PROGRAM DESCRIPTION

Department: Social Services **HB Section(s): 11.700**
Program Name: Pharmacy
Program is found in the following core budget(s): Pharmacy

1a. What strategic priority does this program address?

Access safe and cost effective medications for MO HealthNet (MHD) participants

1b. What does this program do?

The MO HealthNet Pharmacy Program reimburses outpatient prescription drugs for managed care and fee-for-service eligible participants. The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) significantly expanded the coverage of pharmacy provisions to include reimbursements for all drug products of manufacturers that have entered into a rebate agreement with the Federal Department of Health and Human Services (HHS). States have the authority to manage state specific drug purchasing and formulary decisions through Drug Utilization Review boards. MHD has a robust Drug Utilization Review process to ensure medications are clinically and fiscally appropriate. This process is ongoing as new pharmaceutical agents are approved frequently. In addition, OBRA-90 included provisions requiring both a prospective and retrospective drug use review program.

The Centers for Medicare and Medicaid Services (CMS) published a final rule on January 1, 2016, pertaining to Medicaid reimbursement for covered outpatient drugs. The purpose of the final rule is to implement changes to the prescription drug reimbursement structure as enacted by the Affordable Care Act (ACA). States are required to establish actual acquisition cost (AAC) as the basis of ingredient cost reimbursement to providers, as well as evaluate the professional dispensing fee reimbursement. With the final rule, states must also establish a payment methodology for 340B entities and 340B contract pharmacies.

Entities that are 340B covered are eligible to purchase discounted drugs through the Public Health Service Act's 340B Drug Discount program. Examples of 340B entities include federally qualified health centers, hemophilia treatment centers, disproportionate share hospitals, sole community hospitals, AIDS drug assistance programs, and family planning clinics. MHD is working collaboratively with stakeholders to encourage 340B participation by covered entities. By working with covered entities, savings from 340B pricing for MHD participants' prescriptions are shared with the Medicaid program.

Effective December 16, 2018, MHD drug reimbursement will be made by applying the following hierarchy methodology:

- National Average Drug Acquisition Cost (NADAC), plus professional dispensing fee, if there is no NADAC
- Missouri Maximum Allowed Cost (MAC), plus professional dispensing fee if no NADAC or MAC
- Wholesale Acquisition Cost (WAC), plus professional dispensing fee
- The usual and customary (U&C) charge submitted by the provider if it is lower than the chosen price (NADAC, MAC, or WAC)
- 340B providers will be reimbursed at WAC minus 25%

CMS approval is pending for the above reimbursement methodology.

WAC is the manufacturer's published catalog or list price for a drug product to wholesalers; NADAC is based on CMS's monthly surveys of retail pharmacies to determine average acquisition cost for covered outpatient drugs; and MAC is the maximum reimbursement for drugs set at a state level. MHD uses its electronic tools incorporating clinical and fiscal criteria derived from best practices and evidence-based medical information to adjudicate claims through clinical and fiscal edits, preferred drug list edits, and prior authorization.

Pharmacies doing business in Missouri are also assessed a provider tax. Funds from this tax are used to provide dispensing fee payments and to support MHD pharmacy payments. See the Pharmacy Reimbursement Allowance tab for more detail.

Rebate Program

The U.S. Congress created the Medicaid outpatient prescription drug rebate program when it enacted the Omnibus Budget Reconciliation Act (OBRA) '90. The goal of the program is to reduce the cost of outpatient prescription drugs by requiring drug manufacturers to pay a rebate directly to state Medicaid programs. The purpose of the program is to reduce the cost of prescription drugs without placing an undue burden on pharmacies. The intent of this rebate is to allow state and federal governments to receive price reductions similar to those received by other high volume purchasers of drugs.

OBRA '90 requires all drug manufacturers to enter into a drug rebate agreement with CMS before their product lines will be eligible for coverage by Medicaid. Currently, approximately 700 manufacturers have signed agreements with Centers for Medicare and Medicaid Services (CMS) and participate in the Drug Rebate Program. For MHD participants, approximately 570 manufacturers have products dispensed and invoiced quarterly. Once the drug manufacturer has entered into the agreement, the state Medicaid programs are required to provide coverage of the manufacturers' drug products. However, the state has the option of excluding certain categories of the manufacturer's products or requiring prior authorization for reimbursement of products. Manufacturers are required to calculate and make rebate payments to the state Medicaid agency for the manufacturers' covered outpatient drugs reimbursed by the state during each quarter. Manufacturers are to be invoiced no later than 60 days after the end of each calendar quarter and are required to make payment for the calculated drug rebate directly to the state Medicaid program within 38 days of invoicing.

