request.htm. Interested persons may express their views in writing on whether the proposed transaction complies with the standards enumerated in the HOLA (12 U.S.C. 1467a(e)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than October 15, 2024.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Magnolia Bancorp, Inc., Metairie, Louisiana;* to become a savings and loan holding company by acquiring Mutual Savings and Loan Association, also of Metairie, Louisiana, in connection with the mutual-to-stock conversion of Mutual Savings and Loan Association.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2024–20892 Filed 9–12–24; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than September 30, 2024.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President) 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Oliver Beaman Triplett, IV, George Beaman Triplett, and Olivia Triplett Harrell, all of Forest, Mississippi;* as a group acting in concert, to retain voting shares of First Forest Corporation, and thereby indirectly retain voting shares of Bank of Forest, both of Forest, Mississippi.

B. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198–0001. Comments can also be sent electronically to *KCApplicationComments@kc.frb.org:*

1. *Danielle M. Wheeler, Pine Island, Minnesota; Parker C. Ayres, Olathe, Kansas; and Madisyn L. Matthews, Lincoln, Nebraska;* to become members of the Ayres Family Control Group, a group acting in concert, to acquire voting shares of First of Minden Financial Corporation, and thereby indirectly acquire voting shares of First Bank and Trust Company, both of Minden, Nebraska.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2024–20863 Filed 9–12–24; 8:45 am]

BILLING CODE P

FEDERAL TRADE COMMISSION

[Docket No. C–4374]

Petition of Coopharma To Reopen and Set Aside or Modify Order

AGENCY: Federal Trade Commission.

ACTION: Announcement of petition; request for comment.

SUMMARY: Cooperativa de Farmacias Puertorriqueñas (''Coopharma'' or ''the company'') has requested that the Federal Trade Commission (''FTC'' or ''Commission'') reopen and set aside or modify the Commission's Decision and Order entered on November 6, 2012 (the ''Order''), concerning allegations of agreements among Coopharma's member pharmacies to fix prices with insurers and PBMs. The company requests that the FTC either modify or rescind the order given changes in both the applicable law as well as competitive conditions in the relevant marketplace. Publication of the petition from Coopharma is not intended to affect the legal status of the petition or its final disposition.

DATES: Comments must be received on or before October 15, 2024.

ADDRESSES: Interested parties may file comments online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write: ''Coopharma Petition to Reopen; Docket No. C–4374'' on your comment and file your comment online at *www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, please mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H–144 (Annex P), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Maribeth Petrizzi (202–326–2564), Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(g) of the Federal Trade Commission Act, 15 U.S.C. 46(g), and FTC Rule 2.51, 16 CFR 2.51, notice is hereby given that the above-captioned petition has been filed with the Secretary of the Commission and is being placed on the public record for a period of 30 days. After the period for public comments has expired and no later than one hundred and twenty (120) days after the date of the filing of the request, the Commission shall determine whether to reopen the proceeding and modify or set aside the

Order as requested. In making its determination, the Commission will consider, among other information, all timely and responsive comments submitted in connection with this notice.

The text of petition is provided below. An electronic copy of the filed petition and the exhibits attached to it can be obtained from the FTC website at this web address: *https://www.ftc.gov/system/files/ftc_gov/pdf/c4374petitiontoreopenmodify.pdf.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 15, 2024. Write ''Coopharma Petition to Reopen; Docket No. C–4374'' on your comment. Your comment—including your name and your State—will be placed on the public record of this proceeding, including, to the extent practicable, on the *www.regulations.gov* website.

Because of the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *www.regulations.gov* website. If you prefer to file your comment on paper, write ''Coopharma Petition to Reopen; Docket No. C–4374'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Mail Stop H–144 (Annex P), Washington, DC 20580. If possible, submit your paper comment to the Commission by overnight service.

Because your comment will be placed on the publicly accessible website at *www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other State identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on *www.regulations.gov*—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *https://www.ftc.gov* to read this document and the news release describing this matter. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 15, 2024. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Authority: 15 U.S.C. 46, 5 U.S.C. 552.

April J. Tabor,

Secretary.

Text of Petition of Coopharma To Reopen and Set Aside or Modify the Decision and Order

Concise Statement of the Case

I. Introduction

Cooperativa de Farmacias Puertorriqueñas (''Coopharma'') is currently a party to a Decision and Order, dated November 6, 2012 (the ''Order''). We write to petition the Commission to reopen and set aside or modify the Order. As set forth below, there has been a significant change in the law. The Puerto Rico Legislature passed Act 228, which was signed into law by the Governor on December 15, 2015. Act 228 directly impacts the underlying conduct on which the Federal Trade Commission (''the Commission'') based its Complaint against, and Order directed to, Coopharma. The Commission has previously recognized that Act 228 is the appropriate vehicle pursuant to which health care provider cooperatives can conduct collective negotiations with third party payors, and there is now State oversight of such negotiations in place by a designated government body that has issued relevant regulations. Accordingly, in light of the change of law, factual and market changes and their impact on the public interest, and the Commission's own rescission of prior guidance as to Pharmacy Benefit Managers (''PBMs''), the Order is unnecessary and inequitable. We, thus hereby, request that the Commission grant this Petition and reopen and set aside the Coopharma Order.

II. Statement of Facts

A. Cooperatives in Puerto Rico and the Legal Framework

It is important to understand the backdrop in which Coopharma operates, which is unique from other pharmacy groups or associations in the United States. Because Puerto Rico is a small economy, the Commonwealth encourages the development of non-profit business cooperatives. The Puerto Rican Cooperative Movement is a ''socioeconomic system which pursues the enfranchisement of human beings and their integrated betterment through economic justice and social cooperation. A cooperative is an autonomous association of persons who have united voluntarily to address their common economic, social and cultural needs and aspirations through a jointly-owned and democratically controlled enterprise.'' [1] Cooperatives are vital to fostering economic opportunity and the availability of services to consumers.[2] Since the first adoption of legislation governing the cooperative movement in 1946 in Puerto Rico, there have been hundreds of cooperatives created across the Island in almost every sector of the economy.[3] And more recently, ''[b]etween 2018 and 2022, the number of members in the Puerto Rican cooperative system increased by roughly 12 percent to more than 1.1 million individuals, and total assets, capital, deposits, and loans have risen by an even greater pace during that same period.'' [4]

Puerto Rico has a rich history of creating small business cooperatives and the government has taken numerous actions to foster their development. In 1994, Puerto Rico enacted Act No. 50

(''Act 50'') known as the ''General Cooperative Associations Act,'' which the Legislature promulgated ''to stimulate activities such as production and services through the cooperative structure and to govern . . . cooperatives.'' [5] Subsequently, in 2004, the Legislature enacted the 2004 General Cooperative Associations Act of Puerto Rico, 5 L.P.R.A. § 4381 *et seq.* (''Act 239'') repealing and replacing Act 50.

Act 239 articulates an unambiguous legislative intent to create and improve the legal framework in support of continued development of Puerto Rican cooperatives: ''the Cooperative Movement constitutes an integral piece and a stronghold for the economic and social development of the Island, for which reason, the growth and the strengthening of the cooperative movement in Puerto Rico is highly invested with public interest.'' [6] In its efforts to further the growth of cooperative businesses, Act 239 allows for substantial contracting freedom and provides immunity from business conduct being viewed as restraints of trade.[7]

Puerto Rican law also provides a comprehensive framework for the regulation and oversight of cooperatives in Puerto Rico. Act 239, as amended by Act 247,[8] provides the Corporación para la Supervisión y Seguro de Cooperativas de Puerto Rico (''COSSEC''),[9] a regulatory body, with the authority to oversee, supervise and otherwise regulate the creation and operations of cooperatives. COSSEC is the main governmental entity created by the Legislature to regulate Puerto Rican cooperatives. COSSEC's mission is to ensure ''the integrity and financial strength of the Cooperative Movement of Puerto Rico, through monitoring and oversight . . . of all Cooperatives'' [10] and to ''promote the safety, soundness and global competitiveness addressed to the socio-economic development of [Puerto Rico], through . . . ensuring balance and fairness . . . [in] the development of cooperation.'' [11]

B. Coopharma Background

Coopharma was formed in 2002 as a cooperative regulated under Act 239.[12] Coopharma was created for the purpose of fostering the growth of independent pharmacies.[13] It enables small independent pharmacies to compete more effectively by achieving economies of scale and scope that the large chain pharmacies enjoy.[14] Coopharma's collaborative efforts provide for very efficient group purchasing, joint advertising, negotiation for goods and services, and provision of education services to members in order to improve pharmacy services to patients.[15] Coopharma's membership consists of approximately 500 independent pharmacies/independent pharmacy owners who typically employ approximately 5–10 individuals in their stores.[16] Coopharma members are dispersed throughout 75 different towns across Puerto Rico. In most of these towns, large or chain pharmacies are not present, thus, the independent, local pharmacy is the only alternative for patients to be able to obtain their prescription medication and receive proper and timely counsel as to their medications.[17]

