



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

Version 11.0

February 23, 2022

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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 transition of Medi-Cal's pharmacy benefit (collectively referred to as "Medi-Cal Rx"). As the Department of Health Care Services (DHCS) receives additional questions, this document will be updated as indicated by the version number and date on the title page. 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 DHCS' dedicated [Medi-Cal Rx Transition website](#). In addition, general questions regarding Medi-Cal Rx may also be submitted to DHCS via email at RxCarveOut@dhcs.ca.gov.

General Information

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

DHCS 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 to increase overall access by allowing beneficiaries to receive pharmacy services from the broader fee-for-service 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 DHCS. For more information on CalAIM, please visit [DHCS' website](#).

2. What is Medi-Cal Rx?

Medi-Cal Rx is the name DHCS has given to the collective pharmacy benefits and services that will be administered through the fee-for-service delivery system by Magellan Medicaid Administration, Inc. (MMA) upon full Assumption of Operations.

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3. What does full Medi-Cal Rx Assumption of Operations (AOO) represent?

Medi-Cal Rx AOO represents the date MMA assumes operational responsibility for all remaining administrative services necessary to support Medi-Cal Rx, including but not limited to claims management, prior authorization and utilization management, provider and beneficiary support services, and other ancillary and reporting services. Medi-Cal Rx full AOO, as described in **questions #23-25**, will take place on January 1, 2022. For additional details, please see **questions #28-30**.

4. 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 (MCP) 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 with over 13.5 million beneficiaries.

5. Does DHCS need to seek federal approval to implement Medi-Cal Rx?

Yes. DHCS has requested federal approval from the Centers for Medicare and Medicaid Services (CMS) to transition pharmacy benefits from the managed care delivery system to fee-for-service through the [CalAIM Section 1915\(b\) waiver application](#). The waiver application reflects the carve-out of pharmacy benefits that are billed by a pharmacy on a pharmacy claim including covered outpatient drugs and physician administered drugs, as described in the Medi-Cal Rx All Plan Letter ([APL 20-020](#)), effective January 1, 2022.

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6. What Medi-Cal Managed Care Plans (MCPs) are and are not impacted by Medi-Cal Rx?

All Medi-Cal MCPs, 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).

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

Medi-Cal Rx will apply to both CCS and GHPP. After the Medi-Cal Rx full Assumption of Operations, all requests for prior authorization (PA) (formally Service Authorization Requests or Treatment Authorization Requests, respectively) – for both independent and dependent counties, and CCS-only, GHPP only, and CCS/GHPP Medi-Cal beneficiaries – will process through Medi-Cal Rx for pharmacy benefits billed on pharmacy claims.

As noted in **question #24 below**, DHCS will maintain all drug coverage and policy responsibility as well as set all criteria relative to PA adjudication. Moreover, recognizing the specialized health care needs of the CCS/GHPP populations, DHCS will continue to work closely and in partnership with the CCS Advisory Group and other key stakeholders in this space.

8. 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).

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- 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.

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

As noted in question #8 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 Managed Care Plan’s (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.

10. What pharmacy benefits will be “carved out” of Medi-Cal managed care due to Medi-Cal Rx?

After the Medi-Cal Rx full Assumption of Operations (AOO), Medi-Cal Rx will take over the responsibility from Medi-Cal MCPs for administering the following when billed by a pharmacy on a pharmacy claim:

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

For more information, please see DHCS’ [Medi-Cal Rx Scope document](#) on DHCS’ website. This document provides additional context and information related to DHCS’ implementation of the Medi-Cal managed care to fee-for-service pharmacy carve-out after the Medi-Cal Rx full AOO. It also provides an inventory of the Medi-Cal pharmacy benefit, characterized as either not subject to the carve-out (i.e.,

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those pharmacy benefits that are billed on medical and institutional claims) or subject to the carve-out (i.e., all pharmacy benefits that are billed on pharmacy claims).

11. How will DHCS approach coverage of diabetic supplies, which includes test strips, lancets, glucometers, control solutions, and lancing devices, after the Medi-Cal Rx full Assumption of Operations (AOO)?

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. This information is available in the Medi-Cal Rx Provider Manual and on the Medi-Cal Rx Web Portal.

Specific Glucometers, Control Solutions, and Lancing Devices will become a pharmacy-billed medical supply benefit through Medi-Cal Rx, effective January 1, 2022, restricted to the products on the newly created *List of Covered Self-Monitoring Blood Glucose Systems (Glucometers), Control Solutions, and Lancing Devices*, available on the Medi-Cal Rx Web Portal. NDC-billed claims submitted after transition to Medi-Cal Rx for products not found on this list will be denied.

Non-contracted products not found on the *List of Covered Self-Monitoring Blood Glucose Systems (Glucometers), Control Solutions, and Lancing Devices* are reimbursable through either Medi-Cal Managed Care Plans (MCPs) or the fee-for-service Fiscal Intermediary as a HCPCS-billed Durable Medical Equipment benefit on a medical claim. Quantity restrictions will remain unchanged.

12. How does DHCS approach coverage of disposable external ambulatory insulin delivery systems (Omnipod and V-Go) currently, and will that change after the Medi-Cal Rx full Assumption of Operations (AOO)?

