C.21 Pharmacy Benefits

REQUIREMENT: RFP Section 60.7.C.21
21. Pharmacy Benefits (Section 31 Pharmacy Benefits)
a. Describe the Contractor's proposed approach to administration of pharmacy benefits and related pharmacy services, including the following in its response:
   i. If using a Pharmacy Benefit Manager (PBM), provide a copy of the Subcontract, approach to integration with other services, as well as assuring transparency in pricing and reporting.
   ii. Methods to ensure access to covered drugs and adherence to the preferred drug list.
   iii. Responsibilities and composition of the P&T Committee.
   iv. Proposed DUR Program, including approaches to collaborate with the Department on pharmacy initiatives.
   v. Proposed Maximum Allowable Cost (MAC) program.
   vi. Approach to operation of a pharmacy call center.
b. Describe the Contractor's pharmacy claims payment administration, including an overview of the Point of Sale (POS) system and processes for complying with dispensing fee requirements.
c. Describe the Contractor's processes and procedures to provide timely, accurate and complete data to support the Department's rebate claiming process and ensure the Department maintains current rebates levels.
d. Describe the Contractor's processes and procedures to provide data and support Department-based efforts and initiatives for 340B transactions.
e. Describe the Contractor's pharmacy Prior Authorization process, including the following as part of the response:
   i. Transparency in communicating the conditions for coverage to providers.
   ii. Required credentials for staff reviewing, approving and denying prior authorization requests.
   iii. Use of pharmacy and/or medical claims history to adjudicate prior authorization requests.

Molina's enhanced pharmacy program includes stringent oversight and performance measures to ensure transparency and enhanced Enrollee access to pharmacy benefits.

Pharmacy benefits are a critical component of an effective Medicaid program. It is important to not only provide coverage of a robust formulary of prescription drugs, it is also essential to ensure Enrollees have timely access to prescriptions in their community and support from their local pharmacist. Molina is well aware of the Department's growing frustration with Pharmacy Benefit Managers (PBMs) and the critical need to achieve their full compliance with Senate Bill 5. From greater transparency in pricing to protecting the interests of independent pharmacies, every issue warrants deliberate action.

Helping Ensure the Future of Independent Pharmacies

Molina recognizes the immense value that Kentucky's independent pharmacies provide, especially in underserved and rural areas. As part of our commitment to the Commonwealth and to help ensure Enrollees have appropriate access to care and services, we will reimburse select independent pharmacies in rural areas an additional $1.25 per paid pharmacy claim.

As a result, Molina has been on the ground in Kentucky attending meetings of the Pharmacy Technical Advisory Committee and meeting face-to-face with key Commonwealth representatives, elected officials, and advocates (including the Kentucky Pharmacists Association and Kentucky Independent Pharmacist Alliance) to address the need for improved MCO oversight and drug pricing.

We also have redesigned our pharmacy benefit program and implemented sustainable policies and processes to improve PBM accountability and address the concerns of our state Medicaid program customers enterprise wide.

As a proposed new Medicaid MCO in Kentucky, we pledge our commitment to deploying the necessary resources and expertise to meet or exceed all requirements set forth in Attachment C, Draft Medicaid Managed Care Contract, Section 31, Pharmacy Benefits, including the requirements of Item 31.18, High Cost Drug Stop Loss Program, in providing the Department with a pharmacy benefit program that sets a new standard in Kentucky.

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a. PROPOSED APPROACH TO ADMINISTRATION OF PHARMACY BENEFITS AND RELATED SERVICES

Molina's approach for the Kentucky Medicaid program will provide the Department an integrated, tightly managed solution that includes targeted clinical programs, Enrollee and provider engagement strategies, utilization management and quality of care oversight, administrative and fiscal efficiencies, and assured Enrollee access to services.

Enterprise-wide, 14 of our affiliated health plans currently administer the pharmacy benefit for approximately 3 million Medicaid members. As we will do in Kentucky, we employ a hands-on, transparent approach that includes a highly skilled ***in-house team of pharmacy professionals that perform most activities in-house***, such as prior authorization, instead of delegating these high-touch provider and Enrollee activities to the PBM.

We also have enhanced our oversight of the PBM and added numerous performance guarantees to our contract with the PBM to increase accountability for delivering high-quality and compliant service levels. Our proven organizational experience, in-house management, and enhanced PBM oversight positions us to exceed the Department's requirements for pharmacy benefits.

Highlights of our proposed approach include:

- **Preferred Drug List (PDL) Development and Maintenance.** Molina will maintain a high-performing PDL developed with input from Kentucky-registered pharmacists and physicians that will include appropriate utilization management mechanisms in line with Commonwealth and federal law and Contract requirements.
- **Drug Utilization Review (DUR).** Molina will perform DUR activities in-house using an experienced and dedicated team of clinicians. Our activities will be supported by Molina's DUR Committee that will be charged with enhancing and improving the quality of pharmaceutical care and Enrollee outcomes by encouraging optimal drug use.
- **Prior Authorization Reviews and Appeals.** Performed in-house by Molina, licensed and registered pharmacists, certified pharmacy technicians, and medical doctors will use evidence-based criteria to make and communicate determinations within 24 hours of initial request.
- **Specialty Drug Management.** Molina's specialty drug management program will include a Starter Fill program for Enrollees beginning treatment with certain specialty medications with a high incidence of dosing changes or discontinuations due to drug-adverse events. This program will reduce waste of high-cost drugs due to dose changes or discontinuations.
- **Physician Administered Drug List.** Molina will develop and maintain a list of physician-administered drugs. This list will be updated at least quarterly. We will reimburse physician-administered drugs in accordance with Contract requirements and Commonwealth and federal law, and upon receipt of a paper or electronic claim with an appropriate Healthcare Common Procedure Coding System (HCPC) J-code.
- **Claims Processing.** We will use an online and real-time adjudication platform that leverages up to 500 systemic rules to verify Enrollee enrollment and provider network status/rates and apply benefit and safety edits within seconds to ensure Enrollees receive timely and appropriate drug therapy.
- **Pharmacy Network and Provider Payments.** With more than 68,000 pharmacies nationwide, our Kentucky Medicaid program PBM network is compliant with Kentucky's "any willing provider" statute and will include more than 1,100 retail pharmacies (54% of which are independent pharmacies) in the Commonwealth, specialty pharmacies, and mail order pharmacies.

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- **Mail Order Services.** To support Enrollee medication adherence and lower drug costs in Kentucky, Enrollees will have the option to receive their medications through a high-quality mail order program.
- **Rebate Management.** To optimize the Department's rebate collection efforts, we will provide timely, accurate, and complete reporting on utilization of covered outpatient and prescribed drugs in the format prescribed by the Department as well as support the Department's rebate dispute and resolution activities.
- **Maximum Allowable Cost (MAC) Schedule Management.** We will tightly manage our MAC to ensure the Commonwealth receives the best value while complying with Department requirements and Commonwealth and federal laws. Our contract with the PBM requires that they notify Molina in advance of any changes to MAC pricing.
- **Senate Bill 5 (SB5).** Molina will take specific, deliberate action to see that independent pharmacies are adequately reimbursed. ***We will provide an additional $1.25 reimbursement per paid pharmacy claim, to independent pharmacies in counties that have less than five independent pharmacies in operation. This is incremental to the required additional dispensing fee of $2.00.*** We estimate that over a third (34%) of Kentucky's independent pharmacies will benefit from this Molina program. In addition, we will monitor and manage to the 5% threshold on product-level MAC pricing change requests. Through our PBM agreement and our oversight, we will ensure that we adhere to the threshold. We will also work closely with pharmacy providers to roll-out additional pharmacy reimbursable services, such as Medication Therapy Management and immunizations, and design systems to pay pharmacists for injectable drug administration.
- **Pharmacy Utilization Data Analytics and Reporting.** Molina will provide all standard and ad hoc reporting required by the Commonwealth and Medicaid Managed Care Contract accurately and timely.

In partnership with the PBM, Molina will offer Enrollees a co-branded discount card as a value-added service. The discount card will provide our Enrollees with a 20% discount on thousands of regularly priced CVS Health pharmacy brand health-related items such as pain relievers; allergy, cough and cold remedies; heartburn and stomach remedies; vitamins; first aid; and baby care.

Key to our approach is forming collaborative partnerships with local community pharmacy providers and organizations across the Commonwealth who share our commitment to improve quality of care and clinical outcomes for Kentucky's Medicaid population. We have been meeting with these entities and exploring innovative ways to combine the vast experience and expertise of Molina's in-house pharmacy clinical team with the high-quality, personalized service that Kentucky's community pharmacists offer beyond dispensing medications.

We are exploring innovative value-based care initiatives with Kentucky community pharmacy representatives that use their clinical expertise and scope of licensure to address conditions that are priority areas for the Commonwealth, such as substance use disorders, chronic obstructive pulmonary disease (COPD), and diabetes.

Using enhanced education, clinical monitoring, and evidence-based interventions, our proposed model will connect community-based pharmacists with Molina's integrated clinical team to extend the reach and effectiveness of our care management program. Using diabetes as an example, the community-based pharmacists will:

- Provide education on diabetes self-care to Molina Enrollees, including monitoring activities and lifestyle choices
- Monitor medication adherence and communicate consistent non-adherence to the Enrollee's PCP

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- Inquire about recommended diabetes testing and screening services and provide or refer for services, as indicated
- Collaborate and communicate with the Enrollee's providers and Molina's Care Management staff

We will augment these strategies with Molina's comprehensive diabetes care management program and value-added services. This augmentation will include our Healthy Rewards program that provides Enrollees with gift cards for obtaining and receiving diabetes testing and screening services as well as vouchers to attend WW (Weight Watchers) workshops. We look forward to continuing these discussions and bringing thoughtful, scalable strategies that address the Commonwealth's priorities.

a.i. MOLINA'S PBM

Although Molina performs many administrative functions in-house, we use a PBM to perform certain functions as detailed in Table C.21-1. Molina's PBM for the Kentucky Medicaid managed care program will be CVS Health.

CVS Health has been processing claims using a real-time and rules-based point-of-sale (POS) system for more than 26 years, including more than six years for the Kentucky Medicaid program.

