UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND
(Northern Division)

PLANNED PARENTHOOD OF MARYLAND, INC., *et al.*, *Plaintiffs*, v. ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services, in his official capacity, *et al.*, *Defendants*.	Civil Action No. CCB-20-00361

SUPPLEMENTAL MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

On May 8, 2020, after the parties filed their cross-motions for summary judgment, Defendants (hereinafter, "HHS") published an Interim Final Rule ("IFR") that postponed the Separate-Billing Rule's implementation deadline by sixty days, to August 26, 2020, in light of the COVID-19 pandemic.[1] Plaintiffs moved to supplement their complaint to challenge the IFR, *see* ECF No. 39, and the parties subsequently submitted a joint motion for a stipulated briefing schedule, *see* ECF No. 46. In accordance with that schedule, Plaintiffs submit this brief to address why the August 2020 implementation date remains arbitrary and capricious under the Administrative Procedure Act ("APA").

STATEMENT OF UNDISPUTED FACTS

In the IFR, HHS explained that it delayed implementation of the Separate-Billing Rule's requirements by sixty days in light of "extraordinary circumstances" related to the COVID-19 public health emergency and the "immediate need for . . . issuers to devote resources to respond to" that emergency. 85 Fed. Reg. at 27,599. HHS stated that some issuers requesting a delay had explained that addressing the COVID–19 pandemic "ha[d] led to an overall reduction in resources available for other initiatives," including preparation to implement the Separate-Billing Rule, and that "already existing challenges to timely compliance with the separate billing policy pose an even greater obstacle when considered in conjunction with the mounting demands on . . . issuers in responding to the COVID–19" pandemic. *Id.* at 27,600. HHS acknowledged that for many issuers, "some, if not all, of their daily work is being accomplished while staff is working remotely, adding yet another barrier to timely compliance." *Id.*

[1] *See* Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program, Interim Final Rule, 85 Fed. Reg. 27,550, 27,553 (May 8, 2020).

Without reference to supporting evidence, HHS then concluded that a "60-day delay w[ould] sufficiently alleviate burden on resources in the short-term, as well as provide sufficient time for . . . issuers and Exchanges, such that responding to the COVID–19 [public health emergency] and timely compliance with the separate billing policy are both practical." *Id.* HHS stated that it did not "anticipate formally extending the compliance deadline again." *Id.* Instead, it indicated that issuers still unable to meet the August 26 deadline, despite good-faith efforts, could ask HHS to exercise its enforcement authority to delay implementation on a case-by-case basis. However, HHS stated that enforcement was unlikely to be delayed "more than [one] year" after the Separate-Billing Rule's publication, i.e., past December 27, 2020, or more than six months after the end of the COVID–19 public health emergency, "whichever comes later." *Id.*

ARGUMENT

As Plaintiffs explained in their earlier summary judgment briefing, even before the COVID-19 pandemic began, most issuers would have needed at least eighteen to twenty-four months to implement the Separate-Billing Rule. *See, e.g.*, Blue Cross Blue Shield Association ("BCBSA") Comment at 4, AR 080264; America's Health Insurance Plans ("AHIP") Comment at 11, AR 080215. Moreover, the undisputed evidence in the administrative record showed that implementation of the Separate-Billing Rule in the middle of the 2020 plan year would increase consumer confusion and leave issuers without a sufficient amount of time to test new systems required to comply with the rule and to train customer service staff. *See, e.g.*, AHIP Comment at 11, AR 080215; BCBSA Comment at 5, AR 080265; National Association of Insurance Commissioners ("NAIC") Comment at 1–2, AR 079065–66. *See generally* Final Mem. Supp. Pls.' Mot. Summ. J. 10–14 (hereinafter, "Pls.' SJ Br."), ECF No. 41; Opp'n to Defs.' Cross-Mot. Summ. J. and Reply Supp. Pls.' Mot. Summ. J. 13–16, ECF No. 42.

Even with the IFR's sixty-day extension—which effectively gives issuers eight months instead of six to implement the Separate-Billing Rule—the implementation date remains arbitrary and capricious under the APA. The majority of issuers will still be required to comply with the rule in the middle of a plan year, which runs from January 1 to December 31. Pls.' SJ Br. 4. These issuers will still have to comply with the rule at least ten months before most issuers have indicated that they would be prepared to comply. And now issuers will have to do so *in the middle of a pandemic* under "extraordinary circumstances." 85 Fed. Reg. at 27,599.