The Affordable Care Act of 2010 provided enhancements to the Federal Drug Rebate requirements. Rebates are as follows:

- 23.1% of the Average Manufacturer Price (AMP) for single-source brand-name drugs
- 13% of AMP for multi-source generic drugs
- 17% of AMP for single-source generic drugs

The manufacturer may also be required to pay an additional rebate amount, based on a calculation related to the Consumer Price Index and price increases for a drug. Approximately 35% of the total rebates collected are used as a state share funding source rather than using General Revenue funds. Based on the FMAP rate, approximately 65% of the rebates collected are returned to the federal government.

In addition to the Federal Drug Rebate Program, MO HealthNet may negotiate additional discounts in the form of Supplemental Drug Rebates. Drug manufacturers may contract to pay National Drug Code (NDC)-specific Supplemental Drug Rebates as a condition for placement on the state's Preferred Drug List (PDL). MHD invoices and collects these rebates from manufacturers, along with the federal rebates, and submits the federal portion of the rebates to CMS while retaining the state share.

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Benefit Management and Cost Savings Tools

Clinical Management Services and System for Pharmacy Claims and Prior Authorization (CMSP)

Through a contract with Conduent (formerly Xerox), MHD operates an innovative electronic web-based clinical editing process for its point-of-sale pharmacy and medical claims, medical and drug prior authorization, and Drug Utilization Review (DUR) processes. The current CMSP claim processing system allows each claim to be referenced against the participant's claims history including pharmacy, medical, and procedural data (ICD-9/10 and CPT codes), providing real time data to participating MHD providers. For patients that meet approval criteria, the claim will be paid automatically. In instances when a phone call is necessary, the hotline call center is available seven days a week, which allows providers prompt access to a paid claim for the requested product or service. In addition to receiving messages regarding the outcome of the processing of claims and the amount to be reimbursed, pharmacy providers receive prospective drug use review alert messages at the time prescriptions are dispensed.

The contract with Conduent utilizes their CyberAccessSM tool to create integrated patient profiles containing prescription information, as well as patient diagnoses and procedure codes for a running 24 months of history. CyberAccessSM provides:

- Daily updated participant claims history profiles
- Identification of all drugs, procedures, related diagnoses and ordering providers from claims paid by MHD for a rolling 36 month period
- 3 years of Point of Service (POS) pharmacy claims refreshed every 10 minutes

Fiscal and Clinical Edits

Fiscal and Clinical Edits optimize the use of program funds and enhance patient care through improved use of pharmaceuticals. Since the implementation of the OBRA '90, education on the use of pharmaceuticals has been accomplished primarily through DUR. However, the prospective DUR alerts currently generated by the fiscal agent have been largely ignored by pharmacy providers as they are more general in nature and few are tied to claim reimbursement. Other third party payers have successfully utilized more extensive evidence based claims screening edits in an effort to control costs. These edits apply within MHD to achieve similar cost controls.

Point-of-Service Pharmacy

Claims are routed through Conduent's automated system to apply edits specifically designed to assure effective utilization of pharmaceuticals. The edits are founded on evidence-based clinical and nationally recognized expert consensus criteria. Claims will continue to be processed by Wipro, MHD's fiscal agent, for all other edits and final adjudication. After processing by Conduent and Wipro, the claim is sent back to the provider with a total processing time of approximately 10 seconds. Claims which are denied by the system edits will require an override from the existing help desk. Providers seeking an override must contact the help desk for approval, which will be granted if medically necessary.

PROGRAM DESCRIPTION

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Preferred Drug List (PDL) Edits

The PDL utilizes information from various clinical sources, including the UMKC Drug Information Center (DIC), the Oregon Evidence-Based Drug Research Consortium, MHD clinical contractors, and MHD's clinical research team. Clinical information is paired with fiscal evaluation to develop a therapeutic class recommendation. The resulting PDL process incorporates clinical edits including step therapies into the prescription drug program. Clinical edits are designed to enhance patient care and optimize the use of program funds through therapeutically prudent use of pharmaceuticals. Pharmacy claims are routed through an automated computer system to apply edits specifically designed to ensure effective and appropriate drug utilization. The goal is to encourage cost effective therapy within the selected drug class.

