

**[DATE]**

Lina Khan

Chair

Federal Trade Commission

600 Pennsylvania Avenue, NW

Washington, DC 20580

**RE: Solicitation for Public Comments on the Impact of Prescription Benefit Managers’ Business Practices**

Dear Chair Khan,

On behalf of the Association for Utah Community Health (AUCH), thank you for the opportunity to provide input and recommendations on the impact of Prescription Benefit Managers’ (PBMs’) business practices.

AUCH is Utah’s federally-designated Primary Care Association and it represents Utah’s 14 Federally Qualified Health Centers (FQHCs) operating 59 clinic locations across the state. Utah’s FQHCs provide medical, dental, pharmacy, laboratory, behavioral health, and enabling services to over 150,000 low-income Utahns. These clinics serve patients from 28 of Utah’s 29 counties. The Centers provide a Medical Home to one out of every 20 individuals in the state, one out of every six low-income individuals, one out of every five uninsured individuals, one of every six rural residents, and nearly one out of every 11 Medicaid beneficiaries in the state.

The 340B Drug Pricing Program is a vital source for Utah’s FQHCs to provide affordable and accessible medications to patients who need them the most. Savings from the 340B program enable these centers to expand their primary and preventive care services to address the needs of their communities. 340B savings support clinical pharmacy services and enabling services that address social determinants of health, like transportation and housing services. With the statutory and legal obligation to reinvest every dollar back into patient care, Utah’s FQHCs depend on fair contracts and adequate reimbursement from Pharmacy Benefit Managers (PBMs). FQHC pharmacies need a stable business environment that maximizes patient care without operating at a financial loss. Additionally, Utah’s FQHCs use 340B savings to provide care to under- and uninsured patients. Both the access to affordable medications and preventive care helps prevent and manage chronic conditions and keep patients out of the emergency room, ultimately improving health outcomes for vulnerable groups and saving the health care system money.

Over the last few years, PBMs have instituted a number of aggressive business practices to steal FQHC 340B savings and increase PBMs’ profit margins. Discriminatory reimbursement not only subverts the purpose of the federal 340B laws by transforming them into a subsidy for for-profit middlemen, but also deprives safety net providers of the savings and revenue they desperately need to support services to low-income patients and other vulnerable populations.

AUCH appreciates the opportunity to comment about the practices of PBMs, as we have concerns about the impact of their practices on patients, providers, and health centers’ ability to provide affordable medications to their patients. Without federal oversight, Utah’s FQHCs are at the mercy of PBMs, suffering daily consequences due to unequal bargaining power. We strongly urge to FTC to issue regulations that will create regulatory protections for providers and patients to stop PBMs’ anticompetitive practices and provide an avenue for recourse to hold vertically integrated PBMs responsible.

AUCH urges the Federal Trade Commission (FTC) to carefully consider the following:

