UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA FORT MYERS DIVISION

THE FOUNDATION FOR GOVERNMENT ACCOUNTABILITY,

Plaintiff,

v.

Case No. 2:23-cv-207-JLB-KCD

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants.

DEFENDANTS' MOTION FOR AN EXTENSION OF TIME

The United States Department of Health and Human Services (HHS); Xavier Becerra (in his official capacity as Secretary of the Department of Health and Human Services); the United States Department of Labor; Julie A. Su (in her official capacity as the Acting Secretary of Labor); the United States Department of the Treasury; and Janet L. Yellen (in her official capacity as the Secretary of the Treasury) (collectively, "Defendants") hereby move for a 45-day extension of time to file their summary-judgment reply brief in this case, to account for intervening policy developments that may moot (or at least significantly alter) this litigation, in whole or in part. As good cause for this request, to which Plaintiff consents in part, Defendants offer the following:

- 1. Plaintiff filed the complaint in this case on March 23, 2023. ECF No. 1. Plaintiff challenges portions of three "Frequently Asked Questions" documents that were posted on the website of HHS's Centers for Medicare & Medicaid Services in August 2021, April 2022, and August 2022. *See* Compl. ¶¶ 44, 49, 51. The complaint includes one count, alleging a violation of the notice-and-comment requirements of the Administrative Procedure Act. *See id.* ¶¶ 65-73.
- 2. Pursuant to two agreed-upon scheduling orders issued by the Court, ECF Nos. 32, 38, the parties have now filed three of four summary-judgment briefs. ECF Nos. 33, 39, 40. One brief remains outstanding: Defendants' reply in support of their motion for summary judgment, which is currently due this Tuesday, September 19.
- 3. As recognized by all parties' filings, the non-enforcement policy at the core of this case was always intended to be temporary. *See, e.g.*, Defs.' Mot., ECF No. 39, at 5 ("Defendants announced their intent to 'defer enforcement of the requirement . . . while it considers, through notice-and-comment rulemaking, whether the prescription drug machine-readable file requirement remains appropriate.'" (quoting FAQs Part 49, ECF No. 39-2, at 2)); Pl.'s Mot., ECF No. 33, at 19 ("Though the Agencies announced that they would not enforce the Rule while they go through 'notice-and-comment rulemaking' to decide whether it remains 'appropriate,' they have taken no steps to begin that process over a year later.").
- 4. After further policy deliberations within the Executive Branch, Defendants are now on the cusp of publishing a new document about Defendants' enforcement posture that is likely to significantly alter the factual landscape on which

this case rests. Indeed, although that proposed policy is necessarily non-final until it is published, the forthcoming publication of this document may very well moot this case in its entirety (or at least in substantial part), by rescinding (in whole or in part) the non-enforcement policies that are challenged in Plaintiff's complaint and that have been the subject of the parties' summary-judgment briefing.

- 5. Although both the content and the timing of this policy announcement are necessarily subject to change, undersigned counsel has been informed by Defendants that they expect to publish a document on this subject imminently, and no later than within the next 14 days.
- 6. Defendants respectfully submit that, under these circumstances, it would not be an efficient use of resources, for the parties or the Court, for summary-judgment briefing to continue on the current schedule, because the entire case may be mooted (or at least substantially altered) by material policy developments, either immediately before or after Defendants file their next brief. And even if the litigation continues in some form, many of the arguments in the parties' previous briefs are likely to have been overtaken by events.
- 7. Accordingly, Defendants respectfully request a 45-day extension of time to file their summary-judgment reply brief. Defendants hope and expect that, immediately after publication of the policy document referenced above, the parties will meet and confer regarding the future of this litigation (if any), and (if necessary) can attempt to reach agreement on a joint proposal for further proceedings at that time,

accounting for these significant intervening developments. Defendants may request at that time that the existing summary-judgment schedule be vacated in its entirety.

- 8. If, however, in the unlikely event that the litigation does continue in its current form (contrary to Defendants' expectations), Defendants will be ready to file a summary-judgment reply brief on November 3, resulting in only a minor (possible) delay, which would not cause any meaningful prejudice to Plaintiff.
- 9. Finally, although this extension request is motivated by the potentially imminent publication of a policy document that will alter the landscape of this litigation, undersigned counsel also notes that there is also (in the alternative) good cause to grant this extension due to undersigned counsel's significant scheduling conflicts. Due to the press of other time-sensitive litigation deadlines (several of which arose only after the most recent modification to the briefing schedule, including briefing and oral argument in other significant and time-sensitive matters), as well as ongoing efforts to support the policy deliberations described above, undersigned counsel would respectfully require additional time to prepare and finalize the summary-judgment reply brief even in the absence of the imminent policy developments described above. Accordingly, to the extent it is necessary, Defendants also request (in the alternative) the same extension of time on the basis of undersigned counsel's scheduling conflicts.

Local Rule 3.01(g) Certification

10. Pursuant to Local Rule 3.01(g), on September 6th and 13th, counsel for Defendants conferred with counsel for Plaintiff by telephone and email. Counsel for

Plaintiff reported that Plaintiff consents to the relief requested in this motion only in part, and reported Plaintiff's position as follows: "Plaintiff consents to a 10-day extension of the Agencies' reply deadline to allow for the Agencies to make a final decision on any new document that they might publish. Plaintiff would consent to a further extension for the parties to consider and confer about any new documents once they have come out, but does not believe such an extension is warranted at this point."

Dated: September 13, 2023 Respectfully submitted,

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