

Medi-Cal Rx: Transitioning Medi-Cal Pharmacy Services from Managed Care to Fee-for-Service – Frequently Asked Questions (FAQs)

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The following Frequently Asked Questions (FAQs) document provides additional guidance and clarification to Medi-Cal members, 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.

For information regarding Medi-Cal Rx, visit DHCS' dedicated [Medi-Cal Rx Transition page](#). In addition, general questions regarding Medi-Cal Rx may also be submitted to DHCS via email at Medi-Cal.PharmacyBenefits@dhcs.ca.gov.

General Information

1. Why did DHCS transition the Medi-Cal pharmacy benefit from the Medi-Cal managed care delivery system to a fee-for-service (FFS) delivery system?

DHCS transitioned Medi-Cal pharmacy services from the Medi-Cal managed care delivery system to the Medi-Cal FFS delivery system as a result of Governor Gavin 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 members, and to increase overall access by allowing members to receive pharmacy services from the broader FFS 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 about CalAIM, visit the [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 are administered through the FFS delivery system by Prime Therapeutics State Government Solutions LLC (Prime) as of full Assumption of Operations (AOO).

3. What does full Medi-Cal Rx AOO represent?

Medi-Cal Rx AOO refers to the date Prime assumed operational responsibility for all remaining administrative services necessary to support Medi-Cal Rx, including but not limited to claims management, prior authorization (PA) and utilization management (UM), provider and member support services, and other ancillary and reporting services. Medi-Cal Rx full AOO, as described in questions #22-24, took place on January 1, 2022. For additional details, see questions #27-29.

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4. What are the advantages of transitioning Medi-Cal pharmacy benefits from managed care to FFS?

Transitioning pharmacy services from Medi-Cal managed care to FFS accomplishes the following, among other things:

- Standardizes the Medi-Cal pharmacy benefit statewide, under one delivery system.
- Improves 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.
- Applies statewide UM protocols to all outpatient drugs, as appropriate.
- Strengthens California's ability to negotiate state supplemental drug rebates with drug manufacturers as the largest Medicaid program with more than 15 million members.

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

Yes. DHCS requested federal approval from the Centers for Medicare & Medicaid Services (CMS) to transition pharmacy benefits from the managed care delivery system to FFS 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 (CODs) and physician administered drugs (PADs), as described in the [Medi-Cal Rx All Plan Letter \(APL 22-012\)](#), effective January 1, 2022.

6. Which Medi-Cal MCPs are and are not impacted by Medi-Cal Rx?

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

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

Medi-Cal Rx applies to both CCS and GHPP. Since the Medi-Cal Rx full AOO, all requests for PAs (formerly Service Authorization Requests [SARs] or Treatment Authorization Requests [TARs]) – for both independent and dependent counties, and CCS-only, GHPP-only, and CCS/GHPP Medi-Cal members – process through Medi-Cal Rx for pharmacy benefits billed on pharmacy claims.

As noted in question #23, DHCS maintains all drug coverage and policy responsibility and sets all criteria relative to PA adjudication. Moreover, recognizing the specialized health care needs of the CCS/GHPP populations, DHCS continues to work closely and in partnership with the CCS Advisory Group and other key stakeholders in this space.

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8. What has not changed as part of Medi-Cal Rx?

Medi-Cal Rx did 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 (LTC) setting (including Skilled Nursing Facilities [SNFs] and other Intermediate Care Facilities [ICFs]), regardless of delivery system.
- Existing Medi-Cal managed care pharmacy carve-outs (for example, blood factor, HIV/AIDS drugs, antipsychotics, or drugs used to treat substance use disorder [SUD]).
- Any pharmacy services that are billed as a medical and/or institutional claim instead of a pharmacy claim.
- The State Fair Hearing (SFH) process, as defined in applicable California state law.

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

As noted in question #8, if a drug is provided as part of the bundled rate for services provided by an LTC/SNF, then it will remain the responsibility of the MCP. Otherwise, if prescription drugs are not part of the bundled rate for services provided by an LTC/SNF and instead are billed on an FFS basis, then the financial responsibility for those drugs is 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 are 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 is responsible, or the California Medicaid Management Information System Fiscal Intermediary (CA-MMIS FI), if the member is in FFS.

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

Medi-Cal Rx has taken over the responsibility from Medi-Cal MCPs for administering the following when billed by a pharmacy on a pharmacy claim:

- CODs, including certain PADs
- Specific medical supplies
- Enteral nutrition products

Drugs included in services that are not capitated to MCPs (for example, blood factor, HIV/AIDS drugs, antipsychotics, or drugs used to treat SUD) remain noncapitated (carved out) regardless of claim type (that is, pharmacy or medical claim). Medical claims for these classes of drugs should continue to be submitted as FFS claims to the Medi-Cal FI. Medical providers are reminded that drugs not listed on the pharmacy Contract Drugs List (CDL) and administered by a nonpharmacy-based medical health care professional should typically be billed as medical claims by the administering provider and not billed by a pharmacy.

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New additions to the list of noncapitated classes of drugs carve-out list typically take at least 60 days before claims can be successfully billed. Providers are asked to hold their claims until the system is ready to accept them.

Only specific medical supplies and enteral nutrition products listed in the covered products lists located on the [Contract Drugs & Covered Products Lists](#) page of the [Medi-Cal Rx Web Portal](#) are covered Medi-Cal Rx benefits. Medical supplies and enteral nutrition products are identified as “partial” carve outs in the [Medi-Cal Rx Scope document](#); contracted or covered Medi-Cal Rx medical supplies and enteral nutrition claims billed on a pharmacy claim must be submitted to Medi-Cal Rx. Non-listed or non-contracted medical supplies and enteral nutrition products could be reimbursable through either Medi-Cal MCPs or the FFS FI, as an HCPCS-billed Durable Medical Equipment (DME) benefit on a medical claim. NDC-billed claims submitted after transition to Medi-Cal Rx for products not found on this list are denied.

