Medi-Cal Rx: Transitioning Medi-Cal Pharmacy Services from Managed Care to Fee-For-Service Frequently Asked Questions

The following Frequently Asked Questions (FAQ) document provides additional guidance and clarification to Medi-Cal beneficiaries, providers, plan partners, and other interested parties, regarding the January 2021 transition of Medi-Cal's pharmacy benefit (collectively referred to as "Medi-Cal Rx"). As the Department of Health Care Services (Department) receives additional questions, this document will be updated as indicated by the version number and date in the footer. Any new and/or revised questions or language from the prior version of the FAQs will be denoted through the use of **bold** and underlined text, e.g., "**Sample**".

For information regarding Medi-Cal Rx, please visit the Department's dedicated Medi-Cal Rx: Transition website at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Medi-CalRX.aspx. In addition, general questions regarding Medi-Cal Rx may also be submitted to the Department via email at RxCarveOut@dhcs.ca.gov.

GENERAL INFORMATION

1. **Why is the Department transitioning the Medi-Cal pharmacy benefit from the Medi-Cal managed care delivery system to fee-for-service delivery system?**

   The Department is transitioning Medi-Cal pharmacy services from the Medi-Cal managed care delivery system to the Medi-Cal fee-for-service delivery system as a result of Governor Newsom's January 7, 2019 Executive Order N-01-19, for the purpose of achieving cost-savings for drug purchases made by the state, to standardize the pharmacy benefit statewide for all Medi-Cal beneficiaries and increase overall access by allowing beneficiaries to receive pharmacy services from the fee-for-service broader pharmacy network. In addition, this standardization is a critical step for the success of the California Advancing and Innovating Medi-Cal (CalAIM) initiatives being proposed by the Department. For more information on CalAIM, please visit the Department's website at https://www.dhcs.ca.gov/calaim.

2. **What is Medi-Cal Rx?**

   Medi-Cal Rx is the name the Department has given to this new system of how Medi-Cal pharmacy benefits will be administered through the fee-for-service delivery system, beginning on January 1, 2021.

3. **What are the advantages of transitioning Medi-Cal pharmacy benefits from managed care to fee-for-service?**

   Transitioning pharmacy services from Medi-Cal managed care to fee-for-service will, among other things:

   - Standardize the Medi-Cal pharmacy benefit statewide, under one delivery system.
   - Improve access to pharmacy services with a pharmacy network that includes the vast majority of the state's pharmacies and is generally more expansive than individual Medi-Cal Managed Care Plan pharmacy networks.
   - Apply statewide utilization management protocols to all outpatient drugs, as appropriate.

- Strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers as the largest Medicaid program in the state with approximately 13 million beneficiaries.

4. Does the Department need to seek federal approval to implement Medi-Cal Rx?

No, the Department does not need to seek federal approval from the Centers for Medicare and Medicaid services to implement Medi-Cal Rx. Since the Department is not changing the availability of the pharmacy benefit but rather is modifying which delivery system through which the benefit will be provided, no specific federal approval is required. Changes will be made administratively to Medi-Cal Managed Care Plan contracts.

5. What Medi-Cal Managed Care Plans are and are not impacted by Medi-Cal Rx?

All Medi-Cal Managed Care Plans, including AIDS Healthcare Foundation, are impacted. Medi-Cal Rx will not apply to Programs of All-Inclusive Care for the Elderly (PACE) plans, Senior Care Action Network (SCAN) and Cal MediConnect health plans, or the Major Risk Medical Insurance Program (MRMIP).

6. Will Medi-Cal Rx apply to California Children's Services (CCS) and the Genetically Handicapped Persons Program (GHPP), and if yes, will Medi-Cal Rx change California Children's Services, and how does it intend to address California Children's Services-unique issues?

Medi-Cal Rx will apply to both **CCS and GHPP**. The Department is continuing to work with the CCS Advisory Group **and other key stakeholders in this space** to identify and evaluate the potential impacts that Medi-Cal Rx may have on the CCS and **GHPP** populations. For example, members of the CCS Advisory Group responded to a Department-issued survey, which was analyzed and the feedback from that survey will help to inform the Department's implementation efforts future forward, and ensure that the CCS **and GHPP populations have their specialized health care needs considered appropriately as part of the transition. Similarly, the Department held a dedicated breakout session for the CCS AG members, and other key partners, to further discuss these populations. As the Department works towards go-live, it will continue to work in close partnership with the CCS AG members and other key partners to further refine and solidify policy approaches designed to ensure a smooth and effective transition for these populations.**

7. What will not change as part of Medi-Cal Rx?

Medi-Cal Rx will not change the following:

- The scope of the existing Medi-Cal pharmacy benefit.
- Provision of pharmacy services as part of a bundled/all-inclusive billing structure in an inpatient or long-term care setting (including Skilled Nursing Facilities and other Intermediate Care Facilities), regardless of delivery system.
- Existing Medi-Cal managed care pharmacy carve-outs will continue (e.g., blood factor, HIV/AIDS drugs, antipsychotics, or drugs used to treat substance use disorder).

- Any pharmacy services that are billed as a medical and/or institutional claim instead of a pharmacy claim.
- The State Fair Hearing process, as defined in applicable California state law.

8. How does Medi-Cal Rx affect payment of drugs provided in an inpatient or long-term care (LTC) setting?

As noted in question #7 above, if a drug is provided as part of the bundled rate for services provided by an LTC/Skilled Nursing Facility (SNF), then it will remain the Medi-Cal MCP's responsibility. Otherwise, if prescription drugs are not part of the bundled rate for services provided by an LTC/SNF, and instead are billed on a fee-for-service basis, then the financial responsibility for those drugs would be determined by the claim type on which they are billed. If the drugs are dispensed by a pharmacy, and billed on a pharmacy claim, then they would be carved out and paid by Medi-Cal Rx. If the drugs are furnished by the LTC/SNF and billed on a medical/institutional claim, the MCP would be responsible, or the California Medicaid Management Information System (CA-MMIS) Fiscal Intermediary, if the beneficiary is in Fee-For-Service.

9. What pharmacy benefits will be "carved out" of Medi-Cal managed care due to Medi-Cal Rx?

As of January 1, 2021, Medi-Cal Rx will take over the responsibility from Medi-Cal Managed Care Plans for administering the following when billed by a pharmacy on a pharmacy claim:

- Covered Outpatient Drugs, including Physician Administered Drugs (PADs)
- Medical Supplies
- Enteral Nutritional Products

For more information, please see the Department's Medi-Cal Rx Scope document, which is available on the Department's website at: https://www.dhcs.ca.gov/provgovpart/Documents/MRx-Scope-09-04-2020.pdf.This document provides additional context and information related to the Department's implementation of the Medi-Cal managed care to fee-for-service pharmacy carve out, effective January 1, 2021. It also provides an inventory of the Medi-Cal pharmacy benefit, characterized as either not subject to the carve out (i.e., those pharmacy benefits that are billed on medical and institutional claims), versus those subject to the carve out (i.e., all pharmacy benefits that are billed on pharmacy claims).

