

STATE OF CALIFORNIA
Budget Change Proposal - Cover Sheet
 DF-46 (REV 08/15)

Fiscal Year 2016-17	Business Unit 4150	Department Department of Managed Health Care	Priority No. 3
Budget Request Name 4150-102-BCP-BR-2016-GB		Program 3870-Health Plan Program	Subprogram

Budget Request Description
 Outpatient Prescription Drug Formularies (AB 339)

Budget Request Summary

The Department of Managed Health Care (DMHC) requests limited-term resources of \$733,000 for FY 2016-17; \$700,000 for FY 2017-18; \$558,000 for FY 2018-19; and \$558,000 for FY 2019-20 to meet the Department's operational needs in order to address the short-term workload resulting from the implementation of AB 339 (Chapter 619, Statutes of 2015).

This request includes \$196,000 in contracted consulting costs for FY 2016-17, FY 2017-18, FY 2018-19, and FY 2019-20 to assist DMHC offices with developing implementation standards and identifying health plan clinical standard deficiencies during the survey process.

Requires Legislation <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Code Section(s) to be Added/Amended/Repealed
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Does this BCP contain information technology (IT) components? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <i>If yes, departmental Chief Information Officer must sign.</i>	Department CIO	Date
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For IT requests, specify the date a Special Project Report (SPR) or Feasibility Study Report (FSR) was approved by the Department of Technology, or previously by the Department of Finance.

FSR SPR Project No. Date:

If proposal affects another department, does other department concur with proposal? Yes No
Attach comments of affected department, signed and dated by the department director or designee.

Prepared By Jennifer Clark, CFO	Date January 4, 2016	Reviewed By <i>Carolina McSeagart</i>	Date 1-4-2016
Department Director <i>Mark A. ...</i>	Date 1/4/2016	Agency Secretary <i>...</i>	Date 1-6-16

Additional Review: Capital Outlay ITCU FSCU OSAE CALSTARS Dept. of Technology

BCP Type: Policy Workload Budget per Government Code 13308.05

PPBA <i>Greg N. Matt</i>	Date submitted to the Legislature
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JAN 07 2016

Analysis of Problem

A. Budget Request Summary

The DMHC requests limited-term resources of \$733,000 for FY 2016-17; \$700,000 for FY 2017-18; \$558,000 for FY 2018-19; and \$558,000 for FY 2019-20 to meet the Department's operational needs in order to address the short-term workload resulting from the implementation of AB 339 (Chapter 619, Statutes of 2015).

This request includes \$196,000 in contracted consulting costs for FY 2016-17, FY 2017-18, FY 2018-19, and FY 2019-20 to assist DMHC offices with developing implementation standards and identifying health plan clinical standard deficiencies during the survey process. Limited-term contracted consulting costs include \$46,000 to assist Office of Plan Licensing (OPL) with developing implementation standards related to new legislation and communicating this information with the health plans, and \$150,000 to assist Division of Plan Surveys (DPS) with identifying health plan deficiencies related to the clinical standards required by this legislation.

B. Background/History

Resource History (Dollars in thousands)

Program Budget	FY 10-11	FY 11-12	FY 12-13	FY 13-14	FY 14-15
Authorized Expenditures	There are no authorized AB 339 resources to date.				
Actual Expenditures					
Revenues					
Authorized Positions					
Filled Positions					
Vacancies					

Workload History

Workload Measure	FY 10-11	FY 11-12	FY 12-13	FY 13-14	FY 14-15	FY 15-16
N/A						

The passage of AB 339 allows California to take the next step, building on the federal guidance and existing general anti-discrimination provisions with more robust, specific, and enforceable parameters for drug benefit designs. AB 339 aligns with Covered California's current approach to address the high out-of-pocket costs for medically necessary drugs and incorporating a sunset date of 2020 for the out-of-pocket cost limitations and drug tiering provisions. AB 339 takes an appropriate measured approach in addressing the competing challenges of providing access to medically necessary drugs for consumers without severely hampering health plans' ability to contain costs through drug price negotiations. Moreover, AB 339 aligns with and incorporates new federal standards regarding the prescription drug Essential Health Benefits, including the requirements regarding pharmacy and therapeutics committees, formulary transparency, and reasonable access to retail pharmacies (rather than mail-order pharmacies). Adding these provisions to California law ensures they will be enforceable by the DMHC.

Additional provisions of AB 339 include:

- Requires health care service plan contracts (other than Medi-Cal managed care contracts) to cover medically necessary prescription drugs, including medically necessary single-tablet antiretroviral drug regimens for AIDS/HIV, except as specified.
- Limits cost sharing for a 30-day supply of a prescription to no more than \$250 (or \$500 for a bronze-level plan or its actuarial equivalent for large group), except that an applicable deductible must be satisfied, as specified.