Prior Authorization

Any covered outpatient drug can be subject to Prior Authorization (PA). Effective August 1, 1992, a PA process was implemented for certain specific drugs under the pharmacy program. In conjunction with MHD Advisory groups (see below), approval criteria are established with the minimum being approved FDA clinical indication. MHD may establish additional clinical and/or fiscal criteria for approval or denial. Drug PA requests are received via telephone, fax or mail. All requests for a drug PA must be initiated by a physician or authorized prescriber (advanced practice nurse) with prescribing authority for the drug category for which a PA is being requested. As specified in OBRA '90, drug PA programs must provide a response by telephone or other telecommunication device within 24 hours of receipt. All requests must include all required information. Requests received with insufficient information for review or received from someone other than a physician or authorized prescriber will not initiate a PA review nor the 24-hour response period. Drug PA requests received via telephone are keyed on-line and notification of approval will be given at the time of the call or by return fax or phone call. MHD technicians who staff this hotline work through algorithms developed by the Drug Prior Authorization Committee with the assistance of UMKC-DIC School of Pharmacy. These algorithms are sets of questions used to make a determination to approve or deny the request. Making the prior authorization determination on-line allows the PA file to be updated immediately. For approvals, the requestor will be given an authorization period. Pharmacies may record this information for this purpose as well.

Drug Utilization Review

This process is currently provided by Conduent and will be an extension of the current process with some enhancements. Under the new contract, this initiative will utilize the same database/computer system as the previously described components. This system uses a relational database capable of interfacing MHD paid claims history with flexible, high quality clinical evaluation criteria. The process is designed to identify high-risk drug use patterns among physicians, pharmacists, and beneficiaries, and to educate providers (prescribers and dispensers) in appropriate and cost-effective drug use. This process is capable of identifying providers prescribing and dispensing practices which deviate from defined standards, as well as generating provider profiles and ad hoc reports for specified provider and participant populations. The goal of the program is to maximize drug therapy and outcomes and optimize expenditures for health care.

PROGRAM DESCRIPTION

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Board and Committee Support and Oversight

MHD operates both prospective and retrospective Drug Utilization Review (DUR) as required by federal and state law. The DUR program is focused on educating health care providers in the appropriate use of medications and informing them of potential drug therapy problems found in the review of drug and diagnostic information obtained from MHD claims history. The DUR Board is central to all DUR program activities, and its duties and membership requirements are specified in state and federal law. DUR Board members are appointed by the Governor with advice and consent of the Senate, and its 13 members include six physicians, six pharmacists, and one quality assurance nurse. In an ongoing process, the DUR Board reviews and makes changes to the clinical therapeutic criteria used to generate prospective and retrospective DUR interventions. The DUR Board also advises the division on other issues related to appropriate drug therapy and produces a quarterly newsletter for providers on selected drug topics. In addition to the Board, a Regional DUR Committee, comprised of physicians and pharmacists, evaluates individual participants' retrospective drug regimens and advises their providers on appropriate drug use or potentially problematic drug therapies. The MHD Drug Prior Authorization (PA) Committee is established in state regulation. This advisory committee is charged with reviewing drugs and recommending those drugs which are appropriate for reimbursement as a regular benefit verses those which should be placed on prior authorization status. All such recommendations made by the Drug PA Committee are referred to the DUR Board, as they are the statutorily-appointed advisory group for final recommendation to the division.

The Advisory Council on Rare Diseases and Personalized Medicine is established in state regulation. This board will serve as an expert advisory committee to the DUR board in regards to beneficiary access to drugs or biological products for rare diseases. The Advisory Council on Rare Diseases and Personalized Medicine members are appointed by the Director of the Department of Social Services, and members include 5 physicians, 2 medical researchers, 1 registered nurse, 1 pharmacist, 1 professor, 1 individual representing the rare disease community, 1 member of the rare disease foundation and 1 representative from a rare disease center within a comprehensive pediatric hospital. The DUR board shall request and consider information from the Advisory Council on Rare Diseases and Personalized Medicine when making recommendations or determinations regarding prior authorization and reauthorization criteria for rare disease drugs and other topics related to rare diseases.

