

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

Fiscal Year 2016-17	Business Unit 0845	Department California Department of Insurance	Priority No. LEG - 3
Budget Request Name 0845-015-BCP-BR-2016-GB		Program 0520 – Regulation of Insurance Companies and Insurance Producers	Subprogram 0520028 - Licensing

Budget Request Description
 Outpatient Prescription Drugs

Budget Request Summary

The California Department of Insurance (CDI) requests an increase in special fund expenditure authority of \$242,000 in Fiscal Year (FY) 2016-17 and \$235,000 in FY 2017-18 and ongoing to support 1.0 permanent Attorney I position and a \$100,000 consulting services contract with a pharmacist. This will provide the Department with the appropriate level of resources to comply with the mandates of Assembly Bill (AB) 339 (Chapter 619, Statutes of 2015).

Requires Legislation <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Code Section(s) to be Added/Amended/Repealed	
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

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 Sandy Chu	Date 12/14/2015	Reviewed By Crista Hill <i>Crista Hill</i>	Date 12/14/2015
Department Director for Erika Sperbeck <i>Erika Sperbeck</i>	Date 12/14/2015	Agency Secretary N/A	Date

Department of Finance Use Only

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

BCP Type: Policy Workload Budget per Government Code 13308.05

PPBA	Original signed by Jeff Carosone	Date submitted to the Legislature <i>1-7-16</i>
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DEPARTMENT OF FINANCE
GOR/JUD

BCP Fiscal Detail Sheet

BCP Title: Outpatient Prescription Drugs (AB 339)

DP Name: 0845-102-BCP-DP-2016-GB

Budget Request Summary

	FY16					
	CY	BY	BY+1	BY+2	BY+3	BY+4
Positions - Permanent	0.0	1.0	1.0	1.0	1.0	1.0
Total Positions	0.0	1.0	1.0	1.0	1.0	1.0
Salaries and Wages						
Earnings - Permanent	0	80	80	80	80	80
Total Salaries and Wages	\$0	\$80	\$80	\$80	\$80	\$80
Total Staff Benefits	0	37	37	37	37	37
Total Personal Services	\$0	\$117	\$117	\$117	\$117	\$117
Operating Expenses and Equipment						
5301 - General Expense	0	8	2	2	2	2
5304 - Communications	0	1	1	1	1	1
5320 - Travel: In-State	0	1	1	1	1	1
5320 - Travel: Out-of-State	0	1	1	1	1	1
5324 - Facilities Operation	0	9	9	9	9	9
5340 - Consulting and Professional Services - External	0	100	100	100	100	100
5346 - Information Technology	0	5	4	4	4	4
Total Operating Expenses and Equipment	\$0	\$125	\$118	\$118	\$118	\$118
Total Budget Request	\$0	\$242	\$235	\$235	\$235	\$235
Fund Summary						
Fund Source - State Operations						
0217 - Insurance Fund	0	242	235	235	235	235
Total State Operations Expenditures	\$0	\$242	\$235	\$235	\$235	\$235
Total All Funds	\$0	\$242	\$235	\$235	\$235	\$235
Program Summary						
Program Funding						
0520028 - Licensing	0	242	235	235	235	235
Total All Programs	\$0	\$242	\$235	\$235	\$235	\$235

Analysis of Problem

A. Budget Request Summary

The California Department of Insurance (CDI) requests an increase in special fund expenditure authority of \$242,000 in Fiscal Year (FY) 2016-17 and \$235,000 in FY 2017-18 and ongoing to support 1.0 permanent Attorney I position and a \$100,000 consulting services contract with a pharmacist. This will provide the Department with the appropriate level of resources to comply with the mandates of Assembly Bill (AB) 339 (Chapter 619, Statutes of 2015).

B. Background/History

AB 339 was enacted on October 8, 2015 and established mandates on health insurer prescription drug cost sharing and formularies for their health insurance policies and coverage beginning January 1, 2017. The bill establishes requirements for health insurers to follow for creation of their drug benefits and coverages and how the Commissioner will review and enforce those requirements.

The bill does the following in addition to the current requirements:

- 1) Adds section 10123.193 to the Insurance Code as follows:
 - Requires compliance by all non-grandfathered health insurance policies offered, renewed, or amended after January 1, 2017.
 - Requires policies that provide coverage for outpatient prescription drugs to cover medically necessary prescription drugs, including medically necessary non-formulary drugs.
 - Mandates drug formularies not discriminate or discourage enrollment of individuals based upon health conditions or reduce benefits in compliance with both federal and state statutes, regulations and guidance.
 - Formulary limitations or utilization management shall be consistent with and based upon clinical guidelines and peer-reviewed scientific and medical literature.
 - Requires non-formulary drugs authorized for use to have cost sharing equivalent to formulary drugs and provides for limits and caps on cost-sharing.
 - Creates formulary tiering requirements that shall be based upon various criteria and limitations.
 - Allows various reasonable medical management practices for handling of formularies.

