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HHS Faces IRA Implementation Risk Without Notice and Comment

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In the Inflation Reduction Act of 2022 ("IRA")[1], Congress made some of the most significant changes to the Medicare program since Congress first passed a prescription drug benefit in 2003. Successfully implementing these recent changes will require the Centers for Medicare & Medicaid Services ("CMS" or "the agency") to understand and balance competing stakeholder concerns. Federal agencies often do so by engaging in rigorous notice-and-comment processes. However, citing provisions in the IRA authorizing implementation by "program instruction or other forms of program guidance," CMS recently moved to implement core provisions of the IRA's Drug Price Negotiation Program ("Negotiation Program") without notice and comment.[2] These actions are dubious as a matter of law and troubling as a matter of public policy.

The Negotiation Program is one of the IRA's most consequential changes to the Medicare Program, and it authorizes CMS (through a delegation from the Secretary of the Department of Health and Human Services ("HHS")) to negotiate prices for select Medicare Part B and Part D drugs on an annual basis.[3] By September 1, 2023, CMS will select ten Part D drugs and establish through negotiations with their manufacturers a "maximum fair price," effective in 2026.[4] The section of the IRA setting forth this program states that the Secretary of HHS "shall implement this section . . . for 2026, 2027, and 2028 by program instruction or other forms of program guidance."[5] Other provisions of the IRA include similar language.[6]

On March 15, 2023, CMS released guidance implementing the Negotiation Program for 2026. This guidance solicits comments on certain aspects of the Negotiation Program; however, CMS issued as "final" and "without a comment solicitation" the guidance for how CMS will select the ten drugs subject to price negotiations in 2026.[7] Moreover, while CMS is accepting comments on other aspects of the Negotiation Program—such as negotiation procedures and data manufacturers must submit to facilitate negotiations[8]—CMS has not indicated that it will engage with, and respond to, these comments in a

[1] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818.

[2] *See* Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (Mar. 15, 2023), https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf.

[3] *See* 42 U.S.C. § 1320f *et seq.*

[4] *See* 42 U.S.C. § 1320f–2(a)(1).

[5] IRA § 11001(c).

[6] *See* IRA § 11201(f); IRA § 11401(e); IRA § 11406(d); IRA § 11407(e).

[7] *See* Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Program: Initial Memorandum at 2.

[8] *Id.* at 2, 34, 37–38.

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manner consistent with typical notice-and-comment procedures.

For actions taken to implement the Medicare program, these default procedural requirements derive from two sources. First, the Administrative Procedure Act ("APA") requires an agency to use notice-and-comment rulemaking when issuing a "substantive rule," which courts define to mean a rule that "bind[s]" the public or has the "force and effect of law."[9] The APA includes exceptions for "interpretive rules" and where an agency finds "good cause" to bypass notice-and-comment rulemaking.[10] In addition, Congress may exempt agencies from compliance with the APA's notice-and-comment requirements, but only "to the extent that [the future legislation] does so expressly."[11] Here, too, courts interpret such congressional exemptions very narrowly. For example, provisions within the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") say that HHS "may promulgate any interim final rules as the Secretary determines are appropriate to carry out this subchapter."[12] But two courts of appeal have concluded that this text still does not rise to the level of "express language exempting agencies from" using notice and comment.[13]

Second, the Medicare Act includes a separate notice-and-comment requirement obligating HHS to provide the public with advance notice and an opportunity to comment on any "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard governing" various aspects of the Medicare program.[14] The Medicare Act, too, includes exceptions where: "a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment," a statute establishes a deadline for agency action that is shorter than 150 days, or the APA's good cause exception is met.[15]

