UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, Plaintiff, v. XAVIER BECERRA, in his official capacity as United States Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services; and CENTERS FOR MEDICARE & MEDICAID SERVICES, Defendants.	Case No. 1:21-cv-01395 (CJN)

CONSENT MOTION FOR LEAVE TO FILE BRIEF OF MCKESSON CORPORATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA

Pursuant to Local Rule 7(o), McKesson Corporation ("McKesson") respectfully moves for leave to file a brief as *amicus curia*e in support of Plaintiff Pharmaceutical Research and Manufacturers of America ("PhRMA"). The Corporate Disclosure is attached as Attachment A. A proposed order is attached as Attachment B. A copy of the proposed brief is attached hereto as Attachment C.

Pursuant to Local Civil Rule 7(o), counsel for McKesson contacted counsel for the parties concerning the proposed brief. Plaintiff and Defendants through their counsel consent to McKesson's participation as *amicus curiae*.

This Court's local rules do not specify the time for filing of *amicus* briefs, but this brief is being filed within the deadline provided in the relevant appellate rule governing *amicus* briefs.

See Fed. R. App. P. 29(a)(6) ("An amicus curiae must file its brief, accompanied by a motion for filing when necessary, no later than 7 days after the principal brief of the party being supported is filed.").

McKesson is one of the world's oldest and largest healthcare companies. We provide vital medicines, medical supplies, healthcare, care-management services, and health-information-technology solutions that touch the lives of over 100 million patients. We serve patients and support providers in healthcare settings that include more than 50,000 retail pharmacies, 5,000 hospitals, 200,000 physician offices, nearly 12,000 long-term-care facilities, and 2,400 home-care agencies. In everything we do, our mission is to improve care in every setting—one product, one partner, one patient at a time. A core pillar of that mission is to improve affordability and access to prescription medications.

At McKesson, we are driven by the core belief that *the patient comes first*. Therefore, we are deeply concerned about the patient harm that the "Accumulator Rule" will cause. Dkt. No. 1, ¶ 9; *see* 85 Fed. Reg. 87,000 (Dec. 31, 2020). Those concerns are informed by our significant, real-world experience operating across the entire electronic prescription claims-processing infrastructure. We operate nearly all the entities that CMS identified as essential to the Accumulator Rule's viability—switches, brokers of patient-assistance programs, pharmacies, and pharmacy-technology solutions. *See*, *e.g.*, *id.* at 87,053 (col. c), 87,054 (col. b).

Given our extensive and pertinent experience and our deep commitment to patient access and adherence to medications, McKesson is in a unique position to help explain why CMS' hopes are not consistent with how the electronic prescription claims-processing infrastructure actually works or could work by January 1, 2023—the effective date of the Accumulator Rule. McKesson is also in a unique position to explain that the Accumulator Rule will hurt the very patients that

CMS seeks to help. For these reasons, the accompanying *amicus* brief will assist the Court by placing the CMS Accumulator Rule in perspective. The brief will also assist the Court in fashioning a remedy by discussing the applicability and limitations of the Accumulator Rule in greater detail than the Parties' briefs.

District courts have "inherent authority" to grant participation by an *amicus curiae*. *Youming Jin v. Ministry of State Sec.*, 557 F. Supp. 2d 131, 136 (D.D.C. 2008). In determining whether to grant leave to participate as an *amicus curiae*, this Court has "broad discretion." *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 519 F. Supp. 2d 89, 93 (D.D.C. 2007). Participation by an *amicus curiae* is generally allowed when "the information offered is timely and useful." *Ellsworth Assocs. v. United States*, 917 F. Supp. 841, 846 (D.D.C. 1996).

Thus, the "filing of an *amicus* brief should be permitted if it will assist the judge 'by presenting ideas, arguments, theories, insights, facts or data that are not to be found in the parties' briefs.'" *Northern Mariana Islands v. United States*, No. 08-1572, 2009 WL 596986, at *1 (D.D.C. Mar. 6, 2009) (quoting *Voices for Choices v. Ill. Bell Tel. Co.*, 339 F.3d 542, 545 (7th Cir. 2003)). Courts generally permit third parties to participate as *amici curiae* when they have "relevant expertise and a stated concern for the issues at stake in [the] case." *District of Columbia v. Potomac Elec. Power Co.*, 826 F. Supp. 2d 227, 237 (D.D.C. 2011).

The proposed attached *amicus* brief satisfies these standards. It presents operational information and related arguments within McKesson's unique expertise that is critical to the case.

WHEREFORE, leave to file the attached *amicus* brief should be granted.

Dated: January 4, 2021

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Attachment A:

Corporate Disclosure of McKesson Corporation

Pharmaceutical Research and Manufacturers of America v. Becerra et al.,

No. 1:21-cv-01395-CJN

CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Rule 7(o)(5) of this Court and Rules 26.1 and 29(a)(4)(A) of the Federal Rules of Appellate Procedure, Movant and proposed *amicus curiae* McKesson Corporation ("McKesson") has no parent company, and no publicly held company holds more than a ten percent interest in McKesson.

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Attachment B:

PROPOSED ORDER GRANTING MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFF PHARMACEUTICAL RESEARCH AND MANUFACTURER'S OF AMERICA'S MOTION FOR SUMMARY JUDGMENT

Pharmaceutical Research and Manufacturers of America v. Becerra et al.,

No. 1:21-cv-01395-CJN

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as United States Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services; and CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants.

Case No. 1:21-cv-01395 (CJN)

[PROPOSED ORDER]

As set forth in the accompanying Memorandum Opinion, it is hereby ORDERED that McKesson's Motion for Leave to File Brief as *Amicus Curiae* in Support of Plaintiff Pharmaceutical Research and Manufacturers of America's Motion for Summary Judgment, Dkt. No. ___, is GRANTED.

IT IS SO ORDERED.

DATED: _____

_____

CARL J. NICHOLS
United States District Judge

Attachment C:

***Amicus Curiae* Brief of McKesson Corporation in Support of Pharmaceutical Research and Manufacturers of America's Motion for Summary Judgment**

Amicus Curiae Brief of McKesson Corporation to be filed following
Court order pursuant to Consent Motion for Leave to File,
Pharmaceutical Research and Manufacturers of America v. Becerra et al.,
No. 1:21-cv-01395-CJN

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,

Plaintiff,

v.

XAVIER BECERRA, in his official capacity as United States Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services; and CENTERS FOR MEDICARE & MEDICAID SERVICES,

Defendants.

Case No. 1:21-cv-01395 (CJN)

***AMICUS CURIAE* BRIEF OF MCKESSON CORPORATION IN SUPPORT OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA'S MOTION FOR SUMMARY JUDGMENT**

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STATEMENT OF IDENTITY AND INTERESTS OF *AMICUS CURIAE* AND AUTHORITY TO FILE

Amicus McKesson Corporation ("McKesson") is one of the world's oldest and largest healthcare companies. We provide vital medicines, medical supplies, healthcare, care-management services, and health-information-technology solutions that touch the lives of over 100 million patients. We serve patients and support providers in healthcare settings that include more than 50,000 retail pharmacies, 5,000 hospitals, 200,000 physician offices, nearly 12,000 long-term-care facilities, and 2,400 home-care agencies. In everything we do, our mission is to improve care in every setting—one product, one partner, one patient at a time. A core pillar of that mission is to improve affordability and access to prescription medications. The rule at issue in this case, issued by the Centers for Medicare & Medicaid Services ("CMS"), 85 Fed. Reg. 87,000 (Dec. 31, 2020) ("Accumulator Rule"), jeopardizes both affordability and access.