- 2) Adds section 10123.201 to the Insurance Code as follows:
 - Requires health insurers to establish and maintain a pharmacy and therapeutics (P&T) committee responsible for developing, maintaining and overseeing any drug formulary.
 - Creates standards for establishment of a P&T committee and its membership.
 - Requires the P&T committee to develop and document the insurer's formulary based upon various standards and criteria related to medical care and treatment, documented evidence, and the requirements set forth in the Section and consistent with federal and state statutes, regulations, and guidance.
 - Imposes authorization requirements and standards on health insurers for prescription drug benefits.
 - Requires insurers to maintain documentation and make it available to the Commissioner regarding its formularies, the records of the P&T committee on its handling of the formulary, and the insurer's arrangements with the various entities that handle, prescribe, or distribute prescription drugs benefits.
 - Requires the Commissioner to review the performance of insurers in providing prescription drug benefits through market conduct examination and include that information as part of the market conduct examination report.

Analysis of Problem

Legal Branch – Health Policy Approval Bureau Resource History (Dollars in thousands)

Program Budget	FY 2011-12 ^{1/}	FY 2012-13	FY 2013-14	FY 2014-15	FY 2015-16 (Projected)
Authorized Expenditures ^{2/}	\$1,370	\$1,263	\$1,599	\$1,811	\$2,148
Actual Expenditures ^{3/}	\$606	\$1,335	\$1,605	\$1,796	\$2,148
Authorized Positions ^{4/}	13.0	13.0	19.5	18.5	19.0
Filled Positions ^{4/}	5.8	13.9	14.0	11.3	19.0
Vacancies	7.2	0.0	5.5	7.2	0.0

^{1/} HPAB formed in February 2012; Actual expenditures and filled positions represents Feb-Jun months only.

^{2/} Based on Allotments.

^{3/} Based on FM13 year-end budget reports.

^{4/} Based on Salaries & Wages (7A).

C. State Level Considerations

This proposal will not negatively impact other state agencies and does not impact the General Fund. AB 339 establishes similar requirements on Department of Managed Health Care for the health plans it regulates. This proposal is consistent with the requirements of state policy, the Commissioner's mission to protect consumers, and the mandates set forth in the Insurance Code and established by AB 339.

D. Justification

Pharmacy Consultant

HPAB will need to confirm that formularies are accessible and searchable on an insurer's Internet website as required by Section 10123.192. These formularies will need to be reviewed for compliance both by HPAB legal staff attorneys and the pharmacy consultant, since the legal staff lacks medical or pharmaceutical expertise.

Section 10123.193 requires that formularies do not discriminate against insureds with particular conditions and meet other requirements as previously noted. HPAB legal staff does not have the medical expertise to properly or adequately review the formularies or understand the various medical conditions treated by prescription drug benefits. HPAB will need a pharmacy consultant to review formularies and advise HPAB attorneys regarding insurer formularies, how to formulate appropriate legal objections, and assist with negotiations with insurers for compliance.

HPAB will need to promulgate regulations to define, interpret, and develop specific requirements for formulary design, formulary submission requirements, interpreting the requirements of 10123.193 pertaining to anti-retrovirals and tiering, etc. Pharmaceutical expertise that the Department does not possess will be needed to establish those regulatory requirements and to make needed changes to the regulations as formularies and prescription drugs change.

HPAB will need to review for compliance both with formulary design and meeting medical standards, which require an insurer to maintain a P&T committee responsible for developing, maintaining, and overseeing any formulary that is to be submitted with its insurance policy filings. Insurers must also maintain records developed by the P&T committee for review by the Department. HPAB will need to promulgate regulations to define, interpret, and develop specific requirements for examining insurer P&T committee compliance, such as submission requirements per Section 10123.201, similar to regulations that set for the standards for insurer examination in other lines of insurance. Pharmaceutical expertise that the Department does not possess will be needed to review how insurers' P&T committees established their formularies based upon the criteria set forth in the statutory provisions of AB 339.

The Department is requesting \$100,000 in FY 2016-17 and ongoing to contract with a pharmacist.

Analysis of Problem

Insurer Drug Formulary Requirements and P&T Committee Review

Attorney review of insurer formularies, P&T committee documentation, and findings of the pharmacy consultant, along with consultation with the pharmacy consultant on responses and objections to insurer formularies will result in additional Attorney I work hours over the current work hours and activities. Approximately 30 active health insurers, with various formularies, will be creating committees and providing documentation to support the insurers' formularies for their various health insurance filings. It is estimated at this time that insurers will have a minimum of one and up to four or more formularies depending upon how the insurer wishes to structure its formularies for the various plans the insurer intends to file with the Department. The Department estimates an average of two formularies per insurer.