10. How will the Department approach coverage of glucometers and related testing supplies as of January 1, 2021?

Diabetic test strips (for urine, blood glucose and ketones) and lancets benefit policy will not change under Medi-Cal Rx, and will be subject to the list of contracted products and the criteria currently published in Medical Supplies section of the Medi-Cal Provider Manual. Glucometers compatible with the contracted test strips are available by most of

the manufacturers through various means at no cost for dispensing to eligible Medi-Cal beneficiaries. Glucometers, control solution and lancing devices compatible with the contracted test strips and lancets will be subject to a partial carve out and can be billed through Medi-Cal Rx delivery system if not available at no cost for dispensing to Medi-Cal beneficiaries.

During the Medi-Cal Rx 180-day transition period, non-contracted test strips and lancets can be billed to Medi-Cal Rx. However, MCP beneficiaries must transition to glucometers compatible with the contracted test strips and lancets prior to the end of the transition period. On or after July 1, 2021, only test strips and lancets on the list of contracted products will be reimbursable under Medi-Cal Rx. Only glucometers, control solution and certain lancing devices compatible with the contracted test strips and lancets can be billed through Medi-Cal Rx delivery system effective on or after January 1, 2021. Glucometers that require non-contracted test strips will not be covered through Medi-Cal Rx during the transition period and thereafter.

11. How will the Department approach coverage of disposable external ambulatory insulin delivery systems (Omnipod and V-Go) currently and as of January 1, 2021?

Currently, disposable insulin delivery systems (Omnipod and V-Go) are provided and billed by enrolled Medi-Cal fee-for-service pharmacy providers on a medical claim form (CMS-1500) using the durable medical equipment (DME) supply billing code, HCPCS A9274 (External ambulatory insulin delivery system, disposable, each), with an approved Treatment Authorization Request or Service Authorization Request, as applicable.

Disposable insulin delivery systems are not currently billed to the fee-for-service delivery system on a pharmacy claim; therefore these products will not be included under Medi-Cal Rx. They will remain the responsibility of the MCPs in the managed care delivery system; or, in the fee-for-service delivery system, billed to the California Medicaid Management Information System (CA-MMIS) Fiscal Intermediary on a medical claim using HCPCS code A9274 with approved authorization, as they are today. Medi-Cal MCPs can choose whether to continue to provide disposable insulin delivery systems through a pharmacy billed on a medical claim, or as otherwise deemed appropriate.

12. How will the Department approach coverage of Continuous Glucose Monitors (CGMs), other durable medical equipment (DME), DME supplies and disposable medical supplies, currently and as of January 1, 2021?

Currently, a CGM may be approved with a Treatment Authorization Request (TAR)/Service Authorization Request (SAR), pursuant to the Early and Periodic Screening, Diagnostic and Treatment benefit and based upon medical necessity, for

eligible Medi-Cal beneficiaries in Medi-Cal and the California Children Services' (CCS) program and Genetically Handicapped Persons Program (GHPP), respectively, and billed using HCPCS on a medical claim form. The billing policy will remain the same (i.e., billed on a medical claim form using HCPCS code) in the fee-for-service (FFS) delivery system. CGMs will not be included under Medi-Cal Rx, effective January 1, 2021, and will remain the responsibility of the Medi-Cal MCPs in the managed care delivery system; or, in the fee-for-service delivery system, billed to the California Medicaid Management Information System (CA-MMIS) Fiscal Intermediary, as they are today.

Except for the medical supplies subject to partial or full carve out pursuant to the Medi-Cal Rx Scope document (https://www.dhcs.ca.gov/provgovpart/Documents/MRx-Scope-09-04-2020.pdf) and the glucometers and related testing supplies pursuant to FAQ # 10, DME, DME supplies and disposable medical supplies will remain the responsibility of the MCPs in the managed care delivery system; or, in the fee-for-service delivery system, billed to the CA-MMIS Fiscal Intermediary on a medical claim using a HCPCS code, as they are today.

13. Does Medi-Cal Rx include pharmacy benefits billed on medical and/or institutional claims?

No, as of January 1, 2021, Medi-Cal pharmacy services billed on a medical or institutional claim by a pharmacy, or any other provider, will continue to be billed, through either Medi-Cal Managed Care Plans or the California Medicaid Management Information System (CA-MMIS) Fiscal Intermediary, as they have been prior to January 1, 2021. This also includes drugs currently "carved-out" of managed care delivery system (e.g., blood factor, HIV/AIDS drugs, antipsychotics, or drugs used to treat substance use disorder).

PROCUREMENT INFORMATION

14. How will the Department administer Medi-Cal Rx?

The Department released Request for Proposal #19-96125 on August 22, 2019 to procure an administrative services contractor to administer the Medi-Cal fee-for-service pharmacy services for over 13 million Medi-Cal beneficiaries. On December 13, 2019, the Department awarded a contract to Magellan Medicaid Administration (Magellan) to provide a comprehensive suite of administrative services as directed by the Department, which include but are not limited to, claims management, prior authorization and utilization management, pharmacy drug rebate administration, provider and beneficiary support services, and other ancillary and reporting services to support the administration of the Medi-Cal pharmacy benefit.

15. What is the Medi-Cal Rx procurement timeline?

Below is the timeline for Medi-Cal Rx procurement-related efforts.

- July 22, 2019: Draft Medi-Cal Rx Request for Proposal #19-96125 released for a two-week public comment period.
- August 22, 2019: Final Medi-Cal Rx Request for Proposal #19-96125 released.
- August 29, 2019: Final Medi-Cal Rx Request for Proposal #19-96125 questions due to the Department.
- September 17, 2019: Answers to questions related to the Final Medi-Cal Rx Request for Proposal #19-96125 and addenda posted.
- October 1, 2019: All Medi-Cal Rx Request for Proposal #19-96125 proposals due.
- November 7, 2019: Notice of Intent to Award posted to the Department's website.
- December 13, 2019: The Department awarded contract to Magellan Medicaid Administration, Inc.
- December 20, 2019: Contract Effective Date.
- January 1, 2021: Medi-Cal Rx Assumption of Operations takes place.

16. Who is the Medi-Cal Rx Contractor selected through the procurement process?

The Medi-Cal Rx Contractor selected to administer Medi-Cal fee-for-service pharmacy services is Magellan Medicaid Administration, Inc.

17. What roles and responsibilities will Medi-Cal Managed Care Plans maintain as of January 1, 2021?

Medi-Cal Managed Care Plans will be responsible for activities including, but not limited to, the following:

- Overseeing and maintaining all activities necessary for enrolled Medi-Cal beneficiary care coordination and related activities, consistent with contractual obligations.
- Providing oversight and management of all the clinical aspects of pharmacy adherence, including providing disease and medication management.
- Processing and payment of all pharmacy services billed on medical and institutional claims.
- Participating in meetings related to the Medi-Cal Global Drug Utilization Review Board and other Department-driven pharmacy committee meetings.
- **Continued and ongoing participation in post-claim adjudication Drug Utilization Review (DUR) activities such as Retrospective DUR (RetroDUR) (as necessary for care coordination), educational programs, and submission of DUR annual report.**

18. What roles and responsibilities will the Department maintain as of January 1, 2021?

The Department will be responsible for activities including, but not limited to, the following:

- Developing, implementing, and maintaining all Medi-Cal pharmacy policy, including, but not limited to:
  - Drug coverage
  - State supplemental drug rebates
  - Prior authorization/utilization management
- Negotiation of, and contracting for, state supplemental drug rebates.