HHS's assertion that the August 2020 implementation deadline will be "operationally and administratively feasible" during the pandemic is completely unsupported by the narrow administrative record on which the IFR is based. *Id.* at 27,601.[2] The record demonstrates that, even before HHS published the IFR in early May, four issuers had already asked about extensions to the implementation deadline. Two of those issuers made general inquiries, Evolent Health Email, IFR-AR 000139; Softheon Email, IFR-AR 000150, and therefore do not support the view that a sixty-day delay would be sufficient to address concerns. The other two issuers requested implementation extensions until the first quarter of 2021, and July 1, 2021, respectively. *See* Cigna Letter at 2, IFR-AR 000152; Community Health Options ("CHO") Letter at 2, IFR-AR 000145. Both periods of time are, of course, far longer than the IFR's sixty-day extension, and the requests show why that extension is inadequate. As one issuer explained, it is engaged in "extensive IT and Operations department efforts to configure and implement state of emergency regulations such as payment of claims for Providers credentialed at other locations; relaxation of telehealth requirements; first-dollar coverage of COVID-19 screening and testing; and[] changes to Physician

[2] HHS did not provide advance notice or solicit public comment on the IFR before promulgation, instead relying on the APA's good-cause exception to the notice-and-comment requirement. *See* 5 U.S.C. § 553(b).The propriety of HHS's reliance on that exception is not at issue here.

Assistant billing rules." CHO Letter at 2, IFR-AR 000145. That issuer also identified other impediments to timely compliance that would likely require a timeframe "far exceeding the six (6) months allotted" by the Separate-Billing Rule. *Id.* at 2–3, IFR-AR 000145–46. HHS provides no reason for rejecting this "specific, contradictory evidence," *Ergon-W. Va., Inc. v. EPA*, 896 F.3d 600, 613 (4th Cir. 2018), while announcing in a conclusory manner that a far shorter period will suffice. Because the agency's conclusion is "clearly at variance" with the only facts borne out by the administrative record, it is arbitrary and capricious. *United States v. F/V Alice Amanda*, 987 F.2d 1078, 1085 (4th Cir. 1993) (citation omitted).

HHS's sixty-day extension is also irrational because it ignores the impact of implementation on consumers, patients, and state regulators. In particular, HHS fails to acknowledge, much less contend with, critical points made in letters it received from the American College of Obstetricians and Gynecologists ("ACOG") and seven state attorneys general, all of whom urged HHS to delay implementation until the COVID-19 pandemic is contained and the economy has recovered. *See* Att'y Gen. of N.Y., et al., Letter, IFR-AR 000153–56; ACOG Letter, IFR-AR 000157–59. These stakeholders urged HHS to consider the impact of implementation on "the unique needs of women and their families," ACOG Letter at 1, IFR-AR 000157, and on state health and insurance regulators focused "on the mission-critical functions of assuring access to and maintenance of health coverage for treatment and testing of COVID-19," Att'y Gen. of N.Y. Letter at 3, IFR-AR 000155. ACOG stated, for example, that the rule would "increase costs to states, result in more uninsured individuals, and compromise the ability of Americans to obtain access to care during this public health crisis." ACOG Letter at 1, IFR-AR 000157. It also explained that the Separate-Billing Rule's cost calculations now likely "represent a substantial underestimate of the costs of implementing" the rule during the pandemic, *id.* at 2, IFR-AR

000158, because job loss is a basis for special enrollment in an ACA exchange throughout the plan year, 45 C.F.R. § 155.420(d). Since the beginning of the pandemic, more than forty million Americans have lost their jobs, Patricia Cohen, *'Still Catching Up': Jobless Numbers May Not Tell Full Story*, N.Y. Times (updated June 4, 2020), https://www.nytimes.com/2020/05/28/business/economy/coronavirus-unemployment-claims.html, and many of those individuals will "look to the Exchanges for coverage," ACOG Letter at 2, IFR-AR 000158. At a minimum, HHS has an obligation to acknowledge the impact of implementation on these consumers and to explain why it is jeopardizing their healthcare at a time like this. Its failure to address this "important aspect of the problem" renders the IFR arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983).

CONCLUSION

For the foregoing reasons, and those set forth in Plaintiffs' earlier briefs, Plaintiffs respectfully request that the Court enter summary judgment in their favor, declare the Separate-Billing Rule, including as modified by the IFR, invalid under the APA, and immediately set aside the Separate Billing Rule, including as modified by the IFR.

Respectfully submitted,

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