For far too many patients, the barrier to medication access and adherence is affordability. That is true even for patients with insurance. High deductibles, coinsurance, and other cost-sharing obligations often mean that prescription drugs are too expensive. As a result, many do not initiate or adhere to their therapies. That lack of access and adherence can be the difference between life and death. And to make matters worse, that financial barrier disparately harms our minority populations and those who require costly specialty drugs for rare, life-threatening, or complex chronic conditions.

To help patients start and stay on their medications, pharmaceutical manufacturers provide billions of dollars each year to assist patients with high cost-sharing obligations under their health

plans. Such assistance can take the form of coupons, copay cards, rebates, or automatically applied electronic savings at the point of sale.[1]

In response to patient-assistance programs, some health plans "are being instructed or encouraged" by their pharmacy benefit managers ("PBMs"), which administer prescription-drug benefits for plans, to not count such patient assistance toward patients' deductibles and out-of-pocket maximums.[2] CMS refers to this practice as "PBM accumulator programs." *E.g.*, 85 Fed. Reg. at 87,052 (col. a).[3]

PBM accumulator programs harm patients and financially benefit plans. CMS explained that PBM accumulator programs "result[] in the health plan delaying the application of its plan benefit to the patient to the *detriment of the patient* or consumer, thus generating *savings for the plan*."[4] CMS also recognized that this problem is getting worse as PBM accumulator programs "are increasing in scope and number." *Id*. at 87,052 (col. a); *see supra* n.3. And in response, more and more states have banned PBM accumulator programs.

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[1] CMS refers to that manufacturer-sponsored assistance in several ways, including as "manufacturer assistance programs" and "patient assistance programs." *See, e.g.*, 85 Fed. Reg. at 87,051 (col. c) and 87,054 (col. b) (Dec. 31, 2020). For simplicity and consistency, this brief refers to such assistance as "patient-assistance programs" or "patient assistance."

[2] *Id*. at 87,048 (cols. b-c).

[3] *See* Adam Fein, *Copay Accumulators: Costly Consequences of a New Cost-Shifting Pharmacy Benefit*, January 3, 2018, *available at* www.drugchannels.net/2018/01/copay-accumulators-costly-consequences.html (explaining that, under PBM accumulator programs, "the manufacturer's payments no longer count toward a patient's deductible or out-of-pocket maximum"). Dr. Fein is a respected industry expert on, *inter alia*, PBM accumulator programs. CMS relied on Dr. Fein for his expert insights. *See id.* at 87,099 n.147 (col. b).

[4] 85 Fed. Reg. at 87,048 (col. c) (emphases added); *see also id*. at 87,049 (col. c) ("It is our understanding that PBM Accumulator Programs shift costs back to the patient *prematurely* by not applying the full value of the manufacturer-sponsored assistance to a patient's health plan deductible." (Emphasis added)); 87,099 (col. b) (explaining that PBM accumulator programs "potentially imped[e] [patients'] ability to obtain their medications").

We agree with CMS that PBM accumulator programs harm patients. We agree that patient-assistance programs provide patients with "access to much needed medication which will in turn have positive outcomes and also improve adherence." *Id*. at 87,050 (col. b). And we agree that those benefits to the patient would increase if plans do not exclude patient assistance from patients' deductibles and out-of-pocket maximums. *Id*. But we respectfully disagree with CMS' counter-productive and unworkable approach to preserving patient assistance while trying to ensure that PBMs and plans apply that assistance toward their patients' deductibles and out-of-pocket maximums.

In amending the regulations, CMS hoped to mitigate the patient harm caused by PBM accumulator programs by requiring manufacturers to "ensure" that plans and PBMs apply the full value of the patient assistance to deductibles and out-of-pocket maximums. *Cf. id.* at 87,055 (col. a) ("Satisfying this regulatory requirement is the responsibility of the manufacturer[.]"). The Accumulator Rule imposes no obligations on plans and their PBMs even though they are the only ones who decide whether to apply a PBM accumulator program. They are the only ones who know, for certain, when a PBM accumulator program applies. They are the only ones who can "ensure" that patient assistance counts toward deductibles and out-of-pocket maximums. And they are the ones who financially benefit from those programs—to the "detriment" of patients. *Id*. at 87,048 (col. c); *see also id.* at 87,099 (col. b) (CMS acknowledging that "it seems clear that as the value of these patient assistance programs to *patients* continue to *erode*, the economic benefits to *health plans increase*, given that the health plan's spending on drugs for a patient decreases." (Emphases added)).

CMS received numerous comments, including from McKesson, explaining that manufacturers have no way to ensure that plans and PBMs apply patient assistance to deductibles and out-

of-pocket maximums—for every patient and every drug in every instance. *Id*. at 87,054 (col. b). We also warned that the severe financial implications of CMS' proposed amendments would lead to the very consequence that CMS hopes to avoid—forcing manufacturers to cease or reduce patient-assistance programs. *Id*. at 87,054 (col. b).

But CMS dismissed those concerns based on little more than hope: "We are *hopeful* that manufacturers will not eliminate these programs under this policy, but [1] will work with their current partners to reform or restructure the programs as has been stated in public documents, or [2] find another mechanism to provide the assistance." *Id*. at 87,099 (col. c).

The Accumulator Rule rests on CMS' hopes that manufacturers can somehow operationalize at least one of those options by January 1, 2023—the effective date of the rule. *See id*. at 87,056 (col. b). As we explain below, those hopes are not realistic and the Rule is not workable. And even if they were workable, the Accumulator Rule would still harm patient access and adherence to essential medications.

At McKesson, we are driven by the core belief that *the patient comes first*. Therefore, we are deeply concerned about the patient harm that the Accumulator Rule will cause. Those concerns are informed by our significant, real-world experience operating across the entire electronic prescription claims-processing infrastructure. We operate nearly all the entities that CMS identified as essential to the Accumulator Rule's viability—switches, brokers of patient-assistance programs, pharmacies, and pharmacy-technology solutions. *See, e.g.*, *id*. at 87,053 (col. c), 87,054 (col. b).

For example, McKesson's RelayHealth Pharmacy Solutions ("RelayHealth") is the leading and most reliable pharmacy switch network in the United States. It connects retail pharmacies to key stakeholders across the healthcare spectrum. RelayHealth processes more than 18 billion

prescription transactions annually, routing pharmacy claims among over 50,000 pharmacies, PBMs, and payors—including healthcare plans and patient-assistance programs.

When it comes to brokers of patient-assistance programs, McKesson's LoyaltyScript and eVoucherRx help millions of patients afford their medications each year. LoyaltyScript and eVoucherRx provide patient assistance for branded drugs that, for the most part, do not have clinically appropriate generic equivalents. LoyaltyScript and eVoucherRx apply discounts at the point of sale—for example, when patients fill their prescriptions at the pharmacy counter. *Cf. id*. at 87,053 (col. c).