Although CVS Health performs several pharmacy management functions, Molina has ultimate responsible for those functions. Our in-house pharmacy team will diligently monitor all PBM activities for our Kentucky Medicaid program administration by leveraging qualified and knowledgeable resources.

Table C.21-1. Administrative Functions

Activity	Molina	PBM
PBM oversight	✓	
PDL	✓	
P&T Committee	✓	
Prior authorization	✓	
DUR	✓	
Pharmacy network		✓
Claims payment		✓
Rebate administration		✓
Encounter submission, including 340B transactions	✓	
24/7 Pharmacy Call Center		✓
Pharmacy Call Center for prior authorization and Enrollee/provider support	✓	
Participation in Medicaid Pharmacy Director Workgroup	✓	
Pharmacy reporting	✓	

Molina will administer pharmacy benefits and related services in accordance with the Contract and all applicable Commonwealth and federal laws and regulations. We will require the PBM to meet all applicable Kentucky Medicaid program Contract requirements and performance standards under its contract with Molina and by extension, Molina's Contract with the Department. ***Molina embraces the Kentucky Medicaid program requirements of pass-through pricing; we are confident in our ability to implement this pricing model because it mirrors our existing book of business.***

We know some MCOs have been slow to adopt pass-through pricing; however, we believe embracing this approach enables transparency, provides faster access to more robust data to respond to inquiries, and allows for more efficient and effective oversight activities. Additionally, we included performance guarantees in our contract with the PBM that test timeliness and quality in areas that are of concern to the Department, such as responsiveness to inquiries, and timely and accurate reporting. We believe our philosophy of pricing transparency and vendor oversight aligns with the Department's, and we are confident that our administration of the pharmacy benefit on behalf of Kentucky will deliver high-quality results for the Department, Enrollees, and the communities we serve.

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Monitoring the PBM and PBM Subcontractors

Molina's dedicated Pharmacy team is charged with contractual oversight of the PBM and will work with our Kentucky-based chief compliance officer on Commonwealth-specific needs and issues. ***Daily meetings with the PBM's account management and back office teams will ensure all services are optimally performed within expectations of our agreement with the PBM, the Kentucky Medicaid program Contract, and all applicable Commonwealth and federal laws.***

We understand the Commonwealth's growing concerns surrounding pharmacy costs and the need for greater transparency, and we have acted to address these concerns. ***Over the past year, our parent company has restructured our agreement with the PBM to include pass-through pricing, replaced all standard performance guarantees, and increased oversight activities to not only address the concerns of our state clients, but to do our part and be good stewards of taxpayer dollars.*** A copy of our new PBM Oversight and Surveillance program descriptions is provided in Attachments to C.21. Key facets of our plan include:

- **Dedicated and Qualified Staff.** Molina will staff our Kentucky health plan with a pharmacy director licensed in Kentucky and subject matter experts in PDL management, PBM contract and operations oversight, prior authorization, and analytics and reporting.
- **PBM Contract Performance Guarantees.** Molina currently has 16 performance guarantees built into our contract with the PBM, with the ability to renegotiate the performance guarantees annually. By keeping performance guarantees up-to-date, we can ensure the operations of the PBM align with the evolving needs of the Department.
- **Comprehensive Quality Assurance of Pharmacy Benefit and PDL System.** Molina will consistently query the PBM's POS system to validate appropriate system configuration of the benefit and PDL.

Approach to Integration with Other Services

Molina will integrate our pharmacy program and PBM activities with our other clinical activities to maximize the effectiveness of the services we provide to Enrollees and providers. Since we perform most pharmacy-related functions in-house, including prior authorization; Pharmacy and Therapeutics (P&T) Committee meetings; PDL development and management; DUR; specialty drug management; analytics and reporting; Enrollee Services; and enrollment management, we can easily integrate services while achieving administrative and fiscal efficiencies.

For pharmacy claims administration, we will work closely with the PBM to obtain pharmacy data, which we will integrate into our clinical and quality programs. We will use this integrated data in our care management, population health management, and quality improvement activities. For example, we will identify Enrollees for our High-Risk OB program by examining pharmacy claims data and sharing identified Enrollees with our High-Risk OB care managers for assessment and possible participation in our High-Risk OB program.

We also will integrate pharmacy data with medical data to identify Enrollees receiving prophylactic treatment to support Enrollee adherence and education, which will lead to improved outcomes.

Ensuring Transparency in Pricing and Reporting

As previously noted, Molina is steadfast in our commitment to increasing transparency. **Our PBM agreement includes best-in-class contract terms to ensure transparency.**

Pricing and reporting requirements included in our agreement with the PBM include:

- Direct access to their systems and people
- Attestations from PBM leadership on reimbursement configuration and reporting

- Details provided by the PBM in support of summarized reporting
- Ability for Molina to audit any part of the delegated functions
- National Drug Code-level rebate reporting monthly pricing via drug lists made available to Molina, including the rationale when a MAC change is beyond Molina's specified threshold

We will verify pricing transparency in three cycles: during benefit/formulary setup and maintenance, ongoing claims surveillance using claims and encounters data, and annual audits using an independent third party.

PBM Subcontract

Molina's PBM subcontract is a national contract entered into by our parent company, on behalf of itself and its subsidiary health plans. Molina will be providing the portions of the subcontract applicable to the Kentucky Medicaid program line of business.

Specifically, Molina is providing the following attachments:

- **Attachments to C.21, Prescription Benefit Services Agreement**, effective January 1, 2016, between Caremark PCS Health, L.L.C, a Delaware limited liability company, CVS Caremark Part D Services, L.L.C., a Delaware limited liability company (collectively, "Caremark"), and Molina Healthcare, Inc., on behalf of itself and its wholly owned health plans ("Client"). (Portions included are applicable to the Kentucky Medicaid program line of business.)
- **Attachments to C.21, Twenty-First Amendment to Prescription Benefit Services Agreement**, effective December 20, 2018, between Caremark and Client. (Portions included are applicable to the Kentucky Medicaid program line of business.)
- **Attachments to C.21, Twenty-Fourth Amendment to Prescription Benefit Services Agreement**, effective July 1, 2020, between Caremark and Client. (Amendment specifically adds Kentucky Medicaid program line of business.)

All other portions of the PBM subcontract, including other amendments, are not applicable to the Kentucky Medicaid program line of business.

a.ii. METHODS TO ENSURE ACCESS TO COVERED DRUGS AND ADHERENCE TO THE PDL

Molina will ensure that our Enrollees have access to all medically necessary covered outpatient drugs consistent with Section 1927 of the Social Security Act regardless of Molina's PDL status of the covered outpatient drug.

Access to Covered Drugs

We will ensure access to covered drugs through our "any willing provider"-compliant network of pharmacies, mail order program, and Enrollee and provider education. Moreover, as stated earlier, **we will provide additional reimbursement to select independent pharmacies to help ensure Molina's Enrollees continue to have access to this important resource.** The services independent pharmacies offer is particularly important in underserved and rural areas. It is in these areas where pharmacists often provide services beyond dispensing medications, such as medication counseling, immunizations medication management, and blood pressure monitoring.

> **Access to Covered Drugs**
>
> While ensuring access to covered drugs, we want to make sure drugs are prescribed and taken appropriately.
>
> As part of our opioid strategy, we will supply information on risks to all providers requesting prior authorization for opioid prescriptions. We will refer providers to CDC guidelines for prescribing opioids for chronic pain.

Molina will provide an additional $1.25 reimbursement per paid pharmacy claim (this is incremental to the required additional dispensing fee of $2.00) to independent pharmacies in counties that have less than five independent pharmacies in operation. We

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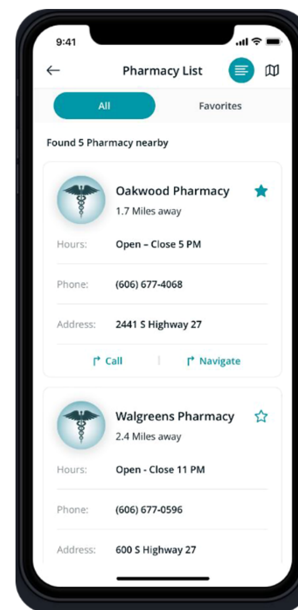
estimate that more than 34% of Kentucky's independent pharmacies will benefit from this Molina program. Our Medicaid pharmacy retail network in Kentucky will include more than 1,100 pharmacies, including 609 independent pharmacies. Enrollees will be able to easily view retail network pharmacies that are nearby using Molina's mobile app.

We will educate Enrollees on how to access pharmacy benefits through various avenues including our new Enrollee welcome calls, Welcome Kit, Enrollee website, Molina Mobile, and Call Center. ***We will educate our pharmacy providers and provider community*** on access to covered drugs. Our educational programs for the Kentucky Medicaid pharmacy provider community will reflect the requirements in Draft Contract, Section 27.5, Provider Orientation and Education, and will include:

- **Provider Letters and Bulletins.** We will supply providers with relevant information and important changes through quarterly newsletters. Fax and email blasts will be used to convey urgent and important information and bulletins.
- **PDL Drug Changes and Distribution.** Targeted communications will be sent to providers around specific PDL initiatives and PDL changes. We will post to our electronic provider Web portal a searchable full PDL with any updates and will also provide updates in quarterly provider newsletters. Molina provider services representatives will personally engage with network providers on changes to the PDL that impact specific Enrollees and other relevant changes to services.
- **POS Messaging.** We will leverage extensive POS messaging to ensure clear and transparent communication to pharmacies and prescribing providers. This will assist pharmacists in performing thorough prospective DUR (drug-to-drug interaction, age precautions, therapeutic duplication, excessive duration, early refills, or suboptimal dosing). POS messaging also will provide the dispensing pharmacist with information on other prescriptions paid by Molina to other pharmacies that may otherwise be unknown during the dispensing process. The formulary status of medications and possible alternatives also will be conveyed through POS messaging to provide dispensing pharmacists with proactive and relevant benefit information to promote collaboration with prescribers as part of the multidisciplinary team. This extensive messaging will provide a high level of actionable information to our pharmacist partners to ensure access to care and high-quality service for Enrollees.



