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Memo

Date:	July 17, 2020
To:	JC Scott, President and Chief Executive Officer, PCMA Kristin Bass, Chief Policy & External Affairs Officer, PCMA Wendy Krasner, Senior Vice President, Regulatory Affairs, PCMA
From:	Thomas R. Barker, Partner Ross Margulies, Senior Associate
Regarding:	Legal Assessment of Ability of HHS-OIG to take Action on Rebates

You have asked for a legal analysis of the ability of the Department of Health and Human Service Office of Inspector General (HHS-OIG) to resurrect the policies contained in its 2019 rebate rule without first going through a new round of notice-and-comment rulemaking. Below we analyze possible pathways the agency could pursue to achieve this goal, including by finalizing the original 2019 proposed rule, issuing the rule as an interim final rule (IFR), or finalizing the policy through guidance or some other sub-regulatory means. Regardless of the method used, we conclude that the agency lacks the legal authority to circumvent notice-and-comment rulemaking procedures. Irrespective of whether the agency seeks to finalize the rebate rule as proposed, or seeks to substitute an alternative policy with the same or similar effect, it must first issue a notice of proposed rulemaking and seek public comment before finalizing any new rebate policy.

I. Background

On February 6, 2019 HHS-OIG published in the Federal Register a proposed rule that would have amended the agency's existing safe harbor regulations to exclude from protection under the Anti-Kickback Statue (AKS) certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors or PBMs under Medicare Part D or Medicaid managed care (the "rebate rule").[1] During a 60-day public comment period the agency received nearly 20,000 comments, many in opposition. Exactly one month later, on July 10, 2019, the Office of Management and Budget (OMB) announced that HHS-OIG was formally "withdrawing" the proposed rule and listed the rule as a "Completed Action" on its website.[2] In response to the withdrawal, HHS spokesperson Caitlin Oakley stated the Administration would continue pursuing other drug pricing

reforms: "President Trump and Secretary Azar are taking bold action to end foreign free riding, examine how to safely import lower-cost prescription drugs, empower patients with meaningful transparency, and the list goes on."

We understand the Administration may now be reconsidering its decision to withdraw the rebate policy. PCMA has asked us for an analysis of the ability of HHS-OIG to take action on rebates, either as a final rule (without a new notice of proposed rulemaking, or NPRM), as an interim final rule (IFR), or as a guidance or policy statement (completely circumventing the rulemaking process). We examine each of these possibilities below.

II. Can HHS-OIG finalize the rebate rule without issuing a new NPRM?

Unlikely. Before a rule is proposed, withdrawn, finalized, or even challenged, an agency must comply with certain formalities. Virtually all agency rulemaking – including the now-withdrawn rebate rule – goes through a rulemaking process commonly referred to as notice-and-comment rulemaking, consisting of an NPRM, a public comment period, and a final rule.[3] When an agency engages in this type of rulemaking it must comply with the requirements of section 553 of the APA, which generally "sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts."[4] In addition, any rule, requirement, or statement of policy that "establishes or changes a substantive legal standard governing … the payment for services" in the Medicare program must go through an even more enhanced level of scrutiny by the public and agency review.[5]

HHS-OIG followed the APA's procedural standards for its 2019 rulemaking up to and including its withdrawal of the proposed rebate rule.[6] In particular, HHS-OIG set forth a reasonable and detailed notice of its proposal,[7] made reference to the legal authority under which the rule was proposed,[8] and gave interested persons the opportunity for public comment.[9] The agency then concluded the rulemaking process by issuing a final agency action based on these comments – a withdrawal of the proposed rule.[10,11]

That the rulemaking process concluded with a final agency action is important to the analysis here, as it clearly signals to the public that such a withdrawn policy could be resurrected *only* through a new rulemaking cycle consisting first of a new NPRM, given that the public is no longer on notice of the agency's intention to adopt the policies previously contained in the rebate rule.[12] This condition precedent to finalizing any new rebate policy would apply irrespective of whether the agency seeks to finalize the rule as proposed, or some variation of this policy. The definitional section of the APA makes clear a withdrawal is included in the term "agency action."[13] Case precedent also makes clear such agency action is *final* when it is "definitive" and has a "direct and immediate effect on the day-to-day business of the party challenging or subjected to the action."[14] Put differently, two conditions must be satisfied for an agency action to be deemed "final":