- Reviewing and issuing final determinations regarding all prior authorization denials for Medi-Cal Rx benefits.
- Providing oversight of, and facilitation for, the State Fair Hearing process.
- Establishing Medi-Cal Rx pharmacy reimbursement methodologies, consistent with applicable state and federal requirements.
- Establishing and maintaining the Medi-Cal pharmacy provider network.
- Overseeing the Medi-Cal Global Drug Utilization Review Board and other Department-driven pharmacy committees, in collaboration with the Medi-Cal Rx Contractor.
- Contract management and oversight/monitoring of the Medi-Cal Rx Contractor.

19. What roles and responsibilities will the Medi-Cal Rx Contractor assume as of January 1, 2021?

The Medi-Cal Rx Contractor will be responsible for activities including, but not limited to, the following:

- Providing claims administration, processing, and payment functionalities for all pharmacy services billed on pharmacy claims.
- Overseeing coordination of benefits with other health coverage, including Medicare.
- Providing utilization management functionalities, including ensuring pharmacy prior authorization adjudication occurs within 24 hours (note: all pharmacy prior authorization denials will require the Department's review prior to final determination).
- Providing Prospective and Retrospective Drug Utilization Review (DUR) services.
- Providing drug rebate administration services, which are compliant with federal and state laws, and adhere to the Department's policies and direction.
- Providing twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year, excluding approved holidays, or unless otherwise directed by the Department, Customer Service Center to support all provider and beneficiary calls, as well as outreach, training, and informing materials.
- Providing data feeds (at least daily) to Medi-Cal Managed Care Plans to support their responsibilities of beneficiary care coordination, carrying out clinical aspects of pharmacy adherence, and disease and medication management.
- Providing real-time access into the Medi-Cal Rx Contractor's electronic environment via a secure portal to all Medi-Cal providers (prescribers and pharmacies) and Medi-Cal Managed Care Plans, Mental Health Plans, and Substance Use Disorder Plans.
- Providing direct Medi-Cal Managed Care Plans liaisons to assist with care coordination and clinical issues.

20. How will the Department ensure that the Medi-Cal Rx Contractor does not use patient data, including prescription information, for any purpose other than Medi-Cal Rx administrative services?

The requirements for appropriate use of Medi-Cal beneficiary information are outlined, clearly and in detail, in Medi-Cal Rx Request for Proposal #19-96125, which becomes part of the final executed contract language. In addition, the Medi-Cal Rx Contractor is required to adhere to

all existing state and federal requirements as well as the Department's policies relating to sensitive data and privacy.

21. Where can I find more information about the Medi-Cal Rx Request for Proposal #19-96125?

For more information about Medi-Cal Rx Request for Proposal #19-96125, please visit the FI$Cal/Cal eProcure website at: https://caleprocure.ca.gov/event/4260/19-96125. Final Proposals were due by October 1, 2019 at 4:00 PM PDT. The Procurement process is now closed.

TRANSITION INFORMATION

22. Will Medi-Cal Rx use a "phased" approach to transition services?

No, effective January 1, 2021, the Medi-Cal pharmacy benefit will transition from the Medi-Cal managed care delivery system to fee-for-service delivery system (collectively "Medi-Cal Rx"). At the same time, the new Medi-Cal Rx Contractor will assume responsibility for all administrative services necessary to support Medi-Cal Rx, including but not limited to, claims management, prior authorization and utilization management, pharmacy drug rebate administration, provider and beneficiary support services, and other ancillary and reporting services. As mentioned in a prior response, this transition is a critical step of the broader California Advancing and Innovating Medi-Cal (CalAIM) initiative of the Department.

23. How will the Department ensure that the knowledge and experience of Medi-Cal Managed Care Plans, and other stakeholders, is leveraged in the transition process to achieve a successful continuity of services?

The Department has proactively engaged external partners in multiple ways and through multiple avenues, to ensure that knowledge and experience is leveraged to make Medi-Cal Rx successful. The Department intends to continue these types of engagement efforts and is committed to working with its external partners, including Medi-Cal Managed Care Plans (MCPs), counties, providers, consumer advocates, and beneficiaries, to ensure a smooth and successful transition. For example, the Department has established a dedicated Medi-Cal MCP Workgroup and a Medi-Cal Rx Advisory Workgroup consisting of various stakeholder representatives that meet regularly to discuss various issues, identify best practices, and provide workable solutions and strategies to support the Department's implementation efforts.

Going forward, the Department will also continue to actively explore opportunities to streamline and enhance existing stakeholder engagement and outreach efforts around Medi-Cal, which will include targeted Medi-Cal Rx workgroup meetings and discussions to collaborate on best practices and implementation strategies that meet the needs of all impacted parties.

24. How will information about the Medi-Cal Rx transition and other related changes be communicated?

The Department will work in collaboration with the Medi-Cal Rx Contractor to ensure all interested parties (including, but not limited to, Medi-Cal Managed Care Plans, Mental Health Plans, Substance Use Disorder Plans, providers, and beneficiaries) are informed of transition and other related changes. Communication will be disseminated via several methods including, but not limited to:

- A new www.Medi-CalRx.dhcs.ca.gov website launched in June 2020 and serves as a platform to educate and communicate available resources, information, and changes to interested parties. Educational content and frequently asked questions are posted and updated frequently.
- Starting in June 2020 a Medi-Cal Rx subscription service was made available from the Medi-CalRx website to allow interested parties to sign up and receive regular Medi-Cal updates by email.
- From August 2020 onwards, interested parties can see bulletins regarding changes posted on the new Medi-CalRx website.
- A series of trainings and educational materials for Medi-Cal providers and MCPs four months prior to transition will be available from the new Medi-CalRx website. MCPs and providers will have the ability to sign up for training and education events starting in September 2020.
- Notices to Medi-Cal beneficiaries, Managed Care Plans and fee-for-service providers, at **90-, 60-, and 30-day intervals, starting on or about October 1, 2020**; additional notices will be released, as needed.
- **Medi-Cal Managed Care Plan Medi-Cal Rx Outreach Campaign, either conducted through a traditional outbound call campaign, or other alternative communication modalities, as approved by the Department, to enrolled members.**
- Updates to Medi-Cal Managed Care Plan Member Handbook (Evidence of Coverage), as well as informing materials for other impacted entities.
- Updates to the Medi-Cal Provider Manual, as well as new provider guidance and materials published by the Medi-Cal Rx Contractor, as directed by the Department.
- Updates to Medi-Cal Managed Care Plan contracts, as needed, to reflect the transition of the pharmacy benefit from managed care to fee-for-service.
- **Creation of a new Medi-Cal Rx All Plan Letter for Medi-Cal Managed Care Plans, and other related informational notices for county-based providers and other key partners at the county level.**
- **Creation of a new Department of Managed Health Care All Plan Letter, relative to Medi-Cal Rx, for Medi-Cal Managed Care Plans that provides guidance from a regulatory, compliance, and filing perspective.**
- Updates to the Medi-Cal Managed Care Plans rates.

- Regular updates via existing stakeholder processes and workgroups, including but not limited to, the Department's bi-monthly Stakeholder Communication Update, Medi-Cal Rx Public Forum, Medi-Cal Global Drug Utilization Review Board, Medi-Cal Pharmacy Directors' Meeting, Stakeholder Advisory Committee, California Children Services Advisory Committee, etc.

25. How will the Department ensure Medi-Cal beneficiaries transitioning to Medi-Cal Rx do not experience a disruption in their care and/or inability to access necessary prescription medications?