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- **Pharmacy Provider and Provider Community Training.** We will fully support all training sessions as requested by the Department, and we will provide comprehensive training, as needed, through webinars, the provider Web portal, quarterly newsletters, and email/fax blasts. Furthermore, through our six regional Molina One-Stop Help Centers, we can offer in-person provider training (walk-in and scheduled) to assist with any pharmacy needs. Additionally, Molina's in-house Pharmacy staff will undergo extensive training, including a Kentucky Medicaid program overview and discussion about prevalent health conditions impacting the Kentucky Medicaid population. Quarterly, our Pharmacy staff will undergo inter-rater reliability testing to ensure consistent review and processing of pharmacy prior authorization requests.
- **Billing Instructions and Claim Resolution.** The PBM has dedicated staff that is available 24/7 to address all billing and claim issues, concerns, and inquiries.
- **Website Postings of the PDL.** Molina's provider Web portal includes an electronic copy of the PDL, including the status (preferred, non-preferred); an indication if prior authorization is required; information necessary to initiate a request for prior authorization or access to a non-preferred drug; and quantity limits.

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- **Prior Authorization Processes and Procedures.** We will educate pharmacy providers on prior authorization processes and procedures. This will include providing Enrollees a 72-hour emergency supply of medications when a prescription is awaiting prior authorization; Molina is unable to reach the prescribing physician; and the dispensing pharmacist deems the prescription necessary to avoid imminent harm or injury to the Enrollee.

Molina offers a comprehensive optional mail-order pharmacy program that is convenient to Enrollees. We will identify Enrollees where mail order may improve their adherence and compliance to medications by routinely scanning pharmacy data for Enrollees who use maintenance medications for chronic conditions.

We will educate Enrollees on the benefits of mail-order services and offer to work with them or their prescriber to facilitate use of the mail-order service. The PBM's regional distribution will allow dispensing and shipping from the mail facility that is most appropriate for our Enrollees based on several factors, including the most efficient prescription order processing time and the proximity to an Enrollee's desired shipping destination.

We will make it easy for our Enrollees to enroll in mail order:

- Enrollees can obtain maintenance medication from Molina's mail-order program by enrolling online, through mail, or by calling the PBM's Customer Care Center.
- Additionally, the Enrollee's physician may submit prescriptions to the PBM via e-prescribing, telephone, or fax.

We will cover many specialty medications using National Drug Codes for billing and specialty pharmacy medications dispensed to Enrollees and providers. We recognize some of these same medications may be covered through the medical benefit using HCPC J-codes through paper or electronic medical claim submission. During review of a request for prior authorization, Molina Pharmacy staff will determine the most cost-effective, clinically appropriate benefit (medical or pharmacy) of select specialty medications. If we establish it is a covered pharmacy benefit, the PBM will coordinate with Molina and ship the medication directly to the provider office or Enrollee home. The service also will offer the additional convenience of enclosing needed ancillary supplies (needles, syringes, and alcohol swabs) with each prescription at no charge.

Adherence to the PDL

Molina will maintain a PDL that meets Kentucky Medicaid program requirements and applicable laws and regulations. Our affiliated health plans administer formularies of varying degrees of complexity in 14 Medicaid markets. Our dedicated, in-house Pharmacy team has extensive experience managing formularies and is ready to collaborate with the Commonwealth as needed. To help ensure adherence to the PDL, our P&T Committee will meet quarterly and review all therapeutic categories of drugs on at least an annual basis.

Drugs and/or drug formulations that are new to market will be reviewed within 30 days by our Pharmacy and Therapeutics Policy Committee, exceeding the Contract requirement of 75 days.

During this period, these medications will be available through Molina's prior authorization process.

Promoting Adherence to the PDL

POS messaging will include the formulary status of medications and possible alternatives. We will post the PDL to Molina's provider website, including the status (preferred, non-preferred), an indication if prior authorization is required, information necessary to initiate a request for prior authorization or access to a non-preferred drug, and quantity limits.

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Publishing and Making Available the PDL

Molina will make the PDL available to Enrollees and providers through electronic media, in hard copy form, and through e-prescribing. ***Molina is implementing an innovative online PDL lookup feature that will be available by the Contract start date.***

This tool reaches beyond a simple electronic version of a PDL. Molina's Kentucky Medicaid Enrollees will be able to simply key in the name of a drug, press enter, and immediately receive information about the drug's coverage status. Exhibit C.21-1 provides a screenshot of the tool.

Formulary Search

Enter the first few letters of the drug you wish to add then select the drug from the drop-down menu.
starts with
(2 character minimum)

B = Brand Drug G = Generic Drug
Save

omeprazole 20mg cap-delayed rel G Remove	Covered (Tier 1 - Preferred Generic) This drug is covered in the gap.	

Formulary last updated: 06/01/2019
Learn more about Drug Coverage & Exceptions

Exhibit C.21-1. Making Formulary Look-up Easy for Enrollees

Molina will update our Kentucky Medicaid PDL at least quarterly. Updates will include new drugs and changes in the status of a drug (preferred/non-preferred), quantity limits, and prior authorization requirements. Our Enrollee and provider websites will include an electronic copy of the PDL, including the PDL status (preferred, non-preferred); an indication if prior authorization is required, and information necessary to initiate a request for prior authorization or access to a non-preferred drug; and quantity limits.

Managing the PDL

Molina's PDL management strategies are built on objective value-based assessments that consider a drug's therapeutic advantages in terms of efficacy, safety, side-effect profile, and therapeutic need.

Our evaluation process will include an initial review of the new drug characteristics as well as a clinician's insight into the quality of literature, discussion around clinical practice experience, and assessment of the potential clinical outcomes and relative place in therapy of the medication and medication class.

After completing a thorough clinical review, Molina's Pharmacy Clinical Strategies team, in collaboration with Medical Affairs and Finance teams, will evaluate the economic value, including net cost, market share, drug utilization trends of clinically similar medications, impact of generic drugs or drugs designated to become available over-the-counter, brand and generic pipeline, applicable manufacturer agreements, and potential impact on our Enrollees.

The sources we will use to assess value include the Institute for Clinical and Economic Review value framework, Real Endpoints, and National Comprehensive Cancer Network evidence blocks, as applicable. For specific therapeutic classes, rebate contracts may not be pursued with manufacturers because a lower net cost strategy may exceed the value of the rebate. For example, recent generic launches of an asthma medication allowed Molina to make nimble formulary changes that will provide our Enrollees with access to a generic alternative rather than continuing to pursue branded products.

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Another example is in the area of diabetes medications. Current guidelines show there are many agents from which to choose. Molina's formulary strategy is aligned with best practice to allow providers to choose the therapy that best fits their patient's individual needs to keep them compliant. By driving compliance in the diabetes area, we can provide a broader value than just drug cost. While providing an agile PDL strategy, Molina recognizes that communications to both Enrollees and providers will be extremely valuable to the success of formulary programs. Before the effective date of PDL changes, we will provide notifications to affected Enrollees and all providers to minimize any disruption in therapy or care. Molina will create fully transparent and service-friendly prospective PDL communications to ensure continuity of care and no undue disruption of Enrollee access to care. To further ensure continuity of care for affected Enrollees, we will allow Enrollees to continue on the non-PDL medication for up to 60 days, with authorization. This will allow for a transition period to the alternative product or same product requiring a prior authorization.

a.iii. RESPONSIBILITIES AND COMPOSITION OF THE P&T COMMITTEE

An in-house P&T Committee manages pharmacy resources for all Molina affiliated health plans and ensures members receive appropriate and necessary medications. Meeting on a quarterly and ad hoc basis, the P&T Committee includes internal non-voting members and external voting members. Internal members include our national medical director, national medical director for behavioral health, national medical director for quality, vice president for pharmacy clinical strategy, and senior director for pharmacy policy and drug information.

External voting members of our P&T Committee include six independent licensed physicians and three independent licensed pharmacists form various specialties representing the clinical needs of the Medicaid populations we serve.

Upon award of a Kentucky Medicaid program Contract, ***we will add at least one Kentucky-licensed physician and one Kentucky-licensed pharmacist*** who will provide services to Kentucky Medicaid Enrollees via our P&T Committee. New physician and pharmacist committee members will be thoroughly vetted, approved, and appointed to the P&T Committee based on the following criteria:

- Expertise/national recognition in a clinical specialty that best represents the needs of our Enrollees
- Active professional license to practice in at least one state
- Expertise in clinically appropriate prescribing, dispensing, and monitoring of outpatient prescription drugs (drug use review, evaluation, intervention)

P&T Committee Responsibilities

Our P&T Committee is responsible for the following major functions:

- **Developing and updating drug formularies / PDLs to promote safety, effectiveness, and affordability.** The P&T Committee oversees all formulary/PDL and pharmacy program activities for Molina's affiliated health plans, including developing and maintaining formularies/PDLs. On an annual basis, the committee objectively reviews all health plan formularies for the upcoming plan year.
- **Reviewing clinical appropriateness and approving drug utilization management activities.** The P&T Committee reviews clinical coverage and utilization management criteria for new FDA-approved drugs, new clinical indications for existing drugs, and new line extensions. The committee also reviews new clinical data, safety information, evidence-based clinical guidelines, and practice trends that may impact previous drug utilization management decisions. P&T Committee oversight includes prior authorization; step therapy; quantity limits; generic substitutions; medical exception protocols to allow coverage for non-formulary/PDL drugs; other drug utilization management activities that affect access; and providing drug utilization evaluations/intervention recommendations to Molina affiliated health plans.

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- **Evaluating, analyzing, and reviewing policies and procedures to educate and inform healthcare providers about drug products, usage, and P&T Committee decisions**. The P&T Committee develops recommended provider communications on pharmacy and formulary/PDL changes for Molina affiliated health plans. We will supply providers with relevant information and important changes through quarterly newsletters and fax blasts to convey urgent and important information. We also will post a searchable full PDL for use by our providers and Enrollees.

a.iv. PROPOSED DUR PROGRAM

Molina's DUR program will drive positive change, improves Enrollee care, and reduce costs. Our DUR program complies with the requirements in Section 1927(g) of the Social Security Act and 42 CFR § 456, Subpart K. In accordance with Contract requirements, Molina will provide a detailed description of our DUR program activities to the Department annually. We look forward to collaborating with the Department on pharmacy initiatives and sharing our experience and best practices. We also will provide the Department quarterly written reports of DUR activities upon request.

