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DATE: September 18, 2025

ALL PLAN LETTER 25-013 SUPERSEDES ALL PLAN LETTER 22-012

TO: ALL MEDI-CAL MANAGED CARE PLANS

SUBJECT: MEDI-CAL RX PHARMACY BENEFITS, AND CELL AND GENE

THERAPY COVERAGE

PURPOSE:

The purpose of this All Plan Letter (APL) is to provide Medi-Cal managed care plans (MCPs) with guidance on the oversight and administration of the Medi-Cal pharmacy benefit. Effective January 1, 2022, Governor Gavin Newsom's Executive Order N-01-19, required the Department of Health Care Services (DHCS) to transition Medi-Cal pharmacy services from the managed care delivery system to the Fee-For-Service (FFS) delivery system, which is collectively known as "Medi-Cal Rx".

To the extent any existing APLs or Policy Letters (PLs) have inconsistent provisions specific to the Medi-Cal pharmacy benefit, this APL supersedes all inconsistencies in prior APLs/PLs, and DHCS has included a table of affected APLs/PLs in this guidance.

BACKGROUND:

One of the primary goals of the Governor's Executive Order was to achieve costsavings for drug purchases made by the state. As a result, a major component of Executive Order N-01-19 required DHCS to transition Medi-Cal pharmacy services from the managed care delivery system to the FFS delivery system. Transitioning pharmacy services from the managed care delivery system to the FFS delivery system was intended to:

- Standardize the Medi-Cal pharmacy benefit statewide, under one delivery system, creating a single-payer point-of-sale (POS) pharmacy benefit;
- Improve access to pharmacy services with a pharmacy network that includes approximately 94 percent of the state's licensed outpatient pharmacies;
- Apply statewide utilization management protocols to all covered outpatient drugs;
 and
- Strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers, thereby creating additional cost-savings for the state.

¹ Executive Order N-01-19 can be found at: https://www.gov.ca.gov/wp-content/uploads/2019/01/EO-N-01-19-Attested-01.07.19.pdf



DHCS contracted with Magellan Medicaid Administration, Inc. (Magellan) to provide administrative services and support relative to Medi-Cal Rx. In 2023, Prime Therapeutics State Government Solutions LLC. (Prime) acquired Magellan and became the pharmacy benefit administrator for Medi-Cal Rx. Prime provides administrative services, as directed by DHCS, which include claims management, Prior Authorization (PA) and utilization management, pharmacy drug rebate administration, Provider and Member support services, program integrity (PI) activities, and other ancillary and reporting services to support the administration of Medi-Cal Rx.

In addition to the Medi-Cal Rx program for outpatient, POS pharmacy benefits, Medi-Cal Rx also covers all Medically Necessary prescription drugs administered in an outpatient office or clinic setting by a health care professional available through the Member's medical benefit, either through the Medi-Cal FFS delivery system or the Member's MCP. When establishing the scope of benefits, DHCS' intent was to ensure Medi-Cal managed care Members have the same access to these prescription drugs as Medi-Cal FFS members.

POLICY:

Overview

Medi-Cal Rx does not apply to:

- Programs for All-Inclusive Care for the Elderly (PACE)
- Senior Care Action Network (SCAN)

As of January 1, 2022, Medi-Cal Rx is responsible for the following **pharmacy benefits** when billed by a pharmacy Provider on a pharmacy claim:

- Covered outpatient drugs, eligible under the pharmacy benefit;
- Specific, disposable medical supplies which include diabetic supplies (testing supplies, Continuous Glucose Monitoring devices, disposable insulin delivery devices, insulin syringes, and pen needles), miscellaneous medical supplies, and certain contraceptive devices; and
- Enteral nutritional products.

As of January 1, 2022, MCPs are responsible for covered Specific Physician Administered Drugs (PADs). **The MCP is responsible for covering PADs as they are covered under the Member's medical benefit.**

- MCPs must inform their Network Providers how PADs are paid and how claims or Encounters for PADs are submitted. For example, policies and procedures (P&Ps) for how PADs are covered and claims submitted should be made available through MCPs' Provider Portals.
- In limited and specific circumstances, Medi-Cal Rx may allow coverage of PADs through the pharmacy benefit when a PA is submitted with documentation of

Medical Necessity and a clear clinical justification for why the claim could not be submitted under the medical benefit. This exception is intended to offer narrow, case-by-case flexibility and does not replace or override the standard requirement for PADs to be covered through the medical benefit.

For more granular information about pharmacy benefits under each of the categories identified above, please refer to the Medi-Cal Rx web portal or the "Medi-Cal Rx Policy Resources" section of this APL.

DHCS recognizes the unique pharmacy needs of children with complex chronic health care needs enrolled in the California Children's Services (CCS) Program, including those in Whole Child Model (WCM) MCPs. Medi-Cal Rx provides pharmacy benefits to all CCS Members. Pharmacy policy embodied in CCS Numbered Letters was integrated into Medi-Cal Rx policy to ensure continuity of services to support WCM programs.²

The CCS Program covers PADs that are Medically Necessary for CCS-eligible conditions as a medical benefit, while MCPs cover PADs for conditions not eligible for CCS Program treatment services. For Members who reside in WCM counties, all CCS specialty care, including PAD coverage, is integrated into MCPs. This APL does not alter the MCP's obligation to fully comply with the requirements of APL 24-015 or any superseding APL.³

Additionally, DHCS issued CCS Information Notice (I.N.) 20-03 Governor's Executive Order N-01-19, Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal Rx.⁴ The I.N. provided county CCS programs and the Genetically Handicapped Persons Program (GHPP) Providers and staff with guidance on changes to the oversight and administration of the Medi-Cal pharmacy benefit due to Medi-Cal Rx.

DHCS recognizes that Members may have **emergency outpatient pharmacy service needs** and may not have access to a pharmacy enrolled in Medi-Cal Rx. Medi-Cal Rx provides a process to ensure timely and appropriate provision of emergency outpatient pharmacy services including payment to pharmacies that are not enrolled Medi-Cal pharmacy Providers. Medi-Cal Rx allows for an emergency fill by a non-enrolled Medi-Cal Rx pharmacy Provider for a 14-day supply of the Member's medication, which can be repeated once. MCPs are not responsible for covering outpatient emergency pharmacy services. Please refer to the Medi-Cal Rx Provider manual on the Medi-Cal Rx web portal for additional information and restrictions.