When it comes to pharmacies, our Health Mart franchise is the fourth largest pharmacy network in the United States with more than 4,900 independent pharmacies. McKesson's Biologics is our independent specialty pharmacy, specializing in medications for cancer and rare, life-threatening, and complex chronic diseases. Specialty drugs are often among the most expensive and carry a high-cost burden for patients. So Biologics helps patients find coverage options to make their specialty medications affordable, including through identifying and facilitating applications to patient-assistance programs. That experience is especially pertinent because PBM accumulator programs most frequently target specialty drugs to take advantage of patient-assistance programs and generate greater savings for plans. *See* Adam Fein, *Copay Accumulators: Costly Consequences of a New Cost-Shifting Pharmacy Benefit*, January 3, 2018, *available at* www.drugchannels.net/2018/01/copay-accumulators-costly-consequences.html (explaining that "[a]ccumulator programs target specialty drugs" and that the programs will save "big money" for plan sponsors).

When it comes to the technological standards that enable electronic prescription claims processing, McKesson Pharmacy Systems develops and implements pharmacy software-

management systems. Among other things, those systems communicate and process information about patient medications, claims for reimbursement, and payment.

Given our extensive and pertinent experience and our deep commitment to patient access and adherence to medications, McKesson is in a unique position to help explain why CMS' hopes are not consistent with how the electronic prescription claims-processing infrastructure actually works or could work by January 1, 2023. McKesson is also in a unique position to explain that the Accumulator Rule will hurt the very patients that CMS seeks to help.

SUMMARY OF ARGUMENT

The Accumulator Rule cannot be operationalized—and certainly not by January 1, 2023. And even in the best-case scenario envisioned by CMS, the Accumulator Rule would still harm patients. Numerous commentors, including McKesson, voiced those concerns. CMS' responses were neither reasoned nor rational, as required under section 553(c) of the Administrative Procedure Act.

I. *The Accumulator Rule is unworkable*. The rule requires manufacturers to "ensure" that plans and their PBMs apply the full value of patient assistance to deductibles and out-of-pocket maximums. Manufacturers and other industry operators warned that they have no way to do so without cooperation from PBMs. CMS agreed, conceding that "PBMs will *have* to work with the manufacturers and their switches and brokers to assure that the manufacturers have the information necessary to comply with this regulatory requirement." 85 Fed. Reg. at 87,054 (col. c) (emphasis added); *see also id.* at 87,054 (col. b).

But instead of mandating or even facilitating that critical information sharing, CMS did the exact opposite: CMS assured PBMs that they do not have to share any information with manufacturers that "they *believe* to be propriety." *Id*. at 87,504 (col. b) (emphasis added). By doing so,

CMS severely restricted—if not foreclosed—manufacturers' ability to comply with the Accumulator Rule.

And that is just the beginning of CMS' flawed approach. Even if manufacturers could convince PBMs to share the information that CMS told them that they did not need to share, the electronic prescription claims-processing infrastructure cannot accommodate the timely transmission of that information. Changing that infrastructure would require, among other things, changing the underlying data standards. And those changes would require rulemaking, which CMS did not appreciate. And after that, implementing such changes would require several years—well beyond January 1, 2023. Such revisions would require software development, system upgrades, workflow changes and training, and widespread adoption among the tens of thousands of businesses—both big and small—that are connected to drug prescribing. Such changes would impose significant burdens.

CMS also suggested that manufacturers could somehow create "coverage criteria for the use of their patient assistance programs" that could "ensure" that the only eligible patients are those with PBMs and plans that apply patient assistance toward deductibles and out-of-pocket maximums. *Id*. at 87,055 (col. b). Tellingly, CMS did not identify such criteria. That is not surprising. Although the PBMs and plans have such data, CMS made clear that they have no obligation to share it with manufacturers. *See infra* at 13-14. With the historical data that is available to them, manufacturers—at most —can make only an educated *guess* as to whether a PBM accumulator program might apply. And even then, manufacturers cannot anticipate which plans might launch new, or modify existing, PBM accumulator programs until after such changes have been implemented and those changes have affected claims that had already received patient assistance.

A guess—even an educated one—may not be enough. The Accumulator Rule seemingly requires certainty. *See, e.g.*, *id*. at 87,049, 87,102-3 (using "ensure" to describe manufacturer obligations). And CMS closed the only door to that possibility.

Even if manufacturers could accurately identify whether a PBM accumulator program applies to a particular prescription transaction, the result would not be more PBMs and plans counting patient assistance toward deductibles and out-of-pocket maximums. The result would be less patient assistance. When faced with the choice between (1) offering patient assistance and risking devastating financial consequences if a PBM accumulator program applies, or (2) not offering patient assistance at all, many manufacturers will be forced to reduce or eliminate their patient-assistance programs. As a result, fewer patients will be able to afford their medications.

Perhaps realizing those critical flaws, CMS proposed an alternative approach in response to commentors' concerns. According to CMS, manufacturers should consider operating patient-assistance programs entirely outside of the electronic prescription claims-processing infrastructure, which currently handles almost all prescription-drug dispensing. Under that approach, patients would pay first and then seek patient assistance from the manufacturer. Because that process occurs "outside of the electronic claims process," CMS asserted that "the pharmacy and PBM will be unable to identify that the patient used manufacturer-sponsored assistance." *Id*. at 87,053. Therefore, CMS concluded that the alternative approach would "guarantee" that PBMs and plans will count patient assistance toward deductibles and out-of-pocket maximums. *Id*. at 87,053 (col. c). That response is also not reasoned.

First, insured patients turn to patient-assistance programs *because* they cannot afford the cost-sharing obligations for their prescription medications. For many patients, the cost sharing could be thousands of dollars. *Id*. at 87,099 (col. b). CMS' alternative would basically require

those patients to front the cash that they cannot afford then wait for reimbursement. Transforming point-of-sale savings to after-the-sale reimbursements will result in fewer patients accessing and adhering to their prescription drugs. And that will increase hospitalizations and death.

Second, a plan can simply respond to CMS' suggestion by requiring its patients to report any patient assistance that they receive. Given that obvious response, how can CMS say that its alternative approach can "guarantee" that PBMs and plans will apply the patient assistance to deductibles and out-of-pocket maximums? To ask is to answer. And CMS neither asked nor answered.

Third, CMS' alternative undermines its own efforts—working with and encouraging many of the same patient-assistance stakeholders—to modify and operate patient-assistance programs *within* "the electronic claims process" to prevent Medicare Part D beneficiaries from receiving patient assistance and thus avoiding a potential violation of the federal Anti-kickback Statute. Here, CMS asked stakeholders to operate *outside* of that process to avoid a potential violation of the Accumulator Rule. So which is it—provide patient assistance *within* or *outside* of the electronic claims process? Again, CMS neither asked nor answered.

II. *The Accumulator Rule will harm patients*. Limiting patient-assistance programs will reduce access to critical prescription drugs, especially for our most vulnerable patient populations. Those include minorities and patients suffering from rare, life-threatening, or complex chronic conditions. Such conditions often require very expensive specialty medications. The cost-sharing would be a financial struggle—if not an insurmountable barrier—even for those patients with significant savings.

The Accumulator Rule will likely force many manufacturers to cut back or cease their patient-assistance programs. Thus, the rule is a prohibited regulation that creates "unreasonable

barriers to the ability of individuals to obtain appropriate medical care." Affordable Care Act § 1554(1).

The Accumulator Rule should be vacated.