Disposable Insulin Delivery Devices (DIDDs) will become a pharmacy-billed medical supply benefit through Medi-Cal Rx, effective January 1, 2022, restricted to the products on the newly created *List of Covered Disposable Insulin Delivery Devices* on the Medi-Cal Rx Web Portal. These products are identified as "Partial" on the Medi-Cal Rx Scope document; therefore, all DIDD claims billed on a pharmacy claim

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must be submitted to Medi-Cal Rx, and HCPCS-billed medical claims must be submitted to either Medi-Cal Managed Care Plans (MCPs) or the fee-for-service Fiscal Intermediary. NDC-billed claims submitted after transition to Medi-Cal Rx for products not found on this list will be denied.

DIDDs require a prior authorization for reimbursement and specific coverage criteria apply. DIDDs are included in the 180-day transition to ensure beneficiaries already using these products can continue utilization upon implementation of Medi-Cal Rx. An active prior authorization or a recent (within the past 90 days) paid claim found on the beneficiary's historical file supporting continuity of care will allow a claim to pay, subject to products on the contracted List. For claims previously paid as a medical benefit billed on a CMS-1500 form that require prior authorization, providers should include the active prior authorization previously submitted with the medical benefit claim, documentation of the most recently paid medical claim, and written justification for continuation of therapy when they submit the pharmacy claim for the requested product to ensure coverage requirements are met.

13. How will DHCS approach coverage of Continuous Glucose Monitors (CGMs), other durable medical equipment (DME), DME supplies and disposable medical supplies, currently and after the Medi-Cal Rx full Assumption of Operations (AOO)?

Therapeutic CGM Systems will become a pharmacy-billed medical supply benefit through Medi-Cal Rx, effective January 1, 2022. These products are identified as "Partial" on the Medi-Cal Rx Scope document. Therefore, a Therapeutic CGM pharmacy claim must be submitted to Medi-Cal Rx. CGMs may continue to be reimbursable as a HCPCS-billed DME benefit through the fee-for-service Fiscal Intermediary, as submitted on a medical claim, on a case-by-case basis and subject to medical justification and review. A contracted list of covered products is anticipated later in 2022.

Therapeutic CGMs are included in the 180-day transition to ensure beneficiaries already using these products can continue utilization upon implementation of

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Medi-Cal Rx. An active prior authorization or a recent (within the past 90 days) paid claim found on the beneficiary's historical file supporting continuity of care will allow a claim to pay. For claims previously paid as a medical benefit billed on a CMS-1500 form that require prior authorization, providers should include the active prior authorization previously submitted with the medical benefit claim, documentation of the most recently paid medical claim, and written justification for continuation of therapy when they submit the pharmacy claim for the requested product to ensure coverage requirements are met.

14. How will DHCS approach coverage of other medical supplies benefits currently or previously billed as a medical claim, by HCPCS code and on a CMS-1500 form, after the Medi-Cal Rx full Assumption of Operations (AOO)?

Unless otherwise noted on the Medi-Cal Rx Scope Document, all other Durable Medical Equipment (DME) and DME supplies will continue, unchanged, and reimbursable as a HCPCS-billed DME benefit through the fee-for-service Fiscal Intermediary, on a medical claim.

Sterile Syringes with Needles (non-insulin), a disposable medical supplies item currently billed via HCPCS code on a CMS-1500 form, will become a pharmacy-billed medical supply benefit through Medi-Cal Rx, effective January 1, 2022, restricted to products on the newly created *List of Covered Sterile Syringes with Needles (non-insulin)*, which can be found on the Medi-Cal Rx Web Portal.

NDC-billed claims submitted after transition to Medi-Cal Rx for products not found on this list will be denied. These products are identified as "Partial" on the Medi-Cal Rx Scope document; therefore, claims billed on a pharmacy claim must be submitted to Medi-Cal Rx, and claims billed as HCPCS-billed medical claims must be submitted to either Medi-Cal Managed Care Plans (MCPs) or the fee-for-service Fiscal Intermediary. Restrictions will remain unchanged: 200 syringes every 30 days without a prior authorization.

Alcohol Prep Pads, a disposable medical supplies item currently billed via HCPCS code on a CMS-1500 form, will become a pharmacy-billed medical supply benefit through Medi-Cal Rx, effective January 1, 2022, not restricted to a specific list.

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These products are identified as “Partial” on the Medi-Cal Rx Scope document; therefore, claims billed on a pharmacy claim must be submitted to Medi-Cal Rx, and claims billed as HCPCS-billed medical claims must be submitted to either Medi-Cal MCPs or the fee-for-service Fiscal Intermediary. Restrictions will remain unchanged: 200 pads every 30 days without a prior authorization. Alcohol swabsticks are not included in this category and will not be a Medi-Cal Rx benefit. Alcohol swabsticks will continue to be reimbursable as a HCPCS-billed medical supplies benefit through the fee-for-service Fiscal Intermediary.

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

No, after the Medi-Cal Rx full Assumption of Operations (AOO), 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 (MCPs) or the California Medicaid Management Information System (CA-MMIS) Fiscal Intermediary, as they have been prior to the Medi-Cal Rx full AOO. This also includes drugs currently “carved out” of the managed care delivery system (e.g., blood factor, HIV/AIDS drugs, antipsychotics, or drugs used to treat substance use disorder).

16. Will COVID-19 vaccines be “carved out” of Managed Care Plans (MCPs)?

Consistent with the approach being taken by Medicare through Medicare Advantage Plans, DHCS will carve out the COVID-19 vaccine from Medi-Cal MCPs and will reimburse providers under the fee-for-service delivery system for both medical and pharmacy claims. This approach will ease program administration, eliminate challenges with out-of-network provider reimbursements, and keep vaccine administration fee rates consistent for providers regardless of delivery system.