Molina's dedicated DUR Committee will meet quarterly to review, analyze, develop, and recommend changes to all drug utilization activities that occur across our affiliated health plans. ***The DUR Committee is comprised of 16 clinical pharmacists, including pharmacists with board certification in HIV, family practice, pharmacotherapy, multiple sclerosis, and Medication Therapy Management.***

The DUR Committee will submit recommendations to our national P&T Committee for approval and implementation. The committee's primary goal will be to enhance and improve the quality of pharmaceutical care and Enrollee outcomes by encouraging optimal drug use.

Specific functional activities will include making policy recommendations regarding medication coverage, which may include restricting certain medication classes to be covered through prior authorization; establishing and/or approving criteria and standards for DUR; developing and evaluating prospective DUR activities; and developing and evaluating retrospective DUR activities and reporting. Key DUR activities are described below.

POS Claim Edits

To ensure prescriptions meet administrative, plan design, and Enrollee safety criteria, as it does in other Molina markets, the pharmacy claims processing system will conduct up to 500 edits on every prescription. These edits will happen in real-time and within seconds but provide a "compliance safety net." This process also will verify Enrollee eligibility and ultimately support fraud, waste, and abuse monitoring activities. However, POS claim edits are not intended to replace the expertise or sound professional judgment of pharmacists and prescribers. Pharmacists will be responsible for performing pharmacy services consistent within the scope of his/her respective license.

Prior Authorization Management

We will use prior authorization criteria to review medications that may have extreme or dangerous drug interactions; lower cost and equally effective alternatives available; should only be used for very specific health conditions; and are often misused or abused as specified in 42 CFR § 456, Subpart K. Molina will also offer a medical exception process for requests for non-PDL drugs when the Enrollee may require coverage for a drug that offers certain advantages in their unique case.

Molina's DUR Committee will review prior authorization requests by drug and by drug class. The committee also will review retired and new criteria from the previous quarter. Prior authorization criteria will be developed and maintained by Molina's Prior Authorization Core Committee, which will provide recommendations to Molina's P&T Committee for review and approval.

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Therapeutic Duplication Advanced DUR Program

We developed our Therapeutic Duplication Advanced DUR program to address inappropriate duplicate drug therapies and overutilization of dangerous and wasteful drugs. ***This innovative program leverages POS claim edits and prospectively identifies duplicate drugs within specific disease therapies for clinical review.***

Upon identification of a potential duplication, the dispensing pharmacist will receive a message regarding the specific duplication at the POS. If the pharmacist deems the medication appropriate, they will contact Molina for an override to ensure the Enrollee receives their medication.

With the support of prescribers and pharmacies, our Therapeutic Duplication DUR program has grown to more than 20 targeted classes of therapies. The program improves patient safety and reduces waste, while ensuring member access to clinically appropriate care. Several disease-state specific DUR initiatives have resulted from the program, including diabetes, asthma/COPD, and pain management.

Lock-in Program

Molina affiliated health plans in several states have instituted physician and/or pharmacy lock-in programs to address substance abuse and the overutilization of services for pharmacy and non-emergent care.

The most far-reaching is our Coordinated Services program in Ohio, which involves pharmacies and providers, with the goal of combating the same challenges Kentucky faces. We will use lessons learned from this program and customize our offering for Kentucky, based on the population's needs and geography. We will submit our lock-in program description to the Department for approval during Readiness Review.

Through monthly reporting to the Department, we will identify Enrollees who have exhibited at least one of the following behaviors to indicate they should be considered for the program:

- Fraudulent or abusive patterns of service utilization
- Behavior that may indicate substance misuse or medication divergence
- Service overutilization by receiving services that are not medically necessary
- Prescription misuse or behaviors that may represent a danger to the Enrollee

Molina's Coordinated Services Program in Ohio

Ohio's Lock-in Program Since 2015:

- 2,570 members total
- 1,663 currently in program
- 24-month minimum with single prescriber/provider
- Increased support through engagement with care manager
- **Total savings of $7,622,111**

We will design the lock-in program to prevent inappropriate utilization of prescriptions, and to guide those Enrollees through recovery and into better health. We will set system alerts and locks for restricted providers and pharmacies. Our POS claim edits will set locks through our pharmacy claims processing system to prevent other providers and/or pharmacies from billing for unauthorized prescriptions.

A registered nurse clinical reviewer, in consultation with our medical director, will determine whether the Enrollee should be placed in the program. Their review will include all available information (e.g., pharmacy, claims, encounter data) and may include phone consultation with the PCP and other providers. The lock-in program will be part of our quarterly review process through our Quality Improvement Committee. All changes will be approved by plan leadership and submitted to the Commonwealth.

In 2018, our Washington affiliate realized an estimated $2.8 million in cost savings through a physician and pharmacy lock-in program. Our Washington affiliate's lock-in program currently serves 332 members, for an estimated cost savings of $8,477 per member.

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Molina's Pain Safety Initiative

Opioid utilization among Molina affiliated health plan members **decreased by 37%,** and the number of opioid prescriptions per 1,000 members **decreased by 39%** from January 2016 to April 2019.

Molina's opioid strategy will help our Enrollees who are struggling with opioid addiction or overuse engage in treatment. The strategy also will identify sustainable mechanisms to help others avoid potential abuse.

Our organization's national medical director for substance abuse, a board-certified Addiction and Family Medicine practitioner, and our Pharmacy team, will collaborate closely to tailor multiple approaches to the unique needs of Enrollees and the Kentucky Medicaid program. Using a multifaceted approach, we will employ a wide range of initiatives to enhance medical and pharmacy benefits, increase Enrollee and provider education, and improve network performance to combat the epidemic.

Our affiliated health plan in Illinois educated providers by comparing the prescribing habits of dentists and oral surgeons to an average. Provider communications/education included CDC guidelines on opioid prescribing.

For fiscal year 2019, the results were positive, with a significant reduction of prescriptions overall, including a reduction in the average number of days prescribed.

As an additional proof point, our Illinois affiliate drilled down further into the data to compare prescribing habits of dentists and oral surgeons from April to December 2019.

Outcomes were as follows:

- In April 2019, 270 dentists and oral surgeons prescribed more than a 3-day supply compared to 132 dentists and oral surgeons in December 2019.
- Also, in April 2019, 62 dentists and oral surgeons prescribed greater than a 5-day supply, compared to 20 dentists and oral surgeons in December 2019.
- Over the same period, the number of dentists and oral surgeons who prescribed more than a 7-day supply dropped from 3 to 2.

The dental group was surprised to find that many dentists and oral surgeons were prescribing more than a seven-day supply of opioids after procedures.

- In some cases, this same population of dentists and oral surgeons were prescribing opioids when they were probably not needed.
- As part of the process, our Illinois affiliate asked the chief dental officer to personally contact the biggest outlier prescribers.
- To sustain the downward-trending results achieved by our Illinois affiliate, an interdisciplinary team will meet monthly to monitor results and work to facilitate additional improvements.
- The interdisciplinary team will include Molina's pharmacy director, medical directors for physical health and behavioral health, such as our addictionologist, behavioral health director, and other key leaders.

For Kentucky, we propose to leverage a best practice implemented by our affiliated Medicaid health plans and form a Controlled Substance Review Committee that will:

- Assist in resolving issues that involve complex Enrollees on high-risk drug regimens who are not improving after standard interventions have been implemented
- Focus on four primary indicators of health: pharmacologic, physical, cognitive/behavioral, and complementary/alternative medicine

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Molina's Pain Safety Initiative program will aim to:

- Decrease the number of new starts (exposure to opioids and progression from acute to chronic)
- Identify Enrollees who are on high-risk regimens
- Streamline access to buprenorphine and methadone to treat opioid addiction
- Streamline access to naloxone for overdose reversal

Our multifaceted approach is illustrated in Exhibit C.21-2.

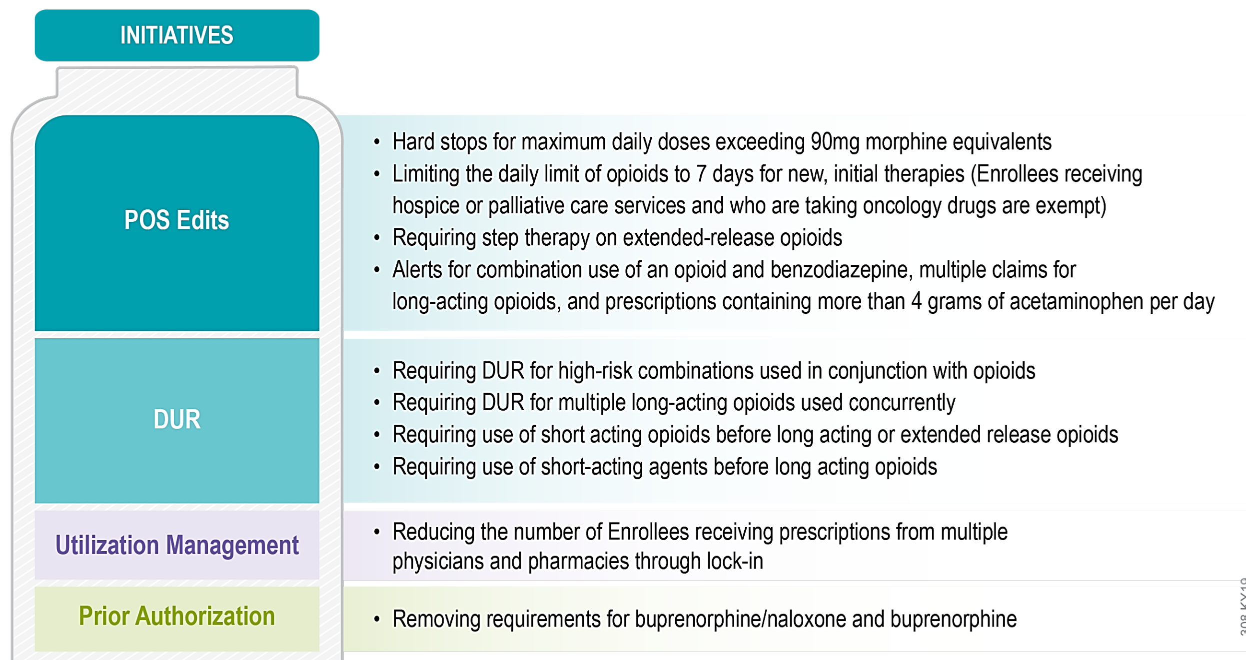

Exhibit C.21-2. Molina's Pain Safety Initiative Includes Multiple Strategies

We want to make sure Enrollees have appropriate access to medically necessary medications. Therefore, pharmacists can contact Molina and request an override of a hard stop POS alert. In our enterprise wide Medicaid population, from January 2016 through April 2019, Molina saw opioid utilizers decrease by 37%. In addition, opioid prescriptions per 1,000 members decreased by 39%.