Coopharma is a cooperative in every sense of the word. It is a non-profit organization whose membership is entirely composed of community pharmacy owners.[18] Unlike private entities in other Commission enforcement actions, Coopharma's concern is for the collective good, providing pharmacy access and lowering prices to patients.[19] Coopharma was formed to address systemic problems in the Puerto Rican health care system, including expanding ready access to pharmaceutical care to thousands of individual across the Island, through collaboration and collective commitment, and pronounces this stated goal publically: ''This Cooperative is organized with the following aims and purposes . . . Promote, use and maintain positive attitudes conducive to resolving together adverse situations that may arise in the purchase-sale of medicines, products, articles and services in the market.'' [20] Coopharma's activities have streamlined pharmacy integration services and provided collective vendor purchasing opportunities, thereby lowering operating and purchasing costs, which translates to more choice, more services and lower prices for consumers.[21]

C. Coopharma's Role in Helping To Alleviate Oppressive Conduct by Pharmacy Benefit Managers

The Consent Order has limited the ability of many independent pharmacies across the Island to obtain favorable contracting terms, leading to many pharmacies being forced out of business.[22] There are only a few pharmacy providers left.[23] As the Commission has recently recognized, PBMs often employ an arsenal of unfair tactics toward independent pharmacies.[24] *See also,* U.S. Federal Trade Commission, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Interim Staff Report at 1 (July 2024) (the ''Interim FTC Report'') (''PBMs also exert substantial influence over independent pharmacies, who struggle to navigate contractual terms imposed by PBMs that they find confusing, unfair, arbitrary, and harmful to their businesses.''). PBMs are much larger, more sophisticated business entities, which can overpower much smaller, independent pharmacies.[25] PBMs unfairly diminish reimbursement rates, reimburse below agreed upon rates, steer patients to affiliated pharmacies or mail order pharmacies located outside of Puerto Rico, marginalize the impact of pharmacy services, and impose onerous terms outside the context of negotiated contracts.[26] The Puerto Rican pharmacists who comprise Coopharma's membership are working pharmacists and not sophisticated businessmen/women.[27] Often their knowledge of English is limited or rudimentary.[28] PBM contracts are long—often 50–60 pages (with accompanying provider manuals continuing over 100 page of additional requirements for pharmacies to adhere to for participation in the PBM's network)—and are presented on a take it or leave it basis (as classic contracts of adhesion).[29] PBMs also often impose amendments on the same unilateral basis.[30] *See also,* Interim FTC Report at 3–4 (''Independent pharmacies generally lack the leverage to negotiate terms and rates when enrolling in PBMs' pharmacy networks, and subsequently may face effectively unilateral changes in contract terms without meaningful choice and alternatives. The proliferation of complex and opaque contract terms and adjustments has increased uncertainty in pharmacy reimbursements, which can make it difficult for smaller pharmacies to manage basic business operations. For instance, the rates in PBM contracts with independent pharmacies often do not clearly reflect the amount the pharmacy will ultimately be paid.'')

The majority of Puerto Rican pharmacies, including Coopharma members, are set in rural locations with relatively unsophisticated sole proprietors who lack the knowledge and time to decipher these complex agreements.[31] This makes Coopharma members, as independent pharmacies primarily located in rural areas of Puerto Rico, particularly vulnerable to PBMs' deceptive conduct and attempts to drive reimbursement rates below competitive levels.[32]

Unfortunately, the Order has limited the ability of many of Coopharma's independent pharmacy members across the Island to obtain just contracting terms, leading to many pharmacies

being forced out of business and the artificial inflation of prices for consumers.[33] Between 2016 and 2022, the approximate number of pharmacies in Puerto Rico decreased from 1,250 to approximately 900, a decrease of 28%.[34] As independent pharmacies located in rural areas make up the majority of Coopharma members, this should be quite alarming to the Commission, which recognizes that ''[c]losures of local pharmacies affect not only small business owners and their employees, but also their patients. In some rural and medically underserved areas, local community pharmacies are the main healthcare option for Americans, who depend on them to get a flu shot, an EpiPen, or other lifesaving medicines.'' Interim FTC Report at 1. Setting aside the Order would allow pro-competitive activity by Coopharma in the form of negotiations with PBMs overseen by COSSEC, pursuant to regulations that that body issues.[35]

Moreover, the Commission is very familiar with the tactics that PBMs use to undermine the competitiveness of independent pharmacies. The Commission's on-going 6(b) study of PBMs explicitly recognizes that:

> The largest PBMs are now vertically integrated with the largest health insurance companies and wholly owned mail order and specialty pharmacies. Those who own competing pharmacies have complained that PBMs impose unfair fees and clawbacks, impose byzantine contracts that often reimburse pharmacies less than their costs of acquisition, and steer patients to PBM-owned pharmacies. PBMs have also been accused of harming patients by extracting rebates and fees in exchange for refusing to cover generic and biosimilar drug products, ultimately raising the price that consumers pay for medicines. Doctors have also complained that PBMs impose unnecessary and burdensome prior authorization and other administrative requirements.[36]

The Complaint in this matter was based on assertions that the Commission believed to be true at the time that, because Coopharma described itself as the ''biggest chain of pharmacies in all of Puerto Rico,'' it therefore had significant market power to ''force Humana to maintain rates.'' [37] These market forces, whether true at the time of the Complaint or not, have since shifted with the significant vertical consolidation of the PBM industry. PBM's consolidation and increase in market power has been very publicly noted by the Commission and is described herein.

A 2023 health market study commissioned by the Office of the Insurance Commissioner of Puerto Rico showed that the Herfindahl–Hirschman index (HHI) [38] for private insurance companies was deemed highly concentrated in Puerto Rico and ranged from 6,207 to 9,201 based on the different types of companies in that market.[39] It is important to note that over ninety percent (approximately 94.9%) [40] of the population of Puerto Rico is insured. The Island also has the highest Medicare Advantage plan penetration of U.S. and its jurisdictions, with 60% of Puerto Rican Medicare beneficiaries enrolled in Medicare Advantage plans.[41]

Since October 2022, only one PBM, Abarca Health (''Abarca''), provides services to the majority of this vast insured population in the Island under the Medicare health insurance plan called Plan Vital, which is managed by the Puerto Rico Health Insurance Administration ((''PRHIA''), commonly referred to as Administración de Seguros de Salud (''ASES'') in Spanish).[42] [43] This means that Abarca is the middleman between pharmacies, insurers, and customers/beneficiaries for the entire Puerto Rican Medicaid market, which is comprised of over 1.6 million of beneficiaries, or about 50% of the insured population in the Island.[44]

Through Plan Vital, the same PBM provides management services for the second largest Medicare Advantage Organization (''MAO'').[45] Separately, Abarca has contracted with the largest private health insurance company [46] [47] and manages the commercial plans for a third health insurer to the Island.[48] The Office of Monopolistic Affairs of the Puerto Rico Department of Justice is currently investigating Abarca for deceptive practices in its contract negotiations with independent pharmacies in Puerto Rico.[49]

D. Consent Order

By way of brief background, in August 2012, the Commission, via a Complaint against Coopharma, alleged a violation of section 5 of the Federal Trade Commission Act, as amended 15 U.S.C. 45. More specifically, the Commission alleged that Coopharma acted to fix prices in negotiations with certain third-party payors, including collectively negotiating contracts and contracting jointly. In order to save the time, expense and burden of an Adjudicative Proceeding, Coopharma elected to enter into the Order.[50]

The Order, in pertinent part, requires Coopharma to refrain from engaging in the following activities:

> A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Pharmacies with respect to the provision of Pharmacy services:
>
> 1. To negotiate on behalf of any Pharmacy with any Payer;
>
> 2. To refuse to deal or threaten to refuse to deal with any Payer, in furtherance of any conduct or agreement that is prohibited by any other provision of Paragraph II of this Order;
>
> 3. Regarding any term, condition, or requirement upon which any Pharmacy deals, or is willing to deal, with any Payer, including, but not limited to, price terms; or
>
> 4. Not to deal individually with any Payer, or not to deal with any Payer other than through Respondent;
>
> B. Exchanging or facilitating in any manner the exchange or transfer of information among Pharmacies concerning any Pharmacy's willingness to deal with a Payer, or the terms or conditions, including price terms, on which the Pharmacy is willing to deal with a Payer;
>
> C. Attempting to engage in any action prohibited by Paragraphs II.A through II.B above; and
>
> D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any Person to engage in any action that would be prohibited by Paragraphs II.A through II.C above.[51]

The provisions of this Order prevent the above-listed actions for twenty (20) years, terminating on November 6, 2032.[52]

III. Overview

Relief Requested

For the reasons described below, Coopharma requests the following relief:

1. That the Order be set aside in its entirety;

2. Or, in the alternative, that the Order be amended to permit Coopharma to collectively negotiate contracts with PBMs and other third party payors consistent with Act 228.