For more information, refer to DHCS’ [Medi-Cal Rx Scope document](#) located on the DHCS website. This document provides additional context and information related to DHCS’ implementation of the Medi-Cal managed care to the FFS pharmacy carve out. It also provides an inventory of the Medi-Cal pharmacy benefit, characterized as either not subject to the carve out (that is, those pharmacy benefits that are billed on medical and institutional claims) or subject to the carve out (that is, all pharmacy benefits that are billed on pharmacy claims to Medi-Cal Rx).

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

The diabetic test strips (for urine, blood glucose, and ketones) and lancets benefit policy did not change under Medi-Cal Rx and is subject to the list of contracted products and the criteria currently published in the *Medical Supplies* section of the [Medi-Cal Rx 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 are pharmacy-billed medical supply benefits through Medi-Cal Rx effective January 1, 2022, and are restricted to the products on the [List of Contracted Self-Monitoring Blood Glucose Systems \(Glucometers\), Control Solutions, and Lancing Devices](#) (available on the Medi-Cal Rx Web Portal).

Applicable products in this category not on this list are considered ineligible for coverage consideration by Medi-Cal Rx as a pharmacy benefit. These non-contracted or non-listed products could be reimbursable through either Medi-Cal MCPs or the FFS FI, as an HCPCS-billed DME benefit on a medical claim.

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12. How does DHCS currently approach coverage of disposable external ambulatory insulin delivery systems (Omnipod® and V-Go®) and has that changed since the Medi-Cal Rx full AOO?

Specific disposable insulin delivery devices (DIDDs) are pharmacy-billed medical supply benefits through Medi-Cal Rx, effective January 1, 2022, and are restricted to the products on the [List of Covered Disposable Insulin Delivery Devices](#) on the [Medi-Cal Rx Web Portal](#). Non-contracted or non-listed DIDD products could be reimbursable through the member's medical benefit, either to the member's Medi-Cal MCP or the FFS FI, as an HCPCS-billed DME benefit on a medical claim.

DIDDs require a PA for reimbursement and specific coverage criteria apply. DIDDs are included in the transition policy. For claims previously paid as a medical benefit billed on a CMS-1500 form, providers should include the active PA previously submitted with the medical benefit 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 does DHCS approach coverage of Continuous Glucose Monitoring (CGM) Systems, other DME, DME supplies, and disposable medical supplies after the Medi-Cal Rx full AOO?

Specific CGM Systems are pharmacy-billed medical supply benefits through Medi-Cal Rx, effective January 1, 2022, and are restricted to products on the [List of Contracted Continuous Glucose Monitoring \(CGM\) Systems](#) and require a PA for reimbursement. Specific coverage criteria continue to apply. Refer to the *List of Contracted Continuous Glucose Monitoring (CGM) Systems* and the [Medi-Cal Rx Provider Manual](#) on the [Medi-Cal Rx Web Portal](#) for specific information. Non-contracted or non-listed CGM products could be reimbursable through the member's medical benefit, either to the member's Medi-Cal MCP or the FFS FI as an HCPCS-billed DME benefit on a medical claim. For non-covered CGM systems and components, Medi-Cal Managed Care members should contact their individual Medi-Cal MCP, as MCPs may determine their own CGM coverage policy, criteria, and reimbursement. CGM systems are a partially carved-out medical supply; therefore, MCPs can determine if they will continue to provide the benefit themselves or through Medi-Cal Rx. Managed Care CGM coverage policies are available on the individual MCP's website for provider and member clarification.

Note: Insulin pumps are not a Medi-Cal Rx benefit. Corresponding insulin pumps for some CGM devices are a DME billable item and are billable as a medical benefit on a CMS-1500 form via an HCPCS code. Refer to the [DME sections](#) of the [DHCS Provider Manual](#) on the [Medi-Cal Providers website](#) for coverage and billing information of DME insulin pumps and accessories for FFS members. Medi-Cal Managed Care members should contact their individual Medi-Cal MCP for insulin pump coverage policy and billing instructions.

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14. How does 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?

Unless otherwise noted on the [Medi-Cal Rx Scope document](#), all other DME and DME supplies continue, unchanged, and are reimbursable as an HCPCS-billed DME benefit through the FFS FI, on a medical claim, or through the member's Medi-Cal MCP medical benefit.

- Effective January 1, 2024, coverage of sterile syringes with needles (non-insulin) is no longer restricted to products on the *List of Covered Sterile Syringes with Needles (Non-Insulin)*, and the *List* is no longer valid as of January 1, 2024.
 - Any active 11-digit Medi-Cal Rx billing code/NDC-like number meeting the description "Syringe, sterile, with Needle (non-insulin), Gauge sizes 18-28, Needle Size 0.5 ml – 1.5 ml, and syringe size 1 ml – 10 ml" will be covered and reimbursed at the Maximum Allowable Product Cost (MAPC) of 0.2000 per each. Quantity and frequency restrictions apply.
 - Sterile syringes with needles (non-insulin) not within the size specification are considered a medical benefit and should be billed on a medical claim via an HCPCS code on a CMS-1500 form through the member's medical plan.
 - Needles (all types except pen needles) and syringes without needles continue to be a medical benefit and should be billed on a medical claim via an HCPCS code on a CMS-1500 form through the member's medical plan.
- Alcohol Prep Pads, a disposable medical supplies item, are a pharmacy-billed medical supply benefit through Medi-Cal Rx.
 - 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 FFS FI.
 - Alcohol swab sticks are not included in this category and are not a Medi-Cal Rx benefit. Alcohol swab sticks will continue to be reimbursable as an HCPCS-billed medical supplies benefit through the FFS FI.