Cost Containment Initiatives

As a result of new drugs, rapidly changing prescribing patterns and increased expenditures in the MHD fee-for-service pharmacy program, MHD continues to implement a number of administrative measures to ensure the economic and efficient provision of the MHD pharmacy benefit. These strategies have been developed through recommendations from a number of sources, including affected state agencies, provider groups, and the pharmaceutical industry. The intent of these initiatives is to ensure that MHD participants get the correct drug to meet their needs, in the correct amount, and for the correct period of time. Examples of some of the cost containment initiatives, processed through clinical management, include:

- Edits - Dose Optimization: Effective for dates of service on or after April 16, 2002, claims submitted to the MO HealthNet Pharmacy Program are subject to edits to identify claims for pharmacy services that fall outside expected patterns of use for certain products. Overrides to these edit denials can be processed through the Pharmacy hotline. Justification for utilization outside expected patterns, such as Food and Drug Administration (FDA) approved labeling, is required for approval of such an override.

- Preferred Drug List (PDL): As a tool for containing costs, the PDL provides access to the most cost-effective drug therapy for specific drug categories. Preferred status on the PDL provides the state with Supplemental Rebates for selected name-brand and/or single-source drugs and lowers the net cost. See above for PDL details. MO HealthNet began the PDL in 2003.
- Diabetic Testing Supplies and Syringes: In December 2003, the MHD moved diabetic testing supplies and syringes from the Durable Medical Equipment (DME) program to the pharmacy program, and initiated a single source diabetic testing supply initiative, continuing to encourage patient blood glucose testing while minimizing state expenditures. In April 2005, the pharmacy program moved to a multi-source diabetic testing supplies initiative. Diabetic testing supply products and syringes are now available in preferred status from multiple manufacturers, providing greater participant choice and generating supplemental rebates to the state.
- Generic Incentives: Effective for dates of service January 1, 2010 and beyond, the MO HealthNet Pharmacy Program began paying pharmacy providers a generic product preferred incentive fee. MHD is having discussions with CMS regarding the level of generic incentive allowed under the January 1, 2016 final rule.
- Expanded Missouri Maximum Allowable Cost (MAC) list: The list of drugs for which the state agency has established a generic reimbursement limit will be monitored and expanded on a regular basis. A mechanism is in place to review existing MACs as well as identify new generic drugs for addition to this list as they become available. This optimizes generic utilization in the MHD program. Effective in June of 2009, MHD updated the MAC list to include specific specialty medications.
- Active Pharmaceutical Ingredients (API) and Excipients: An API is defined by 21 C.F.R. § 207.3(a)(4) as a bulk drug substance that “is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug.” An excipient is an inactive substance that forms a vehicle for the active ingredient in compounding. Effective September 1, 2017 MHD requires prior authorization (PA) on all compounded medications including an API and excipients. Requests for PA are reviewed on an individual patient basis and evaluated for medical necessity. Participant are required to use commercially available products if there are any available that are similar to the compounds being requested.
- Refill-Too-Soon: On February 21, 2018, the refill-too-soon (RTS) edit criteria went from 75% utilization to 85% utilization.
- Morphine-Milligram-Equivalent (MME): Effective May 1, 2018 the MO HealthNet Pharmacy Program implemented a MME Accumulation Clinical Edit. The edit will more accurately calculate the total MME daily dose from all concurrent opioid prescriptions for individual patients.
- New Drugs Review : Prior authorization is required for all new drug entities and new dosage forms, through existing drug entities that have been newly approved by the FDA and become available on the prescription drug market. First Data Bank is the publisher of proprietary pharmaceutical information and provides weekly updates to MHD covered medications, which are reviewed for medical and clinical criteria along with pharmacoeconomic impact to the pharmacy program. Program staff recommend ongoing management (i.e. continue PA, PDL addition, clinical edit, or open access) of each new drug, which goes to the MO HealthNet advisory groups for approval and implementation. The new drug review process was updated in September of 2018.
- NADAC: On December 16, 2018 MHD changed drug reimbursement to the National Average Drug Acquisition Cost (NADAC) model. The NADAC files represent a national pricing methodology based upon a simple average of retail pharmacy acquisition costs for most covered outpatient drugs.
- Non-Traditional Pain Management: In FY19 MHD implemented a non-traditional pain management program which will use alternative treatments such as chiropractic services, physical therapy and acupuncture in lieu of prescribing opioids for pain.
- Enhanced Retrospective Drug Utilization: Enhanced retrospective drug utilization involves retroactively reviewing population-based patterns of drug use, to compare those patterns to approved therapeutic guidelines in order to determine the appropriateness of care, length of treatment, drug interaction, and other clinical issues.
- Provider Audits: Daily provider audits are performed by MHD/Wipro staff for the identification and resolution of potential recoupments.