If the preceding relief is not granted, Coopharma requests in the alternative such relief as the Commission may deem fitting and just.

Commission Standard of Review

According to the FTC Act section 5(b), 15 U.S.C. 45(b), the Commission may at any time ''reopen and alter, modify, or set aside, in whole or in part any report or order made or issued by it under this section, whenever in the opinion of the Commission conditions of fact or of law have so changed as to require such action or if the public interest shall so require.'' *Id.* In other words, under the FTC Act, the standard is that there must be a ''significant change in law or fact'' that makes the order ''unnecessary, inequitable, or harmful to the competition.'' [53] Upon a petition or by the Commission's own action, an order can be reopened and modified or set aside for: (1) changes in fact that matter

to competition; (2) changes in law; and (3) the public interest.[54] Pursuant to FTC Rule 2.51(b), the necessary showing must include affidavits or declarations setting forth admissible facts.[55]

To show that public interest requires a change to an existing Order, ''the burden is on the petitioner to make a 'satisfactory showing' of a prima facie case that modification is in the public interest.'' [56] Like modifications based on changed conditions, ''this showing must be supported by evidence that is credible and reliable.'' [57]

Argument

I. The Consent Order Should Be Set Aside

A. Change in the Law Warrants Reopening and Setting Aside the Order

1. Act 228—State Action Doctrine

In 2015, three (3) years after the entry of the Order, the Puerto Rico Legislature passed Act 228, which became law on December 15, 2015, and is codified at 26 P.R. Laws §§ 3101–3108 (''Act 228''). The Legislature's desire to pass Act 228 was heightened by its recognition that it was becoming increasingly more difficult for Health Care Provider Cooperatives across Puerto Rico, such as Coopharma, to obtain fair contracting terms with, often much larger, and more sophisticated payors.[58] Prior to the enactment of Act 228, certain activity conducted by Health Care Provider Cooperatives, such as Coopharma, was interpreted to fall under the jurisdiction of the Puerto Rico Insurance Code (''Act 203'').[59] Act 203 prohibits groups of health care competitors representing greater than 20% of said competitors across Puerto Rico from jointly negotiating for health care service contracts.[60] It is important to stress that Coopharma believed that it was acting under then-Article 20.5 of Act 239 when it engaged in conduct that allegedly violated section 5 of the FTC Act and which activity is subject to the Order.[61] Act 228 was enacted to clarify this and other issues of misinterpretation of existing laws regulating both health care providers and Health Service Provider Cooperatives and to set the record straight that the Puerto Rican Legislature intended for Act 239 to control negotiations by Health Service Provider Cooperatives.[62]

According to the Preamble of Act 228, Health Service Provider Cooperatives, which include cooperatives of pharmacies, such as Coopharma, were never meant to be ''considered as an organized instrument to reduce competition of any kind, but rather to carry out lawful activities for the benefit of customers and other entities in the market.'' [63] Thus, Act 228 explicitly called for such cooperatives to no longer be interpreted to be ''included under the term of person in [Law 203], so [Health Service Provider Cooperatives] are specifically excluded from'' Act 203.[64]

Act 228 specifically recognized the need to amend Act 239 to implement additional language to ''fully comply with the Doctrine of State Immunity'' (also referred to as the State Action Doctrine), established in *Parker* v. *Brown,* 317 US 341 (1943) and its progeny.[65] Accordingly, Act 228 creates a specific State Action Doctrine framework that: (1) ''allows health services providers to bargain collectively with [third-party payors]'' by expressly articulating the antitrust exemption for Health Service Provider Cooperatives to collectively negotiate and (2) provides active supervision by Puerto Rico's government agency in charge of cooperatives, COSSEC.[66]

2. The COSSEC Letter

As explained above, Act 239, as amended by Act 247, provides the Corporación para la Supervisión y Seguro de Cooperativas de Puerto Rico (''COSSEC''), a regulatory body, with the authority to oversee, supervise and otherwise regulate the creation and operations of cooperatives.[67] COSSEC is the main governmental entity created by the Legislature to regulate Puerto Rican cooperatives.[68] COSSEC's mission is to ensure ''the integrity and financial strength of the Cooperative Movement of Puerto Rico, through monitoring and oversight . . . of all Cooperatives'' and to ''promote the safety, soundness and global competitiveness addressed to the socio-economic development of [Puerto Rico], through . . . ensuring balance and fairness . . . [in] the development of cooperation.'' [69]

In support of its role in setting regulations and engaging in oversight of Coopharma and all other cooperatives in Puerto Rico, in particular after the change in law, COSSEC Executive President, Mabel Jiménez Miranda, signed an affidavit, dated April 4, 2024, which explains the role of COSSEC (referred to internally as the Corporation).[70] It states in pertinent part:

> For the purpose of complying with the public policy of the Government of Puerto Rico, striking a balance in the negotiations between the HPCs, TAs and HSOs, and improving access and the quality of health care services to the patients of the Government of Puerto Rico, as well as exercising the oversight and supervision powers granted by Act No. 239, on February 5, 2020, the Board of Directors of THE CORPORATION approved the Regulation for the Supervision and Oversight of Collective Negotiations between Health Care Provider Cooperatives (HPCs) Third-party Administrators (TAs) and Health Care Services Organizations (HSOs), Regulation No. 9161, in order to establish the supervision and oversight procedures of THE CORPORATION on the activities and actions of HPCs during any negotiation process with HSOs and TAs.[71]

As shown by this affidavit, COSSEC's oversight over Coopharma is established and it has issued Regulation No. 9161 for the governance of the cooperative's actions in negotiating with PBMs. This change in law is a significant deviation from the legal scheme under which the Order was issued, and warrants reopening and review of the Order.

3. Regulation No. 9161 Demonstrates That There Is a Regulatory Scheme in Place for COSSEC's Active Oversight of Coopharma

The Order was based in part on the Commission's concerns that there was a lack of oversight such that the State Action Doctrine could not apply.[72] The Order states that ''[u]nder Law [73] 203, Puerto Rico has not clearly articulated a policy to displace competition with respect to Coopharma's challenged conduct. Moreover, Puerto Rico has not actively supervised that conduct under the state action doctrine.'' [74]

The ''Purpose and Scope'' of Regulation 9161 now in place provides that:

> In the exercise of its functions, COSSEC will ensure that, in and during the negotiation process, a balance permeates the negotiations between the parties, in such a way as to improve access and quality of health services to patients in the Government of Puerto Rico. Specifically, that the [Cooperatives of Health Service Providers] fully comply with all the requirements of the cooperative order and that promote the public policy of the Government of Puerto Rico for the benefit of the orderly development of cooperativism as a business model.[75]

Moreover, the regulation provides for ''controls and procedures to avoid'' and provides COSSEC with the authority to ''investigate and prosecute illicit practices under collective bargaining authorized by the Subchapter 20A of Act No. 239–2004, as amended.'' [76] This language demonstrates the ways in which the promulgation of the regulation has shifted the analysis of the Commission when it initially brought the Complaint against Coopharma, and more recently, the analysis in which the Commission engaged in regard to a previous matter, In the Matter of Cooperativa de Médicos Oftalmólogos de Puerto Rico, File No. 141–014. In that

''Analysis of Agreement Containing Consent Order to Aid Public Comment,'' the Commission acknowledged the passage of Act 228 in Puerto Rico, but stated that ''Puerto Rico has neither issued any regulations nor do we have any record to evaluate how Puerto Rico will supervise negotiations. Therefore, the Commission is unable to assess to whether Act 228 complies with state action requirements.'' [77]

Here, it is clear from the language of the regulation that, not only is there a specific scheme and procedures in place for COSSEC to actively monitor and be engaged in the process of collective negotiations between Health Care Provider Cooperatives and third party payors, but also that COSSEC is actively overseeing such negotiations—namely, the type of negotiations in which Coopharma would engage with PBMs and third party payors. This comports with the standard set forth by the Supreme Court in *Federal Trade Commission* v. *Ticor Title Insurance Company,* to meet the active supervision prong (and, indeed, both prongs) of the Midcal test to qualify for State immunity from the Antitrust Act under the State Action Doctrine.[78] There is sufficient, active oversight because ''a detailed structure governs the challenged anticompetitive conduct here.'' [79]

That detailed structure of COSSEC's active oversight of all negotiations by healthcare cooperatives is clear from the language of Regulation No. 9161. Under the regulation, healthcare cooperatives must follow strict procedures and notify COSSEC of their intention to negotiate. *See* Reg. No. 9161 § 8.04. There are certain criteria for negotiations, including specific terms and conditions which may be negotiated and those which may not. *Id.* § 8.01. Just as in *Morgan* v. *Div. of Liquor Control, Dep't of Bus. Regul., State of Conn.* and *Ports Auth. of Puerto Rico* v. *Compania Panamena de Aviacion (Copa), S.A., see* notes 77 and 78, *supra,* this mandatory fee is set between $3000.00 and $10,000.00 and funds the State supervisory process, thereby promoting State public policy goals. *Id.* § 8.02.