To assist Medi-Cal beneficiaries, providers (prescribers and pharmacies), and Managed Care Plans with the initial transition on January 1, 2021, the Department has developed and will implement a multi-faceted pharmacy transition policy. **The pharmacy transition policy will use strategies such as "grandfathering" previously approved prior authorization requests through their stated duration, not to exceed one (1) full year from the date the prescription was written, unless the drug is included in the list of exceptions allowing for extended/multi-year PAs up to five (5) years for certain drug classes/categories, as described below. The transition period also includes a 180-day period where DHCS will not require PA for existing prescriptions without previously approved PAs from their applicable Medi-Cal MCPs, for drugs not on the MediCal Contract Drug List, or that otherwise have PA requirements under Medi-Cal Rx. This policy does not apply to new prescriptions or drugs that do not have prior authorization requirements under Medi-Cal Rx.** During this transition period, Magellan will provide system messaging, reporting and outreach to provide for a smooth transition to Medi-Cal Rx. This pharmacy transition period will facilitate a smooth, productive transition, ensuring that Medi-Cal beneficiaries do not experience disruption in their access to medically necessary prescriptions while maintaining compliance with all state and federal laws related to the Medi-Cal pharmacy benefit. The Department's pharmacy transition policy is available on the Medi-Cal Rx Transition webpage at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Pharmacy-Transition-Policy-Ver%208.0-08-14-2020.pdf.

26. Will the Department develop a Medi-Cal Rx transition plan, and, if so, what components will that plan include?

Yes, pursuant to the requirements outlined in Request For Proposal #19-96125, Exhibit A, Attachment I – Scope of Work – Takeover, the Medi-Cal Rx Contractor and DHCS will develop a Medi-Cal Rx pharmacy transition approach/plan to include, at a minimum, processes for:

- Providing sufficient notice and flexibility for Medi-Cal pharmacies and prescribers to take all necessary steps to acclimate to the new Medi-Cal Rx Contractor, the Medi-Cal Contract Drugs List, and associated processes.
- Providing appropriate notice and related materials from the Department and Medi-Cal Managed Care Plans to Medi-Cal beneficiaries regarding the transition.
- Providing temporary flexibility for obtaining prior authorization on drugs dispensed during the transition period by allowing ongoing (drug treatments initiated prior to January 1,

2021) drugs to be dispensed and billed without first having an approved prior authorization. However, prospective Drug Utilization Review requirements for drug safety will still apply.
- Pharmacy, provider, and beneficiary assistance, including ensuring that affected parties receive appropriate notification of, and additional information related to, the Medi-Cal Rx pharmacy transitional period and related processes.

27. What strategies will the Department use in the Medi-Cal Rx transition plan to ensure a smooth and effective transition to Medi-Cal Rx for beneficiaries?

DHCS' pharmacy transition policy will use strategies such as:
- "Grandfathering" previously approved PAs through their stated duration, **not to exceed one (1) full year from the date the prescription was written, unless the drug is included in the list of exceptions allowing for extended/multi-year PAs up to five (5) years for certain drug classes/categories, as articulated in the policy.**
- Providing a **180**-day period where DHCS will not require PA for existing prescriptions without previously approved PAs from their applicable Medi-Cal MCPs, for drugs not on the Medi-Cal Contract Drug List, or that otherwise have PA requirements under Medi-Cal Rx.

For more information, please review the DHCS pharmacy transition policy on the DHCS Medi-Cal Rx Transition webpage at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Pharmacy-Transition-Policy-Ver%208.0-08-14-2020.pdf.

28. Should Medi-Cal Managed Care Plans discontinue and/or void any prior authorizations that were adjudicated and approved by the Medi-Cal Managed Care Plan on or before December 31, 2020?

No, Medi-Cal Managed Care Plans should not discontinue and/or void such prior authorizations, and should similarly not have authorizations automatically expire on December 31, 2020. Both the Department and Medi-Cal Managed Care Plans should take necessary steps to ensure Medi-Cal beneficiaries continue to have access to medically necessary pharmacy benefits and services during the transition to Medi-Cal Rx.

DATA FEEDS, ELECTRONIC ACCESS & OTHER CLINICAL SUPPORTS

29. Will Medi-Cal Rx provide the pharmacy data and necessary electronic access for Medi-Cal providers, Medi-Cal Managed Care Plans, and other entities to support care coordination?

Yes, Medi-Cal Rx will provide data feeds (at least daily) to Medi-Cal Managed Care Plans, to support their responsibilities of beneficiary care coordination, carrying out clinical aspects of pharmacy adherence, and disease and medication management. **The Department continues to explore options and recommendations relative to data feeds for Mental Health and Substance Use Disorder Plans, and will be engaging key stakeholders in this space.**

Any agreed upon solution will be implemented after the January 1, 2021 Medi-Cal Rx go live.

In addition, Medi-Cal Rx will provide appropriate real-time access into the Medi-Cal Rx Contractor's electronic environment via a secure portal to all Medi-Cal providers (prescribers and pharmacies) and Medi-Cal Managed Care Plans, Mental Health and Substance Use Disorder Plans, and additional entities as designated by DHCS.

30. What additional clinical and care coordination support will Medi-Cal Rx provide to Medi-Cal Managed Care Plans?

Medi-Cal Rx will provide additional clinical and care coordination support to Medi-Cal Managed Care Plans to meet their contractual obligations relating to Medi-Cal beneficiary care coordination, medication adherence, and other related responsibilities, by:

- Providing a dedicated Medi-Cal Managed Care Plan clinical liaison team to interface with the Medi-Cal Managed Care Plans, other Contractor staff, and the Contractor's portal/environment to assist with and resolve clinical pharmacy-related issues for Medi-Cal Rx, including those involving prior authorization, as directed by the Department.
- Maintaining sufficient staffing ratios of dedicated Medi-Cal Managed Care Plan clinical liaisons to ensure this level of access is maintained for Medi-Cal Managed Care Plans.
- **Providing access to the Medi-Cal Managed Care Plan clinical liaisons through Medi-Cal Rx's dedicated Integrated Voice Response system to assist and resolve clinical pharmacy-related issues, as outlined in this document.**

For more information about the Medi-Cal Rx clinical liaison policy approach, please visit the Department's website at:
https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-MCP-Clinical-Liaison-Policy-081420.pdf.

For more information about the Medi-Cal Rx website and pharmacy portal policy, please visit the Department's website at:
https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Website-and-PharmacY-Portal-Policy-081420.pdf.

PROVIDER OUTREACH, EDUCATION & TRAINING

31. What kinds of provider outreach, education, and training, as well as related supports, is the Department offering and/or planning to do for Medi-Cal Rx?

The Department, in collaboration with the Medi-Cal Rx Contractor, is dedicated to providing Medi-Cal provider customer support services, including but not limited to, the following:

- Twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year, excluding approved holidays, or unless otherwise directed by the Department, customer services center to support all provider calls.
- Outreach, training and informing materials to Medi-Cal providers, Medi-Cal Managed Care Plans, and other entities.

- Web-based services to support communication and tools for Medi-Cal Rx.
- Real-time access into the Medi-Cal Rx Contractor's electronic environment via a secure portal.
- Other services and supports to ensure a smooth and effective transition (e.g., 180 day pharmacy transitional period).