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17. How will Medi-Cal reimburse providers for the administration of the COVID-19 vaccine?

Medi-Cal proposes to reimburse the associated COVID-19 vaccine administration fee at the allowable Medicare rate for all claims (medical, outpatient, and pharmacy) based on the number of required doses. As the federal government will pay for the initial vaccines, there is no Medi-Cal provider reimbursement for the COVID-19 vaccine itself. For more information about the COVID-19 vaccine, please visit <https://covid19.ca.gov/> and DHCS' [COVID-19 Response website](#).

18. Where can I find DHCS' guidance and coverage/reimbursement policy relative to COVID-19 vaccine?

DHCS' initial and upcoming [COVID-19 Vaccine Administration policy](#) can be found on DHCS' website. The policy and reimbursement guidance will be updated upon additional CMS guidance and/or approvals of requested waivers and will be included in future news article(s) and Managed Care All Plan letter(s). Medi-Cal Provider Manual updates-are under development and, once finalized, will be posted to DHCS' Medi-Cal website.

For additional information about COVID-19, please visit <https://covid19.ca.gov/> and DHCS' [COVID-19 Response website](#).

19. Will COVID-19 OTC Self-Administered Antigen Tests be “carved out” of Managed Care Plans (MCPs)?

DHCS' coverage of COVID-19 OTC Self-Administered Antigen Tests as a pharmacy-billed benefit through Medi-Cal Rx was effective February 1, 2022 and in accordance with current Centers for Disease Control and Prevention (CDC) recommendations. Quantity limitations and specific product coverage criteria apply. For additional information, please visit the Medi-Cal Rx Provider Portal via the Medi-Cal Rx Web Portal and refer to the list titled Covered Emergency Use of Authorization (EUA) COVID-19 Antigen Tests under Forms & Information or refer to the Over-the-Counter (OTC) COVID-19 Antigen Test Kits section in the Medi-Cal Rx Provider Manual.

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Procurement Information

20. How will DHCS administer Medi-Cal Rx?

DHCS 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 13.5 million Medi-Cal beneficiaries. On December 13, 2019, DHCS awarded a contract to MMA to provide a comprehensive suite of administrative services as directed by DHCS, 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.

21. 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 DHCS.
- 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 DHCS website.
- December 13, 2019: DHCS awarded contract to Magellan Medicaid Administration, Inc.
- December 20, 2019: Contract Effective Date.
- January 1, 2022: Medi-Cal Rx Full Assumption of Operations takes place.

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22. 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. (MMA).

23. What roles and responsibilities will Medi-Cal Managed Care Plans (MCPs) maintain upon Medi-Cal Rx full Assumption of Operations?

Medi-Cal MCPs 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 Use Review Board and other DHCS-driven pharmacy committee meetings.
- Continued and ongoing participation in post-claim adjudication Drug Use Review (DUR) activities such as Retrospective DUR (RetroDUR) (as necessary for care coordination), educational programs, and submission of DUR annual report.

24. What roles and responsibilities will DHCS maintain upon Medi-Cal Rx full Assumption of Operations?

DHCS 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 (PA)/utilization management
- Negotiation of, and contracting for, state supplemental drug rebates.

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- Reviewing and issuing final determinations regarding all PA denials for Medi-Cal Rx benefits, including those for California Children’s Services (CCS) program/Genetically Handicapped Persons Program (GHPP).
- 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 Use Review Board and other Department-driven pharmacy committees, in collaboration with MMA.
- Contract management and oversight/monitoring of MMA.

25. What roles and responsibilities will the Medi-Cal Rx Contractor assume upon Medi-Cal Rx full Assumption of Operations?

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

- Providing a 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 DHCS, Customer Service Center to support all provider and beneficiary calls, as well as outreach, training, and informing materials.
- Providing direct Medi-Cal Managed Care Plan (MCP) liaisons to assist with care coordination and clinical issues.
- Providing real-time access into MMA’s electronic environment via a secure portal to all Medi-Cal providers (prescribers and pharmacies) and MCPs, Mental Health Plans, and Substance Use Disorder Plans.
- 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 (PA) adjudication occurs within 24 hours, inclusive of CCS

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program/GHPP (note: all pharmacy PA denials will require DHCS' review prior to final determination).

- Providing Prospective and Retrospective Drug Use Review (DUR) services.
- Providing data feeds (at least daily) to Medi-Cal MCPs to support their responsibilities of beneficiary care coordination, carrying out clinical aspects of pharmacy adherence, and disease and medication management.
- Providing drug rebate administration services that are compliant with federal and state laws and adhere to DHCS' policies and direction.

Between January 1, 2021, and Medi-Cal Rx full Assumption of Operations on January 1, 2022, DHCS – in partnership with MMA – will be providing various transitional supports and services (TSS), as outlined in greater detail below in **questions #30 and #31**.

26. How will DHCS 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, MMA is required to adhere to all existing state and federal requirements as well as DHCS' policies relating to sensitive data and privacy.

27. 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](#). Final Proposals were due by October 1, 2019 at 4 p.m. PDT. The procurement process is now closed.

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Transition Information

28. When will the Medi-Cal Rx full Assumption of Operations (AOO) take place?

Medi-Cal Rx full AOO, as described in **questions #23-25**, inclusive of claims administration and prior authorization adjudication functionalities, will take place on January 1, 2022. DHCS will provide updates in this space through existing stakeholder forums and communication channels.