ARGUMENT

I. There Is No Way for Manufacturers to "Ensure" or "Guarantee" that PBMs and Their Plans Count Patient Assistance Toward Deductibles and Out-of-Pocket Maximums

Under the Administrative Procedure Act, 5 U.S.C. § 553(c), an agency must "demonstrate the rationality of its decision-making process by responding to those comments that are relevant and significant." *Grand Canyon Air Tour Coalition v. FAA*, 154 F.3d 455, 468 (D.C. Cir. 1998). An agency "must respond in a reasoned manner" to comments that "raise significant problems." *Huntco Pawn Holdings, LLC v. U.S. Dep't of Defense*, 240 F. Supp. 3d 206, 219 (D.D.C. 2016) (citation and internal quotation marks omitted).

McKesson, along with others that CMS identified as essential to the Accumulator Rule's real-world viability, provided relevant and significant comments explaining the existential problems with the rule. We explained that the rule cannot be operationalized because manufacturers have no visibility or control over PBM accumulator programs. And we explained that the rule will harm patients.

CMS did not respond in a reasoned or rational manner. Instead, CMS responded with unsupported "hope" of "possible" solutions that are anything but. And even in CMS' best-case scenario, patients would still be harmed without any justifiable benefit.

A. Manufacturers Have No Way to Know When a PBM Accumulator Program Applies

To better understand why the Accumulator Rule cannot be operationalized as CMS hopes, it is helpful to first visualize how information flows across the electronic prescription claims-

processing infrastructure and how patient-assistance programs and PBM accumulator programs fit into that infrastructure.

Almost all prescriptions are electronically processed. *See* 85 Fed. Reg. at 87,053 (col. c). When a commercially insured patient brings a prescription to a pharmacy, the pharmacy electronically submits a claim for that drug to the PBM that handles such claims on behalf of the patient's plan. That is known as the primary claim. Patients with coverage will have a bank identification number ("BIN") and processor control number ("PCN") on their prescription-coverage card. Along with other information about the patient and the prescription, the pharmacy sends that BIN and PCN to the pharmacy's contracted switch. The switch uses the BIN and PCN to send the claim to the correct PBM. *Id*. at 87,053 (col. c).

When the PBM receives the primary claim, it determines, among other things, whether the patient and drug are covered under the health plan, the amount the plan will pay the pharmacy, and the amount the pharmacy should collect from the patient in the form of unmet deductible, co-payment, or co-insurance. The PBM returns this information to the pharmacy via the switch.

When the pharmacy receives the information and if the patient has secondary coverage, the pharmacy will initiate a secondary claim. Secondary coverage could be secondary insurance or a patient-assistance program. Secondary coverage will have a separate BIN and PCN. The pharmacy sends the secondary claim to a switch to route the claim to the PBM for the secondary insurance or to the broker administering the patient-assistance program.

The secondary payor (through its PBM or broker) determines how much of the patient's out-of-pocket cost from the primary claim will be covered. The PBM or broker returns this information to the pharmacy via the switch. The pharmacy then collects the remaining out-of-pocket cost (if any) from the patient and dispenses the drug. This flow of information occurs in seconds

before the patient arrives at the pharmacy or while the patient is at the pharmacy counter. The diagram at Exhibit 1 illustrates this process.

Pharmacies can determine whether a secondary insurance or a patient-assistance program paid the secondary claim. That is because there is a limited number of patient-assistance-program brokers in the market. And they use a limited set of BIN, PCN, and group-number combinations. But a particular pharmacy may not have a contractual obligation to report such information to a PBM.

With PBM accumulator programs, the primary insurance initially applies the full value of the patient assistance to the deductible and out-of-pocket maximum. That is because the primary insurance does not know if there is a secondary payor—let alone whether the potential secondary payor would be insurance or a patient-assistance program. If the pharmacy detects a patient-assistance program on the secondary claim and reports it to the primary payor's PBM, the primary insurance backs out that assistance from the patient's deductible and out-of-pocket maximum. That "backing out" can occur days, weeks, or months after the patient had picked up the prescription. Until that occurs, a patient's claims data appear as if there were no PBM accumulator program. During that period, patient-assistance programs may inadvertently help patients afford their medications, believing that there is no PBM accumulator program. The diagram at Exhibit 2 illustrates this process.

The information flow across the electronic prescription claims-processing infrastructure occurs via uniform claims data fields established by the National Council for Prescription Drug Programs ("NCPDP"). There is no data field to convey whether a PBM accumulator program applies to a particular transaction. And that data field cannot be added via a simple or quick fix.

As explained in greater detail below, given the limitations of that infrastructure, the Accumulator Rule cannot be operationalized. And even if it could be operationalized, it certainly could not be done by January 1, 2023.

1. CMS Expressly Permitted PBMs to Withhold the Very Information that CMS Stressed that Manufacturers Must Obtain from PBMs to Comply with the Accumulator Rule

During the rule-making process, CMS received numerous comments from those with extensive, real-world, operational experience, including McKesson. Throughout the preamble, CMS repeatedly stressed that the cooperation of those commentors is essential to manufacturers' ability to comply with the Accumulator Rule. Those commentors warned that manufacturers and their contractors have no "knowledge, visibility, or control" over whether a PBM accumulator program applies to a particular patient and drug. 85 Fed. Reg. at 87,053 (col. b). And without that information, commentors explained that manufacturers cannot comply with the Accumulator Rule.

CMS agreed that the Accumulator Rule "requires that the manufacturer be aware of this action taken by the PBM so that the manufacturer complies with the regulations." *Id*. at 87,051 (col. c). CMS also repeatedly emphasized that PBMs must provide manufacturers with enough information for manufacturers to determine whether a PBM accumulator program applies to a particular transaction:

- "We believe that *the PBMs will have to work with the manufacturers* and their switches and brokers to assure that the manufacturers have the information necessary to comply with this regulation requirement." *Id*. at 87,054 (col. c) (emphasis added).

- "We believe and have the expectation that *PBMs will work with manufacturers* to provide this information to the manufacturers to help them ensure that their assistance is passed through." *Id*. at 87,053 (col. c) (emphasis added).

- "The mechanism by which the manufacturer determines whether or not the full value of its assistance is provided to the patient will be determined by the manufacturer, working with its brokers, *the PBMs*, and plans." *Id*. at 87,054 (col. b) (emphasis added).

- "As we have stated, it is our expectation that manufacturers will work with the various components of the electronic prescription process system, such as *PBMs*, switches, and brokers, among others, to obtain the information they need to accurately determine the pricing benchmarks they need to report each quarter." *Id*. at 87,055 (col. a) (emphasis added).

CMS made abundantly clear that, without PBMs sharing enough information, manufacturers cannot comply with the Accumulator Rule.

Although PBM information sharing is essential, CMS refused to require such sharing. When one PBM and plan commentor opposed sharing "additional information to manufacturers beyond what they already provide," CMS acquiesced. *Id*. at 87,054 (col. a). CMS clarified, "This rule does not require PBMs and health plans disclose or disseminate information they *believe* to be proprietary to manufacturers." *Id*. at 87,054 (col. a-b) (emphasis added). In other words, the Accumulator Rule does not require that withheld information *be* proprietary. A PBM's or a plan's *belief* that information is propriety suffices. And manufactures have no way to challenge that belief under the Accumulator Rule.