In addition, the Medi-Cal Rx Contractor's Pharmacy Service Representatives will act on behalf of the Department to relay and provide subject-matter expertise/support regarding Medi-Cal Rx information and training materials to providers (prescribers and pharmacies) pharmacy billing agents, and plan partners, in a variety of venues. For more information, please see Request For Proposal #19-96125 Exhibit A, Attachment II – Scope of Work – Operations – Education and Outreach.

Additional information about provider outreach, education, and training, including schedules and sign-up information, is and will be made available on the Department's dedicated Medi-Cal Rx website at: https://medi-calrx.dhcs.ca.gov/home/education. In addition, providers and all other interested parties are encouraged to sign up for the Medi-Cal Rx Subscription Service (MCRxSS) to receive news and updates related to Medi-Cal Rx. MCRxSS is available at: https://mcrxsspages.dhcs.ca.gov/Medi-CalRxDHCScagov-Subscription-Sign-Up.

BENEFICIARY CUSTOMER SERVICE & RELATED SUPPORTS

32. What kinds of Medi-Cal beneficiary customer service and related supports is the Department offering and/or planning to do for Medi-Cal Rx?

The Department, in collaboration with the Medi-Cal Rx Contractor, is dedicated to providing beneficiary customer services and related supports, including but not limited to, the following:

- Twenty-four (24) hours per day, seven (7) days per week, three hundred and sixty-five (365) days per year, excluding approved holidays, or unless otherwise directed by the Department, customer services center to support all beneficiary calls.
- Informing materials related to Medi-Cal Rx through different avenues, including but not limited to appropriate notices via U.S. Mail and web-based services (e.g., external facing internet webpage to support communication and tools for Medi-Cal Rx).
- A Medi-Cal Rx Pharmacy Locator Tool (MPL) that will be available through the Medi-Cal Rx website later this year, which will include all Medi-Cal Rx eligible pharmacies.
- An Interactive Voice Response (IVR) system to provide:
    - Recorded information
    - Self-service options
    - Ability to request follow-ups from customer service, such as a call back phone call, information to be provided by mail or email

In addition, the Medi-Cal Rx Contractor's Pharmacy Service Representatives will act on behalf of the Department to relay and provide subject-matter expertise/support regarding Medi-Cal Rx information and related materials to Medi-Cal beneficiaries, in a variety of

venues. For more information, please see Request For Proposal #19-96125 Exhibit A, Attachment II – Scope of Work – Operations – Education and Outreach.

MEDI-CAL FEE-FOR-SERVICE REIMBURSEMENT METHODOLOGY

33. For Medi-Cal pharmacies, how is the Medi-Cal fee-for-service pharmacy reimbursement methodology established, and what are the components?

Medi-Cal fee-for-service pharmacy reimbursement for covered outpatient drugs, as defined by the federal Centers for Medicare and Medicaid Services (CMS) and in the Medi-Cal State Plan, has two components, consistent with applicable state law: (1) drug ingredient cost (average acquisition cost), and (2) a professional dispensing fee (two-tiered based on total Medicaid and non-Medicaid annual pharmacy claim volume (i.e., dispensed prescriptions):

- < 90,000 claims per year: $13.20
- > or = 90,000 claims per year: $10.05

For 340B claims, reimbursement is covered entity's actual drug acquisition cost plus the appropriate professional dispensing fee.

34. As a result of Medi-Cal Rx, will the Department be making changes to existing fee-for-service pharmacy reimbursement methodologies, including for specialty drugs?

The Department will utilize drug reimbursement methodologies as defined in state law and the Medi-Cal State Plan. If the Department implements the use of Maximum Allowable Ingredient Costs (MAICs) for drugs, which have three (3) or more generically equivalent options available, reimbursement for the affected drug(s) may change if the MAIC is "lesser of" the two other benchmarks defined in state law, i.e., National Average Drug Acquisition Cost and Federal Upper Limit.

POLICY CONSIDERATIONS

35. What is Medi-Cal's Contract Drug List?

The Department maintains the Medi-Cal Contract Drug List, which is the Department's preferred set of covered drugs and generally includes drugs for which there is a current state supplemental drug rebate agreement in place. Under the existing Medi-Cal fee-for-service pharmacy benefit, if a drug is listed on the Medi-Cal Contract Drug List, then it would not require an approved prior authorization for coverage. Alternatively, if a drug is not listed on the Medi-Cal Contract Drug List, then it would require an approved prior authorization for coverage. Please note that even if a drug is listed on the Medi-Cal Contract Drug List, it may still require an approved prior authorization for coverage; however, if a certain drug on the Medi-Cal Contract Drug List requires an approved prior authorization, then the Department's policy would clearly articulate that requirement.

36. How will Medi-Cal Rx affect Medi-Cal's Contract Drug List, and does the Department take anything else into consideration for its Medi-Cal drug coverage policies?

Medi-Cal Rx will use the existing Department-approved Medi-Cal Contract Drug List as its preferred set of covered drugs. In addition, the Department's pharmacy drug coverage policies will also take into consideration:

- All Federal Food and Drug Administration-approved covered outpatient drugs, as defined by CMS, subject to medical necessity.
- The Department's business rules that detail requirements for the covered outpatient drugs and non-drug products, and limitations of coverage, which include aid code, program, and/or date-specific.

37. Will Medi-Cal Rx consider local exceptions to Medi-Cal's Contract Drug List?

No. Medi-Cal Rx will use a single, statewide, and Department-approved Medi-Cal Contract Drug List to standardize the Medi-Cal pharmacy benefit.

38. How does the Department make determinations to add or delete drugs from the Contract Drug List (CDL)?

The Department can add drugs to the Medi-Cal CDL based upon receipt of either (1) an external Individual Drug Petition (IDP) request from a manufacturer, physician, and/or pharmacist, or (2) a Department-initiated IDP review, if applicable. Once an IDP is received, the Department conducts an extensive review of the request taking into consideration evidence-based literature, industry best practices, and the following drug review criteria, which are outlined in Welfare and Institutions Code Section 14105.39(c)(1) and (2):

- The safety of the drug
- The effectiveness of the drug
- The essential need of the drug
- The potential for misuse of the drug
- The cost of the drug to the program

In addition to conducting its own internal review, the Department also consults with the Medi-Cal Drug Advisory Committee (Committee), as required by Welfare and Institutions Code Section 14105.4. The Committee is comprised of members who are appointed by the Department's Director – including community physicians and pharmacists, faculty members from academic pharmacy institutions, and Medi-Cal beneficiaries – and assists the Department by providing written recommendations to inform decision-making regarding adding and/or deleting, drug(s) from the Medi-Cal CDL. The Committee's final response with detailed, drug-by-drug recommendations is due within 30 calendar days of the Department requesting consultation, and takes into consideration the Welfare and Institutions Code Section 14105.39(c)(1) and (2) criteria, as well as additional information such as generic name, brand name, Federal Food and Drug Administration-approved indications, manufacturer, fiscal/cost impact, clinical criteria, etc.

The Department then makes an informed and documented decision whether or not to add the drug to the Medi-Cal CDL based upon the Committee's recommendations, state law requirements, and other relevant factors.

39. Are there any statutory changes related to Medi-Cal Rx?
Yes, the Department's proposed Trailer Bill language was part of the Governor's Fiscal Year 2020-21 budget, which made the following changes:

- **Repealed the six-prescription ("6 Rx") drug limit.**
- **Eliminated the Medi-Cal fee-for-service prescription co-pays.**
- **Redefined "Best Price"** for Medi-Cal drugs to allow for drug prices outside the United States to be considered **for state supplemental drug rebate contracts**.