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- Specifies formulary tier definitions for certain non-grandfathered individual or small group products.

C. State Level Considerations

This request provides the additional resources necessary to enable the DMHC to address the short-term workload resulting from the passage of AB 339.

AB 339 adds the same and additional provisions to the Insurance Code to align it with existing law already included in the Knox Keene Health Care Service Plan Act of 1975 (Knox Keene Act), as amended.

D. Justification

The DMHC licenses and regulates health plans that provide full-service and specialty services to more than 25 million Californians. The DMHC regulates health plans under the provisions of the Knox Keene Act. To meet its mission of protecting consumer health care rights and ensuring a stable health care delivery system, the DMHC resolves grievances; conducts onsite medical surveys and financial exams; and reviews and approves plan contracts, disclosures, and vendor arrangements.

Currently, the DMHC regulates a total of 34 full service commercial and behavioral health plans that provide a prescription drug benefit. In order to implement AB 339, the DMHC is required to complete a compliance review of existing plans and any new license applicants as to their prescription drug formularies. Health plans may have a different prescription drug formulary for each of its product types, which may result in each health plan submitting up to 15 different formularies. The extensive review of health plan filings will be performed by the DMHC's OPL and DPS.

In addition, as a result of the passage of AB 339, DMHC's Office of Legal Services (OLS) will need to draft new regulations to update the existing Title 28, CCR Section 1300.67.24, which imposes standards for outpatient prescription drug coverage, limitations, exclusions, and cost sharing.

Office of Plan Licensing (OPL)

OPL is responsible for assuring regulatory compliance of health plans with the Knox Keene Act and the Final Rules. This is accomplished by reviewing applications for licensure, material modifications to existing licenses, and amendments to existing licenses. This review includes requiring health plans to provide legally sufficient documentation of plan organization, disclosures, enrollee benefits, and other aspects of regulatory compliance.

The passage of AB 339 requires that each of the 34 affected health plans submit filings demonstrating compliance with its provisions. DMHC will need to analyze the various provisions of the bill, including whether the cost sharing for this benefit is within the parameters set forth in the bill, the health plans' formularies do not discourage enrollment of individuals with health conditions or reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practice, and verify that the health plans are defining the formulary tiers appropriately. In order to facilitate compliance with AB 339, OPL must review the health plans' Evidences of Coverage (EOCs), Disclosure Forms, combined Evidences of Coverage/Disclosure Forms that contain pharmacy benefits, policies and procedures, and prescription drug formularies for each of the health plans' products.

Ongoing workload consists of the oversight of health plans' compliance with the additional mandated prescription drug requirements and the review of any new license applications for compliance with the language of AB 339. To facilitate the compliance project and review the prescription drug benefit offered by full service health plans, OPL is requesting limited-term resources to perform the following workload from July 1, 2016, through June 30, 2020:

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3.0 Associate Governmental Program Analysts (Temporary Help – July 1, 2016 to June 30, 2020)

These analyst positions will be responsible for the creation and ongoing maintenance of the formulary template for health plans to utilize, filing tracking, serve as the DMHC liaison between clinical consultants and plans, coordinate transfer of documents to clinical consultants for review, coordinate filing teleconferences between the DMHC and clinical consultants, and conduct initial filing review of plan submissions to identify issues and deficiencies with the filings.

Pharmacy or Clinical Consultant (Limited-term – July 1, 2016 to June 30, 2020)

DMHC will need to retain either a pharmacy or clinical consultant to develop standards and communicate to health plans what constitutes reasonable cost sharing and what must be provided to show it does not discourage the enrollment of individuals with health conditions nor reduce the generosity of the benefit for enrollees with a particular condition. Based on similar clinical consulting contracts, OPL estimates the ongoing costs to be approximately \$46,000 per year.

Division of Plan Surveys (DPS)

DPS, part of DMHC's Help Center, is responsible for conducting routine medical surveys of each licensed full service and specialty health plan as required by the Knox Keene Act, as well as non-routine investigative medical surveys as deemed necessary by DMHC's Director. DPS anticipates retaining a clinical consultant during the survey process to assess health plan compliance related to the bill's clinical standards and to make revisions to the applicable audit tool or Technical Assistance Guide (TAG) and associated worksheets.