After repeatedly emphasizing that manufacturers will need information from PBMs to comply with the Accumulator Rule, CMS assured PBMs (and even their plans) that they can withhold that very information. CMS effectively made compliance with its own rule impossible. That is not a reasoned response or a rational decision-making process under the Administrative Procedure Act.[5]

[5] The information already available to manufacturers is not enough for manufacturers to "ensure" that PBMs or plans will count patient assistance toward deductibles and out-of-pocket maximums. As the PBM and plan commentor conceded, some plans and PBMs do not disclose "when direct manufacturer support will not count towards enrollee cost sharing limits[,]" and CMS has not mandated such disclosure. CVS Health Comment Letter at 5 (July 20, 2020), available as comment to CMS-2842-P at regulations.gov as document CMS-2020-0072-25599.

2. The Accumulator Rule Cannot Be Operationalized by January 1, 2023

Even if PBMs and plans were willing to share the necessary information, the Accumulator Rule still could not be operationalized. That is because there is no mechanism to allow the timely movement of that information.

CMS acknowledged, "Almost all prescriptions are electronically processed" and transmitted via the "electronic prescription claims processing infrastructure." *Id*. at 87,053 (col. c). But CMS failed to address the critical fact that information moves across that infrastructure through the standard Health Insurance Portability and Accountability Act transaction data set for prescription transactions. Those standards are known as the NCPDP Telecommunication Standards Implementation Guide. *See* 45 C.F.R. § 162.1102(b)(2). There is no field in the NCPDP data set to report whether a plan uses a PBM accumulator program for a given prescription transaction. Thus, there is no way for a manufacturer or a manufacturer's broker to receive timely information confirming whether a PBM accumulator program applies.

CMS apparently never considered that limitation. Nor did CMS consider that any modification to the NCPDP data set, once developed and ratified by the standards organization and relevant stakeholders, could only be implemented through a separate Department of Health and Human Services (HHS) rulemaking. *See* Social Security Act § 1173(a). And such rulemaking would be subject to a new Regulatory Flexibility Act analysis focusing on the added cost to small entities, such as independent community pharmacies. *See* 5 U.S.C. § 601 *et seq.*; *see also* 85 Fed. Reg. at 87,100 (col. b) (CMS failing to consider those issues when concluding that this rule will not have a "major regulatory impact").

Implementing a new NCPDP standard is costly and burdensome. Vendors must develop, test, and roll out the software that will support the new standard. Pharmacies, switches, brokers, and others connected to the infrastructure must adopt the new software, which requires systems-

integration testing, changing workflows, and training staff.[6] So it is unclear whether such a new rule would pass muster under the Regulatory Flexibility Act.

On timing, there is less than a year before the Accumulator Rule becomes effective. HHS has yet to initiate the rulemaking. And even after the rulemaking, implementation would take several years, as it had for prior revisions to the NCPDP data set.[7] CMS did not explain how an effective date of January 1, 2023 would provide enough time for those lengthy processes. *See id.* at 87,100 (col. a).

CMS' failure to consider its own regulatory obligations and the implementation burdens reinforces that the Accumulator Rule is not the product of reasoned or rational decision-making.

3. Without Enough Information from PBMs, Manufacturers Have No Way to Establish Sufficient "Parameters" or "Coverage Criteria"

Without information from PBMs, manufacturers cannot accurately identify whether a PBM accumulator program applies. Several commentors challenged CMS' assertion that manufacturers can establish "parameters" or "coverage criteria" for ensuring that PBMs and plans will count patient assistance toward deductibles and out-of-pocket maximums. *Id*. at 87,054 (col. b). Those commentors warned CMS that its assertion had "no factual support" and requested "further explanation or guardrails on such parameters or coverage criteria." *Id*.

CMS provided no factual support. *Id*. CMS identified no guardrails. *Id*. And as for further explanation, CMS fell back on the same unsupported "hopes" that manufacturers can work with

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[6] U.S. Dep't of Health and Human Servs., Office of Inspector General, *Executive Summary: Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs* (2014) at 18, *available at* https://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf ("Revising the NCPDP standards is an industrywide process that typically takes years to complete and requires all involved entities to update their claims transaction systems to comply with the new standards.").

[7] *See* NCPDP, *Speed to Standard Creation*, *available at* https://member.ncpdp.org/Member/media/pdf/NCPDPStandardsSwimLaneAnalysis.pdf.

PBMs, plans, switches, and brokers to leverage the electronic pharmacy claims-processing infrastructure into a "possible foundation" for such parameters and coverage criteria. *Id*. (cols. b and c); *id*. at 87,053 (col. c). In doing so, CMS again reiterated that PBM cooperation was essential while at the same time re-emphasizing that PBMs have no obligation to cooperate. *Id*.[8]

Aside from PBM- and plan-held information, the potentially available information cannot reliably predict whether a PBM accumulator program will apply. There are numerous reasons why such claims data may suggest that there is no PBM accumulator program when there in fact is. And there are numerous scenarios where the claims data may suggest that there is a PBM accumulator program when there in fact is not.

For example, if a pharmacy reports a patient-assistance program to the primary payor, the primary payor may not "back out" that patient assistance from the deductible and out-of-pocket maximum until days, weeks, or months after the prescription transaction. And until that "backing out" occurs, someone looking at the claims data would conclude that the plan and its PBM had counted the patient assistance toward the deductible and out-of-pocket maximum, suggesting that there is no PBM accumulator program for that patient and that drug.

If the plan later backs out the patient assistance from the deductible and out-of-pocket maximum, patient-assistance programs have no way to retroactively claw back the assistance from needy patients to avoid the severe financial consequences under the Accumulator Rule. And patient-assistance programs certainly would not demand that patients return their medications—assuming that any remain by the time that the "backing out" may become visible to the patient-assistance program.

[8] Commentors proposed that patient-assistance programs could establish terms and conditions that require patients to certify that no PBM accumulator programs would apply to their prescriptions. *Id*. at 87,055 (col. a). CMS rejected that suggestion. *Id*.

On the flip side, the claims data may suggest that there is a PBM accumulator program, because the claims data indicate that the patient's deductible did not decrease, notwithstanding the patient assistance. But that can simply mean that the plan applies a PBM accumulator program to one medication (perhaps an expensive specialty medication), but not to another. There is no way for the patient-assistance program to be sure. In such situations, the manufacturer may restrict patient assistance more than necessary out of an over-abundance of caution. As a result, many patients may be unnecessarily denied the help that they need to afford their medications.

Another example: a PBM may apply an accumulator program for one plan, but not another. So there is no way to create accurate parameters based on the PBM alone. And even for plans that choose to apply a PBM accumulator program, there may be variations as to when the accumulator program applies. There are myriad permutations that make accurate coverage criteria impossible. There are numerous other examples. But the point is that CMS failed to acknowledge any of those operational barriers. And those barriers make it impossible to implement accurate parameters or coverage criteria around patient assistance without specific information from PBMs and plans, which CMS confirmed that they need not provide.

CMS did not provide reasoned responses to commentors' warnings.

4. Even Under CMS' Best-Case Scenario, the Accumulator Rule Would Still Harm Patients

To recap, under CMS' best-case scenario, (1) *all* PBMs will share essential information with manufacturers that CMS said that PBMs could withhold; (2) HHS finalizes new regulations to establish an essential NCPDP standard; (3) pharmacies, brokers, switches, PBMs, software vendors, plans, and others all implement the new standard before January 1, 2023; and (4) manufacturers can somehow establish coverage criteria for patient-assistance programs—that CMS could not identify—that "ensures" that the only prescription transactions that receive patient assistance

are those without PBM accumulator programs. Even in this highly unlikely, if not impossible, scenario, the Accumulator Rule would still not accomplish CMS' stated purpose for the rule. Quite the opposite, in this best-case scenario, the Accumulator Rule would still cause the very result that CMS seeks to avoid.

