United States Senate
WASHINGTON, DC 20510

July 27, 2018

The Honorable Alex Azar
Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

The Honorable Neomi Rao
Administrator, Office of
Information and Regulatory Affairs
Office of Management and Budget
1650 Pennsylvania Avenue NW
Washington, DC 20503

Dear Secretary Azar and Administrator Rao:

On June 1, 2018, the Department of Health and Human Services (HHS) published notice in the Federal Register of a proposed domestic gag rule on the Title X family planning program, "Compliance With Statutory Program Integrity Requirements; Request for Comment Deadline Extension" (Docket ID No. HHS–OS–2018–0008). The notice provides a 60-day public comment period, which is set to end on July 31, 2018.

As members of the Subcommittee on Regulatory Affairs and Federal Management of the Senate Homeland Security and Governmental Affairs Committee, we have several concerns regarding the rulemaking process that we request you address prior to moving forward, as it is critical that there is a reasonable opportunity to understand the process the proposed rule underwent and to meaningfully comment on the rule. The drastic medical, legal and administrative issues brought forth by this proposed rule require extensive analysis and commentary by stakeholders that was not fully permitted during this process. Therefore, we write to request at least a 60-day extension of the July 31, 2018 comment deadline in order to allow time for those affected by the rule to meaningfully participate in the process.

We are troubled by the lack of advance notice of the proposed rule and about the failure by HHS and the Office of Management and Budget's Office of Information and Regulatory Affairs (OMB/OIRA) to follow the appropriate rulemaking process. Instead of the average review period of 45 days, the proposed rule – for which there was neither a legal obligation to initiate nor an identified need – was moved through OIRA in less than two weeks.

In particular, we have a number of concerns about the steps of the process:

1. There was no mention of the proposal in the Fall 2017 Regulatory Agenda;
2. There was no mention of the proposal in the Spring 2018 Regulatory Agenda;
3. To our knowledge, there was no early outreach to affected stakeholders, as is policy under Executive Order (EO) 13563 (sec 2.c.) and associated OMB/OIRA guidance;

4. Despite that lack of public engagement, the rule was quickly moved through OIRA review with minimal oversight:
    a. Thursday, May 17, 2018 - the draft rule was received by OMB;
    b. Friday, May 18, 2018 - the draft rule was posted to reginfo.gov as under review;
    c. Monday, May 21, 2018 - a number of stakeholder groups requested meetings with OMB as contemplated under EO 12866;
    d. Tuesday, May 22, 2018 - the draft rule was posted to Office of Population Affairs website, despite not having cleared OMB review;
    e. Thursday, May 24, 2018 - stakeholder groups received letters from OMB denying their requests for 12866 meetings and stating that review of the proposed rule was complete;
    f. Tuesday, May 29, 2018 - the proposed rule was posted to public inspection desk;
    g. Friday, June 1, 2018 - the proposed rule officially published in federal register.

Given that the Department acknowledges that there is no statutory or other legal requirement to issue the rule, along with the fact that the rule conveys no quantifiable benefit, we are alarmed and confused by this expedited timeframe. Our concerns are exacerbated because of the drastic changes the rule proposes to a program that has operated successfully with minimal changes for more than forty years.

Because the proposed rule also raises questions on a wide variety of complex medical, legal, and administrative issues, each of which requires careful and in-depth analysis by many stakeholders, the 60-day comment period provided for under the rule is inadequate. More time is needed to fully evaluate the statutory authority for the proposed rule; the interaction of the proposed rule with other federal, state, and local laws and policies; the economic impact and compliance costs associated with the proposed rule; and the public health impact on the people impacted by the proposed rule.

In light of the significant public health and financial ramifications of the proposal and the need to conduct extensive analysis of the regulatory and economic impact on people across the country, we respectfully request that the comment period be extended until at least October 1, 2018 to permit all stakeholders to provide meaningful comments on this proposal.

In addition, we would appreciate answers to the following questions regarding the rulemaking process no later than August 15, 2018:

1. What effort was made by HHS to notify and engage relevant stakeholders prior to issuing the proposed rule? What meetings did HHS have – if any – and with whom?

2. Please identify any quantifiable benefits of the proposed rule. Who did OMB/OIRA consult regarding the impact and cost of the rule? What steps were taken by OMB/OIRA to analyze the cost and impact of the rule?

3. The proposed rule was pushed through OIRA in less than two weeks, when the average review period is 45 days. Why was this process expedited without providing for full public input?

We remain very interested in transparency and fairness in this rulemaking. We look forward to receiving answers to our questions.

Sincerely,

MARGARET WOOD HASSAN
United States Senator

KAMALA D. HARRIS
United States Senator