Under Medi-Cal Rx, all mental health medications, including those currently carved-out (e.g., antipsychotics, lithium, monoamine oxidase inhibitors, and anticholinergics,

https://www.dhcs.ca.gov/services/ccs/Pages/CCSNL.aspx

https://www.dhcs.ca.gov/formsandpubs/Pages/MgdCarePlanPolicyLtrs.aspx

² CCS Numbered Letters can be found at:

³ All APLs and PLs can be found on the DHCS webpage at:

⁴ CCS I.N.s can be found at: https://www.dhcs.ca.gov/services/ccs/Pages/CCSIN.aspx

antidepressants, psychostimulants, benzodiazepines), are covered under one uniform Medi-Cal Rx policy regardless of where the Member is receiving mental health services. Care Coordination processes, roles, and responsibilities between Specialty Mental Health Services provided by County Mental Health Plans and Non-Specialty Mental Health Services covered by MCPs were not impacted by the transition.

Please note that Medi-Cal Rx has not changed the following:

- The scope of existing Medi-Cal pharmacy coverage for prescribed drugs, products, and services;
- The provision of pharmacy services that are billed on medical or institutional claims and/or as part of a bundled/all-inclusive billing structure in an inpatient or long-term care setting, including Skilled Nursing Facilities, regardless of delivery system;
- Covered pharmacy services that have historically been carved out of managed care, including blood factor, HIV/AIDS drugs, antipsychotics, or drugs used to treat a substance use disorder (SUD);
- Any pharmacy services that are billed as a medical and/or institutional claim instead of a pharmacy claim;
- The process for adding drugs or outpatient disposable medical supplies to the Medi-Cal Contract Drugs List (CDL) or Covered Products lists for Medi-Cal Rx covered benefits.

Cell and Gene Therapy Coverage

In March 2025, California applied and was accepted to participate in the federal Cell and Gene Therapy (CGT) Access Model, which is a multi-year initiative intended to expand access to two lifesaving CGTs for sickle cell disease (SCD). This access model will follow patients for five years after they have received treatment to ensure that it has worked. There are specific outcome benchmarks that have been determined by the Centers for Medicare & Medicaid Services (CMS) and the treatment manufacturers that must be reached for the therapy to be considered a success. DHCS, CMS, and the manufacturers will work together to determine that these benchmark outcomes have been reached. The two treatments that are included in this model are LYFGENIA™ from bluebird bio, Inc. and CASGEVY ™ from Vertex Pharmaceuticals⁵. Previously, these two SCD CGTs were included in the MCPs' Capitation Payment because they are medical PADs. However, starting on July 1, 2025 for LYFEGENIA, as approved by CMS, and on October 1, 2025 for CASGEVY, subject to CMS approval, these SCD drugs will be carved out of managed care coverage for MCP Members and not included in the Capitation Payment to MCPs.

MCP Responsibilities:

MCPs may not subject CGT sickle cell disease medications access available under the CGT Access Model to UM review, including prior authorization. Since CGT sickle cell

⁵ These CGTs are approved for the treatment of patients ages 12 and older with SCD and a history of vaso-occlusive events/crises.

disease medications are carved out of managed care, MCP Members may obtain these medications on a FFS basis directly from enrolled, qualified Providers who bill DHCS directly. Members should be informed that they should contact their treating health care Provider or reach out to their MCP to determine eligibility and learn more about CGT sickle cell disease medications. MCPs are responsible for care coordination and assisting their Members with accessing one of the two CGT sickle cell disease medications. MCPs should make referrals as appropriate. MCPs will remain responsible for all associated outpatient or inpatient medical services and non-medical ancillary services⁶ that support Members through their CGT treatments including pre/post-treatment services, and administration associated fees and supplies. MCPs will also remain responsible for timely Non-Emergency Medical Transportation (NEMT) and Non-Medical Transportation (NMT) services and related travel expenses to the CGT Access Model for Members and their caregivers, as applicable.⁷ For questions on CGT coverage policy, please visit the DHCS CGT website at:

https://www.dhcs.ca.gov/services/medi-cal/Pages/CGT.aspx. MCPs may also contact DHCS directly via email at dhcs.ca.gov.

For MCP Members eligible for or enrolled in CCS or GHPP:

Members with SCD are medically eligible for enrollment in the CCS Program up to age 21 and in the GHPP for those 21 years of age and older. As noted in APL 23-023 and any superseding APL, MCPs must refer a Member to the county for a CCS eligibility determination if the Member demonstrates a CCS condition(s) as outlined in the CCS Medical Eligibility Guide. MCPs should work with the County as the CCS / GHPP programs are designed to facilitate access to SCD CGT. Specifically for CGT SCD therapy, MCP should be aware that Providers should submit supporting documents, using the Provider Electronic Data Interchange (PEDI) web portal and notify DHCS:

- For CCS clients: Via email CCSExpeditedReview@dhcs.ca.gov or secure RightFax (916) 440-5306.
- For GHPP clients: Via email <u>FAXGHPP@dhcs.ca.gov</u> or secure RightFax 916-440-5318.

⁶ Because chemotherapy administered prior to gene therapy infusion typically results in infertility, under the CGT Access Model, participating drug manufacturers will financially support up to three rounds of collection and preservation of reproductive materials (i.e., eggs, sperm, ovarian tissue, and testicular tissue) and payment for up to 15 years of storage. These services will be provided at no cost to Members receiving treatment within the model and at no cost to other payers. The manufacturer will also provide financial reimbursement to certain eligible Members for certain costs related to travel, lodging, and meals, if necessary for the receipt of fertility preservation services. This support is only required for Members who receive the model drug during the model test period (January 1, 2025 – December 31, 2030) and for whom Medi-Cal is the primary payer.

⁷ See APL 22-008, Non-Emergency Medical and Non-Medical Transportation Services and Related Travel Expenses, or any superseding APL.