In addition to laying out this formula for fees, which alone could satisfy the active supervision prong of the Midcal test, the regulation creates a seven-member Supervisory Committee, which is comprised of representatives from the Department of Health, the Patient Ombudsman, health insurance companies, third-party administrators, cooperatives, an economist who is a certified actuary, and a COSSEC representative. *Id.* § 6.03. The committee is ''activated'' as soon as the healthcare cooperative notifies it that it intends to collectively negotiate. *Id.* The Supervisory Committee then oversees every single negotiation by being present when any negotiation is held and requiring the negotiating parties to write a detailed initial report, progress reports, and a final report. *Id.* § 8.07. The Supervisory Committee must approve each report at all stages before the next meeting to negotiate may be held. *Id.* § 8.08.

The regulation also outlines how the Supervisory Committee must evaluate the reports and how it should assess the final report to accept, deny, or request amendments to it. *Id.* § 8.08–8.09. The parties may be referred to COSSEC or the Department of Justice's Office of Monopolistic Affairs if they violate the regulation or engage in an unreasonable restriction on trade, to be prosecuted under Puerto Rico's Antitrust law, Act No. 77–1964. *Id.* § 6.01, 9.01–9.02. The regulation outlines the sanctions and penalties that a cooperative which is prosecuted could suffer for violations of the regulation. *Id.* § 9.04.

It is clear from the foregoing that the change in the law has altered the analysis of Coopharma's collective negotiation activity in a substantial and legally significant way. Any concerns that the Commission had about a lack of oversight are clearly addressed by Act 228 and Regulation No. 9161. Moreover, absent the relief requested, Coopharma will be left in the proverbial ''competitive dust'' of other similar entities across Puerto Rico. Those entities unaffiliated with Coopharma and, therefore, unbound by the Commission Order, can take advantage of the ability to collectively negotiate contracts with the same payors that Coopharma cannot. This inequity should now be rectified by further Commission action to set aside the Order.

4. Change to Commission Policy—Withdrawal of Previous Guidance on PBMs

In addition to the change in law described above, the market dynamics concerning PBMs have shifted significantly since twelve (12) years ago when the Order was imposed. In 2012, there was a host of guidance, reports, studies and letters authored by the Commission in support of the supposed ''procompetitive'' impact of PBMs. The policy of such support for PBMs has since been overturned.[80] In her statement on the matter, Chair Khan said the following:

> The FTC is now pursuing an inquiry into the PBM industry, one that is designed to capture and detail the current realities on the ground in this complex marketplace. While we finalize our market study, we urge the public not to continue to cite or rely on these outdated comments, reports, and studies. It is important that the FTC's work reflect current market dynamics. I am pleased that the FTC is alerting the public to the risks of relying on earlier work based on outdated market conditions and assumptions.[81]

This inquiry into the PBM industry by the Commission is in conjunction with increased State and Federal government investigation into PBMs, spurred by independent reporting on the fact that there has been a substantial change in the healthcare/pharmaceutical and health insurance marketplace in the last 10 years.[82] Such inquiries into the role of PBMs focus on PBM price-fixing schemes and their domineering position over independent pharmacies, which allow PBMs to force independent pharmacies into take-it-or-leave it contracts designed to depress the competitive ability of independent pharmacies in comparison to PBM-affiliated pharmacies.[83] [84]

B. The Order Should Be Modified or Set Aside in the Public Interest

The ''public interest'' presumptively favors competition, and restraints on competition harm the public interest by depriving consumers of the benefits of competition including for example, lower prices, better products and increased innovation. A Commission order that restrains competition will be in the public interest only if, and to the extent that, the benefits of preventing or deterring relevant anticompetitive activity outweigh the losses to competition and consumers cause by the restraint.[85] The Commission will set aside orders which ''unnecessarily inhibit[ ] respondent[s] from engaging in conduct which, in and of itself . . . . may, in certain circumstances, be procompetitive.'' [86] For example, in *Nestlé Holdings,* the Commission granted a petition to modify an order, explaining:

> holding [the petitioner] to the [strict terms of the order, as issued], with the resulting disruption to its operations and ability to compete, would likely diminish [its] competitive effectiveness. It is therefore in the public interest to make the change to enable [the petitioner] to continue to compete in the market without disruption of its operations.[87]

And in *Readers' Digest Association,* the Commission eliminated an order provision when ''the costs that the [provision] imposes on respondent appear to outweigh any consumer benefits [that it] may confer.'' [88] Similar logic compels modifying or setting aside the Order in this matter.

1. Puerto Rico's Historical/Ubiquitous Use of Cooperatives Renders the Setting Aside or Modifying of the Order a Matter of Public Interest

The public interest dictates that the Order be reopened and set aside. The Preamble to Act 228 states that its purpose is to authorize Health Service Provider Cooperatives to negotiate collectively with [third-party payors] to prevent the current system of imbalanced negotiations, resulting in contracts of adhesion. The Legislature stated that this was intended to ''improve access and quality of health services to patients in the Commonwealth of Puerto Rico.'' [89]

Puerto Rico suffers from poor health care infrastructure and a rapidly declining health care workforce, rendering the delivery of health care in Puerto Rico severely compromised.[90] Between 2014 and 2015, approximately 900 physicians left the Island, reducing the number of critical care providers by nearly 36%.[91] And, as a result, Puerto Ricans have fewer physicians than ever before and long wait-times when access health care.[92] In fact, the Health Resources and Services Administration has deemed 72 of Puerto Rico's 78 municipalities as medically underserved areas.[93] Clearly, the ability to negotiate fair contracts ''to improve access and quality of health services to'' Puerto Rico patients is vital to the Commonwealth of Puerto Rico. The current Order prevents Coopharma from negotiating lower costs for consumers with PBMs as well being able to provide improved quality pharmacy services desperately needed by the residents of Puerto Rico, which can only be gained through equitable reimbursement and fair treatment under contracts with PBMs.

2. The Existence of Independent Pharmacies Is Threatened as PBMs Have Become More Dominant in the Last 10 Years

Pharmacy advocacy groups such as the National Community Pharmacists Association (''NCPA'') are sounding the alarm about the changing pharmaceutical market and the market power associated with independent pharmacists.[94] NCPA conducted a survey of 10,000 independent pharmacy owners and managers over 10 days in February 2024 and received 815 responses.[95] The conclusion NCPA has drawn from this survey, which was focused on negotiations with PBMs over rates for Medicare Part D, is that ''[n]early a third of independent pharmacy owners may close their stores this year under pressure from plunging prescription reimbursements by big insurance plans and their pharmacy benefit managers.'' [96] The CEO of the organization, B. Douglas Hoey, pharmacist, MBA, made clear that ''[t]his is an emergency.'' [97] Moreover, his conclusion was that ''if Congress fails to act again, thousands of local pharmacies could be closed within months and millions of patients could be stranded without a pharmacy.'' [98]

In locations where there are very few providers, such as Puerto Rico, the impact of the profit margin growth for PBMs and significantly smaller profits for pharmacies is a dire issue indeed. Although Puerto Rico has a unique infrastructure, as described above, it is also akin to a rural location in the mainland United States. As early as 2016, the then-President and Executive Director of the Puerto Rico Community Pharmacies Association, Idalia Bonilla and Marylis Gavillán Cruz, respectively, drafted a letter to Senator Orrin Hatch, Member of the United States Senate's Economic Development Task Force and Jose B. Carrión III, President of Puerto Rico's Financial Oversight and Management Board, to express interest in providing assistance to the Task Force in identifying ''ways and means of providing Puerto Rico equitable access to federal health care programs.'' [99] Bonilla and Cruz stated that community pharmacies, which are ''characterized by mainly and efficiently serving the beneficiaries of the public health programs,'' have seen their ability to continue operations ''greatly affected'' by, among other causes, ''the unjust practices'' of PBMs.[100] They articulated that ''PBMs' unjust practices have created local and global concerns, as they directly and significantly increase the cost of medications.'' [101]

An analysis by the Rural Policy Research Institute (''RUPRI'') Center for Rural Health Policy analysis of data collected by the National Council for Prescription Drug Programs on pharmacies in the United States from 2003 to 2021 supports the conclusion that PBMs have been harmful to independent, and particularly rural, pharmacies.[102] RUPRI concluded that ''[b]etween 2003 and 2021, the number of independently owned retail pharmacies declined in noncore areas by 16.1 percent, and in micropolitan areas by 9.1 percent, while the number in metropolitan areas increased by 28.2 percent during the same period.'' [103]

Moreover, government entities at both the State and Federal levels, including the Commission, the Centers for Medicare and Medicaid, and Congress, have recognized the shift in market status/market share for PBMs and the oversized impact and bargaining power they wield, as well as recognizing the increases in consumer pricing resulting from it.[104] Absent the relief requested herein, the inability of Coopharma to negotiate for fair and reasonable contract terms on behalf of its small, independent pharmacy members will lead to the very real possibility of more independent pharmacy closures. This will further diminish the ability of Coopharma's customers to readily access needed health care services.