Core Safety Monitoring Retrospective DUR

Molina will collaborate with the PBM to target high-risk drug classes and focus on inappropriate use and misuse-related indicators, such as polypharmacy and provider shopping. Quarterly, clinical pharmacists from the PBM will evaluate claims for controlled substances and any available supporting medical data to identify potential medication misuse. Through this evaluation, they will determine if an intervention is necessary and implement an appropriate intervention. During subsequent quarters, pharmacists will conduct follow-up activities using physician responses and current claim activity. Situations identified as being potentially inappropriate will be referred directly to Molina for further individualized action.

All claims will continue to process as normal, and a proprietary algorithm will be applied to identify high-risk profiles. A Molina clinical pharmacist then will review a system-produced 90-day pharmacy history look back to determine need for further action. If action is needed, the history and letter then will be sent to the prescriber, and Molina will be advised of the action. Follow-up will continue quarterly for identified Enrollees.

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Medical Claims Edits Programming

We work closely with a leading clinical analytics firm, which performs clinical validation of claims to manage situation-dependent coding rules of medical claims for drugs and biologics. This innovative clinical validation tool applies advanced coding algorithms to national sourced edits and flags suspect claims that a team of nurses and coding experts review before final adjudication. The payment recommendations are turned around within a couple hours, causing no delays for providers.

Our parent company's in-house Drug and Biologics Committee oversees additions and modifications of the clinical validation policies, and reports findings to the DUR Committee for final approval. This enables us to reduce medical spend by at least 1% while providing nationally recognized coding standards for providers.

Approach to Collaborating with the Department on Pharmacy Initiatives

Molina will strive to meet and exceed all Contract requirements in addition to forging a good partnership with Commonwealth regulators. Molina will work collaboratively with the Department on related pharmacy initiatives such as universal policy implementations, a pharmacy lock-in program, buprenorphine provider programs, and other initiatives as identified by the Department. As requested, Molina will share our experience and expertise with the Department in the design and implementation of universal policies. Moreover, we will make any and all changes necessary to our policies, procedures, and systems pursuant to Department universal policies that affect our pharmacy program, including our operations and the services we provide to Enrollees and providers.

Sharing Best Practices with State Customers

A Molina affiliated health plan recently collaborated with a state agency to improve access to medications to treat mental health disorders, including depression, anxiety, schizophrenia, and bipolar disorder. When state agencies look to partner with us, we are always eager to share our best practices to advance member care.

Upon identification of a new pharmacy initiative that will affect Molina's pharmacy program, we will engage our proven, standardized change process. In addition, Molina will:

- Identify the staff and resources necessary to facilitate implementation of the universal policy, and identify any impact the initiative will have on our Enrollees and providers
- Develop a comprehensive work plan that identifies the time frames and key milestone checkpoints along with the project scope, resources, tasks, deliverables, critical paths, and dependencies

Quality controls will be established to ensure any changes to system configurations are in place and thoroughly tested before go-live, and we will continuously monitor the change after go-live to confirm success and ensure quality of care and access to services for our Enrollees.

Because we manage the pharmacy benefit in-house instead of delegating all aspects to a PBM, Molina can see firsthand the impact of various initiatives and suggest adjustments, as indicated.

Our in-house Pharmacy team is provider-facing and has been a key partner in explaining state and MCO initiatives to provider communities, which is critical to reducing provider abrasion.

We have also worked closely with state and pharmacy providers to roll out additional pharmacy reimbursable services, such as Medication Therapy Management and immunizations, and design systems to pay pharmacists for injectable drug administration.

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a.v. PROPOSED MAC PROGRAM

Under Molina's strict oversight, the PBM will establish and maintain a drug MAC program. The MAC program will be designed to promote generic utilization and cost containment while complying with Department of Insurance requirements and applicable Commonwealth and federal laws.

The analytical process to establish a MAC is at a product level for generics and a multi-source level for brand products. The process involves a thorough review of marketplace dynamics, product availability, and different pricing sources.

Pricing sources include Medi-Span (or any other similar nationally recognized reference), wholesalers, CMS-published MAC lists, and retail pharmacies. MAC prices are subject to frequent change—at least weekly and sometimes more often—and are based on marketplace trends, dynamics, and price fluctuations. Pharmacy providers can access the PBM Pharmacy Online Portal to obtain current MAC prices as well as access upcoming MAC prices, based on the PBM's MAC pricing update schedule.

In support of SB5, the PBM will submit product-level MAC pricing change requests that are more than 5% to the Department through file transfer protocol and request changes in accordance with Department requirements and applicable Kentucky laws and regulations. We recognize the Department's decision to either approve or deny the request will be the final decision. Any changes approved by the Department will be effective as of the effective date approved by the Department.

Molina's contract with the PBM requires that they notify Molina in advance of any changes to MAC pricing. For our Kentucky Medicaid program, the PBM cannot make changes to MAC without notifying Molina in advance.

Molina will receive MAC pricing reports comparing product level unit prices month over month that include the unit cost percentage change month over month and any mid-month changes. MAC reporting from the PBM will provide Molina with additional information to track any changes in reimbursement that may trigger the need for prior approval by the Department.

In accordance with applicable laws, pharmacy providers may appeal the MAC price paid by the PBM at a product level. Submission of a paid claim by pharmacy providers will be required for this process. Pharmacy providers must notify the PBM within 60 days following the initial claim, and provide the following information:

- Date of fill
- Prescription number
- Pharmacy name
- Pharmacy National Council for Prescription Drug Program (NCPDP) / National Association of Boards of Pharmacy (NABP) number
- Chain/affiliation code
- Phone number
- Email address
- Rx BIN

Taking Action to Ensure Compliance with MAC Pricing

Molina's contract with the PBM includes MAC pricing protections. For our Kentucky Medicaid program, the PBM cannot make changes to MAC without notifying Molina in advance.

Chain and Pharmacy Services Administration Organization (PSAO) pharmacies must submit appeals through their respective chain or PSAO, which in turn submits the appropriate data to the PBM.

Independent pharmacies (those which are not affiliated with a PSAO for contracting purposes) will submit appeals using the PBM Pharmacy Online Portal. MAC appeals decisions are typically resolved within 5 calendar days and no more than 10 calendar days.

As part of our enhanced PBM oversight program, Molina will review all future PBM changes to product-level MAC pricing to ensure compliance with applicable Kentucky laws and regulations.

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As part of our support of SB5, if any product-level MAC pricing change requests exceed the 5% threshold, Molina will engage the PBM to ensure the Department was provided the appropriate advance notice.

- If the appropriate notice was not provided, the PBM will be required to correct the change to maintain compliance.
- Molina will track and trend MAC appeal requests to ensure they are completed within 10 calendar days and will verify decision accuracy.

Molina will comply with all MAC laws and administrative regulations promulgated by the Department of Insurance, the Department, or Commonwealth or federal law.

Exhibit C.21-3 includes a sample graph that Molina's pharmacy director will use to monitor timeliness of appeals.

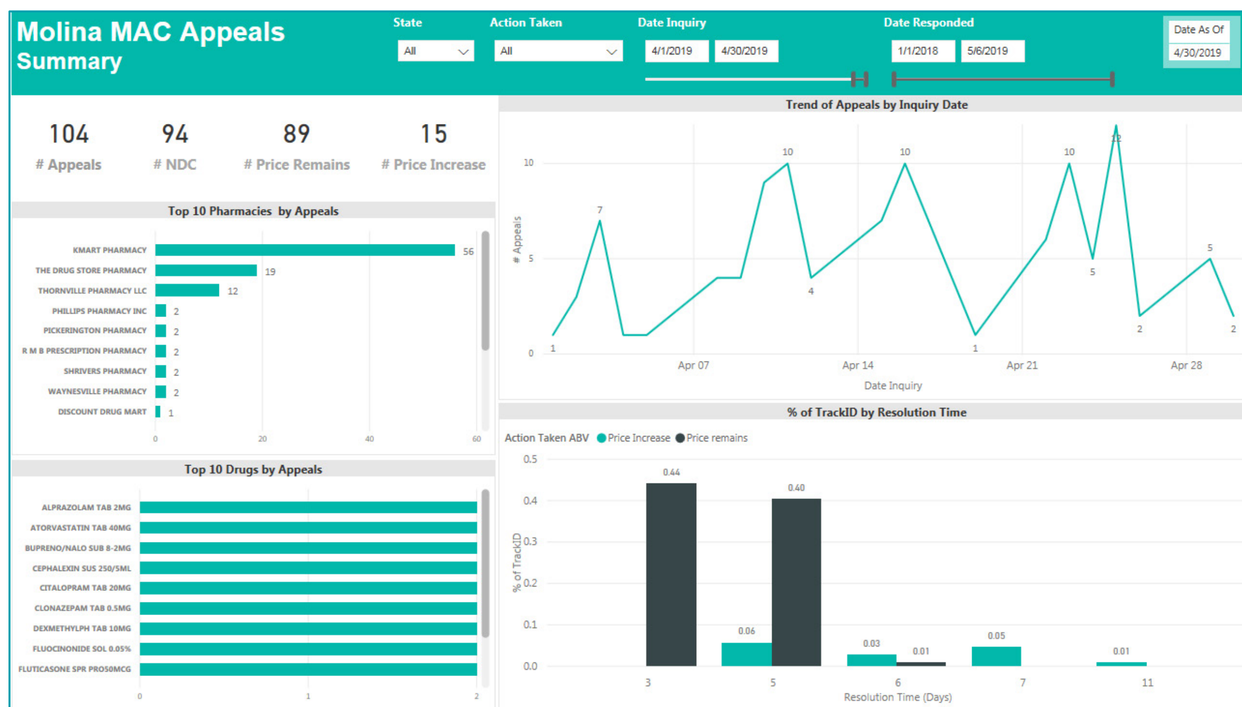

Exhibit C.21-3. Molina will Closely Monitor Pharmacy Appeals

a.vi. APPROACH TO OPERATION OF A PHARMACY CALL CENTER

Pharmacy providers will be able to contact the PBM's custom Molina toll-free pharmacy Call Center 24/7, including for after-hours and holiday support, for assistance with Enrollee eligibility, claim edits/denials, benefit inquiries, system issues, contracting and credentialing status, and general questions.

