3) an authorized activity where funding remains available during the lapse.<sup>7</sup> Under this exception, if the suspension of a related activity would prevent or significantly damage the allowable activity, it may be a “necessarily implied” activity. For example, a “necessarily implied” activity could include administrative support (normally not allowed in a funding lapse) necessary to disburse a benefit payment under an entitlement program where that program’s funds are available to support the entitlement. It is a narrow rule but helps contribute to the lack of clarity on what is or is not funded in agencies.

Multi-year or no-year funds provide another twist on funding that may be available for use during a shutdown. The guidance to agencies is more complicated. Agencies may have discretion on when to engage in activities related to the purpose of specific multi-year and no-year funds. If that discretion is substantial with respect to the timing of when to spend the funds, the agency may not be allowed to elect to spend these funds during a shutdown. The rules are based on the scope and timing of the funding lapse, which can result in changes over time on what an agency can or cannot support during a shutdown.

### **What Happens with Contract or Grant Funding?<sup>8</sup>**

Generally, the routine activities related to a contract or grant administration does not continue for contract or grant administrative activities (i.e., new awards) during a shutdown. In addition, unless it meets one of the exceptions discussed, an agency cannot award a new contract or grant or make new funds available during the funding lapse. For example, if the NIH or the FDA were about to process a new contract or grant, conduct a peer review on a contract or grant, or post a new contract or grant opportunity that was not allowed under the rules above, the actions would not be permitted during a lapse in funding.

If a researcher had an existing grant, awarded with funds already available to be spent, the grantee may proceed with its work during the lapse. For example, if the NIH awarded a grant before the shutdown where the funds were already available for the grantee to spend, the grantee can continue during the shutdown. It is best to communicate in advance with the agency to understand the impact of a shutdown on the various stages of the contract or grant.

If the contract or grant required oversight by a federal employee affected by the shutdown, a problem could occur with continuing with the contract or grant during the shutdown. In most cases, routine activities to support oversight or performance activities by impacted federal employees cannot occur. Again, very limited actions may be possible if it meets the exceptions described above, such as an emergency circumstance that poses an imminent threat to life or property. Again, it is best to communicate in advance with the agency to determine if milestone, performance, or

oversight required is impacted and to what extent if your grant or contract has such terms.

### **How Can Someone Find Out in Advance How the Agency Will Operate During a Funding Lapse or Shutdown?**

OMB works with federal agencies to update the plans of potentially impacted agencies if it appears a funding lapse or shutdown may occur. The plans are publicly available in a central location on the following website: <https://www.whitehouse.gov/omb/information-for-agencies/agency-contingency-plans/>.

In addition, agencies normally have their specific plans on their own website and provide updates during the shutdown as circumstances warrant. For example, the note above from FDA was posted on its website during the most recent 2019 shutdown.

---

<sup>1</sup> FDA, <https://www.fda.gov/AboutFDA/WorkingatFDA/ucm629100.htm> (last visited Feb. 11, 2019).

<sup>2</sup> Congress.gov, <https://www.congress.gov/resources/display/content/Appropriations+for+Fiscal+Year+2019> (last visited Feb. 11, 2019).

<sup>3</sup> An additional small amount for environmental research and training related to Superfund comes from the Interior, Environment, and Related Agencies (Interior-Environment) appropriations act.

<sup>4</sup> *Frequently Asked Questions During a Lapse in Appropriations, I. Basic Principles of Agency Operations during a Lapse in Appropriations*, White House, <https://www.whitehouse.gov/wp-content/uploads/2018/12/Frequently-Asked-Questions-During-a-Lapse-in-Appropriations.pdf> (last visited Feb. 11, 2019).

<sup>5</sup> White House, [https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/a11\\_current\\_year/a11\\_2017.pdf](https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/a11_current_year/a11_2017.pdf) (last visited Feb. 11, 2019).

<sup>6</sup> *Frequently Asked Questions During a Lapse in Appropriations*, *supra* note 4.

<sup>7</sup> *Id.* at B. *Activities that an agency must continue, in the absence of appropriations, because their continuation is “necessarily implied” from the authorized continuation of other activities.*

<sup>8</sup> *Frequently Asked Questions During a Lapse in Appropriations*, *supra* note 4 at II. *Contracts and Grants.*

**Copyright 2019, American Health Lawyers Association, Washington, DC. Reprint permission granted.**