3. The Commission Has Previously Recognized That Absent the Ability To Negotiate, an Entity Without Market Power Cannot Compete

The Commission's own precedent supports taking action to reopen and set aside the Order in this case. In *In Re Toys 'R Us,* the Commission amended an Order based on recognizing a shift in market circumstances and bargaining power for the toy seller.[105] In pertinent part, the Commission found that:

> TRU had market power as a buyer and distributor of toys. TRU has demonstrated that it no longer has market power as a buyer of toys. Walmart and Target have overtaken TRU in competitive strength and market share. TRU has submitted data showing that TRU's loss of competitive position is consistent across product categories.[106]

Moreover, it changed the record keeping requirements based on a recognition of the ''changes in market conditions.'' [107] As with that matter, the prohibited conduct here ''unnecessarily inhibits respondent from engaging in conduct which, in and of itself, is innocuous and may, in certain circumstances, be procompetitive.'' [108]

Further, the Commission has granted petitions to set aside or modify orders where such orders impose a competitive disadvantages on firms that impairs their ability to offer full, vigorous competition. For example, in the matter regarding *Pendleton Woolen Mills, Inc.,* the Commission reopened and modified an order that put the respondent at a ''at a substantial disadvantage'' with respect to its competitors who were not subject to the prohibitions on otherwise lawful conduct that was proscribed by the order.[109] And, in the *Onkyo U.S.A. Corp.* matter, the Commission modified an order when, as a result of the objectionable provisions, the respondent was unable to operate its business as effectively as its competitors and was ''thus competitively disadvantaged in a manner that was not contemplated when the order was issued by the Commission.'' [110]

Additionally, the Commission has modified and set aside orders where the order imposes restrictions to that party

that are not imposed on other members of the industry, creating a competitive disadvantage. For example, in the *Nat'l Fire Hose Corp.* matter, the Commission recognized that ''an order should be modified or vacated if changed circumstances of fact or law place a party to the order under restrictions not applicable to other members of the industry. Fairness and the public interest require that the Commission apply its policies consistently and uniformly among all the members of the industry.'' [111] Where every other Health Care Provider Cooperative in Puerto Rico can take advantage of collective negations with third party payors pursuant to Act 228, including *Cooperativa de Médicos Oftalmólogos de Puerto Rico,* which is still under a separate Commission Order, Coopharma's inability to do so is at a competitive disadvantage, both in terms of its position with other Health Care Provider Cooperatives and with its bargaining position with third party payors. This is directly in line with Commission precedent for reopening and setting aside an Order. Third party payors are currently able to take advantage of Coopharma and its members through low reimbursement rates and other conduct that Coopharma, at the moment, is unable to renegotiate to establish fairer terms for its independent pharmacy members. If allowed, these negotiations would, in turn, translate to benefits to consumers. Thus, the Order should be set aside.

Conclusion

The legal, factual, and market changes described herein are sufficient to meet the Commission's standard to reopen and modify or set aside the Order. First, as stated above, the significant change in law with the enactment of Act 228, in and of itself warrants a modification of the Order. While the Commission recognized, at the time of the Complaint, the applicability of the State Action Doctrine, which Coopharma whole-heartedly believed applied to its conduct given the regulatory scheme of Act 239 and the oversight of cooperative activities by COSSEC,[112] the Commission ultimately concluded that Coopharma's activities did not qualify for State Action immunity.[113] However, the Commission cannot now deny the clear establishment of State Action immunity imposed by Act 228, which allows Health Care Provider Cooperatives the benefit of engaging in collective negotiations with third-party payors, coupled with a specific regulatory scheme and COSSEC's direct, active oversight over the exact conduct which underlies the Order. The State Action Doctrine provides that with this State oversight and the regulations that are currently in place, Health Care Provider Cooperative negotiations in Puerto Rico are State-sanctioned and, therefore, shielded from the Commission's scrutiny that they are anticompetitive.

Second, the public interest also dictates that the Commission reopen and set aside the Order as a result of the changes in the pharmaceutical market and PBMs' increased market share, which has led to multiple government investigations. Federal and State government entities are currently investigating PBMs' vertical integration and market share consolidation as well as their heavy handed policies and contract terms, which have already forced many independent pharmacies out of business entirely.

In the foregoing paragraphs, Coopharma has provided verified information, which shows PBMs' and individual health insurance companies' unprecedented and outsized accumulation and concentration of market power. This market imbalance has placed Coopharma's members, primarily small, rural businesses, in a unique and precarious position given that the Order's restrictions on negotiations are still in place.

Without the ability to negotiate with PBMs due to the Order, Coopharma also stands at a direct competitive disadvantage to all other entities within Puerto Rico that can, and have, taken advantage of Act 228 to ''improve access and quality of health services to patients in the Commonwealth of Puerto Rico. The ability of Puerto Rican independent pharmacies to continue to provide life-sustaining care depends on their ability to collectively negotiate as a cooperative—negotiations which are now regulated and overseen by a State government agency.

For the foregoing reasons, the Commission should reopen and set aside the Consent Order and enter an order in the form attached dismissing the Complaint with prejudice. In the alternative, to the extent the Commission determines that only modification is required, it should amend the order to permit Coopharma to engage in negotiations on behalf of its members with third party payors consistent with Act 228.

Dated: August 7, 2024
Respectfully submitted,

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Endnotes

[1] Statement of Motives, General Cooperative Associations Act of 2004, Act No. 239 at 2 (Sept. 1, 2004) (''Act 239''). ''The members of such cooperatives exercise the decision-making power in equal standing, regardless of the amount of capital they have contributed.'' *Id.* at 2.

[2] Affidavit of Heriberto Ortiz (''Ortiz Affidavit''), ¶ 5.

[3] *Id.* ¶ 6.

[4] NCUA–COSSEC Partnership Will Strengthen Supervision of Cooperativas, *https://ncua.gov/newsroom/pressrelease/2023/ncua-cossec-partnership-will-strengthen-supervision-cooperativas* (Apr. 2023).

[5] Statement of Motives, Act No. 239 at 3 (Sept. 1, 2004).

[6] *Id.*

[7] 5 L.P.R.A. § 4516.

[8] COSSEC replaced the functions of the Inspector of Cooperatives. *See* Puerto Rico Pharmacy Law, Act No. 247- 2004, as amended.

[9] For example, Act 239 requires regulation over the contents of cooperatives' articles of incorporation and bylaw (§§ 4403 and 4404); the CDA must forward bylaws and articles of cooperatives to the Inspector of Cooperatives for review and approval (§§ 4415 and 4422); the Inspector of Cooperatives retains the right to reject creation of a cooperative (§ 4422); CDA has the right to dissolve cooperatives (§ 4555); the Inspector of Cooperatives is required to ensure that all cooperatives comply with the provisions of Act 239 (§ 4646); and, the Inspector must annually audit the operations of all cooperatives (§ 4647). Moreover, Act 239 allows for the direct transfer of goods and services between the government and Cooperatives, without a bidding process required for other third parties (§ 4528); and cooperatives are not required to pay rent for use of facilities in government offices or public corporations (§ 4528). *See* generally §§ 4645–4662, Office of the Inspector of Cooperatives.

[10] *See* ''About Us'' section of COSSEC's website, *http://www.cossec.com/cossec/det_content.asp?cn_id=802* (as translated to English).

[11] *Id.*

[12] Ortiz Affidavit ¶ 7.

[13] *Id.* ¶ 8.

[14] *Id.*

[15] *Id.* ¶ 9.

[16] *Id.* ¶ 10.

[17] Ortiz Affidavit ¶ 10.

[18] *Id.*

[19] *Id.*

[20] *Id.*¶ 12 (citing and appending Ex. 1, Coopharma Clauses of Incorporation, Art. II, § 3).