> "*First*, the action must mark the consummation of the agency's decisionmaking process . . . -- it must not be of a merely tentative or interlocutory nature. And *second*, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow."[15]

Given that courts have interpreted "finality" in a "flexible and pragmatic way,"[16] it would appear that the withdrawal meets this two-part test of a final agency action. First, as set forth in documentation made public by OMB, the withdrawal constituted the concluding action of the rulemaking process for the proposed rebate rule.[17] Statements made to the press at the time of the withdrawal by the agency similarly indicated that the Administration had considered comments (including the $177 billion price tag of the rule) and decided *not* to finalize the rule.[18,19]

Second, legal consequences clearly flowed from the agency's decision to withdraw the rule, keeping in place the longstanding anti-kickback statute treatment of rebates. In particular, given that the rebate rule would have changed the legal standard for rebates paid by pharmaceutical manufacturers to health plans and PBMs, the agency's decision *not* to adopt the rule had similarly significant legal consequences.

The formal withdrawal of a final agency action necessarily requires an agency to re-initiate the rulemaking process as the public no longer has notice of the agency action.[20] In this instance, HHS-OIG cannot support finalizing the policies set forth in the now-withdrawn proposed rebate rule, notwithstanding the other substantive legal and policy barriers to doing so,[21] because the public is no longer on "notice" that the policies are even being considered.[22] So, too, a reviewing court would likely find it <u>not</u> reasonable to anticipate that the agency would turn around and summarily finalize the rebate rule after previously withdrawing its proposal.[23]

III. Can HHS-OIG finalize the Rebate rule through an IFR?

Unlikely. The APA contains an exception to the general NPRM requirements when the agency "for *good cause* finds … that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."[24] One use of the good cause exception allows agencies to issue "interim final" rules or IFRs.[25] When issuing an IFR, an agency invokes good cause, issues a rule with a close-to-immediate (or even retroactive) effective date, and then holds a post-promulgation comment period. If the agency is persuaded by any of the comments and so chooses, the rule can be amended in light of those comments.

Yet, the legislative history and subsequent Court decisions have called into question the ability of a Federal agency to use the "good cause" exception to circumvent normal rulemaking procedures except in truly urgent situations. Courts are generally reluctant to uphold agencies' use of exceptions to the typical course of APA rulemaking:

> "It should be clear beyond contradiction or cavil that Congress expected, and the courts have held, that the various exceptions to the notice and comment provisions of section 553 will be *narrowly construed and only reluctantly countenanced*."[26]

Accordingly, courts have held that the exceptions are "an important safety valve to be used where delay would do real harm," and are not to be used "to circumvent the notice and comment requirements whenever an agency finds it inconvenient to follow them."[27] Congress' intentions with respect to the "good cause" exception are clear in the comments of the Senate committee responsible for the APA's drafting:

> "The exemption of situations of emergency or necessity is not an "escape clause" in the sense that any agency has discretion to disregard its terms or the facts. A true and supported or supportable finding of necessity or emergency must be made and published. "Impracticable" means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings."[28]

The APA itself sets out three exceptions that may constitute good cause: (1) when notice and comment is impracticable, (2) when it is unnecessary, or (3) when it is contrary to the public interest.[29] There is no evidence HHS-OIG faces "a situation in which due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings."[30] Nor can the unnecessary exception apply, given that HHS-OIG *already* took the position that a NPRM was necessary (by issuing a proposed rule). Similarly, promulgation of an IFR would not be justified as such a rule would not address an "emergency" situation affecting the public interest.[31] While drug pricing is certainly a pressing issue, there is no evidence that HHS-OIG confronts an "emergency" or situation in which, failing quick action by the agency, the public interest would be prejudiced.