1. Health centers need more federal protection from pharmacy benefit managers’ anticompetitive practices which negatively impact pharmacy reimbursement and patient access to affordable medications.
* PBMs operate in the middle of the distribution chain for prescription drugs. That’s because they:
	+ develop and maintain lists, or formularies, of covered medications on behalf of health insurers, which influence which drugs individuals use and determine out-of-pocket costs,
	+ use their purchasing power to negotiate rebates and discounts from drug manufacturers that are withheld from the patient and provider, and
	+ contract directly with individual pharmacies to reimburse for drugs dispensed to beneficiaries.
* PBMs profit at nearly every stage of the supply chain, from the drug manufacturer to the patient purchasing the prescription at the pharmacy. They are incentivized to pursue contractual arrangements and rebates that increase profits for the PBM and PBM-owned health insurers and pharmacies.
* Examples of contractual restrictions that impact reimbursement for pharmacies include:
	+ PBMs often structure their contracts to collect fees from pharmacies and keep rebates from manufacturers as a part of an “administrative fee” or “rebate sharing” arrangement with the health plan.
	+ Health centers are forced to accept—without the ability to meaningfully negotiate terms— PBMs’ contracts, amendments (on rates, network contract education – i.e., aberrant product list restrictions), and provider manuals to be placed in network in their communities.
	+ PBMs have begun to place limitations on purchasing of drugs and health centers that do not comply risk audit repercussions via fines, no reimbursement, and threats of network termination.
	+ FQHC pharmacies are subjected to random basis audits that often come with no notice. Each audit comes with the threat of expulsion from the network. Access to community networks are essential to the viability of the FQHCs’ pharmacies.
1. Pharmacy benefit managers discriminate against health centers for participating in the 340B program and force in-house and contract pharmacies to accept lower reimbursement and unfair contracting terms. Certain PBMs knowingly and repeatedly attempt to subvert Utah’s 340B laws.
	* PBMs intentionally reimburse 340B pharmacies at lower rates than non-340B pharmacies for the same prescription drugs simply because health centers receive a 340B discount. This practice is known as “pickpocketing,” because PBMs are picking the 340B savings out of the health center’s pockets.
	* Health centers, small non-profit organizations, frequently have very little negotiating power to fight against PBMs’ discriminatory contracts, as they cannot afford to be excluded from the PBM’s network nor the associated health insurer’s network for medical and mental health services.
	* Health Resources & Services Administration, the federal agency which oversees the 340B program, does not have authority over the PBMs’ business practices. Health centers need the FTC to issue regulations and increase oversight over PBMs’ discriminatory and anti-competitive business practices against 340B covered entities.
	* Some health centers must utilize contract pharmacies because they do not have an in-house pharmacy, or they need to increase access for low-income and vulnerable patients to receive discounted medications in their communities. Health centers using contract pharmacies have been hit especially hard by PBMs’ and pharmaceutical manufacturers’ greedy business practices. PBMs and pharmaceutical manufacturers negotiate contracts that allow PBMs to receive rebate money that is never shared with patients or providers. The manufacturers have tried to conflate the payment of these contractually negotiated rebates to PBMs with the 340B discounts which manufacturers are required to provide by law. Since July 2020, over 16 drug manufacturers have restricted shipments to 340B contract pharmacies until health centers provide claims level pharmacy data to PBMs, data that will be used by PBMs and pharmaceutical manufacturers to continue to pickpocket 340B savings intended for FQHCs.
* These practices have had a disparate impact on rural 340B patients. Without the use of contract pharmacies, some Utah health center patients are forced to travel 100+ miles each way to fill their prescriptions at a price they can afford. With some of these routes becoming impassible during the winter months, and many health center patients facing barriers to transportation, most faced with this trek would either ration or forego their necessary medications.
	+ PBMs have also mandated that pharmacies comply with onerous prescription claims identification requirements. These data requests, which attempt to force health centers to devote large amounts of time and effort into identifying 340B claims, are illegal in Utah. The Utah State Legislature unanimously passed 340B protections in 2020 and 2021, which in part prohibit PBMs from data and identification requests beyond what is required by federal 340B statute. Despite these laws and certain PBMs’ knowledge of said laws, these requests continue.
		- These requests are also unnecessary for health centers, who are required by federal statute to document 340B claims, and subsequently, how 340B savings are used. Any type of data request from PBMs under the guise of compliance or auditing is duplicative.
	+ Without federal protection against these discriminatory practices, Utah’s health centers and their patients are at the mercy of manufacturers and PBMs.