[21] *Id.* ¶ 13.

[22] Ortiz Affidavit ¶ 16.

[23] *Id.* ¶ 17.

[24] *Id.* ¶ 18.

[25] *Id.*

[26] *Id.*

[27] Ortiz Affidavit ¶ 19.

[28] *Id.*

[29] *Id.* (citing *Rumbin* v. *Utica Mutual Ins. Co.,* 254 Conn. 259, 264 n. 6, 757 A.2d 526

(2000) (''Standardized contracts of insurance continue to be prime examples of contracts of adhesion, whose most salient feature is that they are not subject to the normal bargaining processes of ordinary contracts.'') (Internal quotation marks omitted)).

[30] *Id.*

[31] *Id.* ¶ 20.

[32] Ortiz Affidavit ¶ 20.

[33] *Id.* ¶ 21.

[34] *See* Pharmacies—Puerto Rico, STATISTA, *https://www.statista.com/outlook/hmo/pharmacies/puerto-rico#volume* (last accessed November 7, 2023).

[35] Ortiz Affidavit ¶ 25.

[36] Statement of Chair Lina M. Kahn Regarding 6(b) Study of Pharmacy Benefit Managers, Commission File No. P221200 (June 8, 2022).

[37] Complaint, Docket C–4374 ¶¶ 22, 34.

[38] DEP'T OF JUSTICE, Herfindahl-Hirschman Index, *https://www.justice.gov/atr/herfindahl-hirschmanindex#:~:text=The%20term%20%E2%80%9CHHI%E2%80%9D%20means%20the,then%20summing%20the%20resulting%20numbers* (last accessed June 20, 2024) (defining HHI as a commonly accepted measure of market concentration).

[39] *See* NOTICEL, Insurance Commissioner Favors Collective Bargaining with Health Providers, *https://www.noticel.com/ahora/gobierno/top-stories/20230307/comisionado-de-seguros-favorece-negociacioncolectiva-con-proveedores-de-salud/* (Mar. 7, 2023) (as translated to English) (citing Ramón J. Cao García, Ph.D. & José J. Cao Alvira, Ph.D., Un Estudio Económico de las Compañías de Seguros de Salud y sus Proveedores de Servicios para Identificar Posibles Enmiendas a la Regla Núm. 91 de la Oficina del Comisionado de Seguros de Puerto Rico, Estudio Comisionado por la Oficina del Comisionado de Seguros de Puerto Rico, at 16 (2023)).

[40] UNITED STATES CENSUS BUREAU, Result: Without Health Care Coverage in Puerto Rico (2022) is 5.1% (+/− 3%), *https://data.census.gov/all?q=health+insurance+puerto+rico* (last accessed June 20, 2024).

[41] *See* KFF, Nancy Ochieng et al., Medicare Advantage in 2023: Enrollment Update and Key Trends, *https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/* (Aug. 9, 2023) (interpreting data from CMS Medicare Advantage Enrollment Files and March Medicare Enrollment Dashboard, 2013 and 2023).

[42] ABARCA, Abarca selected as PBM for Vital—an ASES Medicaid program in Puerto Rico, *https://www.abarcahealth.com/abarca-selected-as-pbm-for-vital-an-ases-medicaid-program-in-puerto-rico/* (Oct. 20, 2022). *See also* ASES, Vital Beneficiary Manual, *https://www.sssvital.com/wp-content/uploads/beneficiarymanual.pdf* (last accessed June 20, 2024); CMS, Managed Care in Puerto Rico, *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/managedcare/downloads/puerto-rico-mcp.pdf* (last accessed June 20, 2024).

[43] Per its own admission, in an interview of Jason Borschow, CEO of Abarca Health, the largest PBM in Puerto Rico, on the HealthBiz Podcast with David E. Williams, dated March 17, 2022, Abarca controls approximately 70% of the PBM market and 100% of the State Medicaid Program market in Puerto Rico. *See* Interview of Jason Borshow (March 17, 2022), available at *https://www.youtube.com/watch?v=iQD1fER3QgA*.

[44] ASES, October 2023 Annual Report to Congress, *https://www.asespr.org/wp-content/uploads/2023/12/PuertoRico-2023-Annual-Report-to-Congress_Final.pdf* at 7 (Oct. 2023).

[45] CMS, Managed Care in Puerto Rico at 2, *https://www.medicaid.gov/medicaid-chip-program-information/bytopics/delivery-systems/managed-care/downloads/puerto-rico-mcp.pdf* (stating, as of 2021, Plan Vital includes insurers Triple S, First Medical, MMM, and Plan de Salud Menonita). *See also* MMM, MMM celebrates 20 years taking care of the health of more than 720,000 members, *https://www.mmm-pr.com/mmm-celebra* (stating that it is the ''leading health services plan in the Medicare Advantage sector in Puerto Rico'' with 720,000 insureds) (last accessed June 20, 2024); FAEGRE DRINKER, Anthem Acquires Puerto Rico-Based MMM Holdings and Affiliates, *https://www.faegredrinker.com/en/services/experience/2021/6/anthem-acquires-puerto-ricobased-mmm-holdingsand-affiliates* (June 2021) (''MMM is the largest MA plan and the second-largest Medicaid plan in Puerto Rico, with a network that includes over a dozen offices and more than 10,000 health care providers across the island.'').

[46] Insurance Commissioner Favors Collective Bargaining with Health Providers, *https://www.noticel.com/ahora/gobierno/top-stories/20230307/comisionado-de-seguros-favorece-negociacioncolectiva-con-proveedores-de-salud/* (as translated to English). The Commissioner said: [The Study] found that the concentration of the market in Puerto Rico—both from the point of view of distribution of written premiums and distribution of subscribers—is not only high, but has been increasing over the past years. In the segment of medical plans in the commercial sector, it was found that a single company currently has 49.2% of the subscribers and two others make up 64.8% of the subscribers in Puerto Rico. *See also* García & Alvira, Un Estudio Económico de las Compañías de Seguros de Salud y sus Proveedores de Servicios.

[47] TRIPLE–S MANAGEMENT, *https://management.grupotriples.com/en/ourcompanies/#:~:text=With%20more%20than%2060%20years,%2C%20commercial%2C%20and%20Medicaid%20markets* (stating company has ''approximately 1,000,000 insured in their individual, commercial and Medicare markets'') (last accessed June 20, 2024). *See also* ABARCA, Abarca renews, expands partnerships for pharmacy benefit services with Triple-S, CareFirst, *https://www.abarcahealth.com/abarca-expands-two-bcbsa-plans/* (Sept. 30, 2021).

[48] PR NEWSWIRE, First Medical Renews, Expands Partnership With Abarca For Pharmacy Benefit Services, *https://www.prnewswire.com/news-releases/first-medical-renews-expands-partnership-with-abarca-for-pharmacybenefit-services-301400686.html* (Oct. 14, 2021).

[49] *See* Department of Consumer Affairs Complaint No. SAN–2022–0012881, *Oficina de Asuntos Monopolísticos del Dept. de Justicia* v. *Abarca Health LLC, https://www.justicia.pr.gov/departamento-de-justicia-presenta-querella-porpracticas-enganosas-contra-administrador-de-beneficios-de-farmacia/* (Jan. 26, 2023). At this time, the parties are litigating some procedural matters before the Supreme Court of Puerto Rico and Coopharma is an Amici Curiae in said matter, *see* Docket No. CC–2023–0773.

[50] *See* In the Matter of Cooperativa de Farmacias Puertorriqueñas (''Coopharma''), Docket No. C–4374 (Decision and Order, November 6, 2012).

[51] *Id.* at Section II.

[52] *Id.* at 6.

[53] FED. TRADE COMM'N, Putting the Mod in Order Modification, *https://www.ftc.gov/enforcement/competitionmatters/2014/07/putting-mod-order-modification* (2014).

[54] *See* In the Matter of: Toys R Us, Inc., 2014 WL 187460, at *11–12 (F.T.C. Jan. 13, 2014).

[55] 16 CFR 2.51(b).

[56] *Id.* at *12.

[57] *Id.* (citation omitted).

[58] Statement of Motives, P. de la C. 2440 (''Act 228'') (as translated) at 2 (stating the Legislature passed the law ''with the purpose of authorizing [Health Service Provider Cooperatives] . . . to negotiate collectively with Health Service Organizations (HSO) and Third Party Administrators (AT), so that there is a balance in the negotiations of these parties, since currently the contractual terms between these parties are imposed through adhesion contracts.'').

[59] *See id.* at 1–2 (as translated) (stating that it was ''not envisaged'' that Health Service Provider Cooperatives would be part of Law 203 because all cooperatives ''were already regulated and supervised by specialized cooperative laws, such as Law 239–2004, as amended . . . .'').