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

No, since the Medi-Cal Rx full AOO, Medi-Cal pharmacy services billed on a medical or institutional claim by a pharmacy, or any other provider, continue to be billed through either Medi-Cal MCPs or to the CA-MMIS FI, for either Medi-Cal MCP members or FFS members, as they were prior to the Medi-Cal Rx full AOO. However, drugs that are "carved out" of the managed care delivery system (for example, blood factor, HIV/AIDS drugs, antipsychotics, or drugs used to treat SUD) will be billed to CA-MMIS for both FFS and MCP members.

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16. Are COVID-19 vaccines “carved out” of MCPs?

Consistent with the approach being taken by Medicare through Medicare Advantage Plans, DHCS carves out the COVID-19 vaccine from Medi-Cal MCPs and reimburses providers under the FFS delivery system for both medical and pharmacy claims. This approach eases program administration, eliminates challenges with out-of-network provider reimbursements, and keeps vaccine administration fee rates consistent for providers regardless of delivery system.

17. How does Medi-Cal Rx reimburse providers for the administration of the COVID-19 vaccine? Where is guidance regarding coverage/reimbursement policy relative to COVID-19 vaccines and the commercial COVID-19 vaccine?

Reimbursement for COVID-19 vaccines administration is outlined in the [Medi-Cal Rx Provider Manual](#) in the *COVID-19 Vaccine Administration Reimbursement* section.

Reimbursement for commercial COVID-19 vaccines administration is outlined in the [Medi-Cal Rx Provider Manual](#) in the *Commercial COVID-19 Vaccines Administration Reimbursement* section.

Additionally, an All Plan Letter (APL) from DHCS will provide additional guidance to MCPs on COVID-19 vaccines, commercial COVID-19 vaccines, the responsibilities of the MCPs, and contractual requirements.

For additional information about COVID-19, refer to <https://covid19.ca.gov/> and the DHCS [COVID-19 Response web page](#).

18. Are COVID-19 self-administered antigen test kits “carved out” of MCPs?

DHCS’ coverage of COVID-19 self-administered antigen test kits as a pharmacy-billed benefit through Medi-Cal Rx was effective February 1, 2022, in accordance with current Centers for Disease Control and Prevention (CDC) recommendations. Quantity limitations and specific product coverage criteria apply. For additional information, visit the [Medi-Cal Rx Provider Portal](#) via the [Medi-Cal Rx Web Portal](#) and refer to the [Covered Emergency Use of Authorization \(EUA\) COVID-19 Antigen Tests](#) list on the [Forms & Information](#) page, or refer to the *COVID-19 Antigen Test Kits* section in the [Medi-Cal Rx Provider Manual](#).

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Procurement Information

19. How did DHCS administer Medi-Cal Rx?

DHCS released Request for Proposal (RFP) #19-96125 on August 22, 2019, to procure an administrative services contractor to administer the Medi-Cal FFS pharmacy services for, at the time, more than 13.5 million Medi-Cal members. On December 13, 2019, DHCS awarded a contract to Prime to provide a comprehensive suite of administrative services as directed by DHCS, which include but are not limited to claims management, PA and UM, pharmacy drug rebate administration, provider and member support services, and other ancillary and reporting services to support the administration of the Medi-Cal pharmacy benefit.

20. What was the Medi-Cal Rx procurement timeline?

The timeline for Medi-Cal Rx procurement-related efforts was as follows:

- July 22, 2019: Draft Medi-Cal Rx RFP #19-96125 released for a two-week public comment period.
- August 22, 2019: Final Medi-Cal Rx RFP #19-96125 released.
- August 29, 2019: Final Medi-Cal Rx RFP #19-96125 questions due to DHCS.
- September 17, 2019: Answers to questions related to the Final Medi-Cal Rx RFP #19-96125 and addenda posted.
- October 1, 2019: All Medi-Cal Rx RFP #19-96125 proposals due.
- November 7, 2019: Notice of Intent to Award posted to the DHCS website.
- December 13, 2019: DHCS awarded contract to Prime.
- December 20, 2019: Contract Effective Date.
- January 1, 2022: Medi-Cal Rx Full AOO took place.

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

The Medi-Cal Rx Contractor selected to administer Medi-Cal FFS pharmacy services is Prime.

22. What roles and responsibilities are Medi-Cal MCPs maintaining upon Medi-Cal Rx full AOO?

Medi-Cal MCPs are responsible for activities including, but not limited to, the following:

- Overseeing and maintaining all activities necessary for enrolled Medi-Cal member 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 (DUR) Board and other DHCS-driven pharmacy committee meetings.

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- Continued and ongoing participation in post-claim adjudication DUR activities such as Retrospective DUR (RetroDUR) (as necessary for care coordination), educational programs, and submission of the DUR annual report.

23. What is DHCS responsible for upon Medi-Cal Rx full AOO?

DHCS is 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
 - PA/UM
- Negotiation of, and contracting for, state supplemental drug rebates.
- Reviewing and issuing final determinations regarding all PA denials for Medi-Cal Rx benefits, including those for the CCS program/GHPP.
 - **Note:** Denial determinations made by Medi-Cal Rx on behalf of DHCS between 4 p.m. PT on Friday and 5 a.m. PT on Monday, on observed holidays, and any other DHCS-designated time period where DHCS assigns Medi-Cal Rx delegation, may be overturned by DHCS if deemed appropriate.
- Providing oversight of, and facilitation for, the SFH 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 DUR Board and other Department-driven pharmacy committees, in collaboration with Prime.
- Contract management and oversight/monitoring of Prime.

24. What roles and responsibilities has the Medi-Cal Rx Contractor assumed upon Medi-Cal Rx full AOO?

Prime is responsible for activities including, but not limited to, the following:

- Providing a Medi-Cal Rx Customer Service Center (CSC) that is available 24 hours a day, 7 days a week, 365 days per year, excluding approved holidays, or unless otherwise directed by DHCS, to support all provider and member calls, as well as provide outreach, training, and informing materials.
- Providing direct Medi-Cal MCP liaisons to assist with care coordination and clinical issues.
- Providing real-time access into Prime's electronic environment via a secure portal to all Medi-Cal providers (prescribers and pharmacies) and MCPs, Mental Health Plans (MHPs), and SUD Plans.
- Providing claims administration, processing, and payment functionalities for all pharmacy services billed on pharmacy claims.