Medi-Cal Rx Policy Resources

For more information regarding specific Medi-Cal Rx policy, please refer to the following links:

- Medi-Cal Rx Website <u>https://medi-calrx.dhcs.ca.gov/home/</u>
- Medi-Cal Rx Frequently Asked Questions (FAQs)
 https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/Transition-Medi-Cal-Pharm-Services-MC-FFSFAQsV11.pdf
- Medi-Cal Rx Provider Manual https://medi-calrx.dhcs.ca.gov/home/provider-manual/
- Medi-Cal Rx CDL and Medical Supplies Covered Lists (click Covered Products Lists)

https://medi-calrx.dhcs.ca.gov/provider/forms/

Medi-Cal Rx Roles & Responsibilities Clarification Summary

DHCS, Prime, and MCPs are responsible (indicated by an "X") for activities, including but not limited to, listed in the table below. This table is provided to add clarity to areas of concerns related to activity responsibilities for DHCS, Prime, and MCPs.

	Activity	DHCS	Prime	MCPs
1.	Developing, implementing, and maintaining all Medi-Cal pharmacy policy, including, but not limited to: o Drug coverage o State supplemental drug rebates o PA/utilization management	x		
2.	Formulary updates including those based on regional needs, Member specific segment risks, prior utilization, health outcome data, and other considerations.	х		
3.	Providing a printed copy of the "formulary" (CDL) per a Member request.		Х	
4.	Providing future Member, Provider, and pharmacy communications regarding pharmacy benefits/information.	х	Х	
5.	Negotiating and contracting for state supplemental drug rebates.	х		
6.	Providing drug rebate administration services, in compliance with federal and state laws and DHCS' policies and guidance.	х	Х	
7.	Establishing and maintaining the Medi-Cal pharmacy Provider network.	Х		
8.	Reviewing and issuing final determinations regarding all PA denials for pharmacy benefits (except administrative denials due to a 30-day non-response to a PA deferral).	x		

Activity	DHCS	Prime	MCPs
Contract management, inclusive of oversight and monitoring of all Medi-Cal Rx contract requirements and deliverables provided by Prime.	х		
10. Processing and payment of all pharmacy services billed to the MCP on medical or institutional claims.			х
11. Establishing Medi-Cal Rx pharmacy reimbursement methodologies, consistent with applicable state and federal requirements.	х		
Providing claims administration, processing, and payment functionalities for all pharmacy services billed on POS pharmacy claims.		X	
13. Processing coordination of pharmacy benefits with other health coverage, including Medicare.		X	X
14. In partnership with the California Department of Social Services (CDSS), providing oversight of, and ensuring access to, the State Fair Hearing (SFH) process related to Medi-Cal Rx.	X		
15. Providing Medi-Cal Rx Customer Service Center (CSC) to support all pharmacy benefit related Provider and Member calls twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year, inclusive of holidays and weekends unless otherwise directed by DHCS.		X	
16. Providing daily data feeds to MCPs, and other entities as designated by DHCS, to support their responsibilities of Member Care Coordination, carrying out clinical aspects of pharmacy adherence, and disease and medication management.		X	
17. Providing real-time access into the Medi-Cal Rx electronic environment via a secure portal to all Members, Providers (prescribers and pharmacies), MCPs, and other entities as designated by DHCS.		X	
18. Providing dedicated Medi-Cal Rx Clinical Liaisons (CLs) for all MCPs to assist with care coordination and clinical issues, inclusive of Members enrolled in WCM MCPs.		X	
19. Providing CLs supported by appropriate clinical staff, which ensures MCP CLs, and by proxy MCPs, have twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year access to these critical resources, including weekends and holidays unless otherwise directed by DHCS.		x	
20. Providing CLs to help resolve potential PA issues on the front end, with appropriate clinical staff support as needed, to ensure compliance with Medi-Cal Rx policy, which requires a decision to approve, defer, or recommend denial of a PA request within 24 hours.		x	

Activity	DHCS	Prime	MCPs
21. Providing CLs to facilitate intervention for urgent cases, such as after-hours hospital discharges where immediate access to Medically Necessary medication is required.		Х	
22. Providing all CLs, Customer Service Representatives, and supportive clinical staff with training to understand and support the special needs and requirements of WCM MCPs and WCM MCP Members.		x	
23. Overseeing and maintaining all activities necessary for Member care management and coordination, and related activities consistent with legal and contractual obligations.	x	X	х
24. Providing oversight and management of all the clinical aspects of pharmacy adherence, including providing disease and medication management.	x	X	х
25. Monitoring and disseminating information on Class I and Class II Food and Drug Administration (FDA) recalls, disruptions in the supply chain or medication contamination.		X	
26. Reviewing PAs for medical supplies, Enteral Nutritional Products, and covered outpatient drug claims billed on a pharmacy claim by an outpatient pharmacy.	x	X	
27. Ensuring that claims for PADs are processed as a medical benefit. Processing and covering PADs, which are expected to be submitted on medical claims.	x	X	x
28. Providing utilization management functions and ensuring pharmacy PA decisions are made within 24 hours of receipt of the PA request.	x	X	
29. Providing prospective Drug Utilization Review (DUR) services.		X	
30. Providing retrospective DUR services.		X	Х
31. Overseeing the Medi-Cal DUR Board and other DHCS organized pharmacy committees, in collaboration with Prime.	x		
32. Participating in the Medi-Cal DUR Board and other DHCS organized pharmacy committee meetings.			Х
33. Ensuring that DUR program meets or exceeds applicable provisions of Section 1004 requirements of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patient and Communities Act: A retrospective claims review process that monitors when an individual is concurrently prescribed opioids and benzodiazepines, opioids and antipsychotics, or opioids and Medication Assisted Treatment (MAT).	X	X	х