1. AUCH requests more data and transparency from pharmacy benefit managers to understand how manufacturer rebates are calculated and how they impact the cost of drugs for patients.
	* Health centers and patients deserve insight into the process and the data used to calculate PBM rebates from pharmaceutical manufacturers.
	* PBMs are responsible for reimbursing the pharmacy for dispensing the patient’s medication. The pharmacy, who has already incurred a cost for stocking and dispensing the medication, has no control over any aspect of the medication’s sale. It is the PBM who determines the patient’s copay and the PBM who determines in advance how much it will reimburse pharmacies for each medication covered under the drug plan.
		+ PBMs often reimburse small, independent non-profit organizations at much lower rates than those negotiated with large, for-profit corporations. This results in many prescriptions being dispensed at a gross loss to the pharmacy. This disproportionally impacts independent and rural pharmacies, in some cases leading to closure. As a result, many rural patients have decreased access to medications. PBMs should be required to disclose reimbursement rates for all pharmacies.
	* Health centers receive information at the point-of-sale and have little control over how PBMs change drug prices and reimbursement rates based on PBMs rebates.
	* PBMs often receive rebates that are calculated as a percentage of the manufacturer’s list price and receive larger rebates for more expensive drugs. This creates an incentive for PBMs to make formulary decisions based on higher rebates rather than efficiency and value to the patient.
2. By dominating every step of the drug distribution process, pharmacy benefit managers create additional barriers for patients seeking to purchase their preferred medication at their pharmacy of choice. This is especially true of Utah’s rural, frontier, and tribal communities.
* PBMs’ financial interests conflict with the best interest of patients. PBMs have a larger incentive to place expensive drugs on their formularies to increase manufacturer rebates, instead of considering the out-of-pocket costs for patients.
* PBMs can create inflated drug prices as the basis to calculate co-pays and co-insurance, so patients pay a lot more at the counter than they should.
* Due to PBM-created network limitations on health plans, patients are steered towards PBM-owned retail, mail order, and specialty pharmacies to receive specific drugs. This impacts the patient’s ability to choose their pharmacy based on trust and accessibility. Many of Utah’s health centers operate in rural, frontier, and tribal communities. These restrictions are especially burdensome for these patients, increasing travel and wait times, especially in the case of mail order pharmacy restrictions.
	+ Oftentimes there are delays in mail delivery in these communities, and many Utahns in these communities, especially tribal communities, rely solely on P.O. boxes that are located many miles from their home. Delays can be so significant that patients are forced go to their out-of-network local pharmacy to purchase necessary medication that has yet to arrive in the mail. In these instances, many Utahns are forced to pay out-of-pocket as their insurance has already been billed for the mail order drugs that have yet to arrive.
* PBMs not only negotiate which drugs will be covered and at what cost, but they also have direct and proprietary access to their prescription drug benefit plan enrollees and can use their access as a platform to guide, steer, direct or mandate which pharmacy plans enrollees can use. This creates an unfair advantage for vertically integrated companies.
* AUCH requests more transparency into PBMs’ utilization management requirements that interfere with patients receiving the optimal treatment selected in consultation with their physicians. These requirements can delay access to needed care; in some cases, the barrier to care imposed by prior authorization and step therapy lead to the patient receiving a less effective treatment or no treatment at all.
1. Pharmacy benefit managers create barriers to affordable medications for patients with Medicare Part D coverage.
	* In the last five years alone, some retail pharmacies enrolled in Medicare Part D went from paying around $9,000 to over $100,000 in direct and indirect remuneration (DIR) fees a year. Under the current regulation, Part D sponsors have an incentive to opt for higher negotiated prices at the point of sale, which creates the illusion that pharmacies will receive a higher reimbursement until clawbacks occur over six to twelve months later.
	* When DIR fees are applied after point-of-sale, pharmacies lose control over their revenues and profitability, creating undue financial risk. Providing the lowest possible reimbursement at the point of sale will enable pharmacies to make informed business decisions based on accurate data and mitigate cash flow problems due to delayed reimbursement.
	* Currently, pharmacies cannot verify or challenge DIR fees because they cannot connect DIR fees to the original prescription claim or properly evaluate “performance metrics” under their contracts.
	* In the face of CMS’s proposed Medicare rule, for 2023, to get access to one PBM’s Medicare Part D network, one Utah FQHC was given just 10 days to opt out of an amendment that would reimburse them 10% less than their wholesale acquisition cost, provide no dispensing fee, and require them to pay $0.75 per transaction into a “performance pool.”