Historically, some courts had interpreted this provision of the Medicare Act as coterminous with the scope of the APA's notice-and-comment requirement.[16] But in 2019, the Supreme Court held in *Azar v. Allina Health Services* that the Medicare Act's notice-and-comment requirements are broader than the APA standard.[17] In other words, an interpretive rule exempt from notice and comment under the APA may still establish or change a substantive legal standard and require notice and comment under the Medicare Act.[18] Although the Supreme Court did not define what constitutes a "substantive legal standard," it concluded that when the government "establishes or changes an avowedly 'gap'-filling policy, it can't evade its notice-and-comment obligations under" the Medicare Act.[19]

Lower courts applying *Allina* have relied on a functional definition of "substantive legal standard," whereby an agency action constitutes a substantive legal standard if it changes eligibility criteria for

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[9] *See Chrysler Corp. v. Brown*, 441 U.S. 281, 301–02 (1979).

[10] 5 U.S.C. *§* 553(b).

[11] 5 U.S.C. *§* 559.

[12] *See* 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92.

[13] *See Pennsylvania v. President of United States*, 930 F.3d 543, 566 (3d Cir. 2019), *rev'd on other grounds*, 140 S. Ct. 2367 (2020); *California v. Azar*, 911 F.3d 558, 579 (9th Cir. 2018).

[14] *See* 42 U.S.C. *§* 1395hh(a)(2).

[15] *Id. §* 1395hh(b)(2)(A).

[16] *See, e.g.*, *Via Christi Regional Med. Ctr., Inc. v. Leavitt*, 509 F.3d 1259, 1271 n.11 (10th Cir. 2007); *Baptist Health v. Thompson*, 458 F.3d 768, 776 n.9 (8th Cir. 2006).

[17] 139 S. Ct. 1804, 1814 (2019); *see also* Memorandum on Impact of Allina on Medicare Payment Rules, Department of Health & Human Services (Oct. 31, 2019), https://www.law360.com/articles/1222453/attachments/0.

[18] *Id.* at 1811.

[19] *Id.* at 1817.

reimbursement, fills a statutory gap, and/or lacks historical precedent. For example, one district court has explained that if an agency's policy "affects the right to, or amount of reimbursement, it is more likely to be deemed a 'substantive legal standard'" requiring notice and comment.[20] The court further held that any policy functioning as "a gap-filling exercise prompted by the ambiguity of the prior policy" similarly requires notice and comment.[21] Other courts have emphasized the importance of historical precedent, with the lack of comparable past agency action serving as a "marker" that the agency only now established or changed a substantive legal standard.[22]

The CMS rules for selecting negotiation-eligible drugs are just one example of how IRA implementation triggers rulemaking obligations under both the APA and the Medicare Act. In these rules, CMS establishes complex procedures for identifying and selecting the foundation of the negotiation program itself: the "negotiation-eligible" drugs. Such rules are substantive under the APA, not interpretive, because they "grant rights, impose obligations, or produce other significant effects on private interests."[23] They also will establish substantive legal standards under the Medicare Act, because they will affect the amount of reimbursement, gap-fill how the statute sets forth the Negotiation Program's operation, and lack any historical precedent.

However, CMS has taken the position that Congress exempted the agency from both the APA and Medicare Act's notice-and-comment rulemaking obligations where Congress authorized implementation "by program instruction or other forms of program guidance."[24] CMS further explained "to the extent that this guidance establishes or changes any substantive legal standard," the "good cause" exception under the APA is satisfied "in light of this Congressional direction and in light of the complexity of the preparation that must be undertaken in advance of the publication of the selected drug list by September 1, 2023."[25] These conclusions cannot be squared with the case law, however.

First, by virtue of how narrowly courts have interpreted the APA's express exemption clause, CMS has the weaker of the arguments that the IRA satisfies this hurdle. Courts have frequently "looked askance at agencies' attempts to avoid the standard notice and comment procedures, holding that exceptions under [the APA] must be narrowly construed and only reluctantly countenanced."[26] Indeed, "[t]he APA imposes a high bar, met only if Congress has established procedures so clearly different from those required by the APA that it must have intended to displace the norm."[27] For instance, statutory language that directs the agency to "publish in the Federal Register an initial fee schedule and associated collection process as an interim final rule, pursuant to which public comment will be sought and a final rule issued" has been held to satisfy the APA's express exemption clause, because these specific procedures "cannot be reconciled

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[20] 422 F. Supp. 3d 916, 934 (E.D. Pa. 2019); *see also Select Specialty Hospital-Denver, Inc. v. Azar*, 391 F. Supp. 3d 53, 69 (D.D.C. 2019) (holding that CMS's new policy affected a substantive legal standard because it "essentially changed the eligibility criteria for reimbursement").