HPAB will need to annually review for compliance with these new mandates, as insurers file their insurance health plans and submit information regarding their formularies based upon the insurers' P&T committee documentation, changes in FDA approved medications, and changes in health treatment criteria. The Attorney I will also assist with providing legal guidance in market conduct examinations and analyzing the findings of market conduct examiners. The Attorney I will need to consult with the Department's pharmacy consultant to ascertain health care requirements and standards. There are approximately 30 active health insurers who will be submitting P&T committee documentation to support their formularies. Each annual submission will require an estimated 30 hours for review in consultation with a pharmacy consultant. It is also estimated there will be an additional 10 hours to draft objections for formulary non-compliance and negotiate with each insurer.

The additional Attorney workload hours for HPAB to review formularies and P&T committee documentation in support of the filed health insurance policy formulary and follow-up examinations of insurers is estimated to be 2,400 hours (40 hours per formulary x 30 insurers x average of 2 formularies)

The Department is requesting 1.0 permanent Attorney I position based upon 2,400 hours/1,778 hours per Attorney I = 1.35.

If this BCP and requested resources are not approved, the Department will not be able to comply with the mandates of AB 339. Additionally, the lack of resource would prohibit CDI from protecting insureds by ensuring that consumers can afford prescription drug benefits in a non-discriminatory manner towards the most severe and costly medical conditions requiring medications.

E. Outcomes and Accountability

The CDI will have sufficient resources to implement the provisions of AB 339. The Department will have staff and funding necessary to timely review health insurance filings for prescription benefit compliance and avoid a backlog. As a result, consumers will have health insurance plans that provide drug benefits for the most serious medical conditions requiring costly drug therapies. This avoids the current practice of insurers placing the most expensive drugs in their most costly tiers, usually the Specialty Drug tier, where cost sharing levels limit consumers obtaining the medications due to up-front costs or not offering sufficient medications to treat the most serious medical conditions.

CDI has a time/activity reporting system to track staff time, and will therefore monitor the amount of time spent on the associated activities to ensure resources are used appropriately.

F. Analysis of All Feasible Alternatives

Alternative 1 – Approve as requested.

Pros:

- Provides the necessary resources to enable review, objection, and compliance for complex formulary reviews as mandated by AB 339.
- Obtains insurer compliance with the laws concerning drug benefits.
- Assures that consumers will obtain the drug benefit coverage they are entitled.
- Avoids backlog in completing comprehensive review.
- There is a revenue source to offset the expenditures related to policy form filings.

Analysis of Problem

Cons:

- Additional costs to the Insurance Fund.
- Increases position growth in State Government.

Alternative 2 – Absorb workload within existing resources.

Pros:

- Insurance Fund resources will not be impacted.
- No position growth in State Government.

Cons:

- Existing Legal resources are already overcommitted to ongoing reviews and negotiation regarding policy form, rate submissions, and current rulemaking activities, impairing the Department's ability to assure legal compliance in a timely manner that supports a well-regulated and competitive insurance market.
- The CDI does not have the pharmacy expertise to review prescription drug formularies for compliance with AB 339.
- A backlog of filings is created as a result of completing comprehensive reviews.

Alternative 3 – Approve the request as limited-term.

Pros:

- Temporarily provides resources to enable review, objection, and compliance for complex formulary reviews as mandated by AB 339.
- Temporarily obtains insurer compliance with the laws concerning drug benefits.
- Temporarily assures that consumers will obtain the drug benefit coverage they are entitled.
- Temporarily avoids backlog in completing comprehensive review.

Cons:

- Not a sustainable solution.

Alternative 4 – Deny the request.

Pros:

- Insurance Fund resources will not be impacted.
- Does not enable CDI to comply with the mandates of AB 339.

Cons:

- Insurers' health insurance plan filings may not be compliant with the requirements of AB 339 as a result of possible inadvertence, misunderstanding of the requirements, interpretation of the provisions more favorable of the insurer, or due to clear avoidance of the requirements.
- Consumers may be harmed by having fewer plans that afford prescription drug benefits in a non-discriminatory manner towards the most severe and costly medical conditions requiring medications or no plans at all to deal with those conditions.

G. Implementation Plan

Beginning July 1, 2016, the Department will contract with a pharmacist to review insurer prescription drug formularies.

Analysis of Problem

Legal will start the hiring process in April 2016 to ensure the position is filled effective July 1, 2016. The hiring will be contingent upon approval of the position being included in the FY 2016-17 Budget Act.

H. Supplemental Information

Consulting and Professional Services – External - \$100,000.

I. Recommendation

Alternative 1 – This is the only alternative that provides the appropriate level of resources and pharmacy expertise to review and obtain insurer compliance and fulfill its statutory obligations established by AB 339. This will allow the Department to enforce the requirements of this bill and afford to consumers medications in a cost-effective regulated process. Enforcing insurer compliance with AB 339 will address the issues and problems already recognized in insurer prescription drug coverages and formularies and identify hidden issues and trends where insurers lower costs by not addressing consumers' most serious medical needs.

Denial of this proposal will not provide the resources necessary to comply with the mandates of the bill which would prohibit CDI from protecting insureds by ensuring that consumers can afford prescription drug benefits in a non-discriminatory manner towards the most severe and costly medical conditions requiring medications.