The PBM pharmacy Call Center will meet the performance standards contained in Draft Contract, Section 27.2, Provider Services Call Center.

- In 2019, the PBM had a call abandonment rate of 0.7% and answered 92.6% of calls within 30 seconds, exceeding Draft Contract performance standards.
- Molina's in-house Pharmacy team will be available to answer calls from network providers related to drug coverage and prior authorization to ensure timely and high-quality customer service during stated business hours.

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Through a Department-approved pharmacy Call Center quality assurance program, we will monitor calls handled, abandonment rates, average speed of answer, and services level against our own internally developed performance standards as well as the Department's requirements.

- The service-level standards of our quality assurance program will be included in the PBM performance guarantees to support our goal of a high-performing Call Center.
- We recognize and respect the need to have a high-quality and responsive Call Center for pharmacy providers.

b. PHARMACY CLAIMS ADMINISTRATION

Molina's pharmacy claims payment administration system will permit pharmacies to submit claims 24/7. The online and real-time rules-based claims payment system currently meets all RFP and Draft Contract requirements, and SSAE 16 standards. Molina will:

- Ensure that HIPAA-compliant transactions are utilized, where applicable
- Support and comply in a timely manner with the most current HIPAA-mandated standards; the most current NCPDP format and standards (including any optional NCPDP data fields); and any other standards required by applicable laws and regulations.
- Process claims in accordance with the terms of the Contract, including PDL, DUR, other claim edits, and applicable laws including, but not limited to, Commonwealth and federal prompt payment laws.

MEETING CLAIMS PAYMENT CONTRACT REQUIREMENTS

We have thoroughly reviewed the requirements contained in the Draft Contract, Section 31.8, Pharmacy Claims Payment Administration, and we are confident in our ability to meet or exceed them.
Table C.21-2 details how Molina will meet the Draft Contract requirements, including requirements for the POS system.

Table C.21-2. Meeting Pharmacy Claims Administration Draft Contract Requirements

Draft Contract Requirement	How Molina Will Meet the Requirement
A. Ensure the POS system satisfies functional and informational requirements	Pharmacies will be able to submit claims through the POS system 24/7. Upon receipt by the POS system, each claim (including real-time, batch, and paper claims) and its supporting documentation will be assigned a unique Internal Control Number, which will be used to identify and track claims, conduct research, perform reconciliations, and for audit purposes. In collaboration with the PBM, we will manage all Commonwealth and federal program required changes to processing rules to ensure they are implemented accurately and timely. **Typically, these changes will be implemented within 15 business days of initial request, well in advance of the Draft Contract required time frame of 30 days.** When downtime is needed for system enhancements/maintenance, we will submit a written request within five calendar days to the Department for advance approval of scheduled POS claims system downtime. Downtimes will be typically for less than six hours during non-peak times of the day. Pharmacies will be notified in advance of any scheduled downtime with a reminder of the procedures to follow. During scheduled maintenance, pharmacies will receive the message "HOST UNAVAILABLE," prompting them to follow the system downtime procedures. From time to time, unscheduled system maintenance or other circumstances may occur when the POS system may not be available to adjudicate claims for a limited time. At any time, a pharmacy can contact the pharmacy provider Call Center for assistance or information. Pharmacy provider Call Center representatives are available 24/7.

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Draft Contract Requirement	How Molina Will Meet the Requirement
B. Process, adjudicate, and pay pharmacy Claims via an online, real-time POS system	Our organization's online, real-time claims adjudication process maintains the highest performance standards in the pharmacy benefits industry for system availability and claims processing integrity. **Our contract with the PBM includes performance guarantees if system availability falls below 99.5% or claims processing falls below 99.9%.** The actual performance is currently at 99.98% for both measures. The POS system requires pharmacies to submit claims through the POS system using the NCPDP D.0 established standards. Molina will make any updates to the NCPDP D.0 format at no cost to the Department. We require a valid Taxonomy / National Provider Identifier (NPI) on all pharmacy claims submissions. The validation of the NPI is step 7 in a 30-step plan review process that occurs within the POS system within seconds. Pharmacies must report any changes in their NPI or subparts to the PBM as soon as possible, and not to exceed 10 calendar days from the change. Any pharmacy claims that do not include a valid NPI or provider number are denied. The claims system performs online coordination of benefits at the POS to identify any liable third party and ensure pharmacy claims are submitted to the primary payer, and Molina's Medicaid program is billed as the payer of last resort. **Approximately 99% of clean claims are paid within 14 days of receipt, and all claims are paid within 30 days of receipt.** Claims that are denied are immediately transmitted to the pharmacy if the claim is electronic (real-time or batch), including the reason for the denial. If the claim is received by paper, a denial letter with an explanation of reason for denial is sent to the Enrollee using USPS First Class Mail.
C. Provide the ability to process Claims on batch electronic media and paper Claims submitted directly for processing	The PBM can process pharmacy POS claims, batch claims, and paper claims. Batch claims must be submitted in the NCPDP Standardized Version D.0 format, and paper claims must be submitted on the NCPDP Universal Claim Form. **Upon receipt of a clean claim, the PBM will process and adjudicate the claim within 10 days of receipt.** Currently, 100% of clean paper claims are processed in 8 days with 99% accuracy. Each claim, including batch claims, and its supporting documentation, is assigned a unique Internal Control Number immediately at adjudication in real time to 100% of claims. The PBM will maintain electronic backup of batch claims for the duration of the Contract and for 10 years after the transaction occurred or such longer period that is required by applicable law.
D. Notify the Department in writing no later than one calendar day from discovery of any POS processing and/or Claims adjudication issue that is or has the potential to significantly impact processing time for Claims submissions, Claims adjudication, Claims adjudication accuracy, and/or continuity of Enrollee drug therapy	Molina's Kentucky-based chief compliance officer will notify the Department within one calendar day if we identify any POS processing and/or claims adjudication issue that is or has the potential to significantly impact claims processing time and/or continuity of Enrollee drug therapy. Molina has partnered with the PBM to design and implement a custom incident management process. The process is followed if there is at least one access-to-care issue for an Enrollee for any regulatory issue. Issues are identified by constant oversight of PBM operations by a dedicated team at Molina, self-reported by the PBM or inbound to the Call Centers from pharmacies, providers, or Enrollees. **When an issue is identified, a lead from the PBM and Molina will be assigned to collaborate and perform a root cause analysis that will be completed within 24 hours of identification of the issue.** After identification, the issue will be remediated, typically within 24 hours. If a long-term solution is required, such as a system modification, the short-term solution will stay in place while the long-term solution is built and deployed with at least weekly updates on the progress. To ensure the issue is documented, a corrective action plan will be completed and delivered within three business days of the implementation of the short-term solution. All incidents are logged and tracked in SharePoint by Molina and in Salesforce by the PBM.

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Draft Contract Requirement	How Molina Will Meet the Requirement
E. Establish a unique Medicaid-specific Processor Identification (BIN) / Issuer Identification Number (IIN), Processor Control Number (PCN), and Group Number combination for POS pharmacy Claims processing, to ensure Medicaid Claims are not the same as Contractor's commercial and/or Medicare Part D business lines	Molina has already collaborated with the PBM to assign a unique-to-Medicaid PCN (MCAIDADV) and BIN (004336) that will apply to all of our Kentucky Medicaid program pharmacy claims, should we be awarded a Contract by the Department. A unique BIN/IIN, PCN, and Group Number combination for POS pharmacy claims processing will differentiate Kentucky Medicaid program pharmacy claims from our organization's other lines of business. Molina will issue every Enrollee an ID card. The card will include the BIN/IIN and PCN number and Molina's toll-free Call Center number to call for pharmacy questions and assistance. Enrollees will be able to view and print their Molina ID cards from their mobile device through Molina's mobile app.

COMPLYING WITH DISPENSING FEE REQUIREMENTS

Molina's reimbursement rates for pharmacy claims will comply with applicable Contract and Department requirements and reflect CMS guidance. As part of Molina's PBM Oversight and Surveillance program, we will verify that contractual obligations for compliance with Commonwealth, federal, and Contract requirements are being met by the PBM, including compliance with dispensing fees.

To ensure the required additional dispense fee is paid to the pharmacy without reduction of any kind or for any reason, Molina will:

- Confirm the claim adjudication system is configured correctly as least annually
- Validate the dispense fee on a biweekly basis using invoice- and claim-level data
- Audit the PBM annually

As described earlier in our response, as part of our support for SB5, ***Molina will provide an additional $1.25 reimbursement per paid pharmacy claim (this is incremental to the required additional dispensing fee of $2.00) to independent pharmacies in counties that have less than five independent pharmacies in operation.***

We are providing this additional reimbursement because we recognize the valuable service that independent pharmacies offer to Medicaid Enrollees, especially in rural and underserved areas. These services include medication counseling, immunizations, medication management, and other preventive healthcare services.

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c. PROCESSES AND PROCEDURES TO SUPPORT REBATE CLAIMING

Molina understands the Department's obligations to collect CMS-level rebates on all Medicaid MCO utilization and the importance of timely, accurate, and complete encounter data.