It is important to re-emphasize that the result that CMS hopes to *achieve* is "to ensure the full value" of patient assistance applies to deductibles and out-of-pocket maximums. 87,049 (col. b). The result that CMS hopes to *avoid* is less patient assistance for needy patients—thereby, harming patient access and adherence to medications.[9]

But if a manufacturer knows that a PBM accumulator program applies, it will have to choose between devastating financial consequences to themselves (by providing that patient assistance) and avoiding those consequences (leaving many patients without the ability to afford essential medications). Many manufacturers will have no choice but to curtail their patient-assistance programs under the Accumulator Rule. *Id*. at 87,054 (col. b) (commentors highlighting that dilemma). PBM accumulator programs "are growing in number and quickly eroding the value of the manufacturer assistance programs for patients."[10] And as PBM accumulator programs spread, more manufacturers will be forced to reduce or eliminate their patient-assistance programs.

The only way to achieve CMS' goal of ensuring that patient assistance continues and that PBMs and plans count that assistance toward deductibles and out-of-pocket maximums is to ban

[9] 85 Fed. Reg. 87,099 (col. c) ("We are hopeful that manufacturers will not eliminate these programs under this policy[.]"); *id*. at 87,050 (col. b) ("We do not believe that the final policies we are adopting in this final rule will negatively impact patients with rare, life-threatening illnesses who rely on manufacturer assistance programs.").

[10] *Id*. at 87,099 (col. a); *see* Adam Fein, *Employer Pharmacy Benefits 2021: Patient Specialty Costs Rise with Coinsurance and Accumulators*, (December 7, 2021), *available at* www.drugchannels.net/2021/12/employer-pharmacy-benefits-2021-patient.html (discussing the continuing growth of PBM accumulator programs).

PBM Accumulator Programs. *See id*. at 87,054 (col. a). Commentors stressed that point. *Id*. CMS refused to adopt it. *Id*. In doing so, CMS simply said, "Banning PBM accumulator programs is outside the scope of this rule." *Id*.

But just because the right regulatory action is outside the scope of an otherwise unworkable and harmful rule is no reason to reject the only solution for the problem that CMS seeks to solve—even if that solution may require additional rulemaking and delaying the rule into the current Administration. That is yet another example of agency response and decision-making that is neither reasoned nor rational.

B. Providing Patient Assistance Outside of the Electronic Prescription Claims-Processing Infrastructure Cannot "Guarantee" That Plans Will Count Such Assistance Toward Deductibles and Out-of-Pocket Maximums

Perhaps realizing that its "hopes" are operationally problematic, CMS proposed an alternative to manufacturers. *Id*. at 87,053 (cols. b and c). Under that approach, manufacturers would provide patient assistance outside of the electronic prescription claims-processing infrastructure, which handles nearly all prescription transactions. Specifically, CMS proposed that patients should first pay the out-of-pocket cost, then submit a claim to the patient-assistance program and wait for reimbursement. In that way, CMS believes that the "PBM will be unable to identify that the patient used manufacturer-sponsored assistance," which "will guarantee patient's cost sharing applies to the patient's deductible." 87,053 (cols. b and c). There are several problems with that approach.

The patients at issue are insured and have difficulty affording high out-of-pocket costs. Those are often patients with copays or co-insurance amounts in the hundreds, if not thousands, of dollars. *Id*. at 87,099 (col. b). According to the Federal Reserve, more than one-third of adults do

not have enough cash reserves to afford an emergency that costs $400.[11] Many patients simply cannot afford to front hundreds or thousands of dollars and then wait for reimbursement. Given the Accumulator Rule's focus on the "impact on patients," it is troubling that CMS did not analyze this obvious problem or examine how many patients would forego medications if point-of-sale savings were transformed into after-the-sale reimbursements. *Id*. at 87,049 (col. c).

As for a PBM's supposed inability to identify whether a patient had received patient assistance outside of the electronic prescription claims-processing infrastructure, that is again, hope divorced from reality. A plan can simply require their patients to disclose patient assistance and exclude that assistance from deductibles and out-of-pocket maximums. And if that occurs, even once, a manufacturer could potentially face devastating financial consequences that would cause manufacturers to reduce or eliminate their patient assistance. Again, CMS failed to address that obvious flaw in its response to commentors' concerns.

Its alternative approach also undermines CMS' and the industry's ongoing efforts to leverage the existing electronic prescription claims-processing infrastructure to identify and prevent Medicare Part D beneficiaries from receiving patient assistance, which is a potential violation of the federal Anti-kickback Statute ("AKS").[12] Since 2014, and at CMS' request, industry stakeholders and NCPDP have devoted substantial resources developing such a solution, through

[11] Board of Governors of the Federal Reserve System Report, *Survey of Household Economics and Decisionmaking* (May 17, 2021), *available at* https://www.federalreserve.gov/consumerscommunities/sheddataviz/unexpectedexpenses.html.

[12] *See supra* n.6*; see also* U.S. Dep't of Health and Human Servs., Office of Inspector General, *Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons* (2014), *available at* https://oig.hhs.gov/documents/special-advisory-bulletins/878/SAB_Copayment_Coupons.pdf .

changes to the NCPDP telecommunication standards.[13] After asking the industry to modify and operate *within* the current electronic prescription claims-processing infrastructure in order to mitigate the AKS risk of providing patient assistance, CMS now asks patient-assistance programs to provide that assistance *outside* of that very same infrastructure. Because of CMS' conflicting instructions, patient-assistance programs are now stuck between a rock and a hard place. Based on its response to commentors' concerns, it is unclear that CMS was even aware of its conflicting instructions to the very same stakeholders about the very same programs.

CMS' alternative approach does not reflect reasoned responses or rational decision-making.[14]

II. CMS' Accumulator Rule Will Harm Patients—Particularly Minorities and Those with Rare, Life-Threatening, or Complex Chronic Conditions

As explained above, the Accumulator Rule will harm patients by forcing manufacturers to reduce or eliminate patient-assistance programs—an outcome that CMS hopes to avoid. 85 Fed. Reg. at 87,099 (col. c). And fewer patient-assistance programs will mean less access and adherence to essential medications. CMS recently reiterated "that copayment support may help

[13] *See, e.g.*, NCPDP, *Recommendations for Use of the NCPDP Telecommunication Standard to Prevent Use of Copayment Coupons by Medicare Part D Beneficiaries and Applicability to other Federal Programs*, White Paper (2017), *available at* https://ncpdp.org/NCPDP/media/pdf/White-Paper/Recommendations-Telecomm-Standard-Prevent-Copayment-Coupons-by-Part-D.pdf?ext=.pdf; *cf. supra* at 15-17 (generally describing the lengthy and burdensome process for changing NCPDP standards).

[14] CMS notes that pre-paid debit cards could be used to provide patient assistance. *See* 85 Fed. Reg. at 87,099 (col. a). Such an approach may somewhat alleviate the first concern regarding whether a patient could front cost-sharing obligation in cash and then seek reimbursement. But using prepaid debit cards does not address the second or third concern. Plans can still require patients to report patient assistance and then exclude the assistance from deductibles and out-of-pocket maximums. And such cards would operate outside of the current infrastructure.

enrollees by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients." 86 Fed. Reg. 29,164, 29,234 (col. c) (May 14, 2021).