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2a. Provide an activity measure for the program.

Top 10 Products Ranked By Paid Amount of FFS Claims

	4th Qtr (April, May, June) 2020			4th Qtr (April, May, June) 2019		
Drug	**Rank**	**Claims**	**Paid**	**Rank**	**Claims**	**Paid**
PALIPERIDONE PALMITATE (Antipsychotic)	1	6,440	$ 12,301,543	1	5,808	$ 10,789,510
LURASIDONE HCL (Antipsychotic)	2	10,894	$ 9,760,517	2	10,788	$ 9,184,792
ADALIMUMAB (Immunosuppressive) (Humira)	3	1,600	$ 9,749,863	3	1,518	$ 8,497,161
METHYLPHENIDATE HCL (Stimulant)(Ritalin)	4	27,793	$ 7,640,061	8	31,474	$ 5,338,739
INSULIN GLARGINE,HUMAN RECOMBINANT ANALOG (Diabetes)	5	20,095	$ 6,791,262	7	18,884	$ 6,061,972
INSULIN ASPART (Diabetes)	6	13,503	$ 6,741,216	9	12,082	$ 5,052,385
SOMATROPIN (Growth Hormone)	7	1,447	$ 6,654,002	5	1,368	$ 6,321,669
ALBUTEROL SULFATE (Bronchodilator, Asthma)	8	96,120	$ 5,921,652	6	103,879	$ 6,213,828
TRIKAFTA (Cystic Fibrosis)	9	272	$ 5,581,999			
BUDESONIDE/FORMOTEROL FUMARATE(Asthma/COPD)	10	21,654	$ 5,476,605			
SOFOSBUVIR/VELPATASVIR (Hepatitis C) (Epclusa)				4	305	$ 6,829,547
LISDEXAMFETAMINE DIMESYLATE (ADHD)				10	17,633	$ 5,012,966
TOTAL			**$ 76,618,720**			**$ 69,302,569**

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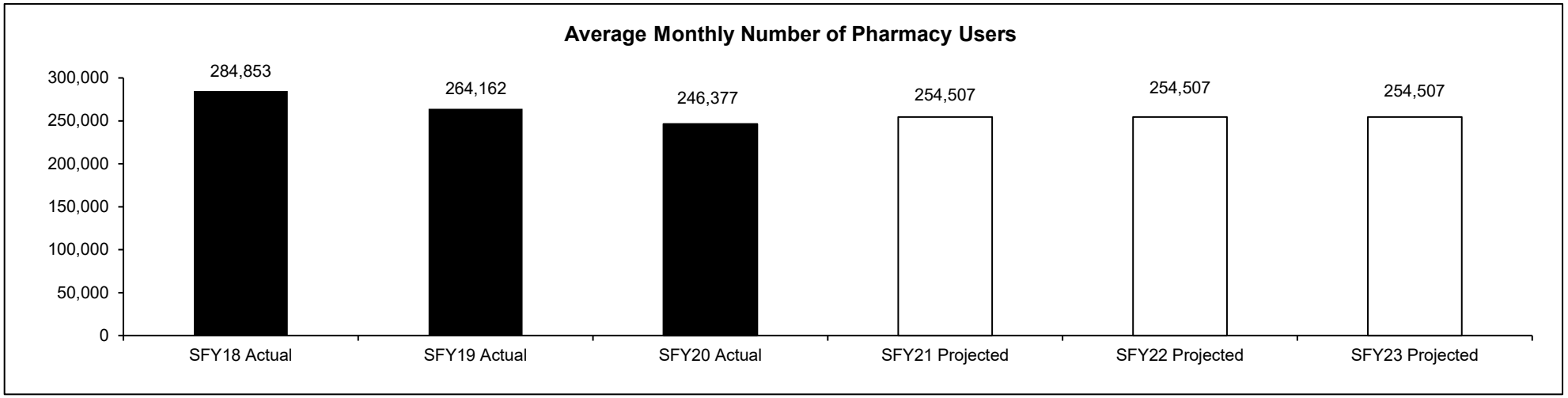
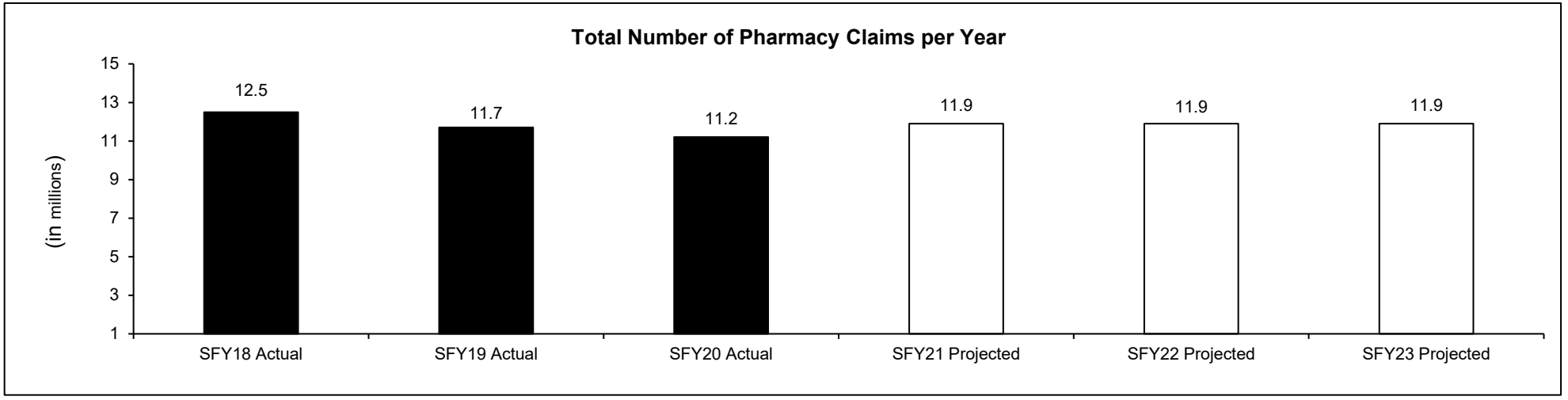