Activity	DHCS	Prime	MCPs
34. Developing and implementing effective retrospective DUR and treatment outcome processes to assure that drug utilization is appropriate, Medically Necessary, and not likely to result in adverse events.8		x	x
35. Developing effective prospective DUR processes to assure that drug utilization is appropriate, Medically Necessary, and not likely to result in adverse events.	x		
36. Implementing effective prospective DUR processes to assure that drug utilization is appropriate, Medically Necessary, and not likely to result in adverse events.	x	X	
37. Reimbursing for pharmacist professional services as required by Assembly Bill (AB) 1114 (Chapter 602, Statutes of 2016) in a community-based outpatient pharmacy setting. ⁹	x		x
38. Processing and payment of all pharmacist professional services allowed by AB 1114 that are billed on medical and institutional claims. 10			X
39. Providing NEMT and NMT services required by Members to access pharmacy services.			Х
40. Providing Fraud and Abuse identification processes that identifies potential Fraud or Abuse of controlled substances by Members, health care Providers, and pharmacies.		х	x
41. Providing PI and oversight of Medi-Cal Rx and Medi-Cal's FFS outpatient pharmacy benefits and services.	Х		
42. Administering the Medi-Cal Rx PI and Compliance Unit and providing support to DHCS through the application of best practices for identifying, sharing, reporting, preventing, or mitigating Fraud, Waste, and Abuse schemes and risks.		x	

furnishing self-administered hormonal contraception; initiating and administering immunizations; furnishing nicotine replacement therapy; furnishing HIV pre-exposure and post-exposure prophylaxis; and furnishing travel medications.

For example, performing

⁸ For example, performing reviews of claims data to identify outlier prescribing trends, inappropriate dispensing activities by a Provider/Providers, patterns suggesting possible misuse/Abuse of medications, etc.

FF248C861B5A/pharmserv.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYyIPyP5ULO 10 Pursuant to WIC Section 14132.968, Pharmacist Services include: furnishing naloxone;

Activity	DHCS	Prime	MCPs
43. Providing Fraud and Abuse reporting, including prompt referral of any potential Fraud, Waste, or Abuse the MCP identifies to the DHCS Audits and Investigations Intake Unit as well as conducting, completing, and reporting to DHCS the results of a preliminary investigation of the suspected Fraud and/or Abuse within 10 working days of the date the MCP first becomes aware of, or is on notice of, such activity.			x

MCP RESPONSIBILITIES

The following section outlines and provides details relative to key programmatic, operational, contractual, and policy requirements that are critical to ensuring MCPs meet expectations for benefit coordination.¹¹

Healthcare Effectiveness Data and Information Set Measures

National Committee for Quality Assurance (NCQA) accredited MCPs are required to report Healthcare Effectiveness Data and Information Set (HEDIS) measures with a pharmacy benefit (Appendix A). MCPs can use the pharmacy daily data feeds and real-time pharmacy portal information provided by Medi-Cal Rx for HEDIS reporting purposes. NCQA considers the daily pharmacy data feeds received from Medi-Cal Rx for carved out pharmacy benefits to be ancillary Provider/Encounter Data rather than supplemental data for reporting purposes, and this data can be used to identify eligible populations. If an MCP uses data from the real-time pharmacy portal information provided by Medi-Cal Rx, the MCP will need to work with their NCQA auditor to determine how these are classified for use because this process may differ by MCP. HEDIS measures requiring pharmacy data will be considered for the MCP's star ratings and will impact the MCP's accreditation status (accredited vs. not accredited).

DHCS will identify specific standards that MCPs will be held accountable for regarding quality work through direct communication with MCPs that is released prior to each reporting year including but not limited to measures related to medication management and reconciliation.

Prime Daily Data Feeds

Medi-Cal Rx provides daily data feeds, in a file format agreed upon with the MCPs, to support MCP obligations for all aspects of Member care management including Basic Population Health Management, Care Coordination, medication management and adherence, Enhanced Care Management (ECM) for populations of focus, and Complex Care Management for high-risk Members.

¹¹ For information about Medi-Cal Rx coverage policy, MCPs should refer to the dedicated Medi-Cal Rx website and associated Medi-Cal Provider Manuals. The dedicated Medi-Cal Rx website can be found at: https://medi-calrx.dhcs.ca.gov/home/.

These data feeds are sent daily and will only be sent to the DHCS-contracted MCPs using the applicable Health Care Plan Code to identify membership in the contracted MCP.

DHCS recognizes that many MCPs have Network Provider Agreements and Subcontractor Agreements. As a result, DHCS anticipates that most DHCS-contracted MCPs already have some type of interface or arrangement with their Network Providers and Subcontractors for data sharing purposes. However, if not, DHCS requires that those DHCS-contracted MCPs work to establish and implement data sharing arrangements with their Network Providers and Subcontractors for purposes of sharing the daily data feeds.

Ultimately, all DHCS-contracted MCPs are required to implement appropriate interfaces or arrangements with each of their Network Providers and Subcontractors to ensure timely access to information to support clinical aspects of pharmacy adherence, and disease and medication management for applicable sub-delegated populations.

Medi-Cal Rx Website/Pharmacy Portals & Clinical Liaison Access

Medi-Cal Rx Website/Pharmacy Portals: DHCS, in partnership with Prime, created a comprehensive Medi-Cal Rx website. ¹² This dedicated website offers content on a public platform that is accessible to the general public, all Medi-Cal Members, Providers (pharmacies and prescribing physicians), MCPs, and other entities as designated by DHCS. Additionally, secure pharmacy portals are available to all Members, Providers (pharmacies and prescribing physicians), MCPs, and other entities as designated by DHCS, to ensure they can access appropriate tools for services that require access to protected health information.

The Medi-Cal RX Subscription Service (MCRxSS) is also available at the Medi-Cal Rx website and allows interested parties to sign up and receive regular Medi-Cal Rx updates by email. Additional information is posted on the Medi-Cal Rx website. For more information, please refer to the Medi-Cal Rx Website/Pharmacy Portal policy, which is available on the DHCS website.¹³

Clinical Liaisons: A primary responsibility of CLs is to work with the MCPs on clinical pharmacy-related issues to ensure Members receive Medically Necessary medications in a timely fashion and based upon the established DHCS Medi-Cal Rx policy.