29. Why was the planned Go-Live date of April 1, 2021 for Medi-Cal Rx full Assumption of Operations delayed?

DHCS delayed the planned Go-Live date of April 1, 2021, for Medi-Cal Rx because of the need to review new conflict avoidance protocols submitted by MMA, the project's contracted vendor.

In January 2021, Centene Corporation announced that it plans to acquire Magellan. Centene operates – through subsidiaries – managed care plans and pharmacies that participate in Medi-Cal. This transaction was unexpected and requires additional time for exploration of acceptable conflict avoidance protocols to ensure that there will be acceptable firewalls between the corporate entities to protect the pharmacy claims data of all Medi-Cal beneficiaries, and to protect other proprietary information.

Medi-Cal Rx remains of utmost importance to the State of California as a tool to standardize the Medi-Cal pharmacy benefit statewide under one delivery system. Medi-Cal Rx will apply statewide utilization management protocols to all outpatient drugs, standardizing the experience for all Medi-Cal beneficiaries and providers. Medi-Cal Rx will also strengthen California's ability to negotiate state supplemental drug rebates with drug manufacturers, helping to reduce pharmaceutical costs.

DHCS has completed its review of the Conflict Avoidance Plan (CAP) submitted by MMA and announced a January 1, 2022, implementation date.

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30. Will Medi-Cal Rx use a “phased” approach to transition services?

No, full implementation of Medi-Cal Rx will take place on January 1, 2022. However, between January 1, 2021 and Medi-Cal Rx full Assumption of Operations, DHCS, in partnership with MMA, will be providing various Medi-Cal Rx Transitional Supports and Services (TSS), including but not limited to:

- Allowing Medi-Cal providers, Managed Care Plans (MCPs), and other interested parties to register for the Medi-Cal Rx secure portals and participate in comprehensive trainings that ensure greater overall understanding of the project and support operational readiness for providers and MCPs.
- Standing up and mobilizing the Medi-Cal Rx Customer Service Center (CSC) to allow experts at the CSC to field and answer questions from Medi-Cal beneficiaries, providers, MCPs, and other interested parties, potentially preempting confusion and other potential challenges once the full implementation of Medi-Cal Rx occurs. While the CSC experts will not be providing the full suite of services, they will be after the Medi-Cal Rx full AOO, they will be able to provide important TSS, including proactive outreach to providers, as well as targeted assistance and critical information, relative to Medi-Cal Rx tools and functionalities.
- Providing additional time for MCPs to interact with and build rapport with dedicated Medi-Cal Rx clinical liaisons, who will help Magellan build accurate and comprehensive MCP profiles to ensure that the individualized needs of the populations served by each MCP are met.
- Allowing DHCS and Magellan to roll out additional Medi-Cal Rx website and secure portal functionalities and tools in advance of Medi-Cal Rx full AOO, including, but not limited to, the new Medi-Cal Rx Pharmacy Locator, Medi-Cal Rx Provider Manual, Contract Drugs List, and other related policy and programmatic information. While all components of the secure portals may not be immediately active, DHCS is planning to phase in other TSS in the future.

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After the Medi-Cal Rx full AOO, MMA will assume responsibility for all remaining administrative services necessary to support Medi-Cal Rx, including, but not limited to, the following:

- Extending CSC hours to 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 DHCS, to support all provider and beneficiary calls, as well as outreach, training, and informing materials.
- Claims management, prior authorization and utilization management, provider and beneficiary support services, and other ancillary and reporting services.

For additional details, please see **questions #23-25**.

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

DHCS 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. DHCS intends to continue these types of engagement efforts and is committed to working with its external partners, including Medi-Cal MCPs, counties, providers, consumer advocates, and beneficiaries, to ensure a smooth and successful transition. For example, DHCS 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 DHCS' implementation efforts.

Going forward, DHCS 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.

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

DHCS will work in collaboration with MMA to ensure all interested parties (including, but not limited to, Medi-Cal MCPs, Mental Health Plans, Substance Use Disorder Plans, providers, and beneficiaries) are informed of the transition and other related changes.

Communication will be disseminated via several methods including, but not limited to, the following:

- A new [Medi-Cal Rx Web Portal](#) 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-Cal Rx Web Portal to allow interested parties to sign up and receive regular Medi-Cal Rx updates by email.
- From August 2020 onwards, interested parties can see bulletins regarding changes posted on the Medi-Cal Rx Web Portal.
- A series of trainings and educational materials for Medi-Cal providers and MCPs are available from the new Medi-Cal Rx website. MCPs and providers have had the ability to sign up for training and education events since September 2020.
- Notices to Medi-Cal beneficiaries in both MCPs and fee-for-service delivery systems were mailed on or about October 1, 2020, November 1, 2020, and December 15, 2020. Notices to Medi-Cal beneficiaries were also mailed beginning in late March 2021 informing them of the delay to the Medi-Cal Rx full Assumption of Operations (AOO). Additional notices to Medi-Cal beneficiaries were mailed on or about November 1, 2021, announcing the AOO on January 1, 2022.
- A Medi-Cal MCP Medi-Cal Rx Outreach Campaign, conducted through either a traditional outbound call campaign or other alternative communication modalities, as approved by DHCS, to enrolled members.