[60] *See* Analysis of Agreement Containing Consent Order To Aid Public Comment to In the Matter of Coopharma, File No. 101–0079 at 3–4 (Aug. 21, 2012) (explaining Law 203).

[61] *See id.* at 4 n.5 (August 21, 2012) (The Commission is aware that Law 239, which regulates cooperatives generally, declared that cooperatives ''shall not be considered conspiracies or cartels to restrict business.'' 5 L.P.R.A. § 4516 (Law 239, § 20.5). The Commission and the Puerto Rico Department of Justice interpret Law 203 (which was passed after Law 239) to supersede Law 239.'').

[62] *See* Statement of Motives, Act 228 (as translated) at 2.

[63] Statement of Motives, Act 228 (as translated) at 2.

[64] *Id.*

[65] *Id.*

[66] *See id.; see also* California Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc., 445 US 97 (1980) (court established a two-prong standard test for a party to satisfy the State Action Doctrine: ''the challenged restraint must be one 'clearly articulated and

affirmatively expressed as state policy''' and ''the policy must be 'actively supervised' by the State itself'') (internal citation omitted).

[67] COSSEC replaced the functions of the Inspector of Cooperatives. *See* Puerto Rico Pharmacy Law, Act No. 247–2004 (''Act 247''), as amended.

[68] *See* Ortiz Affidavit, ¶ 24, appending Ex. 2, Certification of Mabel Jiménez Miranda (explaining the role of COSSEC as its Executive President).

[69] *See* ''About Us'' section of COSSEC's website, *http://www.cossec.com/cossec/det_content.asp?cn_id=802* (as translated).

[70] *See* Ex. 2 to Ortiz Affidavit, Cert. of Mabel Jiménez Miranda, Executive President of COSSEC.

[71] *See* Ex. 2 to Ortiz Affidavit at ¶ 5 (emphasis added).

[72] Analysis of Agreement Containing Consent Order to Aid Public Comment to In the Matter of Coopharma, File No. 101–0079 at 3–4 (Aug. 21, 2012).

[73] Puerto Rican statutes may be referred to as Act or Law interchangeably.

[74] In the Matter of Coopharma, Docket C–4374, Complaint ¶ 47 (Nov. 7, 2012).

[75] *See* ''Regulations for the Supervision and Supervision of Collective Negotiations of the Cooperatives of Health Service Providers (CPSS) with Third Party Administrators (AT) and Health Service Organizations (HSO)''. No. 9161 at Art. IV (Feb. 13, 2020) (as translated to English).

[76] *Id.*

[77] *See* Analysis of Agreement Containing Consent Order To Aid Public Comment to In the Matter of Cooperativa de Médicos Oftalmólogos de Puerto Rico, File No. 141–0194 at 4 (Jan. 19, 2017).

[78] *See Federal Trade Commission* v. *Ticor Title Insurance Company*, 504 U.S. 621, 634 (1992) (stating that the active supervision prong of the Midcal test is met if State officials ''have and exercise power to review particular anticompetitive acts of private parties and disapprove those that fail to accord with state policy'') (citation omitted). *See also Morgan* v. *Div. of Liquor Control, Dep't of Bus. Regul., State of Conn.*, 664 F.2d 353, 356 (2d Cir. 1981) (finding anticompetitive conduct immune from the Antitrust Act under the State Action Doctrine because the State of Connecticut structured ''a detailed mechanism for determining prices for alcoholic beverages'' which satisfied the active supervision requirement); *Destec Energy, Inc.* v. *S. California Gas Co.,* 5 F. Supp. 2d 433, 456 (S.D. Tex. 1997), aff'd sub nom. *Destec Energy* v. *S. California Gas Co.,* 172 F.3d 866 (5th Cir. 1999) (finding that a State entity which ''agreed to modify long-term individually negotiated EOR contracts only upon a finding that the modification was necessitated by the 'public interest' '' satisfied the active supervision prong of the Midcal test because there is no requirement that a regulatory agency ''must retain unfettered discretion'' in order to meet the requirement). The court in Destec cited Ticor to explain that ''the active supervision inquiry is intended to determine whether 'the State has exercised sufficient independent judgment and control so that the details of the rates or prices have been established as a product of deliberate state intervention, not simply by agreement among private parties.' '' Destec, 5 F. Supp. 2d at 457–58 (citing Ticor, 504 U.S. at 634–35). Here, COSSEC's broad and explicit authority to monitor negotiations and, therefore, pharmaceutical reimbursement prices and contracts, between healthcare cooperatives, third party administrators, and health service organizations and to identify illicit practices which do not comply with the law and State policy, as laid out in Regulation No. 9161, satisfies the Midcal requirement for active supervision. COSSEC explains that in order to promote the public policy of having functional healthcare cooperatives, it will ensure balance by overseeing negotiations between those cooperatives, third-party administrators, and health care services organizations, to improve the public's access to quality healthcare services. *See* Ex. 2 to Ortiz Affidavit (COSSEC letter explaining its role as established by Act 239 and Regulation No. 9161). Compliance with the active supervision prong of the Midcal test is further shown because the regulation allows COSSEC to ''investigate and prosecute illicit practices under collective bargaining authorized by the Subchapter 20A of Act No. 239–2004, as amended.'' *See* Regulation No. 9161 at Art. IV (as translated to English).

[79] *Ports Auth. of Puerto Rico* v. *Compania Panamena de Aviacion (Copa), S.A.,* 77 F. Supp. 2d 227, 236 (D.P.R. 1999) (finding that a ''detailed formula for annually adjusting'' a Federal Inspection Service Facility fee satisfied the active supervision prong of the Midcal test). Here, Puerto Rico's Regulation No. 9161 provides for direct oversight by COSSEC over negotiations between healthcare players. This is arguably more stringent than issuing a formula annually, as a court nonetheless found sufficient to satisfy the active supervision prong under *Compania Panamena.*

[80] Statement of Chair Lina M. Khan Regarding the Policy Statement Concerning Reliance on Prior PBM-Related Advocacy Statements and Reports, *https://www.ftc.gov/legal-library/browse/cases-proceedings/publicstatements/statement-chair-lina-m-khan-regarding-policy-statement-concerning-reliance-prior-pbm-related* (July 20, 2023).

[81] *Id.* at 2 (emphasis added).

[82] *See, e.g.,* NYS Committee on Investigations and Gov't Operations, Final Investigative Report: Pharmacy Benefit Managers in New York, *https://www.nysenate.gov/sites/default/files/article/attachment/final_investigatory_report_pharmacy_benefit_managers_in_new_york.pdf* (May 31, 2019). The Committee determined that: PBMs often employ controversial utilization and management tools to generate revenue for themselves in a way that is detrimental to health plan sponsors, patients, and pharmacies. Such practices include maximum allowable cost lists, direct and indirect remuneration fees, rebates, formularies, and most controversially, spread pricing. The Committee also found evidence that PBMs are undermining patient choice by forcing consumers to use their preferred distributors, which are predominantly their own retail and mail order operations. *Id.* at 4–5 (internal citations omitted). *See also* Nat'l Assoc'n of Attys General, A Bipartisan Coalition of 39 State Attorneys General Urge Congressional Action on Pharmacy Benefit Manager Reform, *https://www.naag.org/pressreleases/a-bipartisan-coalition-of-39-state-attorneys-general-urge-congressional-action-on-pharmacy-benefit-manager-reform/* (Feb. 21, 2024); Erin Trish, Ph.D., Karen Van Nuys, Ph.D. & Robert Popovian, PharmD, U.S. Consumers Overpay for Generic Drugs, *https://healthpolicy.usc.edu/research/u-s-consumers-overpay-for-genericdrugs/* (White Paper abstract states that ''PBMs' current practices—coupled with market distortions within the pharmaceutical supply chain—have inflated retail generic prices''); JACOBIN, H. Santoro, Middlemen Are Profiting off the Broken US Pharma System, *https://jacobin.com/2024/03/pharmacy-benefit-managers-drug-prices-congress* (Mar. 10, 2024) (Title excerpt: ''Pharmacy benefit managers push expensive medications and slash drug reimbursement rates, pocketing the profits for themselves. Congress looked set to regulate these shadowy middlemen—but $50 million in industry lobbying later, the effort has stalled.'').