40. For drugs requiring Prior Authorization, do prescribers or providers need to submit a Prior Authorization each time a drug is dispensed?

No, a Prior Authorization can cover multiple fills dispensed within the approved PA duration.

41. Has the Department made policy changes to allow for multi-year prior authorization approvals?

As part of Medi-Cal Rx, the Department is making changes to allow extended duration/multi-year prior authorization for **up to five (5) years** for certain disease conditions and classes of drugs based upon established and documented clinical criteria (e.g. maintenance drugs with a low risk of adverse events). **These drug classes/categories include: Attention-Deficit/ Hyperactivity Disorder medications, Alzheimer's Agents, Anticonvulsants, Anti-Parkinson's, Antihypertensive medications, Cardiac medications (alpha and beta blockers, vasodilators, anti-arrhythmics, Inotropic, diuretics), Antidepressants, Antihistamines, Anti-hyperlipidemic, Bronchodilators, Contraceptives, Glaucoma Agents, Gout, Hormone replacement, Insulin, Multiple Sclerosis Agents, Nasal steroids, Pulmonary Hypertension, Rheumatoid Arthritis /Autoimmune therapy, Thyroid, and Urinary Antispasmodics for Over Active Bladder.**

Please note DHCS will be continuously evaluating coverage policy in this area to ascertain whether adjustments are required future forward, and will be engaging through regular stakeholder processes, as needed, to inform this effort.

42. Will the Department consider making policy changes to allow for enhanced and/or expanded auto-adjudication functionalities?

As part of Medi-Cal Rx, the Department is considering enhancing and/or expanding auto-adjudication functionalities (i.e., automated claim approval and payment) to reduce the number of drugs with prior authorization requirements that require manual review. The following are potential categories of drugs for consideration: nonsteroidal anti-inflammatory drugs (NSAIDs), histamine-2 receptor blockers (H2 Blockers), proton pump inhibitors (PPIs),

discharge medications, selective serotonin reuptake inhibitors (SSRIs), antihistamines, lipid lowering medications, diuretics, etc.

43. Will Medi-Cal Rx include opioid management services?

Medi-Cal Rx will provide opioid management services in accordance with House Resolution 6 Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, Medi-Cal pharmacy policy and procedures, and clinically appropriate, evidence-based guidelines. **To promote transparency and increased awareness, the Department has shared this information externally at various stakeholder events, including but not limited to the Medi-Cal Rx Managed Care Plan workgroup and Medi-Cal Rx Advisory workgroup. For more information regarding the Department's current pharmacy policies and procedures in this space, please see the reference resources and material on the Department's website at: https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/OpioidUtilizationManagement-MRxAdvisWrkgrpMtg-07.29.2020.pdf.**

In addition, as part of Medi-Cal Rx, the Department solicited Proposals as part of the Request for Proposal to further explore enhanced opioid management utilization management tools that go above and beyond what is required by federal law. Going forward, the Department will consider implementing the enhanced opioid management services proposed.

44. Will Medi-Cal Rx include a pharmacy lock-in program?

The Department will not implement a lock-in program as part of its January 1, 2021 implementation but will be evaluating options with the Medi-Cal Rx Contractor future forward. As part of the Medi-Cal Rx Request for Proposal #19-96125, the Department solicited Proposals to explore further pharmacy lock-in program options, including, but not limited to, things such as: use of multiple pharmacies, different prescribers of controlled substances, and number of controlled substances. In addition, the Department is aware that approximately 50 percent of Medi-Cal Managed Care Plans utilize pharmacy lock-in programs today, so through stakeholder engagement efforts, the Department will be looking to learn more and utilize best practices for Medi-Cal Rx.

PRIOR AUTHORIZATION/UTILIZATION MANAGEMENT

45. Under Medi-Cal Rx, how will prior authorization requests be reviewed and adjudicated?

The Department shall, in collaboration with the Medi-Cal Rx Contractor, will process prior authorization requests and provide a response to the submitting provider within 24 hours of receiving a prior authorization request, pursuant to Welfare and Institutions Code Section 14133.37. A more detailed process document will be posted on the Department's website in November, and will be available at the following link: https://www.dhcs.ca.gov/provgovpart/pharmacy/Pages/Medi-CalRX.aspx.

46. Will Medi-Cal Managed Care Plans be allowed to contract with the Medi-Cal Rx Contractor to perform prior authorization?

No. Since Medi-Cal Managed Care Plans will no longer be contractually responsible for the Medi-Cal pharmacy benefit as of January 1, 2021, all prior authorization adjudications and related processes will be handed by the Medi-Cal Rx Contractor, consistent with contractual requirements and at the direction of the Department.

340B FEDERAL DRUG DISCOUNT PROGRAM

47. What is the federal 340B program?

Section 340B of the Public Health Services Act (Title 42 United States Code Section 256b), establishes a federal program known as the 340B Drug Pricing Program (340B program), which was created in 1992 after the adoption of the Medicaid Drug Rebate Program. The Health Resources and Services Administration, an agency under the United States Department of Health and Human Services, administers and manages the program through its Office of Pharmacy Affairs.

The 340B program requires drug manufacturers to offer drugs to certain hospitals and other health care providers (covered entities) at a greatly reduced price. By selling drugs at lower prices, participating drug manufacturers are not required to pay Medicaid drug rebates on drugs purchased through the 340B program and provided to a Medicaid beneficiary (better known as the provision against “duplicate discounts”).

48. Who utilizes the 340B program?

Section 340B(a)(4) of the Public Health Services Act (Title 42 United States Code Section 256b) specifies which covered entities are eligible to participate in the 340B program. These include qualifying hospitals, federal grantees from the Health Resources and Services Administration, the Centers for Disease Control and Prevention, the Department of Health and Human Services’ Office of Population Affairs and Indian Health Service. Eligible covered entities are defined in statute and include HRSA-supported health centers and look-alikes, Ryan White clinics and State AIDS Drug Assistance programs, Medicare/Medicaid Disproportionate Share Hospitals, children’s hospitals, and other safety net providers.

When registering as a covered entity with the Health Resources and Services Administration, a covered entity may choose to not dispense 340B purchased drugs to Medicaid beneficiaries or to dispense 340B purchased drugs to Medicaid beneficiaries. HRSA maintains a file of covered entities that indicates whether the entity dispenses 340B purchased drugs to Medicaid patients. Although covered entities can purchase 340B drugs for all eligible patients, state Medicaid programs may only collect rebates on drugs purchased outside of the 340B program. Additional details are available on the Health Resources and Services Administration’s website at: https://www.hrsa.gov/opa/index.html.

49. What is the interaction of our prescription drug proposal and the 340B program?

Drugs purchased under 340B pricing and dispensed to Medicaid enrollees are excluded from both federal and state rebate collection. This exclusion prevents drug manufacturers from providing duplicate discounts on drugs purchased through the 340B program.

In October 2009, California codified a pre-existing policy that requires 340B covered entities to dispense only 340B inventory to Medi-Cal beneficiaries, and bill at their actual acquisition cost for those drugs when dispensed through the Medi-Cal fee-for-service delivery system, consistent with Welfare and Institutions Code Section 14105.46. The 340B actual acquisition cost billing requirement only applies to the fee-for-service delivery system.