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- Updates to the 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 MMA, as directed by DHCS.
- Updates to Medi-Cal MCP 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 MCPs, 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 MCPs that provides guidance from a regulatory, compliance, and filing perspective.
- Updates to the Medi-Cal MCP rates.
- Regular updates via existing stakeholder processes and workgroups, including but not limited to DHCS' bimonthly Stakeholder Communication Update, Medi-Cal Rx Public Forum, Medi-Cal Global Drug Use Review Board, Medi-Cal Pharmacy Directors' Meeting, Stakeholder Advisory Committee, California Children's Services Advisory Committee, etc.

33. How will DHCS 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 (MCPs) with the Medi-Cal Rx full Assumption of Operations (AOO), DHCS will provide various Medi-Cal Rx Transitional Supports and Services (TSS) between January 1, 2021, through Medi-Cal Rx full AOO on January 1, 2022, as described in more detail **in question #30** above and 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 (PA) 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

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certain drug classes/categories. 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 Medi-Cal Contract Drugs 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 PA 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. DHCS' [Pharmacy Transition Policy](#) is available on the Medi-Cal Rx Transition webpage.

34. Will DHCS 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, MMA 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 DHCS and Medi-Cal Managed Care Plans (MCPs) to Medi-Cal beneficiaries regarding the transition.
- Providing temporary flexibility for obtaining prior authorization (PA) on drugs dispensed during the transition period by allowing ongoing (drug treatments initiated prior to Medi-Cal Rx full Assumption of Operations) drugs to be dispensed and billed without first having an approved PA. However, prospective Drug Use Review requirements for drug safety will still apply.

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- 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.

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

To assist Medi-Cal beneficiaries with the full Medi-Cal Rx transition, DHCS will provide various Medi-Cal Rx Transitional Supports and Services (TSS) between January 1, 2021, through Medi-Cal Rx full Assumption of Operations on January 1, 2022, as described in more detail in **question #30 above**. In addition, DHCS' pharmacy transition policy, as described in **question #33 above**, and in more detail in the link below, will use strategies such as the following:

- "Grandfathering" previously approved prior authorizations (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 Managed Care Plans (MCPs), for drugs not on the Medi-Cal Contract Drugs List, or that otherwise have PA requirements under Medi-Cal Rx.

For more information, please review DHCS' [Pharmacy Transition Policy](#) on the Medi-Cal Rx Transition webpage.

36. Should Medi-Cal Managed Care Plans (MCPs) discontinue and/or void any prior authorizations (PAs) that were adjudicated and approved by the Medi-Cal MCP on or before Medi-Cal Rx full Assumption of Operations (AOO)?

No, Medi-Cal MCPs should not discontinue and/or void such PAs and should similarly not have authorizations automatically expire a day before Medi-Cal Rx full AOO. Both DHCS and Medi-Cal MCPs 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.

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Data Feeds, Electronic Access, & Other Clinical Supports

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

Yes, Medi-Cal Rx will provide data feeds (at least daily) to Medi-Cal MCPs to support their responsibilities of beneficiary care coordination, carrying out clinical aspects of pharmacy adherence, and disease and medication management. DHCS 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 Medi-Cal Rx full Assumption of Operations.

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

38. What additional clinical and care coordination support will Medi-Cal Rx provide to Medi-Cal Managed Care Plans (MCPs)?

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

- Providing a dedicated Medi-Cal MCP clinical liaison team to interface with the Medi-Cal MCPs, other MMA staff, and MMA's portal/environment to assist with and resolve clinical pharmacy-related issues for Medi-Cal Rx, including those involving prior authorization, as directed by DHCS.
- Maintaining sufficient staffing ratios of dedicated Medi-Cal MCP clinical liaisons to ensure this level of access is maintained for Medi-Cal MCPs.
- Providing access to the Medi-Cal MCP clinical liaisons through Medi-Cal Rx's dedicated Integrated Voice Response system to assist and resolve clinical pharmacy-related issues.

For more information, please see the [Medi-Cal Rx MCP Clinical Liaison Policy](#) and the [Medi-Cal Rx Website and Pharmacy Portal Policy](#).

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Provider Outreach, Education, & Training

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

DHCS, in collaboration with MMA, is dedicated to providing Medi-Cal provider customer support services, including but not limited to the following:

- A Customer Service Center (CSC) to support all provider calls, 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 DHCS.
- Outreach, training, and informing materials to Medi-Cal providers, Medi-Cal Managed Care Plans (MCPs), and other entities.
- Web-based services to support communication and tools for Medi-Cal Rx.
- Real-time access into MMA's electronic environment via a secure portal.
- Other services and supports to ensure a smooth and effective transition (e.g., Medi-Cal Rx transitional supports and services (TSS) and 180-day pharmacy transitional period).

In addition, MMA's Medi-Cal Rx CSC Representatives will act on behalf of DHCS 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 DHCS' dedicated [Medi-Cal Rx Web Portal](#). 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.

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Beneficiary Customer Service & Related Supports

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

DHCS, in collaboration with MMA, is dedicated to providing beneficiary customer service and related supports, including but not limited to the following:

- A Customer Service Center (CSC) to support all beneficiary calls, 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 DHCS.
- 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 (MPL) tool is available through the [Medi-Cal Rx Web Portal](#) and includes all Medi-Cal Rx eligible pharmacies.
- An Interactive Voice Response (IVR) system to provide:
 - Recorded information
 - Self-service options
 - Ability to request follow-up from customer service, such as a callback phone call or information to be provided by mail or email

In addition, MMA's Medi-Cal Rx CSC Representatives will act on behalf of DHCS 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.