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- Overseeing coordination of benefits (COB) with Other Health Coverage (OHC), including Medicare.
- Providing UM functionalities, including ensuring pharmacy PA adjudication occurs within 24 hours, inclusive of the CCS program/GHPP.
 - All pharmacy PA denials will require DHCS' review prior to final determination.
 - **Note:** Denial determinations made by Medi-Cal Rx on behalf of DHCS between 4 p.m. PT on Friday and 5 a.m. PT on Monday, on observed holidays, and any other DHCS-designated time period where DHCS assigns Medi-Cal Rx delegation, may be overturned by DHCS if deemed appropriate.
- Providing Prospective and Retrospective DUR services.
- Providing data feeds (at least daily) to Medi-Cal MCPs to support their responsibilities of member 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 AOO on January 1, 2022, DHCS – in partnership with Prime – provided various Medi-Cal Rx transitional support services (TSS), as outlined in greater detail in questions #29 and #30.

25. How does 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 member information are outlined, clearly and in detail, in Medi-Cal Rx RFP #19-96125, which becomes part of the final executed contract language. In addition, Prime is required to adhere to all existing state and federal requirements as well as DHCS' policies relating to sensitive data and privacy.

26. Where can I find more information about the Medi-Cal Rx RFP #19-96125?

For more information about Medi-Cal Rx RFP #19-96125, refer to the [FI\\$Cal/Cal eProcure website](#). Final Proposals were due by October 1, 2019, at 4 p.m. PT. The procurement process has closed.

Transition Information

27. When did the Medi-Cal Rx full AOO take place?

Medi-Cal Rx full AOO, as described in questions #22-24, inclusive of claims administration and PA adjudication functionalities, took place on January 1, 2022.

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28. Why was the planned Go-Live date of April 1, 2021, for Medi-Cal Rx full AOO 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 Prime, the project's contracted vendor.

In January 2021, Centene Corporation announced that it planned to acquire Magellan. Centene operates – through subsidiaries – MCPs and pharmacies that participate in Medi-Cal. This transaction was unexpected and required additional time for exploration of acceptable conflict avoidance protocols to ensure that there were acceptable firewalls between the corporate entities to protect the pharmacy claims data of all Medi-Cal members, 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 applies statewide UM protocols to all outpatient drugs, standardizing the experience for all Medi-Cal members and providers. Medi-Cal Rx also strengthens California's ability to negotiate state supplemental drug rebates with drug manufacturers, helping to reduce pharmaceutical costs.

29. Did Medi-Cal Rx use a “phased” approach to transition services?

No, full implementation of Medi-Cal Rx took place on January 1, 2022. However, between January 1, 2021, and Medi-Cal Rx full AOO, DHCS, in partnership with Prime, provided various Medi-Cal Rx TSS, including but not limited to:

- Allowed Medi-Cal providers, MCPs, and other interested parties to register for the Medi-Cal Rx secure portals and participate in comprehensive trainings that ensured greater overall understanding of the project and supported operational readiness for providers and MCPs.
- Stood up and mobilized the CSC to allow experts at the CSC to field and answer questions from Medi-Cal members, providers, MCPs, and other interested parties, potentially preempting confusion and other potential challenges once the full implementation of Medi-Cal Rx occurred. While the CSC experts were not providing the full suite of services prior to AOO, they were after the Medi-Cal Rx full AOO. They were 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.
- Provided additional time for MCPs to interact with and build rapport with dedicated Medi-Cal Rx clinical liaisons, who helped Prime build accurate and comprehensive MCP profiles to ensure that the individualized needs of the populations served by each MCP continue to be met.

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- Allowed DHCS and Prime 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 [Medi-Cal Rx Pharmacy Locator Tool](#), [Medi-Cal Rx Provider Manual](#), [CDL](#), and other related policy and programmatic information.

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

- Extending CSC hours to 24 hours a day, 7 days a week, 365 days per year, excluding approved holidays, or unless otherwise directed by DHCS, to support all provider and member calls, as well as outreach, training, and informing materials.
- Claims management, PA and UM, provider and member support services, and other ancillary and reporting services.

For additional details, see questions #22-24.

30. How did DHCS ensure that the knowledge and experience of Medi-Cal MCPs and other stakeholders are leveraged in the transition process to achieve a successful continuity of services?

DHCS proactively engages external partners in multiple ways and through multiple avenues to ensure that knowledge and experience are 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 members, 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.

DHCS also continues 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.

31. How is information about the Medi-Cal Rx transition and other related changes communicated?

DHCS works in collaboration with Prime to ensure all interested parties (including, but not limited to, Medi-Cal MCPs, MHPs, SUD plans, providers, and members) are informed of the transition and other related changes.

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

- The [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 FAQs are posted and updated frequently.
- As of June 2020, the [Medi-Cal Rx Subscription Service \(MCRxSS\)](#) allows interested parties to sign up via the Medi-Cal Rx Web Portal and receive regular Medi-Cal Rx updates by email.
- As of August 2020, 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 Web Portal. MCPs and providers have had the ability to sign up for training and education events since September 2020.
- Notices to Medi-Cal members in both MCPs and FFS delivery systems were mailed on or around the following dates: October 1, 2020, November 1, 2020, and December 15, 2020. Notices to Medi-Cal members were also mailed beginning in late March 2021, informing them of the delay to the Medi-Cal Rx full AOO. Additional notices to Medi-Cal members were mailed on or around 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.
- 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 Rx Provider Manual](#), as well as new provider guidance and materials published by Prime, as directed by DHCS.
- Updates to Medi-Cal MCP contracts, as needed, to reflect the transition of the pharmacy benefit from managed care to FFS.
- Creation of a new Medi-Cal Rx APL 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 (DMHC) APL, 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 DUR Board, Medi-Cal Pharmacy Directors' Meeting, Stakeholder Advisory Committee, CCS Advisory Committee, etc.