Our PBM has more than 20 years of experience successfully collecting rebates on behalf of clients with a 98% conversion rate. We will provide the Department timely, accurate, and complete reports on utilization of covered outpatient and prescribed drugs in the format prescribed by the Department.

Information will include, at a minimum, the total number of units of each dosage form dispensed or administered including the:

- Strength
- Date of service
- Paid date
- National Drug Codes for each covered outpatient drug dispensed or covered by Molina
- Amount paid by Molina

We will submit this National Drug Code-level information on drugs, biologics, and other provider-administered products as directed by the Department including, but not limited to, drug codes (e.g., J-Code/Q-Code/A-Code), units, and conversions consistent with federal and Department requirements.

Molina is Committed to Helping the Department Resolve Drug Rebate Disputes

Approximately 20% of the performance guarantees in our contract with the PBM are tied to regulatory reporting and support. For example, we will require the PBM to provide Molina information in response to agency requests, such as those from the Department, at least one business day before the day our response is due. This will allow us time to examine the information to ensure completeness and accuracy, so we can provide the Department with a high-quality response.

Molina will provide detailed claim information requested by the Department / Department contractors to support rebate dispute and resolution activities. Our dedicated Pharmacy team will be available to assist the Department in fully resolving drug rebate disputes with the manufacturer upon the request of the Department. In addition, as part of our processes and procedures to support rebate claiming, we can enforce compliance through POS claim editing.

Our parent company's long history of receiving and transmitting HIPAA-compliant 837 encounter files to state agencies, vendors, providers, and other regulatory agencies reflects the successful combination of a sophisticated end-to-end encounter process, a highly disciplined approach, proactive Provider Services efforts emphasizing partnership and training, and an experienced and dedicated Encounters team.

Molina's affiliated health plan in Mississippi reports on the drug utilization data necessary for the Mississippi Division of Medicaid to bill manufacturers for rebates no later than 30 days after the end of each quarterly rebate period. Utilization information includes, at a minimum, information on the total number of units of each dosage form, strength, the billing provider's NPI number and package size by National Drug Code of each covered outpatient drug covered by Molina's affiliated health plan.

In Florida, our affiliated health plan notifies providers that either may prescribe or are currently prescribing a drug that is being deleted from the Medicaid PDL. The notification is via fax, sent within 30 days of our affiliated health plan being notified of the change by the State. In collaboration with internal IT resources, our affiliated health plan ensures that the PBM receives the weekly comprehensive PDL file and provides all prescription drugs listed in the State's Medicaid Preferred Drug List (PDL). The PBM updates the drug formulary PDL file based upon receipt of the Weekly Comprehensive Drug List. Molina's affiliated health plan also performs random audits to ensure that the PBM is processing the PDL file timely.

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Our affiliated health plan in Ohio is working with the state to maximize the collection of federal and supplemental rebates, ensuring that all supplemental rebates are sent directly to ODM and are not retained by the Medicaid MCPs or their PBM. Claims data will be used to centrally generate invoices to collect rebates, enabling greater accountability and transparency.

In another state where a Molina affiliated health plan operates, the health plan collaborated with the state by identifying issues in state rules that lead to rejected encounters on the back end, causing the state to miss opportunities for Medicaid rebates.

Regarding additional information to track, the NCPDP published a white paper in June 2019 reporting on challenges in the Medicaid drug rebate program. Based on that document, NCPDP recommends that states work with their stakeholders, including MCOs such as Molina, to educate pharmacy and physician providers on the importance of submitting complete and accurate claims information to the state or to the state's Medicaid MCOs. NCPDP also recommended in the document that CMS should work with states to develop a consistent set of claim fields and a standardized layout for states to use when sending Claim Level Data (CLD) to manufacturers.

Configurable systems, mature processes, advanced tools, and appropriate reports are already in place at our affiliated health plans and will be customized to achieve all Kentucky encounter requirements. Molina will generate encounter data for all paid and denied services and extract and submit encounter data as frequently as required to comply with encounter submission requirements and processing needs. ***In fact, as of December 2019, our parent achieved an overall completeness and accuracy rate of 97.15% across all our affiliated health plans, with a timeliness rate of 98.3%.***

d. PROCESSES AND PROCEDURES TO PROVIDE DATA AND SUPPORT 340B TRANSACTIONS

Molina's pharmacy benefit program will meet requirements for Kentucky hospitals and health systems that use 340B pricing. ***We are committed to working collaboratively with the Commonwealth to determine optimal approaches to identifying and processing drugs purchased through the 340B drug discount program, and to establishing/refining protocols for claims processing and rebate collections.***

As part of our processes and procedures to collect and deliver data on 340B transactions, using 340B claim level indicators (i.e. NCPDP D.0 field 420-DK) that indicates that drug claims should be excluded from rebates, we will flag 340B claims using common NDPDP claims processing standards, when submitted by 340B pharmacies on behalf of a covered entity. As an option, we can provide a 90-day window for 340B transactions, which will allow the submitting entity to correct errors in 340B submissions.

The PBM contracts with 340B entities that have a 340B status coded as "38" or "39" in the NCPDP

DataQ database. As required for compliance with the POS clarifications of drugs purchased through the 340B program, these 340B entities must submit claims to the PBM with a Submission Clarification Code of "20" within field (420-DK). Equivalent codes may be adopted for participating pharmacies under the NCPDP D.0 format (or any successor format). Therefore, upon submission, the PBM can identify 340B claims in real-time, prospectively, and retrospectively.

Molina's Prior Authorization program complies with the requirements of Section 1927(d)(5) of the Social Security Act and Department requirements. **To ensure quality, performance, and Enrollee access to services, Molina will perform prior authorization in-house.** Molina's in-house licensed and registered pharmacists and certified pharmacy technicians will perform prior authorization services.

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As part of our processes and procedures, Molina will:

- Reimburse 340B entities in accordance with Contract requirements
- Not discriminate against any 340B entity in a manner that prevents or interferes with the Enrollee's choice to receive such drugs from the 340B entity
- Send all drug encounters identified as 340B, excluding inpatient hospital drug encounters, to the Department

Providers can always check status of a claim in adjudication through the Provider Web portal, the interactive voice response system, or by calling the Call Center. Molina will collaborate with the Department to provide any supplemental claims data or ancillary reporting to support appropriate 340B pricing of claims and accommodate the Department's rebate program requirements.

e. PHARMACY PRIOR AUTHORIZATION PROCESS

Molina's Prior Authorization program complies with the requirements of Section 1927(d)(5) of the SSA and Department requirements. **To ensure quality, performance, and Enrollee access to services, Molina performs Prior Authorization in-house.**

Prior authorization requests will be processed internally by Molina clinical experts using the PBM's specialized software. This Internet-based software has a built-in fax server, allowing images of faxes and related correspondence to be viewed on-screen during review and then electronically stored for future reference. Through rules-based logic using "yes" and "no" answers to criteria questions, we will ensure high inter-rater reliability. We will track and trend prior authorization activity for continual quality improvement.

PRIOR AUTHORIZATION PROCESS

Molina's prior authorization submission process will be provider-friendly, offering multiple methods to allow for the most appropriate process for each practice: electronic prior authorizations, smart prior authorizations, and traditional reviews. Electronic prior authorizations can be submitted electronically through a secure portal using various vendors (e.g., CoverMyMeds, SureScript, ePrescribe, and EPIC) and sent to Molina for any further review. ***The innovative SmartPA® tool will use medical claims data and Enrollee information to automatically prequalify an Enrollee through automatic coding rather than a hard stop to the claim.*** This will not only facilitate speedy processing, it will reinforce evidence-based, quality treatment for our Enrollees. Should the data elements fail to meet the pre-specified criteria, a traditional review will be triggered. Providers can use either the Kentucky Medicaid universal prior authorization form or Molina's Department-approved prior authorization form.

Our prior authorization policies and processes will ensure there is no undue disruption of an Enrollee's access to care and prevent penalization of providers and Enrollees for requests or approvals. Our prior authorization program not only meets but exceeds the minimum requirements in the Draft Contract, Section 31.12, Pharmacy Prior Authorizations including:

- **Using Evidence-based Criteria.** Molina's Prior Authorization Core Committee will manage and maintains pharmacy prior authorization criteria. The criteria will be reviewed annually, at a minimum, or when new medical evidence is published. The committee will be made up of clinical pharmacists with board certification in key specialties, such as HIV, pharmacotherapy, and Medication Therapy Management.

- **Issuing Denials.** All denials to requests for prior authorization will be made by a Molina registered pharmacist or medical director.

- **Physician Peer Reviews.** A Molina registered clinical pharmacist or medical director will be available for peer-to-peer consultations to discuss a denial decision with any treating practitioner regarding medical necessity.

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- **Making and Communicating Prior Authorization Determinations.** We will render a decision on all requests for prior authorization within 24 hours of our receipt of the request. Molina's Regulatory Compliance Committee will review prior authorization compliance reports monthly. Our organization currently operates at more than 99% compliance for timeliness across our entire Medicaid book of business.
- **Documenting Prior Authorization Activities and Decisions.** The PBM's Clinical Authorization System (CAS) is a web-based, user-friendly tool that will allow Molina to manage the prior authorization process for Enrollees. The tool will enable us to document all prior authorization activities and decisions and to store relevant files.
- **Providing a 72-hour Emergency Supply.** If a prescription for a drug is awaiting prior authorization, Molina cannot reach the prescribing physician, and the dispensing pharmacist deems the prescription necessary to avoid imminent harm or injury to the Enrollee, a 72-hour emergency supply of the medication will be provided in accordance with Contract requirements. If the prescribed amount of drug is more than a 72-hour supply but is packaged so that it must be dispensed intact, the pharmacist may dispense the packaged drug, and Molina will pay for this quantity even if it exceeds a calculated 72-hour supply.

Meeting Requirements

We meet requirements for timeliness of prior authorization determinations more than 99% of the time.

- **Providing Enrollees with the Opportunity to Appeal a Denial.** If the request is denied, Molina will provide the Enrollee a written notice of the Adverse Benefit Determination within 24 hours of a denial. The notice will explain the Enrollee's right to appeal the decision, including circumstances under which the appeal process can be expedited.