Clinical Consultant (Limited-term – July 1, 2016 to June 30, 2020)

The clinical consultant will be responsible for the one-time review and revision of the TAG and file review worksheets for use during routine medical surveys and dissemination of training materials to affected plans. The consultant will conduct an assessment of each health plan to verify that prescriptions for medical conditions are not all placed in the highest cost tiers within the formularies, draft deficiencies, and provide clinical follow-up to assess whether the plans corrected deficiencies. Based on similar consulting services contracts, DPS estimates contracting costs to be approximately \$150,000 per year.

Office of Legal Services (OLS)

OLS conducts legislative and legal analyses for the DMHC; leads rulemaking activities, including pre-notice stakeholder engagement, research and analysis, drafts regulatory language, conducts public hearings, responds to comments, and files regulation package(s) with the Office of Administrative Law; and responds to Public Records Act and Information Practices Act requests.

OLS anticipates conducting legal research and producing legal opinion memoranda pertaining to AB 339 between January 1, 2016, and June 30, 2018, as this bill is central to the DMHC's enforcement of anti-discrimination laws prohibiting prescription drug benefit designs that may potentially reduce the benefits for chronically ill individuals. OLS also anticipates promulgating one regulation package in order to update the existing regulation governing cost sharing, limitations, and exclusions of coverage for prescription drugs (title 28, California Code of Regulations, Section 1300.67.24).

1.0 Attorney I (Temporary Help – July 1, 2016 to June 30, 2018)

This position will be responsible for reviewing and processing legal questions related to AB 339. The review of legal questions encompasses all tasks necessary to compose the final determination and present to impacted or requesting divisions. In addition, this position will be responsible for the promulgation of regulations pertaining to AB 339, which includes conducting stakeholder meetings, researching and analyzing policy concerns, drafting regulations, holding public hearings, and drafting the final rulemaking documents.

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E. Outcomes and Accountability

This proposal is intended to provide the resources necessary to enable the DMHC to address the increased workload resulting from the passage of AB 339.

Projected Outcomes

Workload Measure	FY 15-16	FY 16-17	FY 17-18	FY 18-19	FY 19-20
Office of Plan Licensing (OPL)					
Compliance Analysis and Implementation:					
Assist with developing structure of compliance implementation plan.	0	1	1	1	1
Participate in and assist with stakeholder meetings to gather additional information necessary for implementation.	0	3	3	3	3
Develop structure of compliance implementation plan (including external checklists and spreadsheets and templates to be utilized during filing review).	0	3	3	3	3
Identify specific compliance requirements for plan EOCs, formularies, and other disclosure documents.	0	3	3	3	3
Assist with the design of filing review guidelines for internal review (including internal checklists and spreadsheets for filing tracking).	0	3	3	3	3
Assist with the development of clinical consultant workload and scope of review. Work with clinical consultant to revise or update scope as necessary.	0	4	4	4	4
Create and maintain weekly tracking report and documentation of each health plan compliance issues and completion of status.	0	34	34	34	34
Coordinate filing teleconferences between the DMHC, clinical consulting team, and plans.	0	35	35	35	35
Serve as the DMHC liaison between clinical consultants and plans. Prepare and coordinate the transfer of filing documents to clinical consulting team for review.	0	34	34	34	34
Conduct initial filing review of plan submission and subsequent filing amendments to identify administrative issues and deficiencies.	0	510	510	510	510
Participate in training of compliance review processes and updates to anticipated compliance laws.	0	4	4	4	4
Review of Current Licensee Filings:					
Assist in coordination of summary of the filing.	0	51	51	51	51
Assist with the review of plan documents (EOCs, disclosure forms, formularies, policies, and procedures) for compliance.	0	128	128	128	128
Work with clinical consultant to revise or update scope of review as necessary.	0	67	67	67	67
Consult with attorneys to discuss implementation issues as they arise.	0	83	83	83	83
New License Application Review:					
Assist with pre-filing and filing conferences with	0	4	4	4	4

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plans.					
Assist with coordination of summary of the filing.	0	4	4	4	4
Assist with the review of plan documents (EOCs, disclosure forms, formularies, policies, and procedures) for compliance.	0	4	4	4	4
Office of Legal Services (OLS)					
Promulgation of one regulation package. Includes conducting stakeholder meetings, capturing feedback, research and analyze policy concerns, draft proposed regulation, draft APA documents, hold public hearings, summarize comments, analyze and respond to comments, and process regulation through formal rulemaking process.	0	0	1	0	0
Conduct legal research and policy analysis. Includes reviewing legal questions, gathering data and supporting documentation, staff coordination, reviewing applicable law, gathering legal references, crafting position, drafting memos, briefing management, and presenting final determination to impacted staff.	0	4	4	0	0

F. Analysis of All Feasible Alternatives

Alternative 1: Approve the DMHC's request for limited-term resources of \$733,000 for FY 2016-17; \$700,000 for FY 2017-18; \$558,000 for FY 2018-19; and \$558,000 for FY 2019-20 to meet the Department's operational needs in order to address the short-term workload resulting from the implementation of AB 339 (Chapter 619, Statutes of 2015).