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Beneficiary Eligibility, Share of Cost, & Other Health Coverage Related Questions

41. Relative to the transition to Medi-Cal Rx, what happens to the claims if a beneficiary's eligibility is in "on-hold" status and is waiting for the county to adjust the beneficiary's eligibility?

The "on-hold" status pertains to the beneficiary's Medi-Cal Managed Care Plan eligibility status and there is no change to this process under Medi-Cal Rx. Medi-Cal Rx will be evaluating the Health Care Plan (HCP) status in the Medi-Cal Eligibility Data System (MEDS) to determine an active versus inactive status and proceed accordingly.

42. Relative to Medi-Cal Rx, what happens if beneficiary has moved and the county has not updated the beneficiary's eligibility?

There is no change to Medi-Cal's overarching eligibility processes as a result of the transition to Medi-Cal Rx. Medi-Cal Rx will be evaluating the Health Care Plan (HCP) status in on the Medi-Cal Eligibility Data System (MEDS) to determine an active versus inactive status and proceed accordingly.

43. Are there any changes to Medi-Cal's Share of Cost (SOC) policy where self-pay and spend-down has to occur before the Medi-Cal benefits?

Medi-Cal's overarching SOC policy is not changing, and associated processes and policies would remain unchanged under Medi-Cal Rx.

44. When Medi-Cal beneficiaries have Other Health Coverage (OHC), which health coverage and benefit package is considered primary?

Medi-Cal's overarching OHC policy is not changing and, in most instances, Medi-Cal is the payer of last resort.

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45. Will Medi-Cal Rx impact Medi-Cal beneficiaries who have both Medi-Cal and Medicare (Part D) coverage?

No. Medi-Cal Rx does not impact or otherwise change any drug coverage for Medi-Cal beneficiaries who have both Medi-Cal and Medicare (Part D) coverage. Medi-Cal may cover prescription drug benefits that Medicare (Part D) may not, so Medi-Cal beneficiaries should also discuss with their providers.

Medi-Cal Fee-For-Service Reimbursement Methodology

46. 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 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.

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

DHCS will utilize drug reimbursement methodologies as defined in state law and the Medi-Cal State Plan. If DHCS 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).

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48. Will DHCS reimburse specialty pharmacies for medication management services provided to patients identified as “high-risk” for compliance, adherence, or medication misuse concerns?

DHCS is exploring options for reimbursing specialty pharmacies for medication management services.

Policy Considerations

49. What is Medi-Cal’s Contract Drugs List (CDL)?

DHCS maintains the Medi-Cal CDL, which is DHCS’ 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 CDL, then it does not require an approved prior authorization (PA) for coverage. Alternatively, if a drug is not listed on the Medi-Cal CDL, then it requires an approved PA for coverage. Please note that even if a drug is listed on the Medi-Cal CDL, it may still require an approved PA for coverage; however, if a certain drug on the Medi-Cal CDL requires an approved PA, then DHCS’ policy would clearly articulate that requirement.

50. How will Medi-Cal Rx affect Medi-Cal’s Contract Drugs List (CDL), and does DHCS take anything else into consideration for its Medi-Cal drug coverage policies?

Medi-Cal Rx will use the existing DHCS-approved Medi-Cal CDL as its preferred set of covered drugs. In addition, DHCS’ pharmacy drug coverage policies will also take into consideration:

- All federal Food and Drug Administration (FDA)-approved covered outpatient drugs, as defined by CMS, subject to medical necessity.
- DHCS’ 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 coverage.

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51. Will Medi-Cal Rx consider local exceptions to Medi-Cal’s Contract Drugs List (CDL)?

No. Medi-Cal Rx will use a single, statewide, and DHCS-approved Medi-Cal CDL to standardize the Medi-Cal pharmacy benefit.

52. How does DHCS make determinations to add or delete drugs from the Contract Drugs List (CDL)?

DHCS 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 DHCS-initiated IDP review, if applicable. Once an IDP is received, DHCS 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, DHCS also consults with the Medi-Cal Drug Advisory Committee (Committee), as required by Welfare and Institutions Code Section 14105.4. The Committee is composed of members who are appointed by DHCS’ Director – including community physicians and pharmacists, faculty members from academic pharmacy institutions, and Medi-Cal beneficiaries – and assists DHCS 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 DHCS 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

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Food and Drug Administration (FDA)-approved indications, manufacturer, fiscal/cost impact, clinical criteria, etc.

DHCS 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.

As DHCS moves closer to Medi-Cal Rx full Assumption of Operations on January 1, 2022, it is continuing its efforts to closely analyze variances and gaps between Medi-Cal Managed Care Plan (MCP) formularies and the Medi-Cal CDL. As a product of DHCS' analysis, and in an effort to drive down the total number of required prior authorizations, numerous medications have been added to the Medi-Cal CDL since January 2020, and DHCS will continue this review on a monthly basis to add more medications to the Medi-Cal CDL.

53. Are there any statutory changes related to Medi-Cal Rx?

Yes, DHCS' 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.

54. For drugs requiring prior authorization (PA), do prescribers or providers need to submit a PA each time a drug is dispensed?

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

55. Has DHCS made policy changes to allow for multi-year prior authorization (PA) approvals?

As part of Medi-Cal Rx, DHCS is making changes to allow extended duration/multi-year PA 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,

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

56. Will DHCS consider making policy changes to allow for enhanced and/or expanded auto-adjudication functionalities?

As part of Medi-Cal Rx, DHCS 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 (PA) 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.