Recent case precedent further supports this position. In *Dialysis Patient Citizens v. Burwell*, Civil Action No. 4:17-CV-16, 2017 U.S. Dist. LEXIS 10145 (E.D. Tex. 2017), patient groups and dialysis providers challenged an HHS IFR requiring, among other things, that dialysis providers disclose to patients that they are contributing to charities and to receive assurance from insurers that they will accept charitable premium assistance. In that case the court flatly rejected HHS' contentions that there was good cause to issue an IFR, and in particular its contention that emergency rulemaking was necessary to prevent further harm to dialysis patients.[32] The court reiterated the D.C. Circuit's position that NPRM should only be disposed of where "announcement of proposed rule would enable the sort of…manipulation the rule sought to prevent."[33]

IV. Does the current public health emergency (PHE) permit the agency to proceed through the IFR process?

There is nothing about the current PHE that changes our analysis. Agency use of the IFR process is of course more common during a public health emergency (PHE), as regulators attempt to work swiftly to address real and pressing crises. So, for example, on April 6, 2020 CMS published in the Federal Register the first of two IFRs designed to afford healthcare providers and suppliers significant regulatory flexibilities during the COVID-19 pandemic.[34] In issuing the IFR and bypassing the NPRM procedures, CMS noted, in part:

> "The nation is experiencing an emergency of unprecedented magnitude. Ensuring the health and safety of Medicare beneficiaries, Medicaid recipients, and healthcare workers is of primary importance. As this IFC directly supports that goal by offering healthcare professionals flexibilities in furnishing services while combatting the COVID–19 pandemic and ensuring that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare and Medicaid programs, it is critically important that we implement this IFC as quickly as possible.

> As we are in the midst of a PHE, we find *good cause* to waive notice and comment rulemaking as we believe it would be contrary to the public interest for us to undertake normal notice and comment rulemaking procedures."

Unlike the two IFRs issued by CMS, the HHS-OIG rebate policy bears no direct (or even indirect) relation to the current emergency situation. Given that the rebate policy pre-dates the current PHE and was previously issued as an NPRM, any attempt to bypass these procedures now would be highly suspect.

V. Could HHS-OIG finalize a rebate policy through an enforcement alert or other subregulatory guidance?

No. While some have speculated that HHS-OIG could simply change its enforcement position vis-à-vis rebates,[35] we believe that such an action would violate the APA as the policy constitutes a legislative rule.[36] HHS-OIG has already engaged in rulemaking on section 1128B(b) of the Social Security Act which establishes a statutory exception for discounts as part of the anti-kickback statute.[37] In the NPRM, HHS-OIG proposed changes to these regulatory requirements, explicitly acknowledging a regulatory change is *necessary* to effectuate this policy.

The APA distinguishes between "rules" that must be issued pursuant to notice-and-comment, (also referred to as "legislative rules") from those that do not require notice-and-comment, (known as "interpretive rules").[38] The APA does not further define "interpretive rules," but the Supreme Court has stated that a "critical feature" of an interpretive rule is that it is "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers."[39] Importantly, however, interpretive rules "do not have the force and effect of law…."[40] By contrast, "an agency action that sets forth legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements—is a legislative rule."[41]

Subjecting rebates paid by pharmaceutical manufacturers to health plans and PBMs to anti-kickback statute scrutiny very clearly constitutes a legislative rule subject to the APA's rulemaking procedures. This change in the treatment of rebates would impose a "legally binding obligation" on manufacturers, plan sponsors, and PBMs. Because such a requirement would have the "force and effect of law," HHS-OIG must adhere to the APA's procedural strictures in adopting a rebate policy.

VI. Could the White House direct HHS-OIG to implement the policy through an Executive Order?

While the White House is free to issue Executive Orders and direct Federal agencies to take specific actions, there is nothing the White House could include in an Executive Order that would alter this legal analysis. So, for example, while the White House could issue an Executive Order directing HHS-OIG to change its enforcement posture with respect to rebates, this order would carry the same (insufficient) legal weight as a guidance document issued by the agency itself.