The harm to patients is hard to overstate. They include emergency care, hospitalizations, new or increased prescriptions, remedial treatments, and death. For example, nonadherence to medications that prevent cardiovascular disease "has been associated with a significant increase in the risk of premature death from any cause, death, hospitalization for heart attack or heart failure, and coronary revascularization procedures."[15] Similarly, patients who adhere to their antihypertensive medications are 30 to 45 percent more likely to achieve blood pressure control compared to those who do not. *Id.*

The Accumulator Rule will harm some of our most vulnerable populations who rely on patient assistance for their essential medications. Patient-assistance programs are especially important for innovative specialty medications that often do not have clinically appropriate generic options. Those medications also tend to treat complex chronic conditions and rare or life-threatening illnesses. For those medications, the cost sharing under a commercial plan can be thousands of dollars. *See* 85 Fed. Reg. at 87,050 (col. b). Therefore, patient-assistance is vital to access and ongoing adherence.

But because of their high prices, plans target specialty medications with PBM accumulator programs to generate the greatest profits from the lower spending. CMS explained that PBM accumulator programs target our most vulnerable patients who depend on such medications for

[15] Centers for Disease Control and Prevention, *Tailored Pharmacy-Based Interventions to Improve Medication Adherence* (July 22, 2021), *available at* https://www.cdc.gov/dhdsp/pubs/medication-adherence.htm.

rheumatoid arthritis, high cholesterol, HIV, and rare diseases.[16] So the Accumulator Rule will disproportionately harm patients who have no alternative medication options, suffer from the most severe conditions, and need financial assistance the most.

The Accumulator Rule will also disproportionately harm minority communities. For example, with cholesterol-lowering drugs, "Hispanic or African American dominated neighborhoods are 33–56 percent more likely to be nonadherent." *See, e.g.*, T. Gibson, 12 *Impact of Statin Copayments on Adherence and Medical Care Utilization and Expenditures*, 12 AM. J. MANAGED CARE SP11-9 (Dec. 2006). Adherence to cardiovascular drugs is lower among African Americans "and likely contributes to a persistent 7-year lower overall life expectancy in blacks relative to whites." Andrew M. Davis, *et al*., *A National Assessment of Medication Adherence to Statins by the Racial Composition of Neighborhoods*, 4 (3) J. RACIAL ETHNIC HEALTH DISPARITIES (Jun. 28, 2016). And poor adherence to prescribed medications "precludes older African American adult patients from the potential benefits of prescription medications and may in fact contribute to the disproportionate burden of morbidity and mortality in this population." Moshen Bazargan, *et al*., *Non-adherence to medication regimens among older African-American adults*, 17 BMC GERIATRICS 163 (2017), *available at* https://doi.org/10.1186/s12877-017-0558-5.

The government has long sought to reduce those racial health disparities. For instance, section 1554(1) of the Affordable Care Act precludes the HHS Secretary from issuing any regulation that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care[.]"

[16] *See* 85 Fed. Reg. 87,099 (col. a); *see also id.* Fein, *Employer Pharmacy Benefits 2021* (Dec. 7, 2021).

Here, "[m]any commenters raised concerns about the potential impact of the proposals in this section on medication adherence, medical complications, outcomes, and hospitalizations and requested CMS to take patient's special needs into consideration." 85 Fed. Reg. at 87,050 (col. b). CMS did not do so. CMS finalized a rule that will adversely impact medication adherence, increase medical complications and hospitalizations, and contribute to worse health outcomes.

CONCLUSION

The Accumulator Rule is unworkable. The Accumulator Rule will harm patients. McKesson respectfully asks this Court to vacate the rule and to provide such other relief as requested by Plaintiff.

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CERTIFICATE OF COMPLIANCE

I hereby certify this brief complies with the requirements of Local Rule 7(o)(4) and Fed. R. App. P. 29(a)(4) & (5) and 32(g)(1), as applicable, because it is 25 pages or less and is in 12-point font Times New Roman.

Further pursuant to Local Rule 7(o) and FRAP 29(a), counsel certifies that no person—other than the *amicus curiae* or its counsel—contributed money that was intended to fund preparing or submitting this brief.

Dated: January 4, 2022

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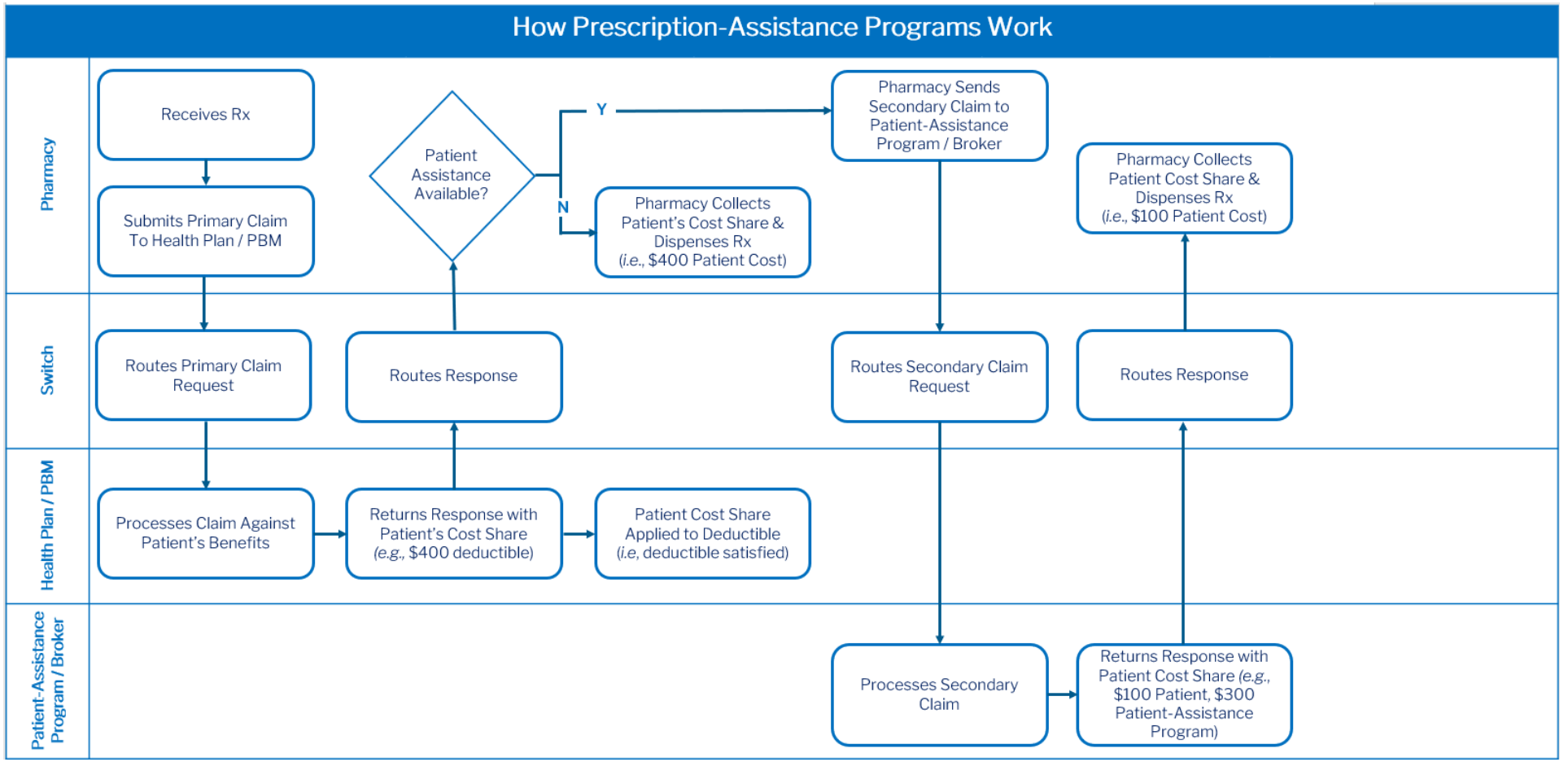
Exhibit 1

How Prescription-Assistance Programs Work

Adapted from *Upstream Reporting of Copay Assistance Issues Brief*, National Council for Prescription Drug Programs (June 2018), *available at* https://www.ncpdp.org/NCPDP/media/pdf/20180604_Upstream_Reporting_of_Copay_Assistance_Issues_Brief.pdf?ext=.pdf.