*FY20 number of Pharmacy users was lower due to COVID-19

Future projections are based on eligibility requirements as of 7/1/20.



Future projections are based on eligibility requirements as of 7/1/20.

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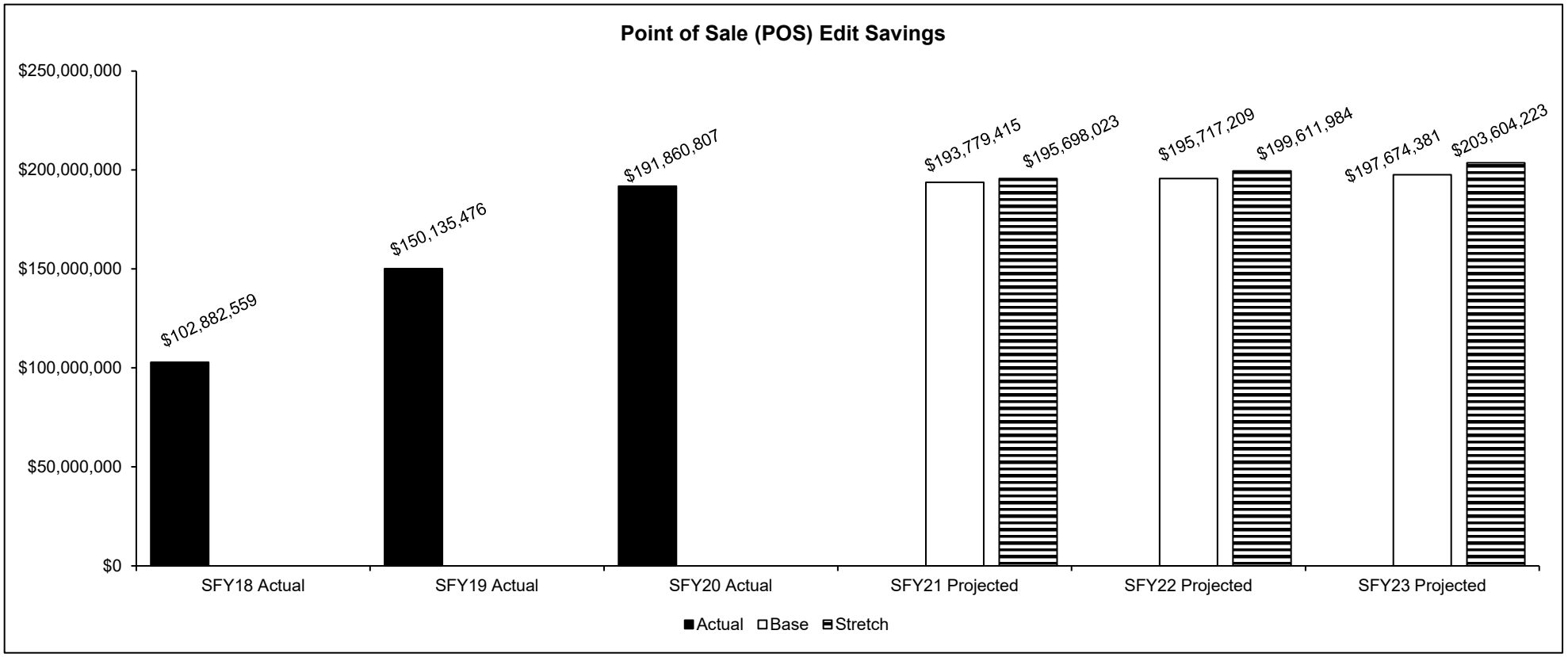
2b. Provide a measure of the program's quality.