This request includes \$196,000 in contracted consulting costs for FY 2016-17, FY 2017-18, FY 2018-19, and FY 2019-20 to assist DMHC offices with developing implementation standards and identifying health plan clinical standard deficiencies during the survey process.

Pros:

- The Department will have the necessary resources to implement the provisions of AB 339.

Cons:

- Increases State expenditures.

Alternative 2: Approve the request at a lower level.

Pros:

- Provides minimal resources to meet all the provisions of AB 339.

Cons:

- Increases State expenditures.
- Less expenditure authority would result in the redirection of staff resources in order to accomplish the necessary tasks/activities associated with AB 339. However, DMHC staff is already at capacity and this would add to existing backlogs in other areas.

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Alternative 3: Deny the request in which case DMHC will have to redirect existing resources in entirety.

Pros:

- Does not increase the size of State government.

Cons:

- The Department may not fulfill all requirements mandated by AB 339.
- Will create a backlog in other areas of the Department's responsibilities.

G. Implementation Plan

DMHC will start recruitment in late FY 2015-16 to enable positions to be filled by July 1, 2016 and activities outlined in this BCP are performed to meet requirements set forth by AB 339. Additionally, the DMHC will start the contract process in late FY 2015-16, so the consultant contracts are in place the beginning of FY 2016-17.

H. Supplemental Information

This request will be funded through annual assessments of the health plans that are regulated by the DMHC. The fiscal impact of this request to full service health plans is approximately \$0.02 per enrollee.

I. Recommendation

Alternative 1: Approve the DMHC's request for limited-term resources of \$733,000 for FY 2016-17; \$700,000 for FY 2017-18; \$558,000 for FY 2018-19; and \$558,000 for FY 2019-20 to meet the Department's operational needs in order to address the short-term workload resulting from the implementation of AB 339 (Chapter 619, Statutes of 2015).

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BCP Fiscal Detail Sheet

BCP Title: Outpatient Prescription Drug Formularies (AB 339)

DP Name: 4150-102-BCP-DP-2016-GB

Budget Request Summary

	FY16					
	CY	BY	BY+1	BY+2	BY+3	BY+4
Salaries and Wages						
Earnings - Temporary Help	0	266	266	186	186	0
Total Salaries and Wages	\$0	\$266	\$266	\$186	\$186	\$0
Total Staff Benefits	0	163	163	118	118	0
Total Personal Services	\$0	\$429	\$429	\$304	\$304	\$0
Operating Expenses and Equipment						
5301 - General Expense	0	41	8	6	6	0
5302 - Printing	0	4	4	3	3	0
5304 - Communications	0	4	4	3	3	0
5320 - Travel: In-State	0	19	19	16	16	0
5322 - Training	0	4	4	3	3	0
5324 - Facilities Operation	0	36	36	27	27	0
5340 - Consulting and Professional Services - External	0	196	196	196	196	0
Total Operating Expenses and Equipment	\$0	\$304	\$271	\$254	\$254	\$0
Total Budget Request	\$0	\$733	\$700	\$558	\$558	\$0

Fund Summary

Fund Source - State Operations						
0933 - Managed Care Fund	0	733	700	558	558	0
Total State Operations Expenditures	\$0	\$733	\$700	\$558	\$558	\$0
Total All Funds	\$0	\$733	\$700	\$558	\$558	\$0

Program Summary

Program Funding						
3870 - Health Plan Program	0	733	700	558	558	0
Total All Programs	\$0	\$733	\$700	\$558	\$558	\$0

Personal Services Details

Salaries and Wages	CY	BY	BY+1	BY+2	BY+3	BY+4
TH00 - Temporary Help (Eff. 07-01-2016)(LT 06-30-2020)	0	266	266	186	186	0
Total Salaries and Wages	\$0	\$266	\$266	\$186	\$186	\$0
Staff Benefits						
5150350 - Health Insurance	0	76	76	57	57	0
5150500 - OASDI	0	20	20	14	14	0
5150600 - Retirement - General	0	67	67	47	47	0
Total Staff Benefits	\$0	\$163	\$163	\$118	\$118	\$0
Total Personal Services	\$0	\$429	\$429	\$304	\$304	\$0