Medi-Cal Rx provides a dedicated Medi-Cal Rx CL team to support MCPs in complying with contractual obligations relating to Member Care Coordination, medication adherence, and other responsibilities related to medication requirements, in accordance with applicable state and federal law. The Medi-Cal Rx CLs are Certified Pharmacy

¹² The Medi-Cal Rx website is available at: https://medi-calrx.dhcs.ca.gov/home/

¹³ The Medi-Cal Rx Website/Pharmacy Portal Policy is available at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Website-and-Pharmacy-Portal-Policy-081420.pdf

Technicians (CPhT) and expert users of the FirstTraxSM contact center system. The Medi-Cal Rx CLs:

- Have in-depth knowledge of the CDL and related PA processes;
- Have access to a Prime Medi-Cal Rx pharmacist twenty-four (24) hours per day, seven (7) days per week, including weekends and holidays to assist MCPs;
- Can assist with any clinical, pharmacy-related matter, including but not limited to urgent or time-sensitive requests, PA statuses, and claims issues; and
- Have direct access to appropriate clinical staff including Registered Pharmacists and other Medi-Cal clinicians as well as a CPhT Supervisor and the CSC Director.

Please note non-clinical and/or non-emergent issues, or general administrative issues, will be forwarded to the Medi-Cal Rx CSC for resolution.

The Medi-Cal Rx CLs have an understanding of the MCP population by developing profiles for each MCP, based on the population the MCP serves, key areas of interest and/or challenges, and other nuances that are necessary to ensure quality customer service and timely access to Medically Necessary prescriptions.

To this end, CLs are able to understand anything that is unique about the MCP's population and intervene in urgent cases that cannot be resolved by the normal pharmacy call center and are escalated by the MCP's designated contact(s).¹⁴

Designated Users: DHCS allows Designated Users (DUs) for each DHCS-contracted MCP, which can be utilized both at the DHCS-contracted plan level as well as for any Network Providers and Subcontractors. The DU access takes into consideration key MCP roles, including but not limited to pharmacy staff, care managers, ECM Providers, and behavioral health staff, that require access to the Medi-Cal Rx secure MCP Pharmacy Portal and the CL.

DUs with CL access privileges are those individuals identified by the MCPs as needing CL access for critical functionalities including but not limited to clinical and Care Coordination, medication adherence, and other responsibilities related to medication requirements. DUs with CL access privileges are provided access to the CLs through Medi-Cal Rx's dedicated Interactive Voice Response (IVR) system to assist and resolve clinical pharmacy-related issues.

Please note that existing contractual requirements between DHCS and MCPs, including requirements to comply with the Health Insurance Portability and Accountability Act (HIPAA) and all Business Service Agreements/Business Use Agreements (BSAs/BUAs), provide sufficient coverage from a sensitive data and privacy perspective. To that end, MCPs must ensure that DUs only access or interact with data

¹⁴ For more information, please refer to the MCP CL policy, which is available at: <u>https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-MCP-Clinical-Liaison-Policy-081420.pdf</u>

and information reasonably necessary to resolve a pharmacy benefit issue for a specific Member or population served, versus all contracted MCP lives.

Each DU has a password and User ID associated with the user's name and MCP. All DUs have access to the Medi-Cal Rx secure MCP Pharmacy Portal using their User ID and password. MCPs can determine whether they want all DUs, or a subset of DUs, to have access to MCP CLs. DUs identified by an MCP to have access to MCP CLs receive a Personal Identification Number (PIN) to access MCP CLs through the Medi-Cal Rx CSC IVR system.

Prime provides each contracted MCP with a Monthly DU Access Report (MDUAR). Each MDUAR captures the following information for each DU:

- User Identity;
- Login/logout date/time; and
- Client Identification Numbers (CINs) whose records were accessed by the DU (reported when a DU selects and goes into that Member record).

Prime delivers the reports to the MCPs monthly via a secure file transfer protocol or other secure method. These MCP specific MDUARs are created in an Excel file format for consumption and utilization by the respective MCP to audit and verify DU lists and appropriate DU access. Prime provides the reports by the fifth business day of each month for the prior month.

MCPs who require Medi-Cal Rx to take action regarding access privileges for any DU must provide that request in accordance with the Medi-Cal Rx DU Access Request Form.

DHCS, in partnership with Prime, has established the following process for receiving and reviewing DU access requests for the Medi-Cal Rx secure MCP Pharmacy Portal and Medi-Cal Rx MCP CLs:

- MCPs will establish and maintain DU Access Request Contact(s) for MCPs to request authorized access to the Medi-Cal Rx secure MCP Pharmacy Portal and MCP CLs;
- Prime will maintain a DU Access Request Agent via an established email inbox that will be responsible for receiving and controlling DU Access Requests only from the DU Access Request Contact(s) for each MCP. Prime will ensure access is granted only to MCP authorized individuals. In order to establish credentials, the DU Access Request Contact(s) for each MCP must submit a DU Access Request that includes the following DU information:
 - o Individual's name, title, MCP, and MCP generated email address;
 - If the individual is a new incremental add or replacing someone who no longer needs access; and
 - If the individual shall have access to MCP CLs and MCP attestation that the individual meets MCP CL access requirements;

- Prime will process MCP DU Access Requests following receipt of a completed DU Access Request from an MCP DU Access Request Contact;
- Prime will provide approved DUs with a User ID and temporary password. DUs authorized to have MCP CL access will also receive a PIN upon completion of registration and training;
 - If a password needs to be reset, the user can do this through Prime's portal system.
 - If the PIN has been lost, the user must contact the Medi-Cal Rx CSC and request a new PIN.
- Prime will complete processing of approved DU Access Requests no later than seven (7) business days from receipt of a completed DU Access Request to providing credentials to the approved DU as well as an approval response to the MCP DU Access Request Contact; and
- Prime will complete processing of disapproved DU Access Requests no later than seven (7) business days from receipt of a completed DU Access Request to providing a disapproval response to the MCP DU Access Request Contact.

MCPs must report all MCP DU changes (such as resignations or terminations) to DHCS and Prime via the Medi-Cal Rx CSC within 24 hours so that the DU's access can be terminated.

MCP DUR Requirements:

The following outlines DUR related responsibilities and supports for MCPs:

- **Prospective DUR** This <u>is not required</u> of MCPs as of January 1, 2022. MCPs can review pro DUR alerts and overrides for their Members and use this information for Provider (prescriber) education and interventions, which is a part of retrospective DUR.
- Retrospective DUR This <u>is required</u> of MCPs. MCPs receive comprehensive claims and PA history for their Members and can use claims data for their own Quality Improvement and retrospective DUR activities. In addition to that, as part of Medi-Cal DUR program, administered by DHCS in collaboration with Prime and the University of California San Francisco (UCSF) School of Pharmacy, retrospective DUR analyses are conducted for the entire Medi-Cal population, and results shared in aggregate, with the DUR Board. The results may be shared with individual MCPs, via the Medi-Cal Rx MCP secure portal, for their populations only.