Savings from denied pharmacy claims as a result of SmartPA edits.

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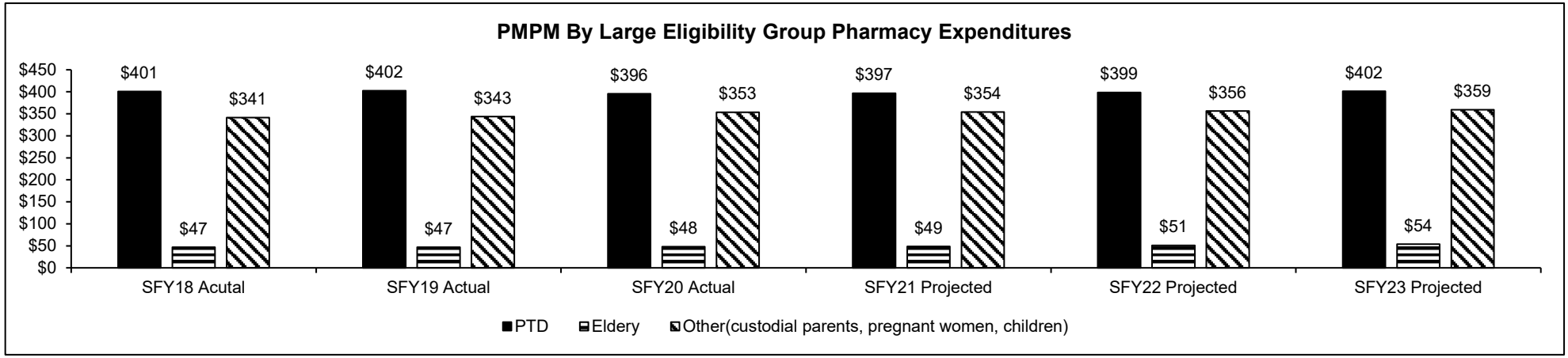
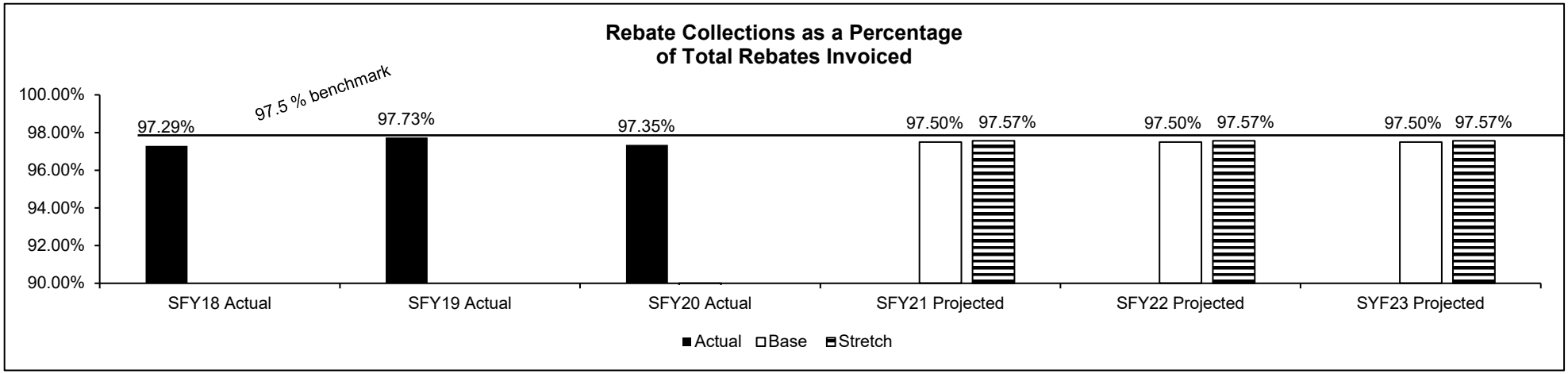
2c. Provide a measure of the program's impact.