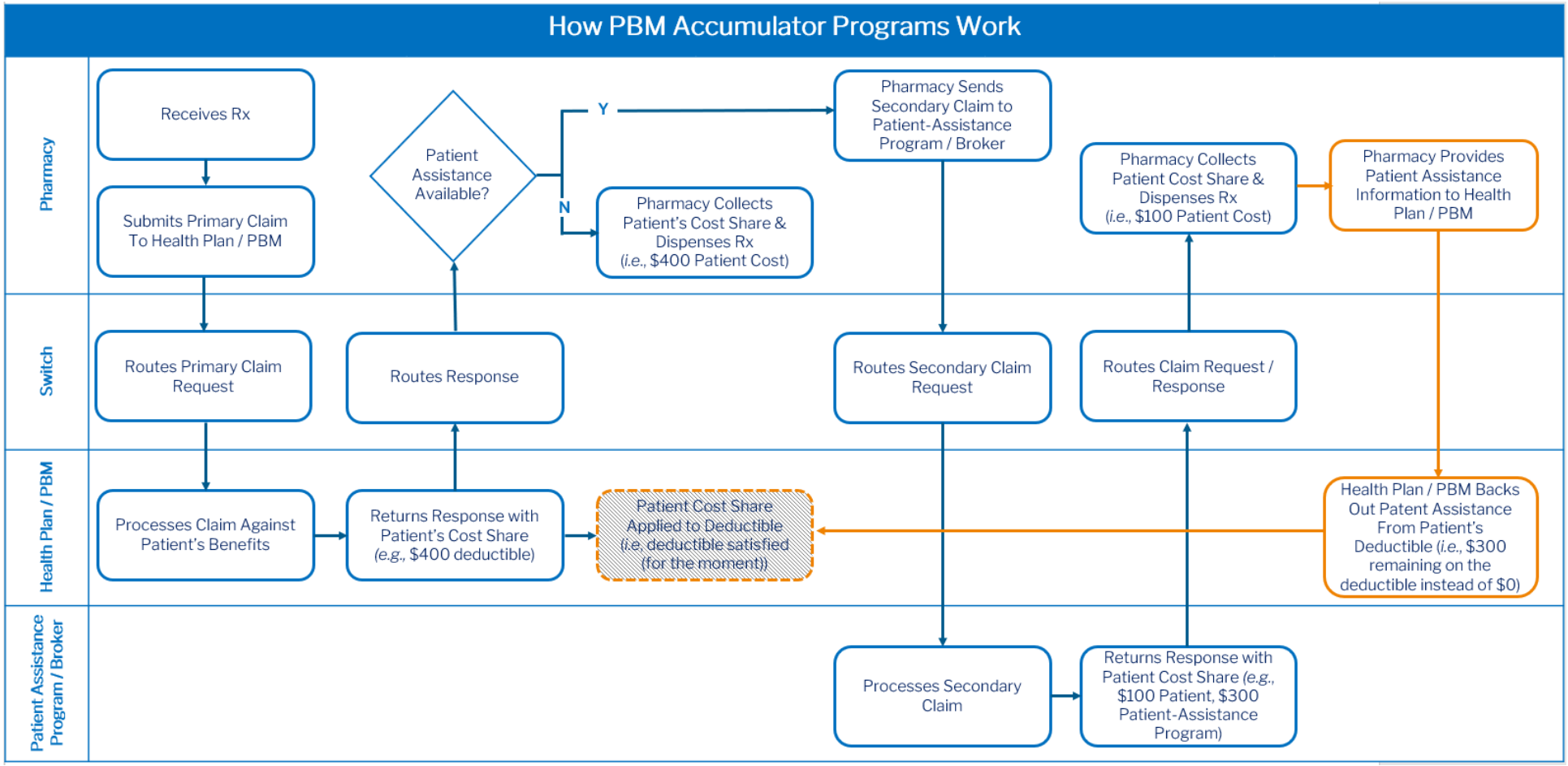

How Prescription-Assistance Programs Work
Pharmacy
Switch
Health Plan / PBM
Patient-Assistance Program / Broker
Receives Rx
Submits Primary Claim To Health Plan / PBM
Patient Assistance Available?
Y
N
Pharmacy Collects Patient's Cost Share & Dispenses Rx (i.e., $400 Patient Cost)
Pharmacy Sends Secondary Claim to Patient-Assistance Program / Broker
Pharmacy Collects Patient Cost Share & Dispenses Rx (i.e., $100 Patient Cost)
Routes Primary Claim Request
Routes Response
Routes Secondary Claim Request
Routes Response
Processes Claim Against Patient's Benefits
Returns Response with Patient's Cost Share (e.g., $400 deductible)
Patient Cost Share Applied to Deductible (i.e, deductible satisfied)
Processes Secondary Claim
Returns Response with Patient Cost Share (e.g., $100 Patient, $300 Patient-Assistance Program)

[i]

Exhibit 2

How PBM Accumulator Programs Work

Adapted from *Upstream Reporting of Copay Assistance Issues Brief*, National Council for Prescription Drug Programs (June 2018), *available at* https://www.ncpdp.org/NCPDP/media/pdf/20180604_Upstream_Reporting_of_Copay_Assistance_Issues_Brief.pdf?ext=.pdf.


How PBM Accumulator Programs Work
Pharmacy
Switch
Health Plan / PBM
Patient Assistance Program / Broker
Receives Rx
Submits Primary Claim To Health Plan / PBM
Routes Primary Claim Request
Processes Claim Against Patient's Benefits
Returns Response with Patient's Cost Share (e.g., $400 deductible)
Routes Response
Patient Assistance Available?
Y
N
Pharmacy Collects Patient's Cost Share & Dispenses Rx (i.e., $400 Patient Cost)
Patient Cost Share Applied to Deductible (i.e. deductible satisfied (for the moment))
Pharmacy Sends Secondary Claim to Patient-Assistance Program / Broker
Routes Secondary Claim Request
Processes Secondary Claim
Returns Response with Patient Cost Share (e.g., $100 Patient, $300 Patient-Assistance Program)
Routes Claim Request / Response
Pharmacy Collects Patient Cost Share & Dispenses Rx (i.e., $100 Patient Cost)
Pharmacy Provides Patient Assistance Information to Health Plan / PBM
Health Plan / PBM Backs Out Patent Assistance From Patient's Deductible (i.e., $300 remaining on the deductible instead of $0)

[i]