Any Provider outreach needed as part of retrospective DUR interventions are recommended to MCPs for their Members. UCSF is responsible for FFS-enrolled Medi-Cal members, and MCPs can use FFS-developed communications (e.g., Provider letter templates) or use their preferred method of Provider communication.

MCPs must provide retrospective DUR (Retro DUR) activities designed to manage care including but not limited to identifying patterns of:

- Therapeutic appropriateness;
- Adverse events:
- Incorrect duration of treatment;
- Over or under utilization;
- Inappropriate or medically unnecessary prescribing;
- Gross overprescribing and use;
- o Fraud, Waste, or Abuse; and
- Assessing medication adherence and identifying opportunities for care management interventions and outreach.
- Educational Outreach This <u>is required</u> of MCPs. UCSF will develop and publish educational bulletins and alerts throughout each year on a variety of topics. MCPs are currently required to disseminate DUR educational articles via their preferred method of Provider communication, which may include posting them on their Provider web page.

MCPs must provide active and ongoing outreach to educate Providers on common drug therapy problems (e.g., asthma medication ratio monitoring, opioid and naloxone co-prescribing, and new prescribing guidelines and advisories) with the goals of improving prescribing and dispensing practices, increasing medication adherence, and improvement of overall Member health.

- Annual DUR Report This <u>is required</u> of MCPs. MCPs must annually submit the modified annual report and must include descriptions of any retrospective DUR activities and any innovative practices implemented by the MCP in the prior federal Fiscal Year.
- Medi-Cal DUR Board Participation This <u>is required</u> of MCPs. MCPs must participate in the activities of the Medi-Cal DUR Board, including but not limited to:
 - Providing advice and feedback related to the nature and scope of the prospective and retrospective DUR programs;
 - Recommendations for DUR interventions;
 - Input regarding innovative DUR practices; and
 - Board meeting attendance and board membership.

To encourage more widespread participation and diversify representation on the DUR Board, DHCS may consider a revision of the bylaws in order to introduce term limits and rotation of the MCPs represented in the DUR Board membership. DHCS may also consider including other stakeholder entities in the DUR Board membership rotation.

 DHCS Organized Pharmacy Committee Meetings – These <u>are required</u> of MCPs. An example of this type of meeting would be the Pharmacy Directors' Meeting.

Pharmacy Directors' Meeting

MCPs must attend the Pharmacy Directors' Meetings hosted by DHCS. These meetings provide a platform where MCPs can engage in discussion on pharmacy benefit-related topics, including utilization management, changes to the Medi-Cal CDL, Care Coordination, Quality Improvement, etc.

H.R. 6, the SUPPORT for Patients and Communities Act

As an active member of the Statewide Opioid Safety Workgroup, the issue of opioid safety is of primary importance to DHCS. As of the transition to Medi-Cal Rx on January 1, 2022, there are no pharmacy lock-in programs for Medi-Cal Members in connection with any aspect of their pharmacy benefit, including opioids. This issue is addressed in the FAQs for Medi-Cal Rx and is summarized below.¹⁵

DHCS did not implement a lock-in program as part of its Medi-Cal Rx implementation, but it will be evaluating options with the Medi-Cal Rx contractor moving forward.

As of January 1, 2022, MCPs are not contractually responsible for the pharmacy benefit and are not able to institute lock-in programs using the resources available through the DHCS Medi-Cal Rx contractor. However, DHCS has adopted several measures designed to limit Abuse, misuse, and fraudulent activities related to opioid medications. These measures include:

- Limitations on maximum day supply;
- Limitations on maximum quantity per day or per dispensing;
- Limitations on early refills;
- Improved access to MAT medications used in the treatment of SUDs;
- Restrictions based on Morphine Equivalent Dose (MED), using CDC guidelines;
 and
- Limitations on concurrent use of opioids and benzodiazepines, muscle relaxants, and/or psychotropic medications.

Member Complaints and Grievances

Medi-Cal Rx is responsible for managing the resolution of complaints and grievances raised by MCP Members, their Authorized Representatives, or other interested parties, regarding a Medi-Cal Rx complaint or grievance.

Medi-Cal Rx complaints and grievances may be filed at any time and are not subject to any specific codified timeframes relative to the subject of the complaint or grievance. Complaints or grievances may be made orally or in writing, consistent with all applicable state and federal law requirements and DHCS (P&Ps).

DHCS oversees the Medi-Cal Rx complaint and grievance process to ensure appropriate and timely handling and resolution occurs. For more information, please

¹⁵ The Medi-Cal Rx FAQ is available at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/Transition-Medi-Cal-Pharm-Services-MC-FFSFAQsV11.pdf

refer to the Medi-Cal Rx Complaints and Grievances policy, which is available on the Medi-Cal Rx website, as well as in the Department of Managed Health Care's APL 20-035 (OPL): Medi-Cal Pharmacy Benefit Carve Out - Medi-Cal Rx (DMHC APL 20-035). 16, 17

Pharmacy-related complaints and grievances received by an MCP for Medi-Cal Rx services must be transferred by the MCP to the Medi-Cal Rx CSC for resolution. Complaints and grievances coming in via phone or secure chat must be appropriately triaged and referred to the Medi-Cal Rx CSC via phone once they are determined to be an MCP complaint or grievance. MCPs must make best efforts to immediately forward complaints and grievances for timely and accurate resolution by the Medi-Cal Rx CSC. Complaints and grievances received in writing must be appropriately triaged and mailed or faxed to the Medi-Cal Rx CSC within three (3) calendar days.

Medi-Cal Rx Member Appeals

For pharmacy-related services covered under Medi-Cal Rx, all MCP Member appeals involving a disagreement with benefit-related decisions, such as coverage disputes, disagreeing with and seeking reversal of a request for PA involving Medical Necessity, etc., that are associated with a Notice of Action (NOA) are adjudicated through the SFH process. Although the Medi-Cal Rx CSC will not be involved in resolving Member appeal issues, please note that contacting the Medi-Cal Rx CSC to ask questions, seeking clarification on the NOA contents, or providing additional information will not impact the Member's right to pursue a SFH.