[1] 84 Fed. Reg. 2,340 (February 6, 2019).

[2] *See* https://www.reginfo.gov/public/do/eoDetails?rrid=129208. *See also* https://www.regulations.gov/docket?D=HHSIG-2019-0001.

[3] See United States v. Fla. E. Coast Ry., 410 U.S. 224, 236–38 (1973) (holding that formal rulemaking is only required if the organic act states that rulemaking must take place "on the record").

[4] 5 U.S.C. § 553 (2012). *See* Franklin v. Massachusetts, 505 U. S. 788, 796 (1992).

[5] Social Security Act § 1871(a)(2); *see also Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019). We note that it is unclear the extent to which section 1871 would apply the HHS-OIG NPRM, as the rule involved matters with respect to Title XI rather than Title XVIII of the Social Security Act.

[6] We note that HHS did not publish a formal notice of the withdrawal in the Federal Register, nor did it provide a reasoned explanation for the withdrawal beyond the single press explanation. However, the withdrawal was noted at both regulations.gov and at OMB's website. In other cases, HHS has formally published a "Withdrawal of Proposed Rule" in the Federal Register, setting forth the basis for its action. *See* 82 Fed. Reg. 46,182 (October 4, 2017) (withdrawal of Part B Drug Payment Model Proposed Rule). *See* also 82 Fed. Reg. 46,181 (October 4, 2017 (withdrawal of Patient's Rights Proposed Rule).

[7] 5 U.S.C. § 553(b)(3).

[8] *Id*. at (b)(2).

[9] *Id. at* (c).

[10] Pursuant to the OIRA: "Agencies may also report 'Completed Action', which are rulemakings that are being Withdrawn or ending their lifecycle with a regulatory action that completes the rulemaking." *See* https://www.reginfo.gov/public/jsp/eAgenda/UA_About.myjsp.

[11] We note the D.C. Circuit Court of Appeals has gone further than recognizing the withdrawal of a rule as a final agency action. In, *Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031 (D.C. Cir. 1979), the D.C. circuit held that withdrawn discretionary proposed rules are nonetheless reviewable. *See also Int'l Union, United Mine Workers of Am. v. United States DOL,* 360 U.S. App. D.C. 113, 116, 358 F.3d 40, 43 (2004) *("*In applying this standard, we give more deference to an agency's decision to withdraw a proposed rule than we give to its decision to promulgate a new rule or to rescind an existing one..")

[12] Such a process would ensure "agency accountability," *Bowen v. American Hospital Assn*., 476 U. S. 610, 643 (1986), "by ensuring that parties and the public can respond fully and in a timely manner to an agency's exercise of authority." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal*., 140 S. Ct. 1891 (2020).

[13] The term "agency action" is defined broadly as: "includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof*, or failure to act*." 5 U.S.C. § 551. *See Animal Legal Def. Fund v. Veneman*, 469 F.3d 826, 837 (9th Cir. 2006). With respect to Medicare regulations, section 1871 of the Social Security Act generally prescribes notice-and-comment rulemaking for any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits…"

[14] Fed. Trade Comm'n v. Standard Oil Co., 449 U.S. 232, 239, 101 S. Ct. 488, 66 L. Ed. 2d 416 (1980)(internal quotations omitted).

[15] *Bennett v. Spear*, 520 U.S. 154, 169, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997) (emphasis added).

[16] *Her Majesty the Queen ex rel. Ontario v. Envtl. Prot. Agency*, 286 U.S. App. D.C. 171, 912 F.2d 1525, 1531 (D.C. Cir. 1990).

[17] https://www.reginfo.gov/public/do/eoDetails?rrid=129208.

[18] *See* Rachel Cohrs, "White House Kills Rebate Rule Because It Would Raise Premiums," Inside Health Policy (July 11, 2019).

[19] A budget projection prepared by the non-partisan Congressional Budget Office (CBO) in May 2019 found that implementing the rule would "increase federal spending by about $177 billion over the 2020–2029 period."