Thank you for your consideration of these comments. If you have any questions, please feel free to contact me at alan@auch.org or at (801) 716-4601.

Sincerely,

Alan Pruhs

Executive Director

Association for Utah Community Health

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Over the last few years, PBMs have instituted a number of aggressive business practices to steal health centers’ 340B savings and increase PBMs’ profit margins. Discriminatory reimbursement not only subverts the purpose of the federal laws by transforming them into a subsidy for for-profit middlemen, but also deprives safety net providers of the savings and revenue they desperately need to support services to low-income patients and other vulnerable populations.

AUCH appreciates the opportunity to comment about the practices of PBMs, as we have concerns about the impact of their practices on patients, providers, and health centers’ ability to provide affordable medications to their patients. Without federal oversight, health centers are at the mercy of PBMs, suffering daily consequences due to unequal bargaining power. We strongly urge to FTC to issue regulations that will create regulatory protections for providers and patients to stop PBMs’ anticompetitive practices and provide an avenue for recourse to hold vertically integrated PBMs responsible.

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* PBMs profit at nearly every stage of the supply chain, from the drug manufacturer to the patient purchasing the prescription at the pharmacy. They are incentivized to pursue contractual arrangements and rebates that increase profits for the PBM and PBM-owned health insurers and pharmacies.
* Examples of contractual restrictions that impact reimbursement for pharmacies include:
	+ PBMs often structure their contracts to collect fees from pharmacies and keep rebates from manufacturers as a part of an “administrative fee” or “rebate sharing” arrangement with the health plan.
	+ Health centers are forced to accept—without legitimate negotiation— PBMs’ contracts, amendments (on rates, network contract education – i.e., aberrant product list restrictions), and provider manuals to get access to patients in network in our area.
	+ Health centers have limitations on purchasing of drugs on limited supply, or risk audit repercussions via fines, no reimbursement, and threats of network termination.
	+ Subjected to random basis audits that often come with no notice. Each audit comes with the threat of expulsion from the network. Access to networks in our community are essential to the viability of my pharmacy.
	+ **[INSERT LOCATION EXAMPLE OF IMPACT ON REIMBURSEMENT, CONTRACT RESTRICTIONS, UNFAIR BUSINESS PRACTICES, LIMITATIONS ON PHARAMCY CHOICE OUTSIDE OF 340B ISSUES]**
1. Pharmacy benefit managers discriminate against health centers for participating in the 340B program and force in-house and contract pharmacies to accept lower reimbursement and unfair contracting terms. Certain PBMs knowingly and repeatedly attempt to subvert Utah’s 340B laws.
	* PBMs intentionally reimburse 340B pharmacies at lower rates than non-340B pharmacies for prescription drugs simply because health centers receive a 340B discount. This practice is known as “pickpocketing,” because PBMs are picking the 340B savings out of the health center’s pockets.
	* Health centers have very little negotiating power to fight against PBMs’ discriminatory contracts, as they cannot afford to be excluded from the PBM’s network nor the associated health insurer’s network for medical and mental health services.
	* As the Health Resources & Services Administration oversees the 340B program, it does not have authority over the business practices related to operating a 340B program. Health centers need the FTC to issue regulations and increase oversight over PBMs’ discriminatory and anti-competitive business practices against 340B covered entities.
	* Health centers utilize contract pharmacies to increase access for uninsured and underinsured patients to receive discounted medications in their communities. PBMs’ greedy business practices to generate higher manufacturer rebates are negatively impacting health centers’ ability to receive 340B priced drugs at contract pharmacies. Since July 2020, over 16 drug manufacturers have restricted shipments to 340B contract pharmacies until health centers provide claims level pharmacy data to help manufacturers limit PBM rebates.
* These practices have had a disparate impact on rural 340B patients. Without the use of contract pharmacies, some Utah health center patients would be forced to travel 100+ miles each way to fill their prescriptions at a price they can afford. With some of these routes becoming impassible during the winter months, and many health center patients facing barriers to transportation, most faced with this trek would either ration or forego their necessary medications.
	+ PBMs have also mandated that pharmacies comply with onerous prescription claims identification requirements. These data requests, which attempt to force health centers to devote large amounts of time and effort into identifying 340B claims, are illegal in Utah. The Utah State Legislature unanimously passed 340B protections in 2020 and 2021, which in part prohibit PBMs from data and identification requests beyond what is required by federal 340B statute. Despite these laws and certain PBMs’ knowledge of said laws, these requests continue. **[PLEASE NOTE IF YOUR HEALTH CENTER HAS CONTINUED TO RECEIVE DATA REQUESTS FROM EXPRESS SCRIPTS AFTER MAY 2021, AND IF POSSIBLE, HOW MANY REQUESTS YOU HAVE RECEIVED]**