In the managed care delivery system, 340B drugs dispensed to Medi-Cal beneficiaries are not subject to the Medi-Cal fee-for-service acquisition-cost billing requirements. This allows covered entities and the Medi-Cal Managed Care Plans and/or contracted Pharmacy Benefits Managers to negotiate reimbursement arrangements that results in a higher reimbursement to the 340B covered entity in the managed care delivery system when compared to how those entities are or would be reimbursed in the Medi-Cal fee-for-service delivery system. These profits are not shared with the state, nor are the amounts of such profits known to the state.

The proposed prescription drug carve out allows for uniformity of policy and improved oversight of claims for medications dispensed and billed through the 340B program.

50. Does the proposal preclude a provider from continuing as a 340B entity?

No. In addition, the proposal does not change or eliminate the 340B Program in California.

51. How is the Department addressing the concerns raised as to the effect of Medi-Cal Rx on the administration of 340B programs?

DHCS recognizes the important role of our safety net providers and the critical work they do for Medi-Cal beneficiaries. DHCS has worked and continues to work collaboratively and engage in discussions with various interested parties and stakeholders on behalf of health care facilities and groups to better understand the impact of the implementation of Medi-Cal Rx on their 340B programs and related processes, as well as to further discuss potential options for mitigation.

52. Has the Department collected any data or information to assess the impact to the 340B Program?

The Department has engaged interested parties and stakeholders to participate in a 340B data collection effort. In October, the Department requested that all clinics/health centers download and complete the provided data template in full and submit it to the Department. The Department has assessed the level of participation and completeness of the data provided in these submissions, and used this information to compile statewide data in order to inform discussions within the Administration and with the Legislature and clinics/health

centers. As a result, DHCS proposed a new supplemental payment pool for non-hospital 340B clinics as a part of the Governor's 2020-21 Budget. The Governor's signed California State Budget included $52.5 million ($26.3 million General Fund) in 2020-21 to provide supplemental payments to specified non-hospital clinics who participated in the federal 340B pharmacy program. These payments would grow to $105 million ($52.5 million General Fund) in 2021-22 and annually thereafter. For more information, please see the Department of Finance's website, which includes the budget summary, at http://www.ebudget.ca.gov/FullBudgetSummary.pdf.

53. How will the Department allocate and/or make available the supplemental payment pool for non-hospital 340B clinics?

The Department is engaged in a stakeholder process and is currently finalizing the distribution methodology. The Department will submit a State Plan Amendment to obtain federal approval. The State Plan Amendment will be published for public comment prior to submission at https://www.dhcs.ca.gov/formsandpubs/laws/Pages/Proposed_2020.aspx.

MEDI-CAL RX COMPLAINTS/GRIEVANCES RESOLUTION & APPEALS PROCESSES

54. What complaints and grievances resolution processes will Medi-Cal beneficiaries have to address pharmacy benefit issues?

The Medi-Cal Rx Contractor **for the Medi-Cal Rx complaints and grievances processes and related protocols, which align with and build upon existing Medi-Cal fee-for-service processes and protocols for the Medi-Cal more broadly. In partnership with the Medi-Cal Rx Contractor, the Department is committed to implementing and overseeing an effective Medi-Cal Rx complaint and grievances process to ensure appropriate triaging, referral, and/or disposition.** Specific requirements are outlined in Request For Proposal #19-96125, Exhibit A, Attachment II – Scope of Work Operations – Complaints and Grievances Resolution. **In addition, the Department's Medi-Cal Rx Complaints and Grievances policy is posted to the Department's Medi-Cal Rx Transition webpage at https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Complaints-and-Grievances-08-25-2020.pdf.**

55. What pharmacy-related complaints and grievances will be handled through Medi-Cal Rx?

All pharmacy-related complaints and grievances for Medi-Cal Rx services provided on or after January 1, 2021, will be handled through Medi-Cal Rx's Customer Service Center for triaging, research, and resolution. For more information, please visit the Department's Medi-Cal Rx Transition webpage at https://www.dhcs.ca.gov/provgovpart/pharmacy/Documents/MRX-Complaints-and-Grievances-08-25-2020.pdf.

56. How will the Department address complaints and grievances that arose for pharmacy-related services provided by the Medi-Cal Managed Care Plans on or before December 31, 2020?

Pharmacy-related complaints and grievances for services rendered or requested on or before December 31, 2020 by a Medi-Cal Managed Care Plan, which are for services the Managed Care Plan was at risk for, must be fully adjudicated by the Medi-Cal Managed Care Plan in accordance with the Department's All Plan Letter 17-006 and any subsequent versions.

Pharmacy-related complaints and grievances received on or after January 1, 2021, by the Medi-Cal Rx Customer Service Center (CSC) for services provided by a Medi-Cal Managed Care Plan on or before December 31, 2020, will be transferred by the Medi-Cal Rx CSC to the appropriate Medi-Cal Managed Care Plan for full resolution. The Medi-Cal Rx CSC will advise Medi-Cal Managed Care Plan members that they should contact their Managed Care Plan for such pharmacy-related complaints and grievances.

The right of Medi-Cal Managed Care Plan beneficiaries to submit complaints and grievances to their Medi-Cal Managed Care Plans for pharmacy-related services rendered on or before December 31, 2020 are not impacted by Medi-Cal Rx.

57. Will Medi-Cal Rx have a mechanism to share information about complaints and grievances with the beneficiary's MCP?

Medi-Cal Managed Care Plans will have complete access to individual records of beneficiaries enrolled in their plan via the Medi-Cal Rx Web Portal, including documentation of complaints and grievances. This information can be reviewed by the plan case manager on a case by case basis as needed. Further, relative to complaints and grievances external reporting, DHCS is exploring options and will leverage existing modalities relative to sharing this information publically through various avenues such as the DHCS website and Open Data Portal.

58. What appeals mechanism(s) will Medi-Cal beneficiaries have to address pharmacy benefit issues?

Appeals go through the State Fair Hearing process, which is administered through the California Department of Social Services. If Medi-Cal beneficiaries do not agree with a denial or change of Medi-Cal Rx services, they can ask for a State Fair Hearing. To ask for a State Hearing, Medi-Cal beneficiaries can fill out the "State Hearing Request" form at www.dhcs.ca.gov/services/medi-cal/Pages/Medi-CalFairHearing.aspx, and send it to:

California Department of Social Services
State Hearings Division
P.O. Box 944243, MS 19-37
Sacramento, CA 94244-2430

Medi-Cal beneficiaries may also call to ask for a State Fair Hearing toll-free at 1(800) 952-5253 (TTY 1-800-952-8349). Please note that the number can be very busy so you may get a message to call back later.

59. If a Medi-Cal beneficiary wants a State Fair Hearing, are there any time limitations?

Yes, Medi-Cal beneficiaries only have 90 days to ask for a hearing, consistent with applicable state law.

60. Can Medi-Cal beneficiaries still get their treatment while awaiting a State Fair Hearing decision?

Yes. To continue receiving the Medi-Cal Rx services that the denial notice is stopping and/or changing, Medi-Cal beneficiaries must ask for a State Hearing within ten days from:

- The date the notice is postmarked
- The date of personal delivery of the notice
- Before the date the notice says your treatment will stop or change

When requesting the State Fair Hearing, Medi-Cal beneficiaries should indicate that they want to keep getting Medi-Cal Rx services during the hearing process. Please note that it can take up to 90 days for a case to be decided and a final determination to be sent to the Medi-Cal beneficiary.

