



# **Intergovernmental Agreement Overview of the 42 Code of Federal Regulations, Section 438**

**Presented by the Substance Use Disorder Program,  
Policy and Fiscal Division**

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# Drug Medi-Cal-Organized Delivery System Intergovernmental Agreement

- Main Components of the Program Specifications (Exhibit A, Attachment I):
  - Drug Medi-Cal-Organized Delivery System (DMC-ODS) waives Freedom of Choice and allows for Selective Provider Contracting.
  - Incorporates the existing standard State/County contract language.
  - Incorporates the 42 Code of Federal Regulations (CFR) 438 requirements.
- Intergovernmental Agreements (IAs) are up to 3-year terms.
- IAs will be amended annually to allow the Contractor (i.e. the county) to adjust billing rates.



# Drug Medi-Cal-Organized Delivery System Intergovernmental Agreement

## What are the 42 CFR 438 regulations and why the Contractor must comply?

- 42 CFR 438 governs the Centers for Medicare and Medicaid (CMS) Medicaid Managed Care (MMC) delivery system.
- Under the DMC-ODS Waiver, the Contractor will operate as a Prepaid Inpatient Health Plan (PIHP), a type of managed care.
- As a PIHP, the Contractor is subject to all applicable Medicaid laws and regulations under 42 CFR 438.
  - Not all 438s apply to PIHPs and many 438s have deemed inapplicable or waived by CMS under the DMC-ODS Waiver.



# **Agenda Overview Regarding New 438 Requirements**

- I. Subpart A – General Provisions
- II. Subpart B – State Responsibilities
- III. Subpart D – Prepaid Health Insurance Program (PIHP) Standards
- IV. Subpart F – Grievance and Appeal System
- V. Subpart H – Additional Program Integrity Safeguards
- VI. Overview of Network Adequacy



## **Subpart A – General Provisions**

**Begins no later than rating period for contracts  
starting on or after July 1, 2017**



# Subpart A – General Provisions

## §438.3 Standard Contract Requirements (previously 438.6). This requirement was revised.

- Authorizes Department of Health Care Services (DHCS) and CMS to inspect and audit “any records or documents” and “inspect the premises, physical facilities, and equipment where Medi-Cal activities or work is conducted” of PIHP and their subcontractors...**at any time.” At any time language is a new requirement.**
- DHCS and CMS **may audit for 10 years** from the date the state-PIHP IA expires or from the date of the completion of any audit, whichever is later. **May audit for 10 years is a new requirement.**



# Subpart A – General Provisions

## **§438.3 Standard Contract Requirements (previously §438.6) – Continued**

### **§438.3(m) is a new requirement.**

- (m) Audited finance IA reports. PIHPs must submit audited finance IA reports regarding the contract annually.
- The audit shall be conducted in accordance with Generally Accepted Accounting Principles and Generally Accepted Audit Standards.



# Subpart A – General Provisions

## **§438.10 Information Requirements. This requirement was revised.**

- PIHPs must make available in electronic form and, upon request, in paper form a provider directory.
- Information included in a paper provider directory must be updated at least monthly and electronic provider directories must be updated no later than 30 calendar days after the PIHP receives updated provider information.
- Provider directories must be made available on the PIHP's website in a machine-readable file and format.





# Subpart A – General Provisions

## **§438.14 Requirements that Apply to Indians, Indian Health Care Providers (IHCPs), and Indian Managed Care Entities (IMCEs). This is a new requirement.**

- (b) IAs between DHCS and a PIHP require the PIHP to demonstrate sufficient IHCPs participating in the provider network to ensure timely access to services available under the contract for Indian enrollees.
- The PIHP must require that IHCPs, whether participating or not, be paid for covered services provided to Indian beneficiaries who are eligible to receive such services.
- Indian enrollees will obtain services covered under the contract between DHCS and the PIHP from out-of-network IHCPs when a beneficiary receives such services.



## **Subpart B – State Responsibilities**

**Begins no later than rating period for  
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## Subpart B – State Responsibilities

### **§438.62 Continued Services to Beneficiaries. This is a new requirement.**

- DHCS will arrange Medi-Cal services provided without delay to any Medi-Cal beneficiary if this IA is terminated.
- DHCS will provide a Transition of Care Policy to ensure continued access to services during a transition from fee-for-service (FFS) to the PIHP.
- DHCS must provide Transition of Care Policy to ensure continued access to services during a transition from FFS to a PIHP or during a transition from one PIHP to another, when the absence of continued services would result in a serious detriment to the beneficiaries health.