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32. How did DHCS ensure Medi-Cal members transitioning to Medi-Cal Rx did not experience a disruption in their care and/or inability to access necessary prescription medications?

To assist Medi-Cal members, providers (prescribers and pharmacies), and MCPs with the Medi-Cal Rx full AOO, DHCS provided various Medi-Cal Rx TSS from January 1, 2021, through Medi-Cal Rx full AOO on January 1, 2022, as described in more detail in question #29, and developed and implemented a multi-faceted Pharmacy Transition Policy. This pharmacy transition period has facilitated a smooth, productive transition, ensuring that Medi-Cal members did 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. For the most up-to-date information regarding the Pharmacy Transition Policy, refer to the Medi-Cal Rx Reinstatement web page, which is available by selecting [Education & Outreach](#) from the [Medi-Cal Rx Web Portal](#), and then selecting **Medi-Cal Rx Reinstatement**. Also refer to DHCS' [Pharmacy Transition Policy](#), which is available on the Medi-Cal Rx Transition web page.

33. Did DHCS develop a Medi-Cal Rx transition plan, and, if so, what components did that plan include?

Yes, pursuant to the requirements outlined in RFP #19-96125, Exhibit A, Attachment I – Scope of Work – Takeover, Prime and DHCS developed a Medi-Cal Rx pharmacy transition approach/plan that included, at a minimum, processes for:

- Providing sufficient notice for Medi-Cal pharmacies and prescribers to take all necessary steps to acclimate to the new Medi-Cal Rx Contractor, the [CDL](#), and associated processes.
- Providing appropriate notice and related materials from DHCS and Medi-Cal MCPs to Medi-Cal members regarding the transition.
- Providing direction for obtaining PA on drugs dispensed during the transition period by allowing ongoing (drug treatments initiated prior to Medi-Cal Rx full AOO) drugs to be dispensed and billed without first having an approved PA. However, prospective DUR (ProDUR) requirements for drug safety still apply.
- Pharmacy, provider, and member 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.

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34. What strategies did DHCS use in the Medi-Cal Rx transition plan to ensure a smooth and effective transition to Medi-Cal Rx for members?

To assist Medi-Cal members with the full Medi-Cal Rx transition, DHCS provided various Medi-Cal Rx TSS from January 1, 2021, through Medi-Cal Rx full AOO on January 1, 2022, as described in more detail in question #29. In addition, DHCS' Pharmacy Transition Policy, as described in question #32, and in more detail in the link below, used strategies such as the following:

- "Grandfathering" previously approved PAs through their stated duration, not to exceed one 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 years for certain drug classes/categories, as articulated in the policy.

For the most up-to-date information regarding the Pharmacy Transition Policy, refer to the Medi-Cal Rx Reinstatement web page, which is available by selecting [Education & Outreach](#) from the [Medi-Cal Rx Web Portal](#), and then selecting **Medi-Cal Rx Reinstatement**. Also refer to DHCS' [Pharmacy Transition Policy](#), which is available on the Medi-Cal Rx Transition web page.

Data Feeds, Electronic Access, and Other Clinical Supports

35. Does Medi-Cal Rx provide the pharmacy data and necessary electronic access for Medi-Cal providers, Medi-Cal MCPs, and other entities to support care coordination?

Yes. Medi-Cal Rx provides data feeds (at least daily) to Medi-Cal MCPs to support their responsibilities of member 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 MHPs and SUD plans and will be engaging key stakeholders in this space.

In addition, Medi-Cal Rx provides appropriate real-time access to Prime electronic environment via a secure portal to all Medi-Cal providers (prescribers and pharmacies) and Medi-Cal MCPs, MHPs and SUD plans, and additional entities as designated by DHCS.

36. What additional clinical and care coordination support does Medi-Cal Rx provide to Medi-Cal MCPs?

Prime provides additional clinical and care coordination support to Medi-Cal MCPs to meet their contractual obligations relating to Medi-Cal member 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 Prime staff, and Prime's portal/environment to assist with and resolve clinical pharmacy-related issues for Medi-Cal Rx, including those involving PA, as directed by DHCS.

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- 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 interactive voice response (IVR) system to assist and resolve clinical pharmacy-related issues.

For more information, refer to the [Medi-Cal Rx Managed Care Plan \(MCP\) Clinical Liaison \(CL\) Policy](#) and the [Medi-Cal Rx Website and Pharmacy Portal Policy](#).

Provider Outreach, Education, and Training

37. 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 Prime, is dedicated to providing Medi-Cal provider customer support services, including but not limited to the following:

- The CSC supporting all provider calls, 24 hours a day, 7 days a week, 365 days per year, excluding approved holidays, or unless otherwise directed by DHCS.
- Outreach, training, and informing materials to Medi-Cal providers, Medi-Cal MCPs, and other entities.
- Web-based services supporting communication and tools for Medi-Cal Rx.
- Real-time access into Prime's electronic environment via a secure portal.
- Other services and supports to ensure a smooth and effective transition.

In addition, Prime's Customer Service Representatives (CSRs) 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, see RFP #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 available on the [Medi-Cal Rx Web Portal](#). In addition, providers and all other interested parties are encouraged to sign up for the [MCRxSS](#) to receive news and updates related to Medi-Cal Rx.

Member Customer Service and Related Supports

38. What kinds of Medi-Cal member customer service and related supports does DHCS offer and/or plan to do for Medi-Cal Rx?