For more information about the Medi-Cal Rx SFH appeals process, please see DHCS' existing SFH policy and processes which are available on the DHCS' and CDSS websites, respectively. 18, 19 Please refer to DMHC APL 20-035 for additional information related to Member appeals.

Provider Claim Appeals

Provider claim appeals are a method to resolve claim payment problems (e.g., resubmission, non-payment, underpayment, overpayment, etc.). DHCS' Medi-Cal Rx Provider Claim Appeals policy aligns with and builds upon existing Medi-Cal FFS processes and protocols for the Medi-Cal program. Providers will complete the Medi-Cal Rx Provider Appeal form and submit the completed form to:

¹⁶ The Medi-Cal Rx Complaints and Grievances policy document is available on DHCS' website at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Complaints-and-Grievances-08-25-2020.pdf.

¹⁷ DMHC APL 20-035 is located at: https://www.dmhc.ca.gov/Portals/0/Docs/OPL/APL%2020-035%20-%20Medi-Cal%20Rx%20(10 6 2020).pdf?ver=2020-10-06-165704-497

¹⁸ DHCS' SFH webpage is available at: <a href="https://www.dhcs.ca.gov/services/medi-cal/Pages/Medi-cal/Pages

¹⁹ CDSS' Hearing page is available at: https://www.cdss.ca.gov/hearing-requests

Medi-Cal Rx CSC, Provider Claims Appeals Unit P.O. Box 610
Rancho Cordova, CA, 95741-0610.

Once the Medi-Cal Rx Provider Appeal form is submitted, Medi-Cal Rx will acknowledge each appeal within 15 days of receipt and make a decision within 45 days of receipt. If Medi-Cal Rx is unable to make a decision within this time period, the appeal is referred to the professional review unit for an additional 30 days. If the appealed claim is approved for reprocessing, it will appear on a future Remittance Advice Details. The reprocessed claim will continue to be subject to Medi-Cal policy and claims processing criteria and could be denied for a separate reason.

Medi-Cal Rx will send a letter of explanation in response to each appeal. Providers who are dissatisfied with the decision may submit subsequent appeals, as stated in the Medi-Cal Rx Provider Manual.²⁰ Medi-Cal Providers also retain their right to seek judicial review of an appeal determination, as authorized under state law.²¹

More information about the Medi-Cal Rx Provider Appeal process, including accessing the Medi-Cal Rx Provider Appeal form is available on the Medi-Cal Rx website.

Provider PA Appeals

Providers can appeal Medi-Cal Rx PA denials, delays, and modifications.²² Providers will submit appeals of PA adjudication results, clearly identified as appeals, to:

Medi-Cal Rx CSC, Provider Claims Appeals Unit P.O. Box 610
Rancho Cordova, CA. 95741-0610.

Medi-Cal Rx will acknowledge each submitted PA appeal within three days of receipt and make a decision within 60 days of receipt. Medi-Cal Rx will send a letter of explanation in response to each PA appeal. Providers who are dissatisfied with the decision may submit subsequent appeals. Medi-Cal Providers may seek a judicial review of the appeal decision, as authorized under state law.²³ For more information about the Medi-Cal Rx Provider PA appeal process, please visit the Medi-Cal Rx website.

DHCS and DMHC APL Guidance

On October 6, 2020, DMHC issued an APL on Medi-Cal Rx (DMHC APL 20-035) specific to various MCP regulatory and compliance requirements for the transition. This APL incorporates all those provisions by reference. In the event there are any conflicts

²⁰ See the Medi-Cal Rx webpage for more information, available at: https://medi-calrx.dhcs.ca.gov/home/

²¹ Welfare and Institutions Code (WIC) section 14104.5. WIC is searchable at: http://leginfo.legislature.ca.gov/

²² WIC section 14133.05.

²³ WIC section 14133.05.

between the provisions of DMHC's APL 20-035 and this APL, the provisions of this APL will apply. For more information, please see DMHC's APL.

Existing DHCS APL/Policy Letter Policy

To assist MCPs in understanding Medi-Cal Rx considerations related to APL and PL guidance, the following table provides supplementary guidance. To the extent <u>any existing APLs or PLs</u> have inconsistent provisions specific to the Medi-Cal pharmacy benefit, this APL supersedes all inconsistencies in prior APLs or PLs. For more information, please see DHCS' APL and PL websites, as well as the Medi-Cal Rx Policy Resources section of this APL.

Resources section of this APL	
APL / PL	Summary
APL 23-001 Network Certification Requirements	Refer to APL 23-001, or any superseding APL, for all Network Certification Requirements. Refer to DMHC APL 20-035 "Network Adequacy" section for additional guidance.
APL 19-017 Quality and Performance Improvement Requirements	DHCS will provide further instruction regarding Quality and Performance Improvement Requirements in the form of annual updates to this APL prior to each RY.
APL 17-018 (superseded by APL 22-006) Medi-Cal Managed Care Health Plan Responsibilities for Outpatient Mental Health Services	To determine carved-out pharmacy services in support of outpatient mental health services, refer to the Medi-Cal Rx Policy Resources section of this APL. Per existing guidance to MCPs, DHCS is responsible for ensuring compliance with mental health parity provisions for drugs carved-out through specific contract agreements between MCPs and DHCS. Note, this APL has been superseded by APL 22-006, Medi-Cal Health Plan Responsibilities for Non-Specialty Mental Health Services.
APL 22-008 Non-Emergency Medical and Non-Medical Transportation Services and Related Travel Expenses	NMT MCPs must provide NMT services for Members to access all Medi-Cal covered services, including those services that are carved-out of the MCP's contract. This includes pharmacy trips for medications that are carved-out under Medi-Cal Rx. NEMT MCPs must provide NEMT services for pharmacy trips for medications that are carved-out under Medi-Cal Rx. MCPs are capitated for NEMT services for pharmacy trips for medications that are carved-out under Medi-Cal Rx, and DHCS will make any necessary rate adjustments as part of its standard processes. MCPs have access to real-time claims and PA data through the Medi-Cal Rx portal that will identify the dispensing pharmacy.