## Subpart B – State Responsibilities

### **§438.62 Continued Services to Beneficiaries - (Continued)**

- The PIHP must implement a Transition of Care Policy consistent with DHCS' Transition of Care Policy.
- DHCS will make the Transition of Care Policy publicly available and provide materials and instructions to beneficiaries on how to access continued services when transferred.
- The Contractor must utilize the DHCS' model Beneficiary's Handbook and notices to incorporate all minimum requirements that describe Transition of Care Policies for beneficiaries.
  - The Contractor is expected to modify the Beneficiary's Handbook to add additional or specific information.



## Subpart B – State Responsibilities

### **§438.66 State Monitoring Requirements. This is a new Requirement.**

- (a) *General requirement.* The State agency will monitor all PIHP programs.
- (b) DHCS will address aspects of the performance of each PIHP entity in the following applicable areas:
  1. Administration and management.
  2. Appeal and grievance systems.
  3. Claims management.
  4. Enrollee materials and customer services, including the activities of the beneficiary support system.
  5. Finance.
  6. Information systems, including encounter data reporting.



## **Subpart D – Prepaid Inpatient Health Plans’ Standards.**

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## **Subpart D – Prepaid Inpatient Health Plans Standards**

### **§438.208 Coordination and Continuity of Care, Revised Requirement**

**This rule is similar to prior requirements but new requirements involve:**

- Informing upon discharge planning for short term and long-term hospital and institutional stays, coordination between services the enrollee receives from the plan and from the FFS DMC-ODS or community provider, and sharing with DHCS or another PIHP serving the beneficiary.
- Requires a best effort to conduct an initial screening of each beneficiary's needs, within 90 calendar days of the effective date of enrollment, to prevent duplication of services.



## Subpart D – PIHP Standards

**§438.210 Coverage and Authorization of Services. This requirement was revised.**

**This rule is a revision of a previous §438.10 and includes new requirements:**

- IAs between DHCS and a PIHP must identify, define, and specify the amount, duration, and scope of services the PIHP is required to offer.
- Includes requirements on processing requests for IA and continuing authorizations of services and required contract components.
- Requires PIHPs to provide notice of adverse benefit determination.
- Establishes timeframes for authorization decisions.
- Covers compensation for utilization management activities.





## Subpart D - PIHP Standards

**§438.230 Subcontractual Relationships and Delegation. This requirement was revised.**

- Changes were made for clarity that are consistent with the standards for subcontractors. Subcontractors are now required to comply with all Medi-Cal laws/rules/subregulatory guidance, and contract provisions. CMS distinguishes between subcontractors and network providers.
- Subcontractors are required to agree to grant state and federal oversight agencies the right to inspect books, contracts, computer or other systems that pertain to the services performed and to make materials available for audit for **ten years from the completion of any audit, whichever is later.**



## Subpart D - PIHP Standards

### **§438.242 Health Information Systems. This requirement was revised.**

- A PIHP must maintain a health information system that collects, analyzes, integrates and reports data, and can achieve the objectives of this rule.



**Subpart F – Grievance and Appeals System  
No later than rating period for contracts  
starting on July 1, 2017**



## Subpart F - Grievance and Appeal System

### **§438.400 Statutory basis, definitions, and applicability. This requirement was revised.**

- **Has changed terminology from “action” to “adverse benefit determination.”**
- Each Plan has only **one level of appeal** for enrollees. It must be exhausted before the beneficiary Intergovernmental Agreement can request a State Fair Hearing.
- An enrollee may request a State Fair Hearing **after receiving notice under § 438.408 that the adverse benefit determination is upheld.**
- With the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State Fair Hearing on behalf of an enrollee.



## Subpart F - Grievance and Appeal System

### **§438.402 General Requirements. This requirement was revised.**

- An enrollee may file a grievance with a PIHP **at any time.**
- The enrollee may file a grievance either orally or in writing.
- Following receipt of a notification of an adverse benefit determination by a PIHP, an enrollee has **60 calendar days from the date on the adverse benefit determination notice to file a request for appeal to the PIHP.**



## Subpart F - Grievance and Appeal System

### **§438.404 Timely and adequate notice of adverse benefit determination. This is a new requirement.**

- This rule requires PIHP to give enrollees timely and adequate notice of an adverse benefit determination.
- The provision includes, but is not limited to the reason for adverse benefit determination and the enrollee's right to receive reasonable access to, and copies of, all documents, records and other information.



# Subpart F - Grievance and Appeal System

**§438.406 Handling of Grievances and Appeals. This a new requirement.**

- The rule was updated to align language on the adverse benefit determination, as defined in §438.2.
- Added the requirement that the PIHP must provide enrollees and their representatives with information considered connected to the appeal of an adverse benefit determination.
- Information must be provided free of charge and sufficiently in advance of the resolution timeframe for appeals.