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

- The CSC supporting all member calls, 24 hours a day, 7 days a week, 365 days per year, excluding approved holidays, or unless otherwise directed by DHCS.

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- 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 (for example, external facing websites to support communication and tools for Medi-Cal Rx).
- The [Medi-Cal Rx Pharmacy Locator Tool](#) is available on the [Medi-Cal Rx Web Portal](#) and includes all Medi-Cal Rx eligible pharmacies.
- An 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, Prime's CSRs act on behalf of DHCS to relay and provide subject-matter expertise/support regarding Medi-Cal Rx information and related materials to Medi-Cal members, in a variety of venues. For more information, see RFP #19-96125 Exhibit A, Attachment II – Scope of Work – Operations – Education and Outreach.

Member Eligibility, Share of Cost, and Other Health Coverage-Related Questions

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

The "on-hold" status pertains to the member's Medi-Cal MCP eligibility status, and there is no change to this process under Medi-Cal Rx. Medi-Cal Rx evaluates the Health Care Plan (HCP) status in the Medi-Cal Eligibility Data System (MEDS) to determine an active versus inactive status and proceeds accordingly.

40. Relative to Medi-Cal Rx, what happens if a member has moved, and the county has not updated the member'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 evaluates the HCP status in MEDS to determine an active versus inactive status and proceeds accordingly.

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

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

42. When Medi-Cal members have 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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43. Does 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 consult with their providers.

Medi-Cal Fee-for-Service Reimbursement Methodology

44. For Medi-Cal pharmacies, how is the Medi-Cal FFS pharmacy reimbursement methodology established, and what are the components?

DHCS utilizes drug reimbursement methodologies as defined in state law and the Medi-Cal State Plan. Medi-Cal FFS pharmacy reimbursement is the lower of the drug's ingredient cost plus a professional dispensing fee or pharmacy's usual and customary charge to the public.

1. DHCS calculates the drug ingredient cost as the lowest of:
 - a. the National Average Drug Acquisition Cost (NADAC) of the drug, or when no NADAC is available, the Wholesale Acquisition Cost (WAC) + 0%, or
 - b. the Federal Upper Limit (FUL), or
 - c. the Maximum Allowable Ingredient Cost (MAIC).
2. A professional dispensing fee (two-tiered based on total Medicaid and non-Medicaid annual pharmacy claim volume [that is, dispensed prescriptions]):
 - Less than 90,000 claims per year = \$13.20
 - 90,000 or more claims per year = \$10.05

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

For more information about DHCS' MAIC program, refer to the [Maximum Allowable Ingredient Cost \(MAIC\) Program Frequently Asked Questions](#).

45. Does DHCS reimburse specialty pharmacies for medication management services provided to patients identified as "high-risk" for compliance, adherence, or medication misuse concerns?

DHCS has established the Medication Therapy Management (MTM) program as authorized in *Welfare and Institutions Code* (W&I Code) Section 14132.969 as part of pharmacist services to support, ensure continued access, and reimburse specialty pharmacies for the services which they offer. Part of this is establishing and maintaining a list of covered specialty drug categories, eligibility criteria, and conditions for which MTM pharmacist services will be reimbursed. DHCS contracts with any willing Medi-Cal enrolled pharmacy providers, as authorized in W&I Code, Section 14105.3, to provide MTM pharmacist

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services to Medi-Cal members for covered specialty drug categories and to patients that meet the eligibility criteria in the contracts. For additional details, refer to the [Update on Medication Therapy Management Pharmacy Services](#) page on the DHCS website.

Policy Considerations

46. What is the [Medi-Cal Rx Contract Drugs List](#)?

DHCS maintains the CDL, which is DHCS' list of covered drugs and includes drugs for which there is a current state supplemental drug rebate agreement in place. Generally, under the existing Medi-Cal FFS pharmacy benefit, if a drug is listed on the CDL, then it does not require an approved PA for coverage. Alternatively, if a drug is not listed on the CDL, then it would require an approved PA for coverage. Note that even if a drug is listed on the CDL, it may still require an approved PA for coverage; however, if a certain drug on the CDL requires an approved PA, then DHCS' policy would clearly articulate that requirement.

Refer to the CDLs on the [Contract Drugs & Covered Products Lists](#) page on the [Medi-Cal Rx Web Portal](#).

47. How does Medi-Cal Rx affect Medi-Cal's CDL, and does DHCS take anything else into consideration for its Medi-Cal drug coverage policies?

The Medi-Cal Rx CDL replaced the previous DHCS-approved Medi-Cal CDL as the list of covered drugs. In addition, DHCS' pharmacy drug coverage policies take into consideration:

- All U.S. 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.

Refer to the CDLs on the [Contract Drugs & Covered Products Lists](#) page on the [Medi-Cal Rx Web Portal](#).

48. Does Medi-Cal Rx consider local exceptions to the CDL?

No. Medi-Cal Rx uses a single, statewide, and DHCS-approved CDL to standardize the Medi-Cal pharmacy benefit. Refer to the CDLs on the [Contract Drugs & Covered Products Lists](#) page on the [Medi-Cal Rx Web Portal](#).

49. How does DHCS make determinations to add or delete drugs from the Medi-Cal Rx CDL?

DHCS can add drugs to the Medi-Cal Rx 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,

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industry best practices, and the following drug review criteria, which are outlined in W&I 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 W&I 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 members – and assists DHCS by providing written recommendations to inform decision-making regarding adding and/or deleting drug(s) from the 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 W&I Code, Section 14105.39(c)(1) and (2) criteria, as well as additional information such as generic name, brand name, 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 CDL based upon the Committee's recommendations, state law requirements, and other relevant factors.

DHCS is continuing its efforts to closely analyze variances and gaps between Medi-Cal MCP formularies and the CDL. As a product of DHCS' analysis, and in an effort to drive down the total number of required PAs, numerous medications have been added to the CDL since January 2020, and DHCS continues this review on a monthly basis to add more medications to the CDL.