APL / PL	Summary
APL 17-008 Requirement to Participate in the Medi-Cal Drug Utilization Review Program	For guidance regarding the DUR, refer to the "Utilization Management" and "Medi-Cal Rx Contractor Roles and Responsibilities" sections of DMHC APL 20-035, and the DUR participation information in this APL.
APL 21-011 Grievance and Appeal Requirements, Notice and "Your Rights" Templates	For guidance regarding Grievances and Appeals, refer to the "Grievances & Appeals" section of DMHC's APL 20-035 and the "Member Complaints and Grievances," "Medi-Cal Rx Member Appeals," and "Provider Claim Appeals" sections of this APL.
APL 16-014 Comprehensive Tobacco Prevention and Cessation Services for Medi-Cal Beneficiaries	The Medi-Cal pharmacy benefit covers all FDA-approved products for smoking cessation. They are all carved-out to Medi-Cal Rx when dispensed and billed by an enrolled Medi-Cal pharmacy Provider. Medical Providers can also legally provide them to their patients. MCPs are responsible for these medical claims just as they would be for any other claim billed by a non-pharmacy Provider.
APL 16-010 Medi-Cal Managed Care Health Plan Pharmaceutical Formulary Comparability Requirement	For additional guidance regarding formularies, refer to the "Standard Formulary Template" section of DMHC APL 20-035. APL 16-010 is to be considered retired as of December 31, 2021.
APL 24-008 Immunization Requirements	Adult immunizations billed on pharmacy claims by an enrolled Medi-Cal pharmacy Provider are in scope for Medi-Cal Rx. The professional services provided by a pharmacist pursuant to AB 1114, including the consultation, assessment of need, and the administration of the injection, will all remain the responsibility of the MCP when provided in an outpatient pharmacy setting.
APL 16-004 Medi-Cal Managed Care Health Plans Carved-Out Drugs	APL 16-004 is superseded by this APL in terms of the pharmacy benefit.
APL 23-028 Dental Services - Intravenous Moderate Sedation and Deep Sedation/General Anesthesia Coverage	In response to related questions by MCPs, intravenous sedation and general anesthesia must be administered by a doctor and are never selfadministered. These drugs are not currently part of the pharmacy benefit and are not covered under Medi-Cal Rx.
APL 07-002 Conlan v. Bonta; Conlan v. Shewry: Court Ordered Medi-Cal Beneficiary Reimbursement Process	All initial claim requests for Beneficiary Reimbursement ("Conlan claims") are currently received by DHCS' California Medicaid Management Information Systems (CA-MMIS) division. CA-MMIS triages and refers these claim requests to the DHCS

APL / PL	Summary
	program and/or external organization responsible for processing (e.g., individual MCPs, other fiscal intermediaries, etc.). CA-MMIS continues its intake responsibilities to triage and refer initial claim requests for pharmacy services administered by Medi-Cal Rx to the Medi-Cal Rx CSC for processing and final disposition. All initial claim requests for Member reimbursement for pharmacy services rendered on or before December 31, 2021, that are received on or after January 1, 2022, are to be triaged and referred by CA-MMIS to the DHCS program and/or external organization responsible on the date of service, which can and will include MCPs.
APL 06-010 Quality and Performance Improvement Program Requirements for 2007	HEDIS rates for Outpatient Drug Utilization services are not required since these services are carved-out to Medi-Cal Rx. Also, this APL was specific to the Quality and Performance Improvement Program Requirements for 2007.
APL 06-008 Contraceptive Devices	The APL 06-008 Standard of Care Policy is not in conflict with Medi-Cal Rx as APL 06-008 cites state law that allows for carve-out of outpatient prescription drug benefits while also providing requirements for MCPs who may pursue a partial carve-out as Medi-Cal Rx scope allows.
PL 14-003 Enteral Nutrition Products	For carve-out guidance to address MCP responsibilities for authorizing and paying for the formula, pumps, and tubing identified in PL 14-003, refer to the "Medi-Cal Rx Policy Resources" section of this APL

In addition to the impacts described for the APLs and PLs in the prior table, the following APLs and PLs are considered retired as of December 31, 2021:

APL 18-013	Hepatitis C Virus Treatment Policy Update
APL 16-010	Medi-Cal Managed Care Health Plan Pharmaceutical Formulary
	Comparability Requirement
PL 08-013	Pharmacy Prior Authorization Requests by California Licensed
	Pharmacists
APL 06-008	Contraceptive Devices
APL 05-012	Medicare Modernization Act; Medicare Part D Prescription Drug
	Plan
APL 03-010	Medi-Cal Managed Care Plan Requirements for Provision of
	Contraceptive Drug Services and Supplies

MCPs must review their contractually required P&Ps to determine if amendments are needed to comply with this APL. If the requirements contained in this APL, including any

updates or revisions to this APL, necessitate a change in an MCP's contractually required P&Ps, the MCP must submit its updated P&Ps to the Managed Care Operations Division (MCOD)-MCP Submission Portal¹ within 90 days of the release of this APL. If an MCP determines that no changes to its P&Ps are necessary, the MCP must attach an attestation to the Portal within 90 days of the release of this APL, stating that the MCP's P&Ps have been reviewed and no changes are necessary. The attestation must include the title of this APL as well as the applicable APL release date in the subject line.

MCPs are responsible for ensuring that their Subcontractors and Network Providers comply with all applicable state and federal laws and regulations, Contract requirements, and other DHCS guidance, including APLs and PLs. These requirements must be communicated by each MCP to all Subcontractors and Network Providers. DHCS may impose Corrective Action Plans (CAP), as well as administrative and/or monetary sanctions for non-compliance. MCPs should review their Network Provider and/or Subcontractor Agreements, including Division of Financial Responsibility provisions as appropriate, to ensure compliance with this APL. For additional information regarding administrative and monetary sanctions, see APL 23-012, and any subsequent iterations on this topic. Any failure to meet the requirements of this APL may result in a CAP and subsequent sanctions.

If you have any questions regarding this APL, please contact your MCOD Contract Manager.

Sincerely,

Bambi Cisneros

Bambi Cisneros, Acting Division Chief

Managed Care Quality and Monitoring Division

Assistant Deputy Director, Health Care Delivery Systems