		- These requests are also unnecessary for health centers, who are required by federal statute to document 340B claims, and subsequently, how 340B savings are used. Any type of data request from PBMs under the guise of compliance or auditing is duplicative.
	+ Without federal protection against these discriminatory practices, health centers and our patients are at the mercy of manufacturers and PBMs.
1. AUCH requests more data and transparency from pharmacy benefit managers to understand how manufacturer rebates are calculated and impact the cost of drugs for patients.
	* Health centers and patients deserve to have access and insight into the process and the data used to calculate PBM rebates from manufacturers. PBMs should disclose information related to fee arrangements with drug manufacturers.
	* PBMs are responsible for reimbursing the pharmacy for dispensing the patient’s medication. The pharmacy, who has already incurred a cost for stocking and dispensing the medication, has no control over any aspect of the medication’s sale. It is the PBM who determines the patient’s copay and the PBM who determines in advance how much it will reimburse pharmacies for each medication covered under the drug plan.
		+ PBMs often reimburse small, independent non-profit organizations at much lower rates than those negotiated with large, for-profit corporations. This results in many prescriptions being dispensed at a gross loss even before accounting for expenses. This disproportionally impacts independent and rural pharmacies, in some cases leading to closure. As a result, many rural patients have decreased access to medications. PBMs should be required to disclose reimbursement rates for all pharmacies.
	* Health centers receive information at the point-of-sale and have little control over how PBMs change drug prices and reimbursement rates based on PBMs rebates.
	* PBMs often receive rebates that are calculated as a percentage of the manufacturer’s list price and receive larger rebates for more expensive drugs. This creates an incentive for PBMs to make formulary decisions based on higher rebates than efficiency and value to the patient.
	* **[INSERT ANY ADDITIONAL EXAMPLES OF HOW TRANSPARENCY WOULD HELP YOUR PHARAMCY]**
2. By dominating every step of the drug distribution process, pharmacy benefit managers create additional barriers for patients seeking to purchase their preferred medication at their pharmacy of choice. This is especially true of Utah’s rural, frontier, and tribal communities.
* PBM’s financial interest conflicts with the best interest of patients. PBMs have a larger incentive to place expensive drugs on their formularies to increase manufacturer rebates, instead of considering the out-of-pocket costs for patients.
* PBMs use inflated drug prices as the basis to calculate co-pays and co-insurance, so patients pay a lot more at the counter than they should.
* Due to PBM-created network limitations on health plans, patients are steered towards PBM-owned retail, mail order, and specialty pharmacies to receive specific drugs. This impacts the patient’s ability to choose their pharmacy based on trust and accessibility. Many of Utah’s health centers operate in rural, frontier, and tribal communities. These restrictions are especially burdensome on for these patients, increasing travel and wait times, especially in the case of mail order pharmacy restrictions.
	+ Oftentimes there are delays in mail delivery in these communities, and many Utahns in these communities, especially tribal communities, rely solely on P.O. boxes that are located many miles from their home as their addresses are not served by the United State Postal Service or other delivery services. Delays can be so significant that patients are forced go to their out-of-network local pharmacy to purchase necessary medication that has yet to arrive in the mail. In these instances, many Utahns are forced to pay out-of-pocket as their insurance has already been billed for the mail order drugs that have yet to arrive.
* PBMs not only negotiate which drugs will be covered and at what cost, but they also have direct and proprietary access to their prescription drug benefit plan enrollees and can use their access as a platform to guide, steer, direct or mandate which pharmacy plans enrollees can use. This creates an unfair advantage for vertically integrated companies.
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* **[INSERT ANY LOCAL EXAMPLE OF PBM RESTRICTIONS THAT DIRECTLY IMPACT PATIENT DRUG CHOICE, PATIENT PHARMACY CHOICE, OR UTILIZATION MANAMGENT REQUIREMENTS]**
1. Pharmacy benefit managers create barriers to affordable medications for patients with Medicare Part D coverage.
	* In the last five years alone, some retail pharmacies enrolled in Medicare Part D went from paying around $9,000 to over $100,000 in direct and indirect remuneration (DIR) fees a year. Under the current regulation, Part D sponsors have an incentive to opt for higher negotiated prices at the point of sale, which creates the illusion that pharmacies will receive a higher reimbursement until clawbacks occur over six to twelve months later.
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	* In the face of CMS’s proposed Medicare rule, for 2023, to get access to on PBM’s Medicare Part D network, our health center was given just 10 days to opt out of an amendment that would pay me 10% less than my wholesale acquisition cost, provide no dispensing fee, and make me pay $0.75 per transaction into a performance pool.
	* **[INSERT ANY LOCAL EXAMPLE OF IMPACT OF DIR FEES]**

Thank you for your consideration of these comments. If you have any questions, please feel free to contact me at alan@auch.org or at (801) 716-4601.