[83] *See, e.g.,* DEP'T OF JUSTICE, Assistant Attorney General Jonathan Kanter Announces Task Force on Health Care Monopolies and Collusion, *https://www.justice.gov/opa/pr/assistant-attorney-general-jonathan-kanter-announcestask-force-health-care-monopolies-and* (May 9, 2024); U.S. GOV'T ACCOUNTABILITY OFFICE REPORT TO CONGRESSIONAL REQUESTERS, Selected States' Regulation of Pharmacy Benefit Managers, *https://www.gao.gov/assets/d24106898.pdf* (Mar. 2024) (stating that GAO conducted the study to review the legislation enacted by states in response to ''certain PBM practices, such as PBMs retaining a share of the rebates and use of spread pricing,'' because every U.S. State has ''enacted at least one PBM-related law between 2017 and 2023''); NYS DEP'T OF FINANCIAL SERVS., DFS Superintendent Adrienne A. Harris Proposes Pharmacy Benefit Manager Regulations to Strengthen Consumer Protections and Address Anti-Competitive Conduct, *https://www.dfs.ny.gov/reports_and_publications/press_releases/pr202402061* (Feb. 6, 2024).

[84] *See also,* Interim FTC Report at 53 (''our initial review of documents received thus far reveals that PBMs can have the ability and incentive to put downward pressure on reimbursement rates for rival, unaffiliated pharmacies—including to a degree that may be unsustainable for small, independent pharmacies.'').

[85] FED. TRADE COMM'N, Putting the Mod in Order Modification, *https://www.ftc.gov/enforcement/competitionmatters/2014/07/putting-mod-order-modification* (2014) (''The modification process helps keep Commission orders from doing more harm than good when conditions change, and as the public interest requires.'').

[86] In the matter of Occidental Petroleum Corp., 101 F.T.C. 373, 1974 WL 175259, at *1. FTC Docket C–2492 (F.T.C. Mar, 9, 1983); *see also, e.g.,* In the matter of Removatron Int'l Corp., et al., 114 F.T.C. 715, 719, FTC Docket No. 9200 (F.T.C. 1991) (setting aside order provision when ''continued application

would be inequitable or harmful to competition'').

[87] In the matter of Nestlé Holdings, Inc., et al., C–4082, 2005 WL 1786402, at *3 (F.T.C. July 15, 2005).

[88] In the matter of the Readers' Digest Ass'n. No. C–2075, 102 F.T.C. 1268, 1971 WL 128725, at *2 (Sept. 30, 1983).

[89] Statement of Motives, P. de la C. 2440 (''Act 228'') (as translated) at 2.

[90] *See* Ximena Benavides, Disparate Health Care In Puerto Rico: A Battle Beyond Statehood, 23 Univ. of Penn. J. of Law and Social Change 163, 175 (2020).

[91] *Id.*

[92] *Id.*

[93] *Id.*

[94] NCPA, Local Pharmacies on the Brink, New Survey Reveals, *https://ncpa.org/newsroom/newsreleases/2024/02/27/local-pharmacies-brink-new-survey-reveals* (Feb. 27, 2024).

[95] NCPA, NCPA Report for February 2024 Survey of Independent Pharmacy Owners/Managers, *https://ncpa.org/sites/default/files/2024-02/Feb2024-DIRsurvey.Exec%20Summary.pdf* (Feb. 2024).

[96] NCPA, Local Pharmacies on the Brink, New Survey Reveals, at 1 *https://ncpa.org/newsroom/newsreleases/2024/02/27/local-pharmacies-brink-new-survey-reveals* (Feb. 27, 2024).

[97] *Id.*

[98] *Id.*

[99] Oct. 24, 2016 Letter to Sen. Orrin Hatch and Jose B. Carrión III, *https://www.finance.senate.gov/imo/media/doc/Puerto%20Rico%20Community%20Pharmacies%20Association%20(Late%20-%20Submission%201).pdf* (Oct. 24, 2016).

[100] *Id.* at 2.

[101] *Id.*

[102] RURAL HEALTH RESEARCH GATEWAY, Research Alert: Sept. 1, 2022, *https://www.ruralhealthresearch.org/alerts/504#:~:text=Between%202003%20and%202021%2C%20the,percent%20during%20the%20same%20period* (last accessed June 19, 2024).

[103] RUPRI CENTER FOR RURAL HEALTH POLICY ANALYSIS, Update on Rural Independently Owned Pharmacy Closures in the United States, 2003–2021, *https://rupri.publichealth.uiowa.edu/publications/policybriefs/2022/Independent%20Pharmacy%20Closures.pdf* (last accessed June 19, 2024).

[104] *See* notes 78 and 79, supra. *See also* ''Letter to Pharmacy Benefit Managers, Medicare Part D Plans, Medicaid Managed Care Plans, and Private Insurance Plans,'' *https://www.cms.gov/newsroom/fact-sheets/cms-letter-plansand-pharmacy-benefit-managers* (Dec. 13, 2023); *see also,* Sens. Wyden, Crapo Call for Swift Passage of Bipartisan PBM Reforms, *https://www.finance.senate.gov/chairmans-news/wyden-crapo-call-for-swift-passage-ofbipartisan-pbm-reforms* (Mar. 14, 2024).

[105] In Re Toys 'R Us, Petition to Modify Order, FTC File No. 131–0052, Docket C–4405, at 4, located at *https://www.ftc.gov/sites/default/files/documents/cases/140109toysruspetition.pdf* (Jan. 3, 2014).

[106] In Re Toys 'R Us, Modified Order, FTC File No. 131–0052, Docket C–4405, at 4, located at *https://www.ftc.gov/system/files/documents/cases/140415toysrusorder.pdf* (Apr. 11, 2014).

[107] *Id.* at 4.

[108] *See* In the Matter of Occidental Petroleum Corp., 101 F.T.C. 373, 1974 WL 175259, at *1.

[109] In the Matter of Pendleton Woolen Mills, Inc., 122 F.T.C. 267, 270, FTC Docket No. C–2985 (1996).

[110] In the Matter of Onkyo U.S.A. Corp., 122 F.T.C. 325, 326. FTC Docket No. C–3092 (1996).

[111] In the Matter of Nat'l Fire Hose Corp., No. C–2935, 1978 WL 206076, at *10 (F.T.C. Nov. 1, 1978).

[112] *See* n. 8, supra.

[113] *See* Analysis of Agreement Containing Consent Order To Aid Public Comment to In the Matter of Coopharma, File No. 101–0079 at 4 (August 21, 2012). It should also be noted that the Commission has recognized the enactment of and applicable of Act 228 ''when negotiating with any Payor in compliance with Act 228.'' *See* In the Matter of Cooperativa de Médicos Oftalmólogos de Puerto Rico, No. C–4603 at 4 (Decision and Order, Mar. 3, 2017). Moreover, Act 228 covers all of the conduct which is addressed in the Order, and, in fact goes further than the Order in prohibiting specific conduct. By way of specific example, 26 P.R. Laws § 3107 explicitly states that any ''threats to boycott, go on strike or other coordinated action by the providers shall be subject to oversight by the Antitrust Affairs Office of the Department of Justice, in order to determine whether the same is in violation of the provisions of this chapter or the Antitrust Act.'' The section further authorizes the imposition of civil and/or criminal liability on any Health Care Cooperative engaged in such conduct.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2024–0065, NIOSH–352–A]

Request for Public Comment on the Draft Hazard Review: Wildland Fire Smoke Exposure Among Farmworkers and Other Outdoor Workers

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) in the Centers for Disease Control and Prevention (CDC), an Operating Division of the Department of Health and Human Services (HHS), requests public comment and technical review on the draft Hazard Review: Wildland Fire Smoke Exposure Among Farmworkers and Other Outdoor Workers.

DATES: Electronic or written comments must be received by November 12, 2024.

ADDRESSES: You may submit comments, identified by docket number CDC–2024–0065 and docket number NIOSH–352–A, by either of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All information received in response to this notice must include the agency name and docket number (CDC–2024–0065; NIOSH–352–A). All relevant comments, including any personal information provided, will be posted without change to *https://www.regulations.gov.* Do not submit comments by email. CDC does not accept comments by email. For access to the docket to read the draft Hazard Review document or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: R. Todd Niemeier, Ph.D., National Institute for Occupational Safety and Health, MS–C15, 1090 Tusculum Avenue, Cincinnati, OH 45226. Telephone: (513) 533–8166.

SUPPLEMENTARY INFORMATION: NIOSH is requesting public comment and technical review of the draft Hazard Review: Wildland Fire Smoke Exposure Among Farmworkers and Other Outdoor Workers, which is accessible in the docket (CDC–2024–0065; NIOSH–352–A). The final document will be edited, so comments that focus on the technical content are requested. The final document will be used as the scientific evidence base to inform the development of supplementary educational materials for workers, employers, and other relevant audiences to support the implementation of the recommendations. Therefore, comments that focus on the understandability, accessibility, and feasibility of the recommendations are requested. To facilitate the review of this document, NIOSH requests that responses to the following specific questions be considered:

1. How could the outdoor worker populations who may be exposed to wildland fire smoke be more completely characterized in Chapter 2? Please provide supporting references.