57. 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, DHCS has shared this information externally at various stakeholder events, including but not limited to the Medi-Cal Rx Managed Care Plan (MCP) workgroup and Medi-Cal Rx Advisory workgroup. For more information regarding DHCS' current pharmacy policies and procedures in this space, please see the reference resources and material on [DHCS' website](#).

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In addition, as part of Medi-Cal Rx, DHCS 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, DHCS will consider implementing the enhanced opioid management services proposed.

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

DHCS will not implement a lock-in program as part of the Medi-Cal Rx full Assumption of Operations on January 1, 2022 but will be evaluating options with MMA in the future. As part of the Medi-Cal Rx Request for Proposal #19-96125, DHCS 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, DHCS is aware that approximately 50 percent of Medi-Cal Managed Care Plans (MCPs) utilize pharmacy lock-in programs today, so through stakeholder engagement efforts, DHCS will be looking to learn more and utilize best practices for Medi-Cal Rx.

59. Where can I find Medi-Cal Rx All Plan Letter for Medi-Cal Managed Care Plans (MCPs) that provides guidance from a policy and programmatic perspective?

DHCS' new Medi-Cal Rx [All Plan Letter APL 20-020](#) for Medi-Cal MCPs can be found on DHCS' website.

60. Where can I find the Department of Managed Health Care All Plan Letter, relative to Medi-Cal Rx, for Medi-Cal Managed Care Plans (MCPs) that provides guidance from a regulatory, compliance, and filing perspective?

The Department of Managed Health Care [All Plan Letter APL 20-035](#) relative to Medi-Cal Rx is available on the Department of Managed Health Care's website.

61. Where can I find the Informational Notice (IN) for the California Children's Services (CCS) program and the Genetically Handicapped Persons Program (GHPP) relative to Medi-Cal Rx?

The [IN 20-03 for CCS and GHPP programs](#) relative to Medi-Cal Rx is available on DHCS' website.

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62. Where can I find the Behavioral Health Information Notice (BHIN) that provides guidance related to Medi-Cal Rx for county mental health and Substance Use Disorder (SUD) services?

The BHIN that provides guidance related to Medi-Cal Rx for county mental health and SUD services is currently under development and, once finalized, will be available on the [Behavioral Health Information Notices page](#) on DHCS' website.

Finalization of this BHIN has been delayed due to the delay of Medi-Cal Rx Assumption of Operations.

Prior Authorization/Utilization Management

63. Under Medi-Cal Rx, how will prior authorization (PA) requests be reviewed and adjudicated?

DHCS shall, in collaboration with MMA, process PA requests and provide a response to the submitting provider within 24 hours of receiving a PA request, pursuant to Welfare and Institutions Code Section 14133.37. A more detailed process document is posted on DHCS' [Medi-Cal Rx Transition website](#).

64. Will Medi-Cal Managed Care Plans (MCPs) be allowed to contract with the Medi-Cal Rx Contractor to perform prior authorization (PA)?

No. Since Medi-Cal MCPs will no longer be contractually responsible for the Medi-Cal pharmacy benefit after the Medi-Cal Rx full Assumption of Operations on January 1, 2022, all PA adjudications and related processes will be handed by MMA, consistent with contractual requirements and at the direction of DHCS.

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340B Federal Drug Discount Program

65. 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”).

66. 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 (HRSA), the Centers for Disease Control and Prevention, the Department of Health and Human Services’ Office of Population Affairs, and the Indian Health Service. Eligible covered entities are defined in statute and include HRSA-supported health centers and lookalikes, 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 HRSA, 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

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eligible patients, state Medicaid programs may only collect rebates on drugs purchased outside of the 340B Program. Additional details are available on HRSA's [340B Drug Pricing Program website](#).

67. 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 (MCPs) 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.

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68. 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.

69. How is DHCS addressing the concerns raised as to the effect of Medi-Cal Rx on the administration of the 340B Program?

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 Program and related processes, as well as to further discuss potential options for mitigation.

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

DHCS convened a stakeholder workgroup to develop the methodology for the distribution of supplemental pool payments to qualifying non-hospital 340B community clinics. The workgroup topics included the eligibility criteria for receipt of supplemental payments, the aggregate amount of pool funding available in a respective fiscal year, and the criteria for apportioning the pool funding among qualifying non-hospital 340B community clinics including the timing, frequency, and amount of the resultant supplemental payments. DHCS is currently finalizing the distribution methodology. DHCS will submit a State Plan Amendment to obtain federal approval. The [proposed State Plan Amendment](#) has been published for public comment.

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Medi-Cal Rx Complaints/Grievances Resolution & Appeals Processes

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

In partnership with MMA, DHCS 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, DHCS' [Medi-Cal Rx Complaints and Grievances Policy](#) is posted to DHCS' Medi-Cal Rx Transition webpage.

72. 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 after the Medi-Cal Rx full Assumption of Operations on January 1, 2022, will be handled through Medi-Cal Rx's Customer Service Center for triaging, research, and resolution. For more information, please see DHCS' [Medi-Cal Rx Complaints and Grievances Policy](#).

73. How will DHCS address complaints and grievances that arose for pharmacy-related services provided by the Medi-Cal Managed Care Plans (MCPs) on or before Medi-Cal Rx full Assumption of Operations (AOO)?