61. Can Medi-Cal beneficiaries request an expedited State Fair Hearing?

Yes. Medi-Cal beneficiaries can request an expedited hearing by submitting a letter from their doctor explaining how waiting for up to 90 days could be risky to their life and/or health. Medi-Cal beneficiaries should send the letter along with their hearing request. For more information about the State Hearing process, please visit the Department's website at: http://www.dhcs.ca.gov/services/medi-cal/Pages/Medi-CalFairHearing.aspx.

62. For appeals of Medi-Cal Rx coverage decisions by the Medi-Cal provider and/or Managed Care Plan, will the Department create a separate Medi-Cal Rx external appeal process where independent medical experts review decisions?

No, at this time, the Department is not exploring creating a separate independent medical review process, akin to that currently overseen by the California Department of Managed Health Care, for Medi-Cal Rx. As a reminder, Medi-Cal Rx denials for pharmacy claims will not be made by Medi-Cal providers and/or Managed Care Plans, rather they will initially be made by the Medi-Cal Rx Contractor and reviewed by the Department for final determination. As mentioned elsewhere in this document, Medi-Cal providers can appeal Medi-Cal Rx denials consistent with the requirements outlined in Request For Proposal #19-96125, Exhibit A, Attachment II – Scope of Work Operations – Claims Administration, and applicable state law requirements and Department policies/procedures

63. What pharmacy-related appeals will be handled through Medi-Cal Rx?

All pharmacy-related appeals for Medi-Cal Rx services provided on or after January 1, 2021, will be handled through Medi-Cal Rx utilizing the existing State Fair Hearing process, administered though the California Department of Social Services, as described in questions 58 through 61, above.

64. How will the Department address appeals from Medi-Cal Managed Care Plan beneficiaries that arose for pharmacy-related services provided by the Medi-Cal Managed Care Plans on or before December 31, 2020?

Medi-Cal Managed Care Plans must resolve all Medi-Cal Managed Care Plan beneficiary appeals that originated as a result of a Managed Care Plan decision relative to pharmacy-related services for which the Managed Care Plan was at risk for on or before December 31, 2020. The right of Medi-Cal MCP members to submit appeals to the Department of Managed Health Care, including but not limited to the right to Independent Medical Review, for pharmacy-related services provided by the Medi-Cal Managed Care Plans rendered on or before December 31, 2020, are not impacted by Medi-Cal Rx.

FISCAL IMPACT/ASSESSMENT

65. Will the Department be completing a fiscal analysis prior to the transition?

Yes. The Department has completed a fiscal analysis for Medi-Cal Rx, and has shared this information publicly. The Department anticipates approximately $405 General Fund million in annual savings by 2022-23. The Department will be including the fiscal estimate for Medi-Cal Rx as part of the bi-annual Medi-Cal Estimate process**, and be providing necessary adjustments, if any, to the fiscal analysis on an ongoing and go-forward basis**.

66. What are the elements of our projected $405 million General Fund (GF) in annual savings by 2022-23?

The elements of the projected $405 million GF savings by 2022-23, include but are not limited to the following factors:

- Additional state supplemental drug rebates resulting from a shift of drug utilization from the managed care delivery system to the **fee-for-service** delivery system;
- Implementation of Maximum Allowable Ingredient Costs (MAICs) for drugs which have three (3) or more generically equivalent options available; and
- Reduction of costs related to administrative functions of multiple pharmacy benefits managers used by various Medi-Cal Managed Care Plans.
- Fiscal is based on current Medi-Cal fee-for-service reimbursement methodology, which includes $10.05/$13.20 dispensing fees.
- Based on current **fee-for-service** reimbursement methodology, including the $10.05/$13.20 dispensing fees, 340B drugs were priced at what Managed Care Plans

paid due to the Department not having knowledge of the 340B entity acquisition cost to properly score the potential 340B savings.

- In addition, DHCS also proposed a new supplemental payment for non-hospital 340B clinics as a part of the Governor's 2020-21 Budget, effective with the Medi-Cal Rx transition date of January 1, 2021, **which was included in the Governor's final enacted 2020-21 budget.** See questions 52 and 53 above for more detailed information.

MISCELLANEOUS/OTHER INFORMATION

67. Will Medi-Cal Rx include mail order pharmacy options?

Yes. Mail-order options are available in Medi-Cal today, and will continue to be available through Medi-Cal Rx. If the pharmacy is an enrolled Medi-Cal pharmacy provider, the pharmacy may dispense the medication on-site or through a mail-order service. The Department will work to ensure continuation of an effective mail-order service option for Medi-Cal pharmacy services.

68. Will the Department make Medi-Cal pharmacy supplemental drug rebate contracts public?

No. Both state and federal law protect the confidentiality of supplemental drug rebate contracts.

69. Will the Medi-Cal Rx Contractor be required to contract with existing pharmacies in the current networks?

No. The Medi-Cal Rx Contractor will not contract with any providers. All provider enrollment activities as well as maintenance of the Medi-Cal pharmacy network will be retained by the Department.

70. How many active, California-licensed pharmacies are there, and how many of those pharmacy providers are enrolled in Medi-Cal fee-for-service?

As of May 2018, data from the Department of Consumer Affairs indicated that there were 6,633 active, California-licensed pharmacies. As of June 2019, data from the Department indicated that 6,223 were enrolled Medi-Cal fee-for-service pharmacy providers.

71. Will Medi-Cal engage in an effort to enroll the pharmacies that are part of MCP networks but not enrolled in Medi-Cal fee-for-service?

On January 1, 2021 Medi-Cal Rx will be using Medi-Cal's extensive statewide network of pharmacies that are enrolled as Medi-Cal Providers. Medi-Cal enrolled pharmacies account for 94% of all California-licensed pharmacies. Medi-Cal Managed Care Plans currently use these same pharmacies as well as some additional pharmacies not yet enrolled as Medi-Cal pharmacy providers. **DHCS has analyzed the MCP pharmacy networks, identified potential gaps where pharmacies are providing services in managed care but are not**

enrolled in fee-for-service, and has sent notices to those pharmacies reminding them they must enroll as a Medi-Cal Pharmacy Provider to continue to serve the Medi-Cal population through Medi-Cal Rx as of January 1, 2021.

72. In what capacity will Medi-Cal Managed Care Plans and other entities be expected to participate in meetings for the Medi-Cal Global Drug Utilization Review Board and other Department-driven pharmacy committees?

Presently and ongoing post-transition, the Department expects that its Medi-Cal Managed Care Plans and other interested parties will continue to participate in meetings related to the Medi-Cal Global Drug Utilization Review Board and in other Department-driven pharmacy committees, as needed. In addition, the Department is actively evaluating and assessing how to better and more effectively engage and collaborate with Medi-Cal Managed Care Plans and other entities in discussions and decisions relating to Medi-Cal pharmacy policy on a going forward basis.

73. Does the Department have a new subscription service for updates and news relative to Medi-Cal Rx?

Yes. The Medi-Cal Rx Subscription Service (MCRxSS) is now live! All interested parties are encouraged to sign up for MCRxSS to receive news and updates related to Medi-Cal Rx. MCRxSS is available at: https://mcrxsspages.dhcs.ca.gov/Medi-CalRxDHCScagov-Subscription-Sign-Up.