[20] 5 U.S.C. § 553(b).

[21] PCMA's comments on the proposed rebate rule set forth a detailed list of regulatory and policy barriers to changing the treatment of rebates. *See* https://www.pcmanet.org/pcma-submits-comments-on-the-administrations-proposed-rule-revising-the-safe-harbors-for-prescription-drug-rebates.

[22] *See Anne Arundel County v. EPA*, 963 F.2d 412, 417-18 (D.C. Cir. 1992) (holding that the EPA did not provide adequate notice because the County "had no reason to anticipate, on the basis of the proposed rule alone, that the [EPA would finalize its determination])

[23] *See id*. at 418; *see also* 5 U.S.C. § 553(b) (requiring that "rule making" start with a general notice of proposed rule making).

[24] *See also* Social Security Act § 1871(b)(2)(C).

[25] "Counting Regulations: An Overview of Rulemaking, Types of Federal Regulations, and Pages in the Federal Register," Congressional Research Services (Updated September 3, 2019).

[26] S.Doc. No. 248, 79th Cong., 2d Sess. 19, 199, 258 (1946); *American Bus [Association v. U.S*., 201 U.S. App. D.C. 66, 627 F.3d 525 (D.C. Cir. 1980)]; *Humana of South Carolina v. Califano*, 191 U.S. App. D.C. 368, 590 F.2d 1070, 1082 (D.C.Cir.1978); *National Nutritional Foods Association v. Kennedy*, 572 F.2d 377, 384 (2nd Cir. 1978); *National Wildlife Federation v. Snow*, 561 F.2d 227, 232 (D.C.Cir.1976).166

[27] *U.S. Steel Corp. v. United States Environmental Protection Agency*, 595 F.2d 207, 214 (5th Cir. 1979) (Emphasis added); See Pennsylvania v. Trump, No. 17-4540, 2017 U.S. Dist. LEXIS 206380, at *40 (E.D. Pa. Dec. 15, 2017) (rejecting the agency's argument supporting an IFR that no notice-and-comment rulemaking was needed because the agency received significant comments on the same topic in previous rounds of rulemaking)

[28] S. Doc. No. 248, 79th Cong., 2d Sess. 200 (1946).

[29] 5 U.S.C. § 553. *See also* Dialysis *Patient Citizens v. Burwell*, Civil Action No. 4:17-CV-16, 2017 U.S. Dist. LEXIS 10145 (E.D. Tex. 2017).

[30] *Id.*

[31] See, e.g., *American Fed'n of Gov't Employees v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981).

[32] *Dialysis Patient Citizens*, at 10.

[33] *Id*. at 10 (citing *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 775 (D.C. Cir. 2001) (internal quotations omitted).

[34] 85 Fed. Reg. 19,230 (April 6, 2020).

[35] We note that the OIG Compliance Program Guidance for Pharmaceutical Manufacturers notes, in part, ""[a]ny rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM's customers' purchases potentially implicate the anti-kickback statute."

[36] Congress has made clear that amendments to the regulatory safe harbors constitute legislative rules. *See* section 14(a) of Public Law 100-93, the Medicare and Medicaid Patient and Program Protection Act of 1987 ("The Secretary of Health and Human Services, in consultation with the Attorney General, not later than 1 year after the date of the enactment of this Act shall publish proposed regulations, and not later than 2 years after the date of the enactment of this Act shall promulgate final regulations, specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) of the Social Security Act and shall not serve as the basis for an exclusion under section 1128(b)(7) of such Act. ny practices specified in regulations pursuant to the preceding sentence shall be in addition to the practices.

[37] In regulation, CMS has established an exception for discount, including rebates, at 42 C.F.R. § 1001.952(h).

[38] *See* 5 U.S.C. § 553(b)(A) (stating that the notice-and-comment process "does not apply" to "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.").

[39] *See Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (internal citations omitted).

[40] *Id*.

[41] See *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251-52 (D.C. Cir. 2014).