Pharmacy-related complaints and grievances for services rendered or requested on or before Medi-Cal Rx full AOO on January 1, 2022, by a Medi-Cal MCP, which are for services the MCP was at risk for, must be fully adjudicated by the Medi-Cal MCP in accordance with DHCS' All Plan Letter 17-006 and any subsequent versions.

Pharmacy-related complaints and grievances received after the Medi-Cal Rx full AOO by the Medi-Cal Rx Customer Service Center (CSC) for services provided by a Medi-Cal MCP on or before Medi-Cal Rx full AOO will be transferred by the Medi-Cal Rx CSC to the appropriate Medi-Cal MCP for full resolution.

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The Medi-Cal Rx CSC will advise Medi-Cal MCP members that they should contact their MCP for such pharmacy-related complaints and grievances.

The right of Medi-Cal MCP members to submit complaints and grievances to their Medi-Cal MCPs for pharmacy-related services rendered on or before Medi-Cal Rx full AOO are not impacted by Medi-Cal Rx.

74. Will Medi-Cal Rx have a mechanism to share information about complaints and grievances with the beneficiary's Managed Care Plan (MCP)?

Medi-Cal MCPs 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 publicly through various avenues such as DHCS' website and Open Data Portal.

75. 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. Fair Hearings can be requested online or by phone, fax, mail, or email. For more information about the State Hearing process, refer to the Notice of Action (NOA) that you received or visit DHCS' [Medi-Cal Fair Hearing website](#) or [California Department of Social Services' website](#). 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.

76. 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.

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77. 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 of the NOA, or before the date the notice says your treatment will stop or change, whichever is later.

When requesting a 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.

78. 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 DHCS' [Medi-Cal Fair Hearing website](#).

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

No, at this time, DHCS 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 MCPs; rather, they will initially be made by MMA and reviewed by DHCS 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, applicable state law requirements, and DHCS' policies/procedures.

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

All pharmacy-related appeals for Medi-Cal Rx services provided after the Medi-Cal Rx full Assumption of Operations will be handled through Medi-Cal Rx utilizing the existing State Fair Hearing process, administered through the California Department of Social Services, as described in **questions #75-78 above**.

81. How will DHCS address appeals from Medi-Cal Managed Care Plan (MCP) beneficiaries that arose for pharmacy-related services provided by the Medi-Cal MCPs on or before Medi-Cal Rx full Assumption of Operations (AOO)?

Medi-Cal MCPs must resolve all Medi-Cal MCP beneficiary appeals that originated as a result of a MCP decision relative to pharmacy-related services for which the MCP was at risk for on or before Medi-Cal Rx full AOO. 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 MCPs rendered on or before Medi-Cal Rx full AOO, are not impacted by Medi-Cal Rx.

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Fiscal Impact/Assessment

82. Will DHCS be completing a fiscal analysis prior to the transition?

Yes. DHCS has completed a fiscal analysis for Medi-Cal Rx and has shared this information publicly. DHCS anticipates approximately \$309 million General Fund in annual savings by 2023-24. DHCS will be including the fiscal estimate for Medi-Cal Rx as part of the biannual Medi-Cal Estimate process, and will be providing necessary adjustments, if any, to the fiscal analysis on an ongoing basis moving forward.

83. What are the elements of our projected \$309 million General Fund (GF) in annual savings by 2023-24?

The elements of the projected \$309 million GF savings by 2023-24 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 that have three (3) or more generically equivalent options available.
- Reduction of costs related to administrative functions of multiple pharmacy benefits managers used by various Medi-Cal Managed Care Plans (MCPs).
- Medi-Cal fee-for-service reimbursement methodology, which includes \$10.05/\$13.20 dispensing fees.
- A new supplemental payment for non-hospital 340B clinics, effective with the Medi-Cal Rx full Assumption of Operations on January 1, 2022, which was included in the 2021-22 budget. See question #70 above for more information.

As noted in question #82 above, any adjustments to the Medi-Cal Rx fiscal estimate, inclusive of savings projections, will be updated as part of the biannual Medi-Cal Estimate process.

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Miscellaneous/Other Information

84. 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. DHCS will work to ensure continuation of an effective mail-order service option for Medi-Cal pharmacy services.

85. Will DHCS make Medi-Cal pharmacy supplemental drug rebate contracts public?

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

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

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

87. 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 DHCS indicated that 6,223 were enrolled Medi-Cal fee-for-service pharmacy providers.

88. Will Medi-Cal engage in an effort to enroll the pharmacies that are part of Managed Care Plan (MCP) networks but not enrolled in Medi-Cal fee-for-service?

After the Medi-Cal Rx full Assumption of Operations (AOO) on January 1, 2022, 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 the vast majority of all California-licensed pharmacies. Medi-Cal MCPs currently use these same pharmacies as well as some additional pharmacies not yet enrolled as

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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 full AOO.

89. In what capacity will Medi-Cal Managed Care Plans (MCPs) and other entities be expected to participate in meetings for the Medi-Cal Global Drug Use Review Board and other DHCS-driven pharmacy committees?

Presently and ongoing post-transition, DHCS expects that its Medi-Cal MCPs and other interested parties will continue to participate in meetings related to the Medi-Cal Global Drug Use Review Board and in other DHCS-driven pharmacy committees, as needed. In addition, DHCS is actively evaluating and assessing how to more effectively engage and collaborate with Medi-Cal MCPs and other entities in discussions and decisions relating to Medi-Cal pharmacy policy moving forward.

90. Does DHCS 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.

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