(SIGNATURE)

**MEMBERS**

Bear Lake Community Health Center, Inc.

Carbon Medical Services Association, Inc.

Community Health Centers, Inc.

Creek Valley Health Clinic

Enterprise Valley Medical Clinic

Family Healthcare

FourPoints Health

Green River Medical Center

Midtown Community Health Center

Mountainlands Family Health Center

Planned Parenthood Association of Utah

Utah Navajo Health System, Inc.

Utah Partners for Health

Wasatch Homeless Health Care, Inc.

Wayne Community Health Centers, Inc.

**AFFILIATE MEMBERS**

First Step House

Odyssey House

Sacred Circle Healthcare

Urban Indian Center of Salt Lake



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* PBMs can create inflated drug prices as the basis to calculate co-pays and co-insurance, so patients pay a lot more at the counter than they should.
* Due to PBM-created network limitations on health plans, patients are steered towards PBM-owned retail, mail order, and specialty pharmacies to receive specific drugs. This impacts the patient’s ability to choose their pharmacy based on trust and accessibility. Many of Utah’s health centers operate in rural, frontier, and tribal communities. These restrictions are especially burdensome for these patients, increasing travel and wait times, especially in the case of mail order pharmacy restrictions.
	+ Oftentimes there are delays in mail delivery in these communities, and many Utahns in these communities, especially tribal communities, rely solely on P.O. boxes that are located many miles from their home. Delays can be so significant that patients are forced go to their out-of-network local pharmacy to purchase necessary medication that has yet to arrive in the mail. In these instances, many Utahns are forced to pay out-of-pocket as their insurance has already been billed for the mail order drugs that have yet to arrive.
* PBMs not only negotiate which drugs will be covered and at what cost, but they also have direct and proprietary access to their prescription drug benefit plan enrollees and can use their access as a platform to guide, steer, direct or mandate which pharmacy plans enrollees can use. This creates an unfair advantage for vertically integrated companies.
* AUCH requests more transparency into PBMs’ utilization management requirements that interfere with patients receiving the optimal treatment selected in consultation with their physicians. These requirements can delay access to needed care; in some cases, the barrier to care imposed by prior authorization and step therapy lead to the patient receiving a less effective treatment or no treatment at all.
1. Pharmacy benefit managers create barriers to affordable medications for patients with Medicare Part D coverage.
	* In the last five years alone, some retail pharmacies enrolled in Medicare Part D went from paying around $9,000 to over $100,000 in direct and indirect remuneration (DIR) fees a year. Under the current regulation, Part D sponsors have an incentive to opt for higher negotiated prices at the point of sale, which creates the illusion that pharmacies will receive a higher reimbursement until clawbacks occur over six to twelve months later.
	* When DIR fees are applied after point-of-sale, pharmacies lose control over their revenues and profitability, creating undue financial risk. Providing the lowest possible reimbursement at the point of sale will enable pharmacies to make informed business decisions based on accurate data and mitigate cash flow problems due to delayed reimbursement.
	* Currently, pharmacies cannot verify or challenge DIR fees because they cannot connect DIR fees to the original prescription claim or properly evaluate “performance metrics” under their contracts.
	* In the face of CMS’s proposed Medicare rule, for 2023, to get access to one PBM’s Medicare Part D network, one Utah FQHC was given just 10 days to opt out of an amendment that would reimburse them 10% less than their wholesale acquisition cost, provide no dispensing fee, and require them to pay $0.75 per transaction into a “performance pool.”

Thank you for your consideration of these comments. If you have any questions, please feel free to contact me at alan@auch.org or at (801) 716-4601.

Sincerely,

Alan Pruhs

Executive Director

Association for Utah Community Health