50. 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 – 2021 budget, which led to the following changes:

- Repealed the six-prescription ("6 Rx") drug limit.
- Eliminated the Medi-Cal FFS prescription copays.
- 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.

51. For drugs requiring a PA, do prescribers or providers need to submit a PA request each time a drug is dispensed?

No. When a PA is approved, it is for a specified length of time and can cover multiple fills dispensed.

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52. Has DHCS made policy changes to allow for multi-year PA approvals?

To reduce administrative burden while ensuring continuation of care and medication safety for members, DHCS has enabled extended duration/multi-year PAs for up to five years for certain maintenance medications used for chronic conditions. Qualified prescriptions are automatically extended. Refer to the [Extended Duration Prior Authorizations for Maintenance Medications](#) alert for additional information.

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

As part of Medi-Cal Rx, DHCS continues to enhance and/or expand auto-adjudication functionalities (for example, automated claim approval and payment) to reduce the number of drugs with PA requirements that require manual review.

54. Does Medi-Cal Rx include opioid management services?

Medi-Cal Rx provides 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 MCP Workgroup and Medi-Cal Rx Advisory Workgroup. For more information regarding DHCS' current pharmacy policies and procedures in this space, refer to the [reference resource](#).

In addition, as part of Medi-Cal Rx, DHCS solicited proposals as part of the RFP 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.

55. Does Medi-Cal Rx include a pharmacy lock-in program?

DHCS did not implement a lock-in program as part of the Medi-Cal Rx full AOO on January 1, 2022, but will evaluate options with Prime in the future. As part of Medi-Cal Rx RFP #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 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.

56. Where can I find the Medi-Cal Rx APL for Medi-Cal MCPs that provides guidance from a policy and programmatic perspective?

DHCS' [Medi-Cal Rx All Plan Letter \(APL 22-012\)](#) for Medi-Cal MCPs can be found on the DHCS website.

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57. Where can I find the DMHC APL, relative to Medi-Cal Rx, for Medi-Cal MCPs that provides guidance from a regulatory, compliance, and filing perspective?

The DMHC [All Plan Letter \(APL 20-035\)](#) relative to Medi-Cal Rx is available on the DMHC's website.

58. Where can I find the Informational Notice (IN) for the CCS program and the GHPP relative to Medi-Cal Rx?

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

59. 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 Services (MHSUDS)?

The BHIN that provides guidance related to Medi-Cal Rx for county MHSUDS is available on the [Behavioral Health Information Notices page](#) on the DHCS website.

Prior Authorization/Utilization Management

60. Under Medi-Cal Rx, how are PA requests reviewed and adjudicated?

DHCS, in collaboration with Prime, processes PA requests and provides a response to the submitting provider within 24 hours of receiving a PA request, pursuant to W&I Code, Section 14133.37. For a more detailed process document, refer to the [Medi-Cal Rx Transition page on the DHCS website](#).

61. Are MCPs allowed to contract with the Medi-Cal Rx Contractor to perform PAs?

No. Since Medi-Cal MCPs are no longer contractually responsible for the Medi-Cal pharmacy benefit after the Medi-Cal Rx full AOO on January 1, 2022, all PA adjudications and related processes are handled by Prime, consistent with contractual requirements and at the direction of DHCS.

340B Federal Drug Discount Program

62. 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 (HRSA), an agency under the U.S. Department of Health and Human Services (HHS), administers and manages the program through its Office of Pharmacy Affairs (OPA).

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

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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 member (better known as the provision against “duplicate discounts”).

63. 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 HRSA, the CDC, the HHS Office of Population Affairs (OASH), and the Indian Health Service (IHS). 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 (DSH), children’s hospitals, and other safety net providers.

When registering as a covered entity with HRSA, a covered entity may choose not to dispense 340B purchased drugs to Medicaid members or to dispense 340B purchased drugs to Medicaid members. 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 HRSA’s [340B Drug Pricing Program website](#).

64. What is the interaction of Medi-Cal Rx 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 members, and bill at their Actual Acquisition Cost (AAC) for those drugs when dispensed through the Medi-Cal FFS delivery system, consistent with W&I Code, Section 14105.46. The 340B AAC billing requirement only applies to the FFS delivery system.

In the managed care delivery system, 340B drugs dispensed to Medi-Cal members are not subject to the Medi-Cal FFS acquisition-cost billing requirements. This allows covered entities and the Medi-Cal MCPs and/or contracted Pharmacy Benefit Managers (PBMs) 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 FFS delivery system. These profits are not shared with the state, nor are the amounts of such profits known to the state.

Medi-Cal Rx allows for uniformity of policy and improved oversight of claims for medications dispensed and billed through the 340B Program.

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65. Does Medi-Cal Rx preclude a provider from continuing as a 340B entity?

No. In addition, Medi-Cal Rx does not change or eliminate the 340B Program in California.

66. 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 members. 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.

67. 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. The [State Plan Amendment \(SPA\)](#) has been approved. Additionally, a [notice](#) published on June 28, 2023, states that DHCS will make supplemental payments for qualifying non-hospital 340B community clinic visits for dates of service (DOS) from July 1, 2023 to December 31, 2023, in accordance with the provisions of Assembly Bill 80.

Medi-Cal Rx Complaints/Grievances Resolution and Appeals Processes

68. What complaints and grievances resolution processes do Medi-Cal members have to address pharmacy benefit issues?

In partnership with Prime, DHCS is committed to continually overseeing an effective Medi-Cal Rx complaints and grievances process to ensure appropriate triaging, referral, and/or disposition. Specific requirements are outlined in RFP #19-96125, Exhibit A, Attachment II – Scope of Work Operations – Complaints and Grievances Resolution. For more information, refer to DHCS' [Medi-Cal Rx Complaints and Grievances Policy](#) located on DHCS' Medi-Cal Rx Transition web page.