Molina requires prior authorizations for certain drugs to ensure clinical appropriateness for Enrollees' medical conditions and maximize the safety, effectiveness, and efficiency of drugs. Prior authorization may be warranted when:

- The drug is subject to significant safety concerns, overuse, misuse, or off-label use
- The drug's primary use is limited to a specific patient population
- The drug has special testing requirements that help determine the best potential response to treatment
- The drug is occasionally used for conditions not included in the pharmacy benefit (e.g., cosmetic reasons)

Molina will ensure continuity of care of Enrollees' drug therapy if there is a change in PDL requirements based on therapeutic indication, Enrollee clinical status, and other clinical factors used to ensure appropriate access to care. For maintenance medications that do not require regular monitoring, Molina will provide an initial 6-month authorization and a 12-month authorization thereafter.

We have taken aggressive action across the enterprise through our Pain Safety Initiative that we will offer in Kentucky. Included in these actions were steps to increase access of our PDL products to non-opioid pain management options (including oral medications) and alternative therapies.

We have worked closely with state agencies to increase access to buprenorphine and buprenorphine/naloxone therapies. Concurrently, we worked with our staff diplomat on the American Board of Addiction Medicine to update our prior authorization criteria for other opioid use disorder therapies to align with industry best practice standards, thereby eliminating barriers while still maintaining criteria for patient safety. The above situations could apply to most FDA-approved drugs; however, drug category examples where prior authorizations may be most applicable include narcotic analgesics, antipsychotics, and biotechnology agents. Prior approval may be required for use of the drugs or for overriding specific DUR warnings at the POS.

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Exhibit C.21-4, at the end of this section, illustrates Molina's tightly managed prior authorization process. Please note that SmartPA, hosted by the PBM, is a registered trademark of Conduent Inc.

e.i. TRANSPARENCY IN COMMUNICATING THE CONDITIONS FOR COVERAGE TO PROVIDERS

Molina is committed to a high-touch and transparent communication with providers including conditions for coverage. Our approach includes use of multiple communication modes to ensure we continually educate our provider network to help facilitate seamless coverage of needed prescriptions for enrollees. **Our Provider Services team will be regionally based and located in our six regional offices across the Commonwealth.**

Our process begins with each provider having an assigned provider services representative who will regularly meet face-to-face to build trust, foster open communication, and develop collaborative relationships.

Specific actions that will support transparency include:

- Molina's **website portal for providers and the Provider Manual** will include conditions for coverage. Information outlining drug coverage, such as prior authorization, step therapy, and utilization management edits (such as quantity limits and gender) will be included.
- **Provider reports** are offered to providers to educate them on their prescribing patterns in comparison to the CDC guidelines for opioid prescribing.
- **Toolkits with multimedia resources** on topics that help prescribers with complex patients on high-risk medication regimens in need of safer pain management plans.
- The **ePA** allows prescribers to communicate with the PBM electronically. Medication description, indications, and uses will be provided before launching an ePA initiation request.
- Prescribers will be able to access the prior authorization decision from their dashboard, which will be provided via a **pop-up message**. Upon submitting a request to the payer/PBM, an acknowledgement of receipt (pop-up) will appear for the prescriber.
- Pop-up messages for drug safety edits (FDA or plan) at the POS (within the pharmacy) can be performed within the electronic health record (EHR).
- Molina's provider services representative will engage with providers regularly and provide clarification and support around the pharmacy benefit.

If needed, a Molina registered pharmacist or medical director will be available for **peer-to-peer consultation** to discuss a denial decision with any treating practitioner regarding medical necessity.

e.ii. REQUIRED CREDENTIALS OF STAFF REVIEWING, APPROVING, AND DENYING REQUESTS

Molina will only use Kentucky-licensed physicians, and pharmacists and pharmacy technicians registered with the Kentucky Board of Pharmacy to review, approve, and deny requests for prior authorization.

This function will be performed in-house by Molina qualified personnel, including pharmacists, pharmacy technicians, and medical doctors, who will use evidence-based criteria to make and communicate determinations within 24 hours of initial request. Any denial of a request of prior authorization will be made by a Molina registered pharmacist or medical director.

A Molina registered pharmacist or medical director will be available for peer-to-peer consultation to discuss a denial decision with any treating practitioner regarding medical necessity.

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e.iii. USE OF PHARMACY AND/OR MEDICAL CLAIMS HISTORY TO ADJUDICATE REQUESTS

In reviewing a request for prior authorization, a Molina pharmacist will review the Enrollee's medical and pharmacy claims history, as available and appropriate, to validate any prior use of the medication requested and determine if the request meets our evidence-based criteria.

We will offer innovative tools to facilitate prior authorization processing that eliminate some of the nuisances associated with traditional prior authorization. For example, ePA will be integrated with certain EHRs or made available through online portals. ePA allows prescribers to submit a request for prior authorization through their existing electronic workflows.

Molina also will use Step Edits and SmartPA. These tools will allow auto-approval of a drug at the pharmacy based on specific clinical criteria. This will be done by leveraging the Enrollee's pharmacy, medical, and/or lab claims data in real-time at the POS. As an example, drug approval requirements may be based on a patient's disease state, age, and use of previous drug. These data points can run through a SmartPA algorithm that allows claims to bypass prior authorization or quantity limit edits when an Enrollee has a qualified diagnosis code and/or lab value available in the PBM adjudication engine. This is a real-time function at the POS, which helps reduce prior authorization requests and facilitate more expeditious Enrollee access to care by bypassing the traditional prior authorization process when medically appropriate. SmartPA is a function hosted by the PBM.

Molina will promote EHR adoption to facilitate prior authorization activities by:

- Offering proactive solutions to address technological and financial barriers faced by some providers
- Providing education and covering 80% of ongoing maintenance fees for providers not currently on an EHR using our EPIC EHR platform, Community Connect

Molina also will leverage data from EHRs to streamline prior authorization decisions and drive quality and efficiency. We are committed to expanding adoption and use of EHRs to improve quality of care and reduce costs. Tapping into the successful experience of our affiliated health plans across the nation, we have designed a range of strategies to encourage adoption and use of EHRs and information exchange in Kentucky that reflect the healthcare landscape and Commonwealth goals.

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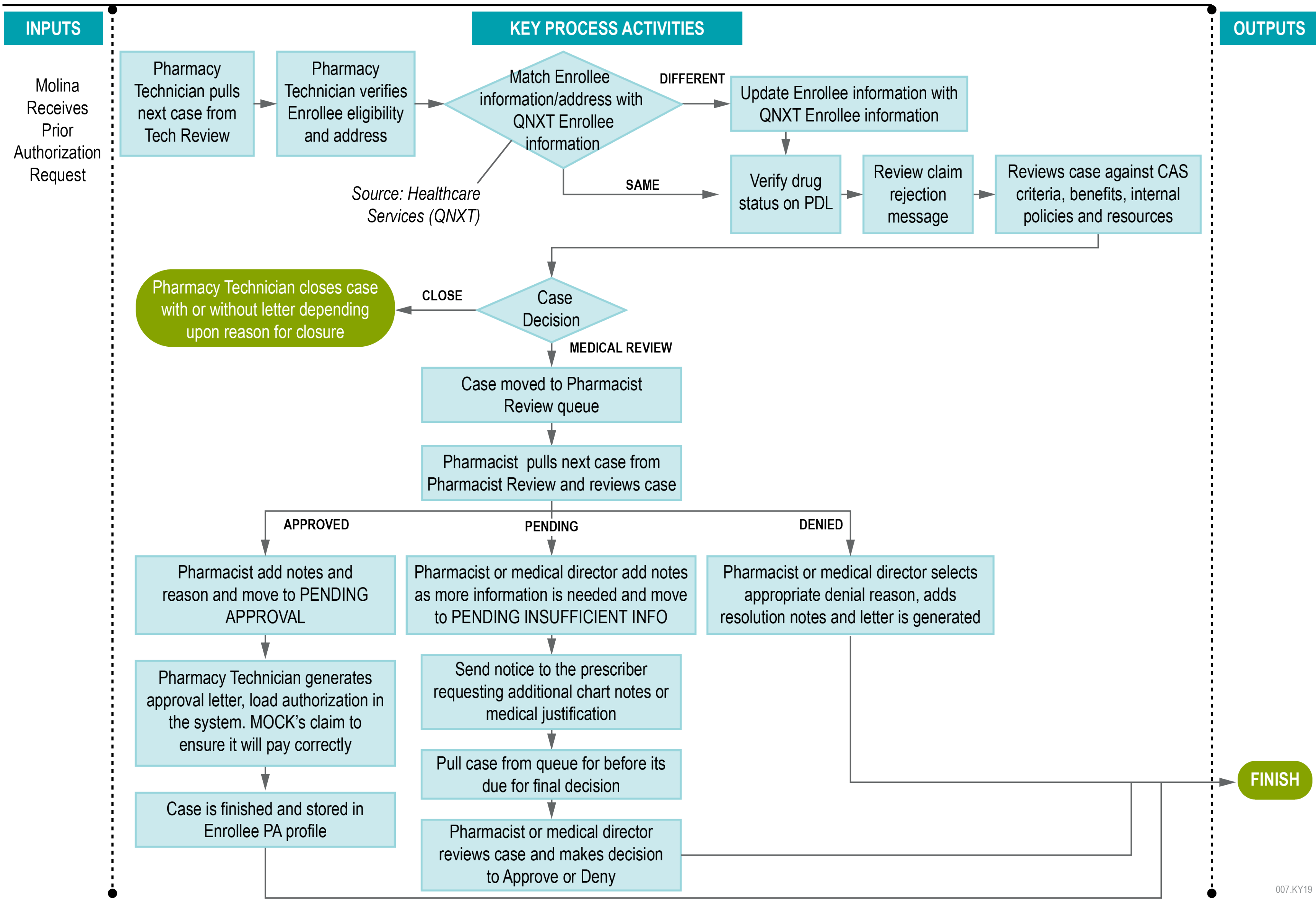

Exhibit C.21-4. Kentucky Pharmacy Prior Authorization Process

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