## Subpart F - Grievance and Appeal System

**§438.408 Resolution and Notification. This is a new requirement.**

- For standard resolution of an appeal and notice to the affected parties, the established timeframe is now to be no longer than **30 calendar days (previously 45 days)** from the day the Plan receives the appeal.
- For expedited resolution of an appeal and notice to affected parties, the established timeframe been changed to **72 hours (previously 3 working days)** after the Plan receives the appeal.
- The rule extends the timeframe for enrollees to request a State Fair Hearing up to **120 days (previously 90 days)**.





# Subpart F - Grievance and Appeal System

## **§438.416 Recordkeeping Requirements. This a new requirement.**

- The record of each grievance or appeal must contain, at a minimum what is established in §438.416 (b), which includes the following:
  - A general description of the reason for the appeal or grievance.
  - The date received.
  - The date of each review or, if applicable, review meeting.
  - Resolution at each level of the appeal or grievance, if applicable.
  - Date of resolution at each level, if applicable.
  - Name of the covered person for whom the appeal or grievance was filed.
- The record must be accurately maintained and accessible to DHCS and **CMS**.



## Subpart F - Grievance and Appeal System

**§438.420 Continuation of Benefits during Pending Appeal or State Fair Hearing. This is a new requirement.**

- There are no longer a continuation of benefits for time period or service limits of a previously authorized service.
  - E.g., if a beneficiary requests that the County continues or reinstate its eligibility while the appeal or State Fair Hearing is pending, the benefits must be continued until one of items listed in §438.420 (c) occurs.



## Subpart F - Grievance and Appeal System

### **§438.424 Effectuation of Reversed Appeal Resolutions. This is a new requirement.**

- This rule requires PIHPs to authorize or provide services within 72 hours of receiving notice of reversal of an adverse benefit determination by the State Fair Hearing officer.
- Previous rule required PIHPs to authorize or provide services as expeditiously as the beneficiary's health condition required.



## **Subpart H - Additional Program Integrity Safeguards**

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## Subpart H - Additional Program Integrity Safeguards

### **§438.602 State Responsibilities. This is a new requirement.**

- The State must post website documentation described in §438.207(b), which states that the certification of the PIHP has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in §438.206.



## Subpart H – Additional Program Integrity Safeguards

**§438.604 Data, Information, and Documentation that must be submitted. This is a new requirement.**

- The PIHPs must submit data, information and documentation as follows:
  - Encounter data in the form and manner described in §438.818.
  - Information on ownership and control described in §455.104 of this chapter from PIHP entities and subcontractors as governed by §438.230.
  - An annual report of overpayment recoveries as required in §438.608(d)(3).



## **Network Adequacy Rules Addressed in a Variety of Provisions Become in Effect 7/1/2018**

- §438.68 Network Adequacy
- §438.206 Availability of Services
- §438.207 Assurance of Adequate Capacity and Services



## **§438.68 Network Adequacy**

- Requires DHCS to develop and enforce network adequacy standards.
- Time and distance standards for behavioral health providers (adult and pediatric).
- Must include all geographic areas covered by the managed care program or contract.
- States permitted to have varying standards for the same provider type based on geographic area.





## **§438.206 Availability of Services**

- (a) The State must ensure that all services covered under the State plan are available and accessible to enrollees of PIHPs in a timely manner.
- The State must also ensure that PIHP provider networks for services covered under the contract meet the standards developed by the State in accordance with §438.68.



## **§438.207 Assurances**

- The State must ensure, through its IAs, that each PIHP gives assurances to the State and provides supporting documentation that demonstrates it has the capacity to serve its enrollment in service areas in accordance with the State's standards for access to care, including the standards at §438.68 and § 438.206(c)(1).
- Documentation must be submitted annually or when there is a significant change in operations.



# Resources and Links

- **Drug Medi-Cal Organized Delivery System Webpage**  
<http://www.dhcs.ca.gov/provgovpart/Pages/Drug-Medi-Cal-Organized-Delivery-System.aspx>
- **Email general DMC-ODS questions to [DMCODSWaiver@dhcs.ca.gov](mailto:DMCODSWaiver@dhcs.ca.gov)**
- **DMC-ODS 2017-18 Boilerplate Intergovernmental Agreement**  
[http://www.dhcs.ca.gov/provgovpart/Documents/DMC-ODS\\_Waiver/DMC-ODS\\_ExhibitA\\_AttachmentI\\_Boilerplate.pdf](http://www.dhcs.ca.gov/provgovpart/Documents/DMC-ODS_Waiver/DMC-ODS_ExhibitA_AttachmentI_Boilerplate.pdf)
- **DHCS Model Beneficiary Handbook**  
[http://www.dhcs.ca.gov/provgovpart/Pages/County\\_Resources.aspx](http://www.dhcs.ca.gov/provgovpart/Pages/County_Resources.aspx)
- **Email Network Provider submissions and questions to [DHCSMPF@dhcs.ca.gov](mailto:DHCSMPF@dhcs.ca.gov)**