Future projections are based on eligibility requirements as of 7/1/20.

2d. Provide a measure of the program's efficiency.



As measured June 1 of each fiscal year. The benchmark is set at 97.5%, and is the average of SFY19 and SFY20.

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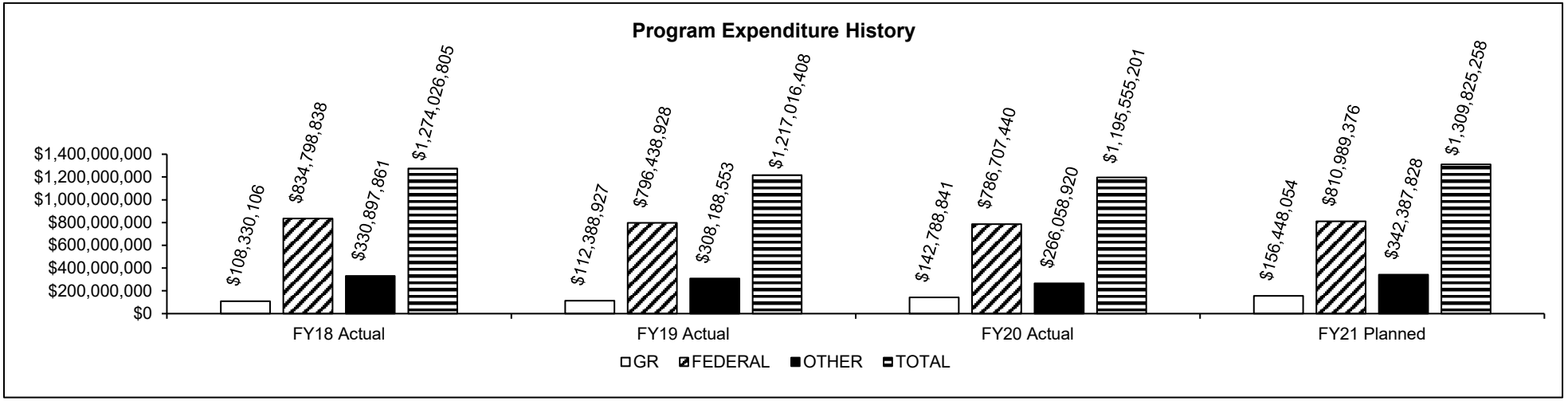
3. Provide actual expenditures for the prior three fiscal years; planned expenditures for the current fiscal year. (*Note: Amounts do not include fringe benefit costs.)*



Planned FY2021 expenditures are net of restricted, reverted and reserves.

4. What are the sources of the "Other " funds?

Pharmacy Reimbursement Allowance Fund (0144), Pharmacy Rebates Fund (0114), Health Initiatives Fund (0275), Third Party Liability Fund (0120), Premium Fund (0885), and Life Sciences Research Trust Fund (0763).

5. What is the authorization for this program, i.e., federal or state statute, etc.? (Include the federal program number, if applicable.)

Missouri Statute: Sections 208.152 and 208.166, RSMo. Federal law: Social Security Act Section 1902(a)(12). State regulation: 13 CSR 70-20. Federal regulation: 42 CFR 440.120.

6. Are there federal matching requirements? If yes, please explain.

The FMAP (Federal Medical Assistance Percentage) fluctuates annually based on state and national economic and population data, but generally the state matching requirement is around 35% and the federal match is around 65%.

7. Is this a federally mandated program? If yes, please explain.

Yes, pharmacy services are mandatory for children if identified as medically necessary health services under the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program. This program is not federally mandated for adults.