[21] *Polansky*, 422 F. Supp. 3d at 936.

[22] *Texas v. Becerra*, 2022 WL 3639525, at *28 (N.D. Tex. Aug. 23, 2022).

[23] *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1284 (D.C. Cir. 2005) (quoting *Batterton v. Marshall*, 648 F.2d 694, 701–02 (D.C. Cir. 1980)).

[24] *Id.* at 2 (citing IRA § 11001(c)).

[25] *See* Centers for Medicare & Medicaid Services, Medicare Drug Price Negotiation Program: Initial Memorandum at 2.

[26] *Lake Carriers' Ass'n v. E.P.A.*, 652 F.3d 1, 6 (D.C. Cir. 2011) (citation omitted).

[27] *Citizens for Resp. & Ethics in Washington v. FEC*, 993 F.3d 880, 890 (D.C. Cir. 2021) (citation and quotation marks omitted); *see also, e.g.*, *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994).

with the notice and comment requirements" of the APA.[28] The IRA's instructions to implement through "guidance" are not similarly irreconcilable with notice and comment procedures.

That Congress intended this guidance to go through notice-and-comment procedures is also compelled by the fact that the IRA is further subject to the Medicare Act's notice-and-comment requirements, which post-*Allina*, clearly can apply to guidance. Yet this IRA language does not satisfy the Medicare Act's own express exemption clause for "a statute [that] specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment." No court has yet interpreted the outer bounds of this exception, however, the language Congress used—program instruction or other guidance—invokes neither interim final regulations nor a comment period of any particular length. This is particularly damaging for the Department's position because Congress knows how to reference interim final rules when it wants to, for example authorizing the Secretary of HHS to "promulgate any interim final rules" under HIPAA. Yet Congress chose not to use such terminology in the IRA.

CMS also invoked "good cause" to skip notice and comment, which can in narrow circumstances serve as an exception under the APA and the Medicare Act. But this justification equally cannot stand, as courts have rejected government arguments that deadlines of a year, or even less, are too tight to accommodate rulemaking.[29] Here, Congress gave CMS over a year to select drugs for the first year of the Negotiation Program, which is sufficient to incorporate notice-and-comment rulemaking.[30]

Insulating large parts of the Negotiation Program from notice and comment not only creates legal risk for HHS but also threatens to undermine the integrity of the process. Indeed, the Negotiation Program is just one of several key aspects of the IRA that impacts the trajectory of healthcare costs and research and development for generations to come. Failure to use proper notice-and-comment procedures will surely create regulatory and market uncertainty for drugs currently on the market, and likely stymie drug discovery investments. Along the way, such shortcuts to implementation may be among the ripest for challenge by private parties.

[28] *See Asiana Airlines v. Fed. Aviation Admin.*, 134 F.3d 393, 398 (D.C. Cir. 1998).

[29] *See, e.g.*, *U.S. v. Johnson*, 632 F.3d 912, 929 (5th Cir. 2011); *Nat'l Ass'n of Farmworkers Organizations v. Marshall*, 628 F.2d 604, 622 (D.C. Cir. 1980); *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 213 (5th Cir. 1979); *Louisiana v. Becerra*, 577 F. Supp. 3d 483, 500 (W.D. La. 2022).

[30] *See, e.g.*, *Texas Med. Ass'n v. U.S. Dep't of Health & Hum. Servs.*, 587 F. Supp. 3d 528, 545–46 (E.D. Tex. 2022).