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69. What pharmacy-related complaints and grievances are handled through Medi-Cal Rx?

All pharmacy-related complaints and grievances for Medi-Cal Rx services provided after the Medi-Cal Rx full AOO on January 1, 2022, are handled through the CSC for triaging, research, and resolution. For more information, refer to DHCS' [Medi-Cal Rx Complaints and Grievances Policy](#).

70. How did DHCS address complaints and grievances that arose for pharmacy-related services provided by the Medi-Cal MCPs on or before Medi-Cal Rx full 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 \(APL 17-006\)](#) and any subsequent versions.

Pharmacy-related complaints and grievances received after the Medi-Cal Rx full AOO by the CSC for services provided by a Medi-Cal MCP on or before Medi-Cal Rx full AOO were transferred by the CSC to the appropriate Medi-Cal MCP for full resolution.

The CSC advised 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 is not impacted by Medi-Cal Rx.

71. Does Medi-Cal Rx have a mechanism to share information about complaints and grievances with the member's MCP?

Medi-Cal MCPs have complete access to individual records of members 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 the DHCS website and Open Data Portal.

72. What appeals mechanism(s) do Medi-Cal members have to address pharmacy benefit issues?

Appeals go through the SFH process, which is administered through the California Department of Social Services (CDSS). If Medi-Cal members do not agree with a denial or change of Medi-Cal Rx services, they can ask for an SFH 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 web page](#) or [California Department of Social Services' website](#). Medi-Cal members may also call to ask for an SFH

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toll-free at 1-800-952-5253 (TTY 1-800-952-8349). Note that the number can be very busy so you may get a message to call back later.

73. If a Medi-Cal member wants an SFH, are there any time limitations?

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

74. Can Medi-Cal members still get their treatment while awaiting an SFH decision?

Yes. To continue receiving the Medi-Cal Rx services that the denial notice is stopping and/or changing, Medi-Cal members must ask for an SFH 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 an SFH, Medi-Cal members should indicate that they want to keep getting Medi-Cal Rx services during the hearing process. 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 member.

75. Can Medi-Cal members request an expedited SFH?

Yes. Medi-Cal members 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 members should send the letter along with their hearing request. For more information about the SFH process, visit DHCS' [Medi-Cal Fair Hearing web page](#).

76. For appeals of Medi-Cal Rx coverage decisions by the Medi-Cal provider and/or MCP, has DHCS created 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 DMHC, 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 Prime and reviewed by DHCS for final determination. Medi-Cal providers can appeal Medi-Cal Rx denials consistent with the requirements outlined in RFP #19-96125, Exhibit A, Attachment II – Scope of Work Operations – Claims Administration, applicable state law requirements, and DHCS' policies/procedures.

77. What pharmacy-related appeals are handled through Medi-Cal Rx?

All pharmacy-related appeals for Medi-Cal Rx services provided since the Medi-Cal Rx full AOO are handled through Medi-Cal Rx utilizing the existing SFH process, administered through CDSS, as described in questions #72-75.

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78. How did DHCS address appeals from Medi-Cal MCP members that arose for pharmacy-related services provided by the Medi-Cal MCPs on or before Medi-Cal Rx full AOO?

Medi-Cal MCPs had to resolve all Medi-Cal MCP member appeals that originated as a result of an MCP decision relative to pharmacy-related services for which the MCP was at risk on or before Medi-Cal Rx full AOO. The right of Medi-Cal MCP members to submit appeals to DMHC, including but not limited to the right to Independent Medical Review (IMR), for pharmacy-related services provided by the Medi-Cal MCPs rendered on or before Medi-Cal Rx full AOO, was not impacted by Medi-Cal Rx.

Fiscal Impact/Assessment

79. Did DHCS complete a fiscal analysis prior to the transition?

Yes. DHCS completed a fiscal analysis for Medi-Cal Rx and shared this information publicly. DHCS anticipates approximately \$309 million General Fund (GF) in annual savings by 2023 – 2024. DHCS included 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.

80. What are the elements of our projected \$309 million GF in annual savings by 2023 – 2024?

The elements of the projected \$309 million GF savings by 2023 – 2024 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 FFS delivery system.
- Implementation of MAICs for drugs that have three or more generically equivalent options available.
- Reduction of costs related to administrative functions of multiple pharmacy benefits managers used by various Medi-Cal MCPs.
- Medi-Cal FFS 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 AOO on January 1, 2022, which was included in the 2021 – 2022 budget. See question #67 for more information.

As noted in question #79, 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

81. Does Medi-Cal Rx include mail-order pharmacy options?

Yes. Mail-order options are available in Medi-Cal 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 has ensured continuation of an effective mail-order service option for Medi-Cal pharmacy services.

82. Does DHCS make Medi-Cal pharmacy supplemental drug rebate contracts public?

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

83. Is the Medi-Cal Rx Contractor required to contract with existing pharmacies in the current networks?

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

84. How many active, California-licensed pharmacies are enrolled in Medi-Cal FFS?

Per January 2023, DHCS data, 6,547 California-licensed pharmacy providers are enrolled in Medi-Cal FFS.

85. Does Medi-Cal engage in an effort to enroll the pharmacies that are part of MCP networks but not enrolled in Medi-Cal FFS?

Since Medi-Cal Rx's full AOO on January 1, 2022, Medi-Cal Rx uses 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 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 FFS, 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.

86. In what capacity will Medi-Cal MCPs and other entities be expected to participate in meetings for the Medi-Cal Global DUR 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 DUR Board and in other DHCS-driven pharmacy committees, as needed. In addition, DHCS is continually and 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.

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87. Does DHCS have a subscription service for updates and news relative to Medi-Cal Rx?

Yes, it is called the Medi-Cal Rx Subscription Service (MCRxSS). All interested parties are encouraged to [sign up for MCRxSS](#) to receive news and updates